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Senate

The Senate met at 9:30 a.m. and was called to order by the Honorable TOM UDALL, a Senator from the State of New Mexico.

PRAYER

The Chaplain, Dr. Barry C. Black, offered the following prayer:

Let us pray.

Lord, who shall abide in Your tabernacle? Who shall dwell in Your holy hill? You have given us the answers. Those who walk upright and work righteousness, who speak the truth in their hearts, will abide in Your presence.

Today, prepare the men and women of this body to dwell with You. Give them the integrity to be true to their duties, always striving to please You. Lord, fix their hearts on You, that everything they say and do will be under Your Lordship. Send out Your light and Your truth that they may shine in this Chamber, and guide our Senators in these challenging times. Join our lawmakers to You with an inseparable bond of love for You. You alone, O God, can guard their hearts with peace.

We pray in the Redeemer's Name. Amen.

PLEDGE OF ALLEGIANCE

The Honorable TOM UDALL led the Pledge of Allegiance, as follows:

I pledge allegiance to the Flag of the United States of America, and to the Republic for which it stands, one nation under God, indivisible, with liberty and justice for all.

APPOINTMENT OF ACTING PRESIDENT PRO TEMPORE

The PRESIDING OFFICER. The clerk will please read a communication to the Senate from the President pro tempore (Mr. BYRD).

The assistant legislative clerk read the following letter:

U.S. SENATE,
PRESIDENT PRO TEMPORE,
Washington, DC, June 3, 2009.

To the Senate:

Under the provisions of rule I, paragraph 3, of the Standing Rules of the Senate, I hereby appoint the Honorable TOM UDALL, a Senator from the State of New Mexico, to perform the duties of the Chair.

ROBERT C. BYRD,
President pro tempore.

Mr. UDALL of New Mexico thereupon assumed the chair as Acting President pro tempore.

RECOGNITION OF THE MAJORITY LEADER

The ACTING PRESIDENT pro tempore. The majority leader is recognized.

SCHEDULE

Mr. REID. Mr. President, following leader remarks, there will be a period of morning business for 1 hour. Senators will be permitted to speak for up to 10 minutes each. The majority will control the first 30 minutes and the Republicans will control the next 30 minutes.

Following morning business, the Senate will resume consideration of the tobacco legislation, H.R. 1256. This is postcloture on the motion to proceed. Upon the use or yielding back of the 30 hours of postcloture debate time, the Senate will turn its consideration to that legislation. We hope that some time can be yielded back. We will wait and see what the will of the Republicans is at this time. We would like to begin the amendment process. We had a number of very good speeches yesterday from Senators who intend to offer amendments to this legislation. I will be speaking with the Republican leader throughout the day.

Mr. President, I note the absence of a quorum.

The ACTING PRESIDENT pro tempore. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mr. MCCONNELL. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

RECOGNITION OF THE MINORITY LEADER

The ACTING PRESIDENT pro tempore. The Republican leader is recognized.

ORDER OF PROCEDURE

Mr. MCCONNELL. Mr. President, at some point we will be back on the postcloture time. When that occurs, I ask unanimous consent that my hour postcloture be given to the Senator from North Carolina, Mr. BURR.

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

TOBACCO REGULATION

Mr. MCCONNELL. Mr. President, I wish to say a few words about the FDA legislation we have been debating on the floor this week. First, I thank Senator ENZI for his hard work in managing this bill. He always does a great job. I also wish to acknowledge Senator BURR's thoughtful leadership on this legislation. This is a complicated set of issues. No one—I repeat, no one—knows the intricacies better than the Senator from North Carolina, Mr. BURR. He has been a good friend and ally of producers and growers dating back to his days in the House, and he has offered a thoughtful alternative to this very flawed legislation which we have before us.

A few years ago, I led the effort in Congress to enact a tobacco buyout which ended the Federal Government's support of tobacco production. Although the number of tobacco farms in

● This "bullet" symbol identifies statements or insertions which are not spoken by a Member of the Senate on the floor.

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Kentucky has decreased as a result of that legislation, thousands of Kentucky farm families and communities still depend on the income from tobacco production. I have concerns about the effect this legislation might have on them.

Still, no one in this Chamber would deny that tobacco is hazardous to the health of those who use it. Everyone knows that. If the purpose of this bill is to reduce the harm it could cause the people who consume it, then forcing the Food and Drug Administration to do the regulating would be the wrong route to take.

Former FDA Administrator Dr. Andrew von Eschenbach has predicted that forcing the FDA to regulate tobacco would undermine the agency's core mission of protecting the public health and ensuring that foods, medicines, and other products don't pose a risk to American consumers. When the FDA approves a product, Americans expect the product to be safe, but as we all know, there is no such thing as a safe cigarette. It doesn't exist. Forcing the FDA to regulate cigarettes will not make them safer for the American people.

This legislation is flawed for other reasons as well. As Senators BURR, ENZI, and others have repeatedly pointed out, the FDA is already overworked in carrying out its core mission of protecting the public health. When it comes to contaminated peanut butter, tainted toothpaste, or unsafe drugs coming into the United States, Americans expect that all of FDA's resources are being used to protect them. Yet instead of freeing additional resources for the FDA to perform this important function, this legislation could divert the agency's limited resources toward an impossible task: Vouching for the safety of a product that cannot be made safe. The American people don't want the FDA's resources diverted on a fool's errand.

It is hard to understand what the supporters of this bill are trying to accomplish. If the goal is to reduce smoking, then why isn't there a single dime—not one dime—in this bill directed at smoking cessation programs? If there is no such thing as a safe cigarette, the best way to help smokers is to help them kick the habit. This bill doesn't do that. If the goal of this legislation is to launch a public campaign to reduce smoking and promote better health, then why is there no focus on Federal programs that are already in place to achieve this goal?

This legislation is the wrong way to regulate tobacco, and that is why Senator BURR will offer a thoughtful way to accomplish the goal. Senator BURR's proposal would create a new agency whose sole responsibility is to regulate tobacco. This would address the problem without undermining FDA's mission or straining its resources.

Forcing the FDA to regulate and approve the use of tobacco would be a distortion of the agency's mission and a tremendous misuse of its overstretched resources. We should be focused on giving FDA the resources it needs to protect the public health, not burdening it with an impossible assignment.

HEALTH CARE REFORM

Mr. MCCONNELL. Mr. President, as we consider the best way to reform health care, some have argued that a so-called government option would not lead to a government takeover of health care. They promise safeguards to ensure a level playing field between private plans and a government-run plan. But no safeguard could ever create a truly level playing field. The reason is simple: Unlike private insurance plans, a government-run plan would have unlimited access to taxpayer money and could borrow as much money as it wants to subsidize the cost of services. The Federal Government is already planning to borrow $1.8 trillion this year alone. If a company were allowed to borrow that much money, it could easily wipe out its competition, set prices, and create a monopoly. That is just what a so-called government ''option'' for health care will, in all likelihood, lead to.

A government-run plan would set artificially low prices that private insurers would have no way of competing with. Rates for private health plans would either skyrocket, leaving companies and individuals unable to afford them, or private health plans would simply be forced out of business. Either way, the government-run plan would take over the health care system, radically changing the way Americans choose and receive their care, from routine checkups to lifesaving surgeries. No safeguard could prevent this crowdout from happening, and no safeguard could, therefore, keep the millions of Americans who currently like the health care they have from being forced off of their plans and onto a government-run plan instead.

This isn't some fantasy scenario. We are already seeing in the government takeover of the auto industry how government interference in business forces firms out of the way by leveraging taxpayer dollars against their private competitors. Now that the government runs General Motors and has provided billions to its financing arm, GMAC, the company is offering interest rates that Ford, which hasn't taken any government money, and other companies which haven't taken any government money just can't compete with. What this means is that one American auto company that actually made the tough decisions so that it wouldn't need a government bailout is now at a competitive disadvantage to a company that is being propped up by billions of dollars of borrowed tax money. This is how the government subsidizes failure at taxpayers' expense and can unfairly undercut good companies, and this is precisely why so many Americans are worried about the trend of increased government involvement in the economy. The government is running banks now. It is running insurance companies. As of this week, it is running a significant portion of the American automobile industry. Now it is thinking seriously about running the entire health care industry, and chances are Americans won't like the result any more than they like the government takeover of the banks or the auto industry.

Americans who now take for granted the ability to choose their care may suddenly find themselves being told by government bureaucrats that they are too old to qualify for a certain kind of surgery or that they have to go to the back of the line for a procedure they can now get right away. As I have said, Americans want health care reform, but this isn't what they have in mind. Americans don't want their health care denied and they don't want it delayed. But once government health care is the only option, bureaucratic hassles, endless hours stuck on hold waiting for government service representatives, restrictions on care, and, yes, rationing, are sure to follow. Americans don't want some remote bureaucrat in Washington deciding whether their mothers and fathers or spouses have access to a lifesaving drug. They don't want to share the fate of Bruce Hardy.

Bruce was a British citizen who was suffering from cancer. According to press reports, his doctor wanted to prescribe a new drug that was proven to delay the spread of his disease. But the government agency that runs Britain's health care system denied the treatment. They said it was too expensive—that Bruce Hardy's life wasn't worth prolonging, based on the cost to the government of the drug he needed to live. In a story discussing Bruce's plight, the New York Times noted that if Bruce had lived in the United States, he likely would have been able to get this treatment.

But that could change. What happened to Bruce Hardy could happen here. Americans who now have the freedom to find the care they need and to make their own health care decisions could be stripped of that right by a new government agency. This happens every single day in countries such as Britain. It happens to people like Bruce Hardy, against their will and against the will of their loved ones. As Bruce's wife put it:

> Everybody should be allowed to have as much life as they can.

In America, we are free to make those decisions ourselves. If Congress approves a government takeover of health care, that freedom could soon be a memory.

Mr. President, I yield the floor.

RESERVATION OF LEADER TIME

The ACTING PRESIDENT pro tempore. Under the previous order, leadership time is reserved.

MORNING BUSINESS

The ACTING PRESIDENT pro tempore. Under the previous order, there will now be a period of morning business for up to 1 hour, with Senators permitted to speak therein for up to 10 minutes each, with the time equally divided and controlled between the two leaders, or their designees, with the majority controlling the first half and the Republicans controlling the second half.

Mr. MCCONNELL. Mr. President, I suggest the absence of a quorum.

The ACTING PRESIDENT pro tempore. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mr. LIEBERMAN. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

DETAINEE PHOTOGRAPHIC RECORDS PROTECTION ACT

Mr. LIEBERMAN. Mr. President, I rise to speak in morning business about supporting President Obama in his efforts to protect the safety and security of the American people, the American military, and the civilian personnel serving us all abroad. This goes to the question of the pending lawsuit by the American Civil Liberties Union that would require the publication of various photographs of treatment by Americans of detainees.

On May 13, President Obama announced that he would not release nearly 2,100 photographs depicting the alleged mistreatment of detainees in U.S. custody. Detainees are what we normally call ''prisoners of war,'' except they have a lower status than that under the Geneva Conventions. Many of these photographs were the subject of a Freedom of Information Act lawsuit filed by the ACLU, while others were discovered during internal Department of Defense investigations into detainee abuse.

Last fall, as part of that lawsuit, the Second Circuit Court of Appeals in New York ordered the release of many of those photographs. Instead of appealing that decision to the Supreme Court at that time, government lawyers agreed to release the images, as well as others that were part of the internal Department of Defense investigation.

Senator LINDSEY GRAHAM and I strongly objected to that decision and wrote a letter to the President explaining our position. We know that photographs such as the ones at issue in the ACLU lawsuit are, in fact, used by Islamist terrorists around the world to recruit followers and inspire attacks against American service men and women. In particular, there is compelling evidence that the images depicting detainee abuse at Abu Ghraib was a great spur to the insurgency in Iraq and made it harder for our troops to succeed safely in their mission there.

After consulting with his commanders on the ground, including General Petraeus and General Odierno, President Obama decided to reverse the decision of the government lawyers and fight the release of these photographs. Of course, I feel very strongly that he made not only a gutsy decision but the entirely right decision.

The President said, in making that decision:

> The publication of these photos would not add any additional benefit to our understanding of what was carried out in the past by a small number of individuals. In fact, the most direct consequence of releasing them, I believe, would be to further inflame anti-American opinion and to put our troops in great danger.

I strongly believe this decision was the right one by the President, acting as Commander in Chief. It will protect our troops in Iraq, Afghanistan, and elsewhere, and it will make it easier and safer for them to carry out the missions we have asked them to do. In fact—and this has become public in recent days, and I heard it earlier around the time the President made the decision—after learning that the release of these photographs was either possible or likely, before President Obama's decision to appeal, Iraq's Prime Minister Maliki said, according to these press reports, that ''Baghdad will burn'' if the photos are released, jeopardizing many of the remarkable security gains our military and civilian personnel have achieved in Iraq in recent years, putting our troops and personnel in danger.

To support the President's decision and establish a procedure to protect the release of similar photos in the future, for the exact same reason, Senator GRAHAM—my colleague and friend, who is now on the floor—and I introduced the Detainee Photographic Records Protection Act. That legislation would authorize the Secretary of Defense, after consultation with the Chairman of the Joint Chiefs, to certify to the President that the disclosure of photographs such as the ones at issue in the ACLU lawsuit would endanger the lives of U.S. citizens and members of the armed services deployed abroad. Essentially, our bill would codify the exact process that President Obama went through in arriving at his decision to fight the release of these photos.

Also, the language in the bill Senator GRAHAM and I introduced is clear, we believe, in that it would apply to the current ACLU lawsuit and block the release of these photographs, preventing the damage to American lives that would occur from that release.

The Senate unanimously supported the inclusion of a slightly modified version of the Detainee Photographic Records Protection Act in the supplemental appropriations bill for the wars in Iraq and Afghanistan. The Senate then approved the supplemental bill by a vote of 86 to 3 before we broke for the Memorial Day recess.

I rise today, along with my friend and colleague from South Carolina, to strongly encourage our colleagues in the Senate and in the House on the conference committee to include the modified version of the Detainee Photographic Records Protection Act in the conference report that is currently being negotiated.

We know there are those who are urging the conferees to delete this provision, or to water it down. That would be a terrible mistake. As President Obama well understands, nothing less than the safety and security and lives of our military service men and women is at stake—not to mention our nonmilitary personnel deployed abroad, not to mention Americans here at home and throughout the world, who may be at risk of terrorist attack by an individual recruited to Islamist extremism and terrorism, as a result of the anger spurred by the release of these photographs.

Bottom line: American lives are at stake. Senator GRAHAM and I feel so strongly about this. I will speak for myself here and then allow him, in a moment, to speak for himself. Any decision to eliminate this provision from the Supplemental Appropriations Act, or to water it down so it has no meaning, would lead me, certainly, much as I support what is in the Supplemental Appropriations Act, to oppose that act, because I think a failure to back up President Obama in this matter would, as I have said, compromise safety and, ultimately, the lives of a lot of Americans, particularly those in uniform.

Let me be clear. By including the Detainee Photographic Records Protection Act in the conference report for the supplemental appropriations bill, Congress will not be condoning the behavior depicted in the photographs. In fact, the exact opposite is true. Such behavior has already been prohibited by Congress in the Detainee Treatment Act and the Military Commissions Act as well as by executive orders issued by President Obama.

We expect that those responsible for the mistreatment of detainees will be held accountable. And that is exactly what the Department of Defense has done with the internal investigations that are finished or are underway.

But the bottom line is that the release of these photographs, and potentially others that may be discovered, will endanger the lives of our military personnel and every U.S. citizen. Every American, whether in a military uniform or not, will always be a target for al-Qaida or supporters of al-Qaida around the world.

The public release of these pictures, which we know will be spread on violent jihadist Web sites around the world immediately after they are published, will only energize the efforts of our enemies.

With the inclusion of the Detainee Photographic Records Protection Act in the supplemental appropriations bill conference report, Congress has the opportunity to support the President in

his primary mission as Commander in Chief—and, frankly, our number one mission as well—to protect the safety and security of the United States.

I strongly urge my colleagues to include our amendment—which had unanimous support in this Chamber—in the final conference report.

I yield the floor for my friend from South Carolina.

The ACTING PRESIDENT pro tempore. The Senator from South Carolina is recognized.

Mr. GRAHAM. Mr. President, I ask that my time be taken from the minority side when it comes to the 30-minute allocation.

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

Mr. GRAHAM. Mr. President, I stand up in support of my friend and colleague from Connecticut, Senator LIEBERMAN. We were able to get passed a piece of legislation, through an amendment on the supplemental bill, that is directly on point regarding the pending court case, the subject matter of which is releasing additional detainee photos of past abuse.

The President has looked at these photos, and we all understand that it is more of the same—that the photos in question came from American troops' cameras, who were engaged in inappropriate activity. Disciplinary action has been taken where appropriate, and nothing new is to be learned. There is no new evidence of crimes by people who have yet to be dealt with.

It would, as my friend from Connecticut said, be voyeurism for the sake of voyeurism. The photos are offensive but no different than what we have already seen.

The reason we are here supporting this legislation and supporting the President is because, as Senator LIEBERMAN said, the consequences of releasing the photos are not a mystery. Americans are going to die.

I just got back from a trip to North Africa, Morocco, and Algeria, and I went to Greece. Every embassy very much was worried about what would happen to Americans if these photos were released. They were preparing to be, quite frankly, under siege.

As Senator LIEBERMAN indicated in the Miami Herald article, when Prime Minister Maliki in Iraq was informed these additional photos may be released, another tranche of photos coming out about detainee abuse, according to American military officials involved, he went pale in the face and uttered the phrase: ''Baghdad will burn.''

To those who are arguing for the release of the photos, I do not question their patriotism, I do not question their motives. I question their judgment. To our House and Senate colleagues who are in conference, please understand that Senator LIEBERMAN, myself, and I think the vast majority of our Senate colleagues—we did not take a recorded vote—believe this is a life-and-death matter. I believe that to release the photos would result in certain death and attack against American interests abroad, particularly against the diplomatic corps and our men and women serving abroad, and no higher purpose would be achieved here at home.

We made compromises in the legislation, but we did not destroy the intent of the legislation. And for the courts that may listen to try to discern the legislative intent, the intent by both authors was to make sure that the photos subject to the pending litigation were never released and Congress weighed in and agreed with the President's decision not to release those photos. We have changed the law, directly on point, to give legislative backing to the idea that these particular photographs, and those like these photographs, should not be released for a period of 3 years, and that is in our national security interests to do so.

I hope the courts will understand what we were trying to do and what we actually did.

To our House and Senate colleagues trying to find compromises on the supplemental legislation, please understand the purpose of this amendment, how important it is to the war effort, why the President is in support of the amendment. He is making a very responsible decision as Commander in Chief. I applaud him for doing that. This language needs to stay as is, intact. Again, it is a matter of life and death. And if for some reason it came out, it would be a disaster—because the court case is pending now—if it came out, please understand that there will be nothing done in the Senate for as long as I am here and Senator LIEBERMAN is here that would not have this amendment attached. You could not name a post office without this amendment. It is not going away.

I thank my colleague from Arkansas for her courtesies.

I yield the floor.

The ACTING PRESIDENT pro tempore. The Senator from Arkansas.

Mrs. LINCOLN. Mr. President, I thank my colleagues, Senator LIEBERMAN and Senator GRAHAM, for their thoughtful dedication to this issue and certainly looking for the right compromise and, more importantly, for their support of our troops, the men and women in uniform and those who serve this country all across the globe.

FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT

Mrs. LINCOLN. Mr. President, I rise today to urge my colleagues to support and pass the legislation that is currently before the Senate, and that is the Family Smoking Prevention and Tobacco Control Act. The Family Smoking Prevention and Tobacco Control Act would implement important marketing restrictions on tobacco products and especially on the marketing practices that have been shown to increase tobacco use among our Nation's young people.

I, like so many of my colleagues, some of whom are experiencing at the same time I am, and some who have already been through it—I am just beginning the teen years with my children. My twin boys will be turning 13 in a couple of weeks. Let me tell you, the pressure on our young people across this country is very real and very tough.

What we are talking about in this bill—the authority—is absolutely critical. The tobacco industry has a long and disturbing history of marketing its products to appeal to young people. Last year, the National Cancer Institute published a comprehensive report on tobacco marketing that documented the powerful influence that tobacco marketing has on our children.

The report found that ''the evidence base indicates a casual relationship between tobacco advertising and increased levels of tobacco initiation and continued consumption'' and that even brief exposure to tobacco advertising influences kids' attitudes and perceptions about smoking, as well as their intentions to smoke.

The tobacco industry spends more than $13 billion per year to promote their products. Many of these marketing efforts directly reach our children. I want to share with folks an ad. Here is an ad that appeared in a convenience store in Delaware. Yes, it says what you think it says. It is a back-to-school special for Camel cigarettes—a back-to-school special.

I have to say, I so enjoyed when my kids were in elementary school and taking them to the store to get their crayons and their pencils and their notebooks. I think about now even in their teen years, we go and maybe we get a couple of new outfits, we talk about graph paper and what they are going to learn and all the exciting things. We prepare them for school, getting back to school. We are ending up school right now, but we will go through it in the fall again. It is unbelievable to me that we would run ads: back to school, get your bargain, here it is, a pack of cigarettes.

The industry also reaches our kids by saturating convenience stores, drugstores, and gas stations with tobacco advertisements, often placing ads and products near the candy and gum displays, or using other visual tricks such as bright colors and also through sponsorship of sports and entertainment events which are obviously what kids are interested in so often in the sports arena and other things with which they are involved.

Tobacco companies know that almost all new smokers begin as kids. They carefully design their products to make them more attractive to kids. For example, in this ad, flavors are used to make the smoke less harsh, more flavorful, and easier for kids to smoke.

We see in this ad, R. J. Reynolds has heavily marketed products with fruit

flavors such as Twista Lime, Warm Winter Toffee, and Winter Mocha Mint. Bright colorful ads for these cigarettes have appeared in magazines that are very popular with our children.

Who do we think candy and fruit-flavored products are for? Certainly they are not for the adults who have been smoking Marlboros or Camels all their lives. Survey evidence shows what we would expect: that these candy and fruit-flavored products are far more popular with our young people than among adults.

Targeting our children like this is absolutely unacceptable—unacceptable for the health of our children and for the well-being of our health care system. Here we are debating health care reform at a time when we realize that it is 18 percent of our GDP, and over the next 10 years health care is going to be one-fifth of our economy. To be advertising to our children to start something that we know is going to be detrimental to their health is absolutely unacceptable.

If we are ever going to address the No. 1 preventable cause of death in the United States, we need to provide the FDA with the authority to restrict tobacco companies marketing to our children.

While progress has been made in the last decade, youth tobacco use remains far too high. More than 20 percent of high school students in my home State of Arkansas smoke, and more than 18 percent of Arkansas's high school boys use smokeless tobacco. Each year, a staggering 13,100 Arkansas kids try cigarettes for the first time, and another 3,900 additional kids become new and regular daily smokers. Ninety percent of all adult smokers began smoking in their teen years. Tobacco companies know they have to attract kids to be able to survive. They know that if they get kids hooked, then they will have those adult smokers, and their marketing efforts have paid off.

According to recent studies by the U.S. Centers for Disease Control and Prevention, more than 80 percent of kids smoke the three most heavily advertised brands. While tobacco companies claim they do not market to our children, they are surely doing a good job of getting kids to use their products.

We simply must do more to protect our children from the tobacco company advertising and promotion. Effective regulation of the tobacco industry must provide FDA with the authority to restrict tobacco company marketing to children. That is one of the key goals of the Family Smoking Prevention and Tobacco Act. It imposes those specific marketing restrictions on tobacco products, restrictions on those forms of tobacco marketing I mentioned earlier that have been shown to increase youth tobacco use.

Even more importantly, the bill gives the FDA the flexibility to further restrict tobacco marketing so it can respond to the inevitable innovative attempts by the tobacco companies to get around specific restrictions. The restrictions on marketing included in the FDA tobacco bill are critical to any effort to prevent kids from starting to smoke and reduce the toll caused by tobacco.

Even though tobacco companies claim they have stopped intentionally marketing to kids, they continue their tradition of designing products that appeal explicitly to new users. The large majority—and we cannot ignore it—the large majority of those new users are our children.

I mentioned that my children are about to be teens, and as the mother of twins about to be teens, I know that parents want to do all they can to protect their children. Children are faced with so much in today's world, whether it is violence, whether it is issues such as this, whether it is peer pressure. Our children are faced with many things. We want to protect them. We want to help them learn to wear seatbelts and bicycle helmets. We want to teach them all that we can, the skills they need in life so they can remain safe and healthy.

I look at the restrictions we put on our children each day to make sure they are wearing those helmets, to make sure they are not on the computer too much, to make sure they are using the computer safely. All of these things we do as parents to ensure we are doing our job to keep our children as safe as we possibly can.

We also need to protect our children from tobacco companies—their advertising and promotion. The Family Smoking Prevention and Tobacco Control Act does this. It would end special protection for the tobacco industry, and it would be safeguarding our children and creating a healthier nation in the process.

Again, I encourage my colleagues to work with me and all of the other Senators working on this bill to move this bill forward on behalf of our children, certainly on behalf of the health care needs of this country but, most importantly, for parents who are trying so hard to ensure their kids will get off on the right foot and that they will learn to make wise decisions and will not be faced with these types of temptations and others to stray in a way that is going to be unhealthy for them and unhealthy for their future.

Mr. President, I ask unanimous consent to reserve the remaining majority time.

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

Mrs. LINCOLN. Mr. President, I yield the floor.

The ACTING PRESIDENT pro tempore. The Senator from Arizona is recognized.

NUCLEAR WEAPONS

Mr. McCAIN. Mr. President, today we celebrate the unveiling in the Capitol of a statue of Ronald Reagan, one of our country's great Presidents and a personal hero to me throughout my political life. While there are many aspects of President Reagan's legacy we might reflect on today, I would like to take the opportunity to discuss one of them—his dream of a world free of nuclear weapons.

Speaking before the Japanese Diet on November 11, 1983, President Ronald Reagan said:

> The only value in possessing nuclear weapons is to make sure they can't ever be used. I know I speak for people everywhere when I say our dream is to see the day when nuclear weapons will be banished from the face of the earth.

That is my dream, too, and it is one shared by many of our most distinguished national security practitioners. In 2007, former Secretaries of State Henry Kissinger and George Shultz, along with former Secretary of Defense William Perry and Senator Sam Nunn, authored an article entitled ''A World Free of Nuclear Weapons,'' in which they laid out their vision of the globe free of the most dangerous weapons ever known.

This is a distant and difficult goal. We must proceed toward it prudently and pragmatically and with a focused concern for our security and the security of allies that depend on us. But the Cold War ended almost 20 years ago, and the time has come to take further measures to reduce dramatically the number of nuclear weapons in the world's arsenals. In so doing, the United States can—and indeed must—show the kind of leadership the world expects from us, in the tradition of American Presidents who worked to reduce the nuclear threat to mankind.

Our highest priority must be to reduce the danger that nuclear weapons will ever be used. Such weapons, while still important to deter an attack with weapons of mass destruction against us and our allies, represent the most abhorrent and indiscriminate form of warfare known to man. We do, quite literally, possess the means to destroy all mankind. We must seek to do all we can to ensure that nuclear weapons will never again be used. As the administration renews its nuclear weapons posture, it should, I believe, seek to reduce the size of our nuclear arsenal to the lowest number possible, consistent with our security requirements and global commitments. This means a move, as rapidly as possible, to a significantly smaller force. As we take such steps, it will be crucial to continue to deploy a safe and reliable nuclear deterrent, robust missile defenses, and superior conventional forces capable of defending the United States and our allies.

Today, we find ourselves at a nuclear crossroads. As rogue nations, including North Korea and Iran, push the nuclear envelope, the perils of a world awash in nuclear weapons is clear. Yet we should also consider the more hopeful alternative—a world in which there are far

fewer such weapons than there are today and in which proliferation, instability, and nuclear terrorism are far less likely.

In achieving this world, Ronald Reagan's dream will be more important than ever before. As Secretaries Kissinger and Shultz wrote with their colleagues in 2008:

> Progress must be facilitated by a clear statement of our ultimate goal. Indeed, this is the only way to build the kind of international trust and broad cooperation that will be required to effectively address today's threats. Without the vision of moving towards zero, we will not find the essential cooperation required to stop our downward spiral.

Make no mistake, we must arrest the downward spiral. North Korea's recent nuclear test is just the latest provocative demonstration of the troubling reality the world faces today. Together with Iran's ongoing commitment to nuclear development, we face real dangers in the proliferation of the world's most terrible weapons. The United States must lead the world not only in reducing the size of existing nuclear arsenals but also in reversing the course of nuclear proliferation. This requires a tough-minded approach to both Iran and North Korea, both of which have gotten away with too much for far too long.

We must also help ensure that other potential nuclear programs do not get off the ground. Last week, former National Security Adviser Brent Scowcroft joined two colleagues in calling on the President to promote the international ban on the spread of fissile materials that can be used in the production of nuclear weapons. I agree and urge the President to do so.

But we must also strengthen enforcement. We must insist that countries that receive the benefits of peaceful nuclear cooperation return or dismantle what they have received if, at any point, they violate or withdraw from the Non-Proliferation Treaty. Leading up to the 2010 Non-Proliferation Treaty Review conference, we should lay the groundwork for building an international consensus to ensure that the International Atomic Energy Agency has the tools to be a meaningful agent for achieving the dream of a nuclear weapon-free world. We should work with allies and partners to interdict the spread of nuclear weapons and materials—including any borne on vessels traveling to and from North Korea—under the Proliferation Security Initiative.

As a nation, we have a number of important decisions in the coming months, including those related to a follow-on to the Strategic Arms Reduction Treaty with Russia, the administration's planned resubmission of the Comprehensive Test Ban Treaty for ratification, and the need for a robust missile defense shield.

As we move ahead with these and other decisions, let us keep in mind the dream of a nuclear-free world, enunciated so eloquently by our 40th President. As Secretary Shultz has written, this was a dream President Reagan pursued with great patience and depth of conviction. We would be wise to follow his lead.

Mr. President, I ask unanimous consent to have printed in the RECORD two articles by George Shultz, William Perry, Henry Kissinger, and Sam Nunn, one of January 4, 2007, and the other of January 15, 2008.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

[From The Wall Street Journal, Jan. 4, 2007]

A WORLD FREE OF NUCLEAR WEAPONS

(By George P. Shultz, William J. Perry, Henry A. Kissinger and Sam Nunn)

Nuclear weapons today present tremendous dangers, but also an historic opportunity. U.S. leadership will be required to take the world to the next stage—to a solid consensus for reversing reliance on nuclear weapons globally as a vital contribution to preventing their proliferation into potentially dangerous hands, and ultimately ending them as a threat to the world.

Nuclear weapons were essential to maintaining international security during the Cold War because they were a means of deterrence. The end of the Cold War made the doctrine of mutual Soviet-American deterrence obsolete. Deterrence continues to be a relevant consideration for many states with regard to threats from other states. But reliance on nuclear weapons for this purpose is becoming increasingly hazardous and decreasingly effective.

North Korea's recent nuclear test and Iran's refusal to stop its program to enrich uranium—potentially to weapons grade—highlight the fact that the world is now on the precipice of a new and dangerous nuclear era. Most alarmingly, the likelihood that non-state terrorists will get their hands on nuclear weaponry is increasing. In today's war waged on world order by terrorists, nuclear weapons are the ultimate means of mass devastation. And non-state terrorist groups with nuclear weapons are conceptually outside the bounds of a deterrent strategy and present difficult new security challenges.

Apart from the terrorist threat, unless urgent new actions are taken, the U.S. soon will be compelled to enter a new nuclear era that will be more precarious, psychologically disorienting, and economically even more costly than was Cold War deterrence. It is far from certain that we can successfully replicate the old Soviet-American "mutually assured destruction" with an increasing number of potential nuclear enemies worldwide without dramatically increasing the risk that nuclear weapons will be used. New nuclear states do not have the benefit of years of step-by-step safeguards put in effect during the Cold War to prevent nuclear accidents, misjudgments or unauthorized launches. The United States and the Soviet Union learned from mistakes that were less than fatal. Both countries were diligent to ensure that no nuclear weapon was used during the Cold War by design or by accident. Will new nuclear nations and the world be as fortunate in the next 50 years as we were during the Cold War?

* * * * *

Leaders addressed this issue in earlier times. In his "Atoms for Peace" address to the United Nations in 1953, Dwight D. Eisenhower pledged America's "determination to help solve the fearful atomic dilemma—to devote its entire heart and mind to find the way by which the miraculous inventiveness of man shall not be dedicated to his death, but consecrated to his life." John F. Kennedy, seeking to break the logjam on nuclear disarmament, said, "The world was not meant to be a prison in which man awaits his execution."

Rajiv Gandhi, addressing the U.N. General Assembly on June 9, 1988, appealed, "Nuclear war will not mean the death of a hundred million people. Or even a thousand million. It will mean the extinction of four thousand million: the end of life as we know it on our planet earth. We come to the United Nations to seek your support. We seek your support to put a stop to this madness."

Ronald Reagan called for the abolishment of "all nuclear weapons," which he considered to be "totally irrational, totally inhumane, good for nothing but killing, possibly destructive of life on earth and civilization." Mikhail Gorbachev shared this vision, which had also been expressed by previous American presidents.

Although Reagan and Mr. Gorbachev failed at Reykjavik to achieve the goal of an agreement to get rid of all nuclear weapons, they did succeed in turning the arms race on its head. They initiated steps leading to significant reductions in deployed long- and intermediate-range nuclear forces, including the elimination of an entire class of threatening missiles.

What will it take to rekindle the vision shared by Reagan and Mr. Gorbachev? Can a world-wide consensus be forged that defines a series of practical steps leading to major reductions in the nuclear danger? There is an urgent need to address the challenge posed by these two questions.

The Non-Proliferation Treaty (NPT) envisioned the end of all nuclear weapons. It provides (a) that states that did not possess nuclear weapons as of 1967 agree not to obtain them, and (b) that states that do possess them agree to divest themselves of these weapons over time. Every president of both parties since Richard Nixon has reaffirmed these treaty obligations, but non-nuclear weapon states have grown increasingly skeptical of the sincerity of the nuclear powers.

Strong non-proliferation efforts are under way. The Cooperative Threat Reduction program, the Global Threat Reduction Initiative, the Proliferation Security Initiative and the Additional Protocols are innovative approaches that provide powerful new tools for detecting activities that violate the NPT and endanger world security. They deserve full implementation. The negotiations on proliferation of nuclear weapons by North Korea and Iran, involving all the permanent members of the Security Council plus Germany and Japan, are crucially important. They must be energetically pursued.

But by themselves, none of these steps are adequate to the danger. Reagan and General Secretary Gorbachev aspired to accomplish more at their meeting in Reykjavik 20 years ago—the elimination of nuclear weapons altogether. Their vision shocked experts in the doctrine of nuclear deterrence, but galvanized the hopes of people around the world. The leaders of the two countries with the largest arsenals of nuclear weapons discussed the abolition of their most powerful weapons.

* * * * *

What should be done? Can the promise of the NPT and the possibilities envisioned at Reykjavik be brought to fruition? We believe that a major effort should be launched by the United States to produce a positive answer through concrete stages.

First and foremost is intensive work with leaders of the countries in possession of nuclear weapons to turn the goal of a world

without nuclear weapons into a joint enterprise. Such a joint enterprise, by involving changes in the disposition of the states possessing nuclear weapons, would lend additional weight to efforts already under way to avoid the emergence of a nuclear-armed North Korea and Iran.

The program on which agreements should be sought would constitute a series of agreed and urgent steps that would lay the groundwork for a world free of the nuclear threat. Steps would include:

Changing the Cold War posture of deployed nuclear weapons to increase warning time and thereby reduce the danger of an accidental or unauthorized use of a nuclear weapon.

Continuing to reduce substantially the size of nuclear forces in all states that possess them.

Eliminating short-range nuclear weapons designed to be forward-deployed. Initiating a bipartisan process with the Senate, including understandings to increase confidence and provide for periodic review, to achieve ratification of the Comprehensive Test Ban Treaty, taking advantage of recent technical advances, and working to secure ratification by other key states.

Providing the highest possible standards of security for all stocks of weapons, weapons-usable plutonium, and highly enriched uranium everywhere in the world.

Getting control of the uranium enrichment process, combined with the guarantee that uranium for nuclear power reactors could be obtained at a reasonable price, first from the Nuclear Suppliers Group and then from the International Atomic Energy Agency (IAEA) or other controlled international reserves. It will also be necessary to deal with proliferation issues presented by spent fuel from reactors producing electricity.

Halting the production of fissile material for weapons globally; phasing out the use of highly enriched uranium in civil commerce and removing weapons-usable uranium from research facilities around the world and rendering the materials safe.

Redoubling our efforts to resolve regional confrontations and conflicts that give rise to new nuclear powers.

Achieving the goal of a world free of nuclear weapons will also require effective measures to impede or counter any nuclear-related conduct that is potentially threatening to the security of any state or peoples.

Reassertion of the vision of a world free of nuclear weapons and practical measures toward achieving that goal would be, and would be perceived as, a bold initiative consistent with America's moral heritage. The effort could have a profoundly positive impact on the security of future generations. Without the bold vision, the actions will not be perceived as fair or urgent. Without the actions, the vision will not be perceived as realistic or possible.

We endorse setting the goal of a world free of nuclear weapons and working energetically on the actions required to achieve that goal, beginning with the measures outlined above.

[From the Wall Street Journal Online, Jan. 15, 2008]

TOWARD A NUCLEAR-FREE WORLD

(By George P. Shultz, William J. Perry, Henry A. Kissinger and Sam Nunn)

The accelerating spread of nuclear weapons, nuclear know-how and nuclear material has brought us to a nuclear tipping point. We face a very real possibility that the deadliest weapons ever invented could fall into dangerous hands.

The steps we are taking now to address these threats are not adequate to the danger. With nuclear weapons more widely available, deterrence is decreasingly effective and increasingly hazardous.

One year ago, in an essay in this paper, we called for a global effort to reduce reliance on nuclear weapons, to prevent their spread into potentially dangerous hands, and ultimately to end them as a threat to the world. The interest, momentum and growing political space that has been created to address these issues over the past year has been extraordinary, with strong positive responses from people all over the world.

Mikhail Gorbachev wrote in January 2007 that, as someone who signed the first treaties on real reductions in nuclear weapons, he thought it his duty to support our call for urgent action: ''It is becoming clearer that nuclear weapons are no longer a means of achieving security; in fact, with every passing year they make our security more precarious.''

In June, the United Kingdom's foreign secretary, Margaret Beckett, signaled her government's support, stating: ''What we need is both a vision—a scenario for a world free of nuclear weapons—and action—progressive steps to reduce warhead numbers and to limit the role of nuclear weapons in security policy. These two strands are separate but they are mutually reinforcing. Both are necessary, but at the moment too weak.''

We have also been encouraged by additional indications of general support for this project from other former U.S. officials with extensive experience as secretaries of state and defense and national security advisors. These include: Madeleine Albright, Richard V. Allen, James A. Baker III, Samuel R. Berger, Zbigniew Brzezinski, Frank Carlucci, Warren Christopher, William Cohen, Lawrence Eagleburger, Melvin Laird, Anthony Lake, Robert McFarlane, Robert McNamara and Colin Powell.

Inspired by this reaction, in October 2007, we convened veterans of the past six administrations, along with a number of other experts on nuclear issues, for a conference at Stanford University's Hoover Institution. There was general agreement about the importance of the vision of a world free of nuclear weapons as a guide to our thinking about nuclear policies, and about the importance of a series of steps that will pull us back from the nuclear precipice.

The U.S. and Russia, which possess close to 95% of the world's nuclear warheads, have a special responsibility, obligation and experience to demonstrate leadership, but other nations must join.

Some steps are already in progress, such as the ongoing reductions in the number of nuclear warheads deployed on long-range, or strategic, bombers and missiles. Other near-term steps that the U.S. and Russia could take, beginning in 2008, can in and of themselves dramatically reduce nuclear dangers. They include:

Extend key provisions of the Strategic Arms Reduction Treaty of 1991. Much has been learned about the vital task of verification from the application of these provisions. The treaty is scheduled to expire on Dec. 5, 2009. The key provisions of this treaty, including their essential monitoring and verification requirements, should be extended, and the further reductions agreed upon in the 2002 Moscow Treaty on Strategic Offensive Reductions should be completed as soon as possible.

Take steps to increase the warning and decision times for the launch of all nuclear-armed ballistic missiles, thereby reducing risks of accidental or unauthorized attacks. Reliance on launch procedures that deny command authorities sufficient time to make careful and prudent decisions is unnecessary and dangerous in today's environment. Furthermore, developments in cyberwarfare pose new threats that could have disastrous consequences if the command-and-control systems of any nuclear-weapons state were compromised by mischievous or hostile hackers. Further steps could be implemented in time, as trust grows in the U.S.-Russian relationship, by introducing mutually agreed and verified physical barriers in the command-and-control sequence.

Discard any existing operational plans for massive attacks that still remain from the Cold War days. Interpreting deterrence as requiring mutual assured destruction (MAD) is an obsolete policy in today's world, with the U.S. and Russia formally having declared that they are allied against terrorism and no longer perceive each other as enemies.

Undertake negotiations toward developing cooperative multilateral ballistic-missile defense and early warning systems, as proposed by Presidents Bush and Putin at their 2002 Moscow summit meeting. This should include agreement on plans for countering missile threats to Europe, Russia and the U.S. from the Middle East, along with completion of work to establish the Joint Data Exchange Center in Moscow. Reducing tensions over missile defense will enhance the possibility of progress on the broader range of nuclear issues so essential to our security. Failure to do so will make broader nuclear cooperation much more difficult.

Dramatically accelerate work to provide the highest possible standards of security for nuclear weapons, as well as for nuclear materials everywhere in the world, to prevent terrorists from acquiring a nuclear bomb. There are nuclear weapons materials in more than 40 countries around the world, and there are recent reports of alleged attempts to smuggle nuclear material in Eastern Europe and the Caucasus. The U.S., Russia and other nations that have worked with the Nunn-Lugar programs, in cooperation with the International Atomic Energy Agency (IAEA), should play a key role in helping to implement United Nations Security Council Resolution 1540 relating to improving nuclear security—by offering teams to assist jointly any nation in meeting its obligations under this resolution to provide for appropriate, effective security of these materials.

As Gov. Arnold Schwarzenegger put it in his address at our October conference, ''Mistakes are made in every other human endeavor. Why should nuclear weapons be exempt?'' To underline the governor's point, on Aug. 29–30, 2007, six cruise missiles armed with nuclear warheads were loaded on a U.S. Air Force plane, flown across the country and unloaded. For 36 hours, no one knew where the warheads were, or even that they were missing.

Start a dialogue, including within NATO and with Russia, on consolidating the nuclear weapons designed for forward deployment to enhance their security, and as a first step toward careful accounting for them and their eventual elimination. These smaller and more portable nuclear weapons are, given their characteristics, inviting acquisition targets for terrorist groups.

Strengthen the means of monitoring compliance with the nuclear Non-Proliferation Treaty (NPT) as a counter to the global spread of advanced technologies. More progress in this direction is urgent, and could be achieved through requiring the application of monitoring provisions (Additional Protocols) designed by the IAEA to all signatories of the NPT.

Adopt a process for bringing the Comprehensive Test Ban Treaty (CTBT) into effect, which would strengthen the NPT and aid international monitoring of nuclear activities. This calls for a bipartisan review, first, to examine improvements over the past

decade of the international monitoring system to identify and locate explosive underground nuclear tests in violation of the CTBT; and, second, to assess the technical progress made over the past decade in maintaining high confidence in the reliability, safety and effectiveness of the nation's nuclear arsenal under a test ban. The Comprehensive Test Ban Treaty Organization is putting in place new monitoring stations to detect nuclear tests—an effort the U.S should urgently support even prior to ratification.

In parallel with these steps by the U.S. and Russia, the dialogue must broaden on an international scale, including non-nuclear as well as nuclear nations.

Key subjects include turning the goal of a world without nuclear weapons into a practical enterprise among nations, by applying the necessary political will to build an international consensus on priorities. The government of Norway will sponsor a conference in February that will contribute to this process.

Another subject: Developing an international system to manage the risks of the nuclear fuel cycle. With the growing global interest in developing nuclear energy and the potential proliferation of nuclear enrichment capabilities, an international program should be created by advanced nuclear countries and a strengthened IAEA. The purpose should be to provide for reliable supplies of nuclear fuel, reserves of enriched uranium, infrastructure assistance, financing, and spent fuel management—to ensure that the means to make nuclear weapons materials isn't spread around the globe.

There should also be an agreement to undertake further substantial reductions in U.S. and Russian nuclear forces beyond those recorded in the U.S.-Russia Strategic Offensive Reductions Treaty. As the reductions proceed, other nuclear nations would become involved.

President Reagan's maxim of ''trust but verify'' should be reaffirmed. Completing a verifiable treaty to prevent nations from producing nuclear materials for weapons would contribute to a more rigorous system of accounting and security for nuclear materials.

We should also build an international consensus on ways to deter or, when required, to respond to, secret attempts by countries to break out of agreements.

Progress must be facilitated by a clear statement of our ultimate goal. Indeed, this is the only way to build the kind of international trust and broad cooperation that will be required to effectively address today's threats. Without the vision of moving toward zero, we will not find the essential cooperation required to stop our downward spiral.

In some respects, the goal of a world free of nuclear weapons is like the top of a very tall mountain. From the vantage point of our troubled world today, we can't even see the top of the mountain, and it is tempting and easy to say we can't get there from here. But the risks from continuing to go down the mountain or standing pat are too real to ignore. We must chart a course to higher ground where the mountaintop becomes more visible.

Mr. MCCAIN. Mr. President, I suggest the absence of a quorum.

The PRESIDING OFFICER (Mr. BENNET). The clerk will call the roll.

The legislative clerk proceeded to call the roll.

Mr. INHOFE. Mr. President, I ask unanimous consent the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

ENERGY

Mr. INHOFE. Mr. President, as the ranking member and previously the chairman of the Environment and Public Works Committee, I understand we are actually the committee of jurisdiction over a lot of the energy concerns we have in this country. It is a real crisis. I know there are other things happening now that people are focused on, but this is certainly something the Presiding Officer is aware of, given the committees on which he is serving. When it comes to developing a comprehensive energy policy in the United States, we are faced with a stark contrast. We can develop and produce domestic supplies of reliable and affordable energy that will help jump-start our economy, create high-paying jobs, and bring down energy costs on consumers, all while making our Nation less dependent on foreign energy supplies, or we can implement policies designed to drive up the costs of energy on American families, shift jobs overseas, and deepen this recession.

For the sake of our economy, our energy security, and environmental goals, I choose the ''all of the above'' approach.

I sit and listen to people who say we want to do something about our dependence on foreign countries for our ability to run this machine called America. At the same time, they are against coal, they are against oil, they are against gas, they are against nuclear. Those are the things that are there, the technology is there and we can use them. But they are looking somehow into the future and saying there has to be some green solution. I am the first one to say, when the technology is there, I am going to be right there with them. It is not there yet.

Over the next several weeks, I am planning to speak on the floor several times about the benefits of nuclear energy and my proposals for reinvigorating that industry. Today, I will discuss how nuclear will help put Americans back to work and move our economy forward as well as focus on the regulatory challenges facing new nuclear construction and what I plan to do to help nuclear energy play an increasing role in meeting our energy needs.

One of the problems we have had is we have had several colleagues coming down, talking about why nuclear is good and why we should do it, but they have not addressed the barriers there and the bureaucratic problems we have right now.

The need to grow our domestic energy supply is clear. The Energy Information Administration projects that our demand for electricity will increase 26 percent by the year 2030, requiring 260 gigawatts of new electricity generation. Every source will need to grow to produce more energy to meet that demand. Curtis Frasier, the executive vice president of Shell America Gas & Power, was recently quoted in Greenwire, warning that the recession could be masking a global energy shortage.

He said:

> When the economy returns, we're going to be back to the energy crisis.

He said:

> Nothing has been done to solve that crisis. We've got a huge mountain to climb.

This is a very significant chart. It shows electricity growth is linked to the American economy. Mr. Frasier voices real concern. As you can see, this graph shows the total energy and shows the GDP. The GDP is the blue line going up and the electricity use and the total energy are lines that go right along with it. In fact, when it flattens out, such as it did in 1990 for about a 3-year period, all three flattened out at the same time. The same thing is true up here when it flattened out during 2005. So we see there is that linkage there, and it is a very real one.

This is not your father's nuclear industry. Today's nuclear industry has demonstrated marked improvement in safety, reliability, and costs since the late 1980s. The industry also has proved that safety and reliable performance are closely linked.

We have a chart here, ''Improved Safety Yields Better Performance.'' If you look at the two lines, we are talking about the line that would be the capacity factor, and this line, the red line, would be significant events. Significant events are things that are problems. We all remember significant events in nuclear energy. The press always highlights these and tries to make us believe this is a dangerous form when it is, in fact, not dangerous. The significant events have been going down. It is hard to see there. It goes from 1988 all up to the present year and it goes down as the capacity factor is going up. This is an indicator of the results, that the industry has dramatically increased its capacity by 45 percent and has operated roughly 90 percent of the time in the last 5 years. This improved performance is demonstrating that nuclear is both safe and reliable. It has made nuclear energy more affordable.

We have another chart that is the ''U.S. Electricity Production Costs.'' Nuclear energy generates nearly 20 percent of the energy that powers our economy and has the lowest production cost compared to other sources. You can see by the chart, not only has nuclear energy had the lowest production costs for the last 7 years, its production cost is very stable and not vulnerable to the price fluctuations here shown by the other resources.

These lines here represent nuclear and coal. They go along pretty much the same. However, if you look at fluctuations in gas and in petroleum, you can see they are moving. This is something that is very significant.

I might mention, even though we only are using 22 percent of our energy

coming from nuclear, countries such as France and other countries are doing 80 percent. That is what we are going to get to. We are going to try to do something to increase our nuclear capacity. Not only will nuclear energy give a boost to our economy by providing safe, reliable, and affordable electricity, it will also produce new jobs. Mark Ayers, the President of the AFL–CIO Building and Construction Trades Department, has described his union's relationship with the industry. He said—and this is the unions I am quoting now:

> We will be there with you to help pursue the adoption of a diverse American energy portfolio that places a high priority on the reemergence of nuclear power.

Why is Mr. Ayers so supportive of nuclear energy? He knows the number of high-quality jobs that just one new nuclear plant would provide. It would be 1,400 to 1,800 jobs during construction for each new plant; 400 to 700 permanent jobs when the plant begins operating, with salaries 36 percent higher than the local average. It would provide 400 to 700 additional jobs providing goods and services.

It is a huge boost for the economy and for the labor unions, so we have their strong support. Clearly, increased development of nuclear energy would strongly benefit our economy by providing energy and putting Americans back to work. However, right now investors in new nuclear plants face political and regulatory risks. The capital investors still remember the cost overruns experienced during the construction of our existing fleet of plants, caused in part by a cumbersome licensing process. The licensing process has been revised but has, as yet, to be fully tested. The risk of licensing delays may be lower, but the potential consequences of regulatory delays remain significant.

This chart shows the locations of the potential new nuclear plants. On September 25 of 2007, the Nuclear Regulatory Commission filed an application to build and operate a plant near Bay City, TX. That was the first application for a new plant that the NRC has received in 34 years. Since then, 16 more applications have been filed for a total of 26 new nuclear reactors.

Let's stop and think about that. We are talking about 2007.

I ask unanimous consent I be given an additional 5 minutes of time.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. INHOFE. That is, since 2007, we have been able to do that. We did nothing for 34 years, and now we have 16 more applications on file which would be for 26 nuclear reactors. Some applications cover more than one reactor. These efforts to develop new plants are critical to meeting our energy needs, and I am committed to doing what I can to help build these new plants.

One of the most significant factors contributing to this revitalization is the NRC's transformation over the last 12 years. In 1997, Republicans were the majority. I was the chairman of the Clean Air Subcommittee of the Environment and Public Works Committee, which had jurisdiction over nuclear energy. At that time, we had not had an oversight hearing in some 12 years, and I tell you, you cannot let a bureaucracy continue to operate without any oversight, so we started having oversight hearings. We gave targets that they had to do certain things by certain dates. As a result of that, they are now coming along and doing a good job.

This chart shows where the 16 applications are, so people can find their own State and see what it would do to the economy of their own State. Unfortunately, we don't have any in my State of Oklahoma. I wish we did and perhaps we will be able to in the future.

The next chart is the ''Applications Under Review By NRC.'' It is a little bit complicated, so I am not going to be using this chart. If anyone wants to know where the status is and what the companies are that have made the applications, certainly we have that information for them.

Despite significant efforts on the part of the NRC staff, this process has not unfolded as smoothly as it should. Schedules are not as detailed or transparent as they should be, and detailed schedules are a critical tool for managing such a large and complex process and to ensure it is thorough, efficient, and timely. Schedules are publicly available for safety evaluation reports and environmental impact statements but not for hearings or Commission consideration, which will ultimately determine when the license is actually issued.

At this time, there appears to be no information readily available regarding any of the actual dates that any of the new plant licenses will be issued. The absence of any specific schedules for issuing licenses seems to indicate a failure of the agency to properly plan and schedule its work, a failure to share such information, or both. This situation is troubling. How could a utility prepare for construction without a firm date when it can expect—be expected to receive their license?

These are huge investments we are talking about. There has to be predictability. How can an investor judge the risk of a project without being able to evaluate progress in the regulatory process? Both licensees and their potential investors would greatly benefit from the increased certainty.

I commend the Commission and staff for the level of effort that is reflected in existing schedules. However, I believe the Commission should pursue these remaining steps. It should require hearing boards to produce and to follow detailed schedules that reflect lessons learned during the review of the LES National Enrichment Facility in New Mexico. We would consider the recommendations we have there.

I firmly believe proper planning, detailed schedules, and the Commission engagement will foster more thorough, consistent, organized, and efficient efforts to issue new plants licenses.

I take my oversight role as the ranking member of the EPW Committee very seriously and will work to ensure that the NRC continues to build on the improvements made since I initiated oversight back in 1997. I intend to increase my focus on this and other licensing issues, including monthly progress reports on licensing activity and regular meetings with Chairman Jaczko. In our committee, we have Democrats and Republicans very supportive of this effort to expand our capability in nuclear energy.

My hope is to see that the NRC issues the first new license before the end of 2011 and eight more by 2013. Given construction estimates of 4 to 5 years, the first 2 reactors could be operational in 2016, with 14 more potentially in operation by the year 2018. Sixteen new reactors would be a good start to rejuvenating an industry that has been stagnant for 34 years. I believe these reactors can revitalize our economy and meet the growing demand for energy. I also agree with labor unions that are excited about the prospect of new jobs and what it will do for low-cost energy for America.

I look forward to the future. I plan to host a roundtable to highlight progress toward advanced design and to stay on board. Back in 1997, we hadn't had an oversight hearing in 12 years at that time, and we will make sure we don't repeat that mistake.

A lot has been done to prepare for nuclear construction, but a lot remains to be done. Whether the industry will succeed in building new plants will greatly depend upon President Obama's leadership. I am disappointed that the administration seems to send mixed signals regarding its support for nuclear energy. Last month in Prague, the President said:

> We must harness the power of nuclear energy on behalf of our efforts to combat climate change and to advance peace and opportunity for all people.

Yet just this month his budget contained language terminating the Yucca Mountain program before the Nuclear Regulatory Commission could even do its review—30 years of research and $7.7 billion down the drain, purely for political reasons. It is unthinkable that could happen, but it has happened.

In addition, President Obama recently appointed, as Chairman of the Federal Energy Regulatory Commission, Joe Wellinghoff, who stated his belief that we won't need any more nuclear plants ever. This isn't right, and it is totally inconsistent.

These mixed messages will soon become clear. President Obama has recently designated a new Chairman of the NRC and is expected to propose two additional nominees soon. Time will tell whether the NRC is an effective and efficient regulator.

In his Senate confirmation hearing, DOE Secretary Steven Chu said:

Nuclear power . . . is going to be an important part of the energy mix. It is 20 percent of our electricity generated today, but it is 70 percent of the carbon-free portion of electricity today. And it is baseload. So I think it is very important that we push ahead.

For that reason and every other reason, for the economy and for the environment and for our ability to provide our own energy in this country and lower our reliance upon foreign countries, I believe we need to move forward rapidly. We intend to do so with nuclear energy.

I yield the floor.

CONCLUSION OF MORNING BUSINESS

The PRESIDING OFFICER. The Senator from Rhode Island.

Mr. WHITEHOUSE. I ask unanimous consent that all time in morning business be yielded back.

The PRESIDING OFFICER. Without objection, it is so ordered.

Morning business is closed.

FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT—MOTION TO PROCEED

The PRESIDING OFFICER. Under the previous order, the Senate will resume consideration of the motion to proceed to H.R. 1256, which the clerk will report.

The legislative clerk read as follows:

A motion to proceed to the bill (H.R. 1256) to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes.

The PRESIDING OFFICER. The Senator from Rhode Island.

Mr. WHITEHOUSE. Mr. President, I rise to speak in support of the Family Smoking Prevention and Tobacco Control Act, a bill that will finally give the Food and Drug Administration the authority to regulate tobacco products.

This was the first bill for which I had the honor of voting in my new role as a member of the Health, Education, Labor, and Pensions Committee—the newest member—but it is the result of years of tireless effort by members of this committee and by their staffs. I especially commend its primary sponsor, our chairman, TED KENNEDY, who has long been committed to protecting our Nation's children from the dangers of tobacco and nicotine addiction, and Senator DODD, who is so ably leading that fight in his stead today. I thank them and our colleagues in the House for the efforts that have brought us this bill before the Senate today.

This legislation is long overdue and very much needed. Just last month, a three-judge panel of the U.S. Court of Appeals for the DC Circuit unanimously upheld the decision of the district court that the tobacco companies had engaged in racketeering. The court found that for at least 50 years, the companies have knowingly kept information from the American public about the health and safety risks of their products and that they continue to do so today. These companies have worked together to deceive the American public and cannot be trusted to regulate themselves.

As generations of customers died from illnesses related to smoking, the tobacco companies have kept their profits up by marketing their products to children through cartoon advertisements, candy flavorings, and sports sponsorships. Public health advocates, lawmakers, prosecutors, and family members who have lost loved ones to the ravages of smoking have attempted to take on the tobacco companies, but they confronted a coordinated effort backed by billions of dollars to protect this deadly business.

In the next year, 400,000 Americans will die from smoking-related illness and more than 450,000 children will become daily smokers. Every day, 3,500 kids pick up a cigarette for the first time.

Even those who do not smoke still pay a price—$96 billion each year in public and private health expenditures to treat illness caused by smoking. The companies will, of course, point to concessions and payouts over the years, but it is clearly not enough. As we work to reform our broken health care system, we cannot ignore this public health menace.

That is why it is vital that we finally pass this legislation. The FDA is the agency most prepared to take on the regulatory, scientific, and public health challenges created by tobacco products. This carefully crafted compromise bill gives FDA the tools necessary to take on the tobacco companies in three major areas: advertising and sales to young people, the composition of cigarettes, and representations of health effects of tobacco products.

We have wasted too much time fighting the same battles over the same issues for years. This legislation finally enacts tough but constitutionally sound regulations on advertising targeted toward young people. It puts a warning label on every pack of cigarettes that covers 50 percent of each side of the package. The companies will finally have to disclose the content of tobacco products, and FDA will have the authority to regulate hazardous ingredients. Tobacco product manufacturers will no longer be able to make unsubstantiated claims about their products—FDA will have to verify any health claim based on its impact on the population as a whole in order to protect tobacco users and potential tobacco users. This will be paid for by the tobacco product manufacturers and importers themselves, taking no resources away from the FDA's other vital missions.

So many of us have been touched by the ravages of smoking and lost family and friends. Yet we still see too many young people become addicted to cigarettes or pick up the newest smokeless tobacco product without knowing the real risks to their health. We cannot leave this to court settlements or to the industry itself. We have been waiting for 50 years, and the evidence shows we are still being deceived. Regulation is long past due. This bipartisan bill, with the support of over 1,000 public health, faith, education, and children's organizations, is the best opportunity to help protect our children from the menace of tobacco. We have delayed long enough.

I again thank Chairman KENNEDY, Senator DODD, and my colleagues on the HELP Committee for their hard work bringing this bill to the floor and getting us closer than any other point in the long history of this legislation to finally seeing the effective regulation of tobacco products.

I yield the floor and suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

Mr. ROBERTS. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

CRAIG THOMAS RURAL HOSPITAL AND PROVIDER EQUITY ACT

Mr. ROBERTS. Mr. President, I rise today to again pay tribute to one of the Senate's finest: our colleague, the late Craig Thomas from Wyoming. Two years ago this week, the Senate lost a steady hand and a man who did much for his State of Wyoming. Craig was dependable in the finest sense of the word. He defined the word ''dependable.'' He was the epitome of a workhorse, not a show horse.

On a personal note, for many Senators, why, Craig was not only a colleague but a dear friend. I will cherish that always. Craig was also a fellow marine. In this case, Semper Fidelis—always faithful—is most appropriate. If anyone faced trouble in their life, the one person you would want by your side would be Craig Thomas.

This is why I am proud and honored again to join with my colleagues KENT CONRAD and TOM HARKIN, and with the new Senator from Wyoming, JOHN BARRASSO, and the distinguished Senator from Utah, ORRIN HATCH, to introduce the Senate Rural Health Caucus bill in honor of Senator Thomas. The bill we are introducing is the Craig Thomas Rural Hospital and Provider Equity Act, with emphasis on the ''equity.''

The people of Wyoming and all of Craig's colleagues knew he fought for rural America and always put the needs of his State above all else. On the health care front, why, Craig was truly

a champion for strengthening our rural health care delivery system and providing relief to our hospitals and other providers in our rural areas.

He served for 10 years as the cochair of the Senate Rural Health Caucus. He actually took over the reins as cochair after my fellow Kansan, Bob Dole, retired from the Senate. And as I know personally, it is hard to follow in the footsteps of Senator Dole—for that matter, Senator Thomas.

However, Craig did this with great ease and great pride. His steady leadership put the caucus on the map, and he made great strides in showing all of our colleagues the true needs of rural health care. We will truly miss him during the current health care debate. I and the members of the caucus miss him and his leadership greatly.

One of the biggest accomplishments for Craig in the Rural Health Caucus was passage of the Medicare Modernization Act in 2003, which provided a big boost to our rural hospitals and providers. There was recognition and support from our colleagues from all of our geographical areas, large and small, for including these badly needed rural health provisions.

These provisions included in the Medicare bill provided much needed relief to rural health providers, enhanced beneficiary access to quality health care services, and improved provider payments in our rural areas. So many times those payments simply do not even come close to the costs of the provider and the service they provide to our rural citizens.

However, you would never know that it was Craig Thomas behind the scenes working to get these rural health provisions included in the Medicare bill. Craig was more concerned with getting the work done rather than taking the credit. So instead of taking individual credit for his hard work and his dedication on the Medicare bill, he applauded the entire Rural Health Caucus and patted everybody else on the back. It is this kind of leadership that set Craig Thomas apart from his colleagues.

However, Craig knew that while passage of the Medicare bill was a giant step for rural health, we still had much work to do to ensure our rural system can continue to survive. Sometimes when they ask me about health care reform—''they'' meaning most of the people interested in health care reform: the media, others, the health care providers—I simply say one of the things we want to do is to make sure we preserve what we have. This is why we were proud and honored to carry on his legacy by introducing the Craig Thomas Rural Hospital and Provider Equity Act in the 110th Congress, and again in this Congress. We can enhance Craig's legacy certainly in this way.

I wish to especially recognize a member of Craig's former staff who has always worked extremely hard to advance rural health care causes and who has remained a champion for Wyoming as a member of Senator JOHN BARRASSO's staff: Erin Dempsey. I know my staff has worked very closely with Erin over the years, and I have a great amount of respect for her hard work. We always have an expression: We are only as good as our staff here—or at least some of us do actually admit to that. Erin, thank you for being such a hero alongside Craig, and now Senator BARRASSO. We are proud of you for everything you have done on behalf of rural health care.

This Congress, with health care reform at the front and center, Senators BARRASSO, CONRAD, HARKIN, HATCH, and I will do our very best to lead in Craig's absence and to ensure that rural health does not get left behind. I have made a personal commitment to make sure we get this bill done and ultimately provide the much needed relief to our rural communities.

The Craig Thomas Rural Hospital and Provider Equity Act recognizes that rural health care providers have very different needs than their urban counterparts and that health care is not one size fits all.

The Craig Thomas Rural Hospital and Provider Equity Act—and the acronym of that, by the way—everything has to be an acronym in Washington—is R-HoPE—so the R-HoPE Act of 2009 makes changes to Medicare regulations for rural hospitals and providers. It recognizes the difficulty in achieving the same economies of scale as large urban facilities. This legislation equalizes Medicare's disproportionate share of hospital payments to bring the rural hospitals in line with our urban hospitals. This bill also provides additional assistance for small rural hospitals that have a very low volume of patients. Often these hospitals have trouble making ends meet under the Medicare payment system.

The Craig Thomas Rural Hospital and Provider Equity Act, R-HoPE Act, also provides a Capital Infrastructure Loan Program to make loans available to help rural facilities improve crumbling buildings and infrastructure. In addition, rural providers can apply to receive planning grants to help assess capital and infrastructure needs.

The bill extends to January 1, 2011, two incentive programs aimed at improving the quality of care by attracting health care providers to health professional shortage areas. The first is the Medicare Incentive Payment Program, which provides a 10-percent bonus payment to physicians who will practice in shortage areas. The second is the Physician Fee Schedule Work Geographic Adjustment—that is a mouthful—but it simply means it will bring rural doctors' Medicare fee schedules for wages more in line with urban doctors.

The bill also recognizes that other providers do play a great role in the rural health care delivery system. Our bill increases the payment cap for rural health clinics to keep them in line with community health centers. It provides a 5-percent add-on payment for rural home health services. And it provides a 5-percent add-on payment for ground ambulance services in our rural areas.

One of the provisions in the bill—and this is the one that Craig Thomas certainly championed—is a provision to allow marriage and family therapists and licensed professional counselors to bill Medicare for their services and be paid the rate of social workers.

Currently, the Medicare program only permits psychiatrists, psychologists, social workers, and clinical nurse specialists to bill Medicare for mental health services that are provided to our seniors. However, most rural counties—most rural counties—simply do not have a psychiatrist or a psychologist. Marriage and family therapists, however, and licensed professional counselors are much more likely to practice in a rural setting and are often the only mental health professionals available.

Finally, this bill uses technology to improve home health services and quality of care by creating a pilot program providing incentives for home health agencies to purchase and utilize home monitoring and also communication technologies and facilitates telehealth services across State lines.

Today I am proud and honored to introduce this bill on behalf of our former Senator and colleague, Craig Thomas. We miss him greatly as a personal friend, a confidante and colleague. Our thoughts and prayers are with his wife Susan, his sons Peter, Patrick, and Greg, and his daughter Lexie.

Mr. President, it is time to pass this bill.

Mr. President, I yield the floor.

The PRESIDING OFFICER. The Senator from New Hampshire.

NATIONAL DEBT

Mr. GREGG. Mr. President, I rise today to return to a topic I have discussed on the floor a number of times but which I think needs to be discussed again because of the severity of its implications for our Nation; that is, the massive amount of debt which we are running up in our country.

This massive expansion of our debt, at levels which we have never seen in our history, as proposed by the President's budget and the budget which passed this Congress, threatens the value of the dollar. It threatens to create instability through massive inflation. And it clearly threatens the future of our children.

I am not the only one who thinks this way. As you look around the world, there are a lot of folks taking a look at where we as a nation are going and asking the question: Can we afford this debt as a country?

Interestingly, just a week and a half ago or so, Standard & Poor's, the rating agency, looked at the English situation and put out a statement that the triple A bond rating of England was in jeopardy. They essentially took the adjective ''stable'' out from their designation of that bond rating and said

they had a negative bias on the triple A rating. They did not reduce it, but they did put out a major warning sign.

What does that mean? Well, if your bond rating as a nation drops, that means the world community does not have a lot of confidence in your ability to repay your debt and it is going to charge you a lot more to lend you money. The effect of a bond rating change for a nation such as the United Kingdom—which is one of the most stable and industrialized countries in the world—is catastrophic. What brought about this decision by Standard & Poor's to put, at least on a watch list, so to say, the bonds of the United Kingdom? It is the fact that England has so expanded its debt that its debt now represents approximately 52 percent of its gross national product.

Well, where do we stand as a nation in our debt relative to our gross national product? This chart reflects the fact that historically, in the last 30 or 40 years, our debt has averaged between 30 percent and 40 percent of GDP, but in this economic downturn, we are seeing a dramatic increase in our debt as a nation. In the short run, I have said many times, we can tolerate this for the purpose of trying to float the economy, for the purpose of the government being the lender of last resort, for the purpose of stabilizing the financial systems. A short-term, huge spike in our debt is not desired, but it can be managed. We have done this in the past. During World War II, for example, our debt went up dramatically. But the key is, it has to come back down. It just can't keep going up.

Well, today, our debt is about 57 percent of our gross national product, our public debt. It is up around here on the chart. As we see from this line, under the budget proposed by President Obama, it continues to go up, almost in a perpendicular manner, to the point where, by the end of the budget as proposed by the President and as passed by this Congress, the public debt will be approximately 82 percent of gross national product. That is not a sustainable situation. Over the next 10 years, under the budget as proposed by the President, we will be running deficits which represent $1 trillion a year, on average—$1 trillion a year, on average. As a percentage of our gross national product, those deficits will be between 4 percent and 5 percent.

As I have said before on this floor, you can't get into the European Union if your deficit exceeds 3 percent of your gross national product and your debt exceeds 60 percent of your gross national product.

These are all big numbers and nobody can catch up with those numbers, but the basic implication is very simple. Under the present path we are on, the debt is going to double in 5 years, triple in 10 years, and the implications to our children are that they are going to inherit a country where the payments required on that debt are going to be the single largest item of the Federal Government—$800 billion a year which will have to be paid in just interest. For every American, they will receive $130,000 of debt—every American household will have $130,000 of debt on that household to pay off the Federal responsibility—and $65,000 in interest payments annually for every American household. That is more than many American households' mortgages and more than their interest payments on their mortgages, but that is what every American household is going to owe as a result of this dramatic expansion in debt.

What is driving this debt? Well, in the short term, obviously, it is the economic downturn. But we are not going to be in this economic downturn forever. Everybody is presuming we are starting to move out of it, and we will because we are a resilient nation. In the outyears, what is driving this debt is spending—it is that simple—new, additional spending put on the books or planned to be put on the books under this budget.

This blue line here, which flattens out where the debt stabilizes over the next 5 years, is if we had current law. In other words, if the law that was in place before the President's budget was passed were to take effect and stay in place, that is the blue line. That is what the debt would do; it would stabilize. But because the President has proposed so much new spending in addition to the spending that is going to come as a result of the retirement of the baby boom generation and the expansion of entitlements, this debt just continues up in an astronomical way.

This is a real concern for us. I recognize it is hard for a Congress to deal with anything but the next election—and what we are talking about here is really what we are doing to the next generation—but we should be very concerned—more than concerned, we should be really focused on this as our primary issue of domestic policy as we go forward as being a threat to our prosperity as a nation.

What are other governments saying? Well, China, which is our biggest creditor—we financed this debt by lending from China. They give us money to spend on our operations as a government. They have always looked on the U.S. debt as something that was a good investment, a safe investment, but the Chinese are having second thoughts. In an extraordinarily embarrassing incident, the Secretary of the Treasury, speaking before an audience of sophisticated college students in Beijing, was asked about the status of our debt that is held by the Chinese. He told them that Chinese assets are very safe, and the audience laughed. The audience actually laughed at the Secretary of the Treasury saying that Chinese assets are very safe. That is an anecdotal incident, but it would never have happened 6 months ago, 2 years ago, because these types of increases in debt as a percentage of our economy were nowhere in sight then—nowhere in sight.

Then Mr. Yu, who is the former adviser to the Central Bank, made the following statement just a couple of days ago. He said:

> The United States Government should not be complacent and it should understand that there are alternatives to China buying U.S. bonds and bills. Investments in Euros are an alternative, and there are lots of raw materials we can buy too. China should not close those options.

Well, if the Chinese Government starts to reduce its purchase of our bonds and our need to sell bonds is going up, what happens? That means the interest on the bonds is going to have to go up because we are going to have to find somebody who wants to buy these bonds and we are going to have to make them attractive around the world. As the interest on the bonds goes up, taxpayers end up having to bear that burden and the next generation ends up having to bear that burden.

So what is the solution? How do we get around the fact that we are now on an unsustainable course which will lead to a fiscal calamity for our Nation and potentially put us in the position where we will have to devalue the dollar or have massive inflation?

Interestingly enough, the Economic Information Daily, another Chinese publication, hit the nail right on the head. Maybe because they are looking from the outside in and because of all they have invested they can see these things, because they said the question that should be asked of Secretary Geithner is, How do you propose implementing fiscal discipline? How will you maintain the stability of the dollar after the crisis—and I emphasize ''after.'' What they are saying is, after we get past this recession and the need to stabilize the financial structure of our country and the need to float the economy, how do we bend this curve back to something reasonable and sustainable? That is the question we should be asking around here as a Congress. We need to start asking it pretty soon.

The President has said—he said it again yesterday—that one way you do this is by addressing the cost of health care, and he is absolutely right. Health care is the primary driver—one of the primary drivers—of this massive increase in expenditures at the Federal level. But the President has put nothing on the table so far that bends the curve on the question of the cost of health care—in fact, just the opposite. His budget proposed that health care spending would go up $1.2 trillion over the next 10 years and, more importantly than that, it sets up a series of entitlements which will cost hundreds of billions—as I said, $1.6 trillion in new spending. He is suggesting that instead of keeping health care spending at about 17 percent of gross national product, which is a huge amount of money, by the way, more than any other industrialized country spends by almost 50 percent—the next closest

country spends about 11 percent on health care—he is suggesting that instead of maintaining health care costs at 17 percent of gross national product, it be allowed to rise to 18, 19, and 20 percent of gross national product. Well, we can't afford that. We can't afford that.

What we need in the area of health care is to address the issue that the President said, which is to control the costs of health care, not by expanding the size of the costs of health care but by using the dollars in the health system more effectively and by getting better quality at lower costs, which can be done, by the way. There are a lot of proposals for doing exactly that. But one of them isn't to create a single-payer plan or a public plan which essentially puts the government in charge of health care and, as a result, drives up the cost of health care significantly and drives the spending up and the borrowing up that goes with it. So, yes, we have to address it, but we have to address it in a way that actually controls spending, controls the rate of growth in spending and health care, and that doesn't aggravate this additional debt.

It is hard to understate the significance of the threat this debt represents. It is hard to understate it. I know I have spoken on this floor about it a number of times, but that is because it is so critical to our future as a nation. We literally are bankrupting the futures of our children by putting this much debt on their backs, by doubling the national debt in 5 years and tripling it in 10 years. I am beginning to feel a little bit like Cato the Elder, who used to speak in the Roman Senate and begin and end every speech with ''Carthago delenda est.'' Finally, somebody listened to him, and they actually did destroy Carthage.

Well, I am saying let's get the debt under control. Let's control the spending of this government. Let's do something about this outyear spending before we get to a position where the world loses confidence in our dollar, loses confidence in our debt, before we get into the position where we have to inflate the economy or we have to place taxes on our children that are so high that they have no chance to have as prosperous and as competitive a life as we have had. It is not fair, as I have said before, for one generation to create this type of debt and pass it on to the next generation to pay. It is not fair. It is not right. It is something we have never done as a nation. Whenever we have run up debt significantly like this, we have always paid it down on an equally quick basis. After World War II, when our debt got to over 100 percent of GDP, we brought it down very quickly. We need to bring it down today. We need to have discipline around here that leads to getting the debt of this Nation back to a responsible level, which means something under 50 percent, hopefully closer to the historic norm of 40 percent; where we get the deficits back to a responsible level, which means under 3 percent, hopefully even headed toward balance; and where we can tell our children that we are passing on to them a stronger nation, not a weaker nation, a more prosperous nation, not a nation confronting massive inflation, leading to the devalue of the dollar or massive tax increases.

Mr. President, I yield the floor and make the point of order that a quorum is not present.

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mr. BURR. Madam President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER (Mrs. GILLIBRAND). Without objection, it is so ordered.

Mr. BURR. Madam President, I needed to come to the floor and apologize for a misstatement I made yesterday on the current bill, the Kennedy tobacco bill. In yesterday's debate, I stated that the CBO, the Congressional Budget Office, report on the bill revealed that if enacted, smoking rates would decline 2 percent annually. In fact, I was wrong.

I prepared a chart yesterday that showed, based upon what CBO said, that we would reduce by 2016 the smoking rate in the country to 17.8 percent, and also the CDC's projection, which if we did nothing, we would reduce it to 15.9 percent, clearly showing the CBO estimate under the current bill we are considering would not bring the smoking rate down as much as doing nothing.

The mistake I made yesterday was I assumed the way I read it that the CBO estimate is it would reduce smoking 2 percent per year. In fact, what the CBO report actually said was it would reduce by 2 percent over 10 years. So, in fact, I have been way too generous to the current bill that it would reduce smoking to a point of 17.8 percent, which was figured based on a 2-percent-per-year reduction. In fact, the gap between doing nothing and passing this bill clearly is much bigger than I had anticipated; that by doing nothing, we get much more value, if the objective through passage of this legislation is to reduce the smoking rate in the United States.

The bill that is being considered does not change existing products. Let me restate that. We grandfather in all the tobacco products that are currently being marketed. What CBO has concluded is that then you have to permanently figure that about the same rate of Americans will continue to smoke because they do not have new options to turn to.

Let me make this pledge to my colleagues. If the CBO report that smoking will decrease by a scant 2 percent under the bill is because of new warning labels and graphic warning labels that are mandated in the bill, then let me say the substitute Senator HAGAN and I will offer provides for the same warning labels and the same graphic warning labels. If that is what gets the 2 percent reduction over 10 years, which clearly it has to be, then I am willing to cosponsor that bill right now and substitute it for the entire Kennedy bill, so we get the full 2 percent we get in the Kennedy bill over 10 years of reductions.

A simple warning label would be a tremendous improvement over this legislation—$787 million, a new mandate to the men and women in our military to pay for it, and it has been portrayed as an effort to reduce the usage of tobacco products with our youth.

I covered for all our colleagues yesterday the fact that when you go down and look at the CDC proposals to States on part of the $280 billion of MSA payments that the industry made to States, that the States had spent a pittance of what CDC projected on cessation programs to get people to stop smoking. But more alarming than the fact that States use the tobacco money to fill their budget gaps and build sidewalks rather than to fund programs to get people to stop smoking is the fact that in practically every case of 50 States, the marijuana prevalence use among youth was higher than the tobacco prevalence.

Let me say that again. Marijuana usage by our youth is projected by CDC to be higher in practically every State than what they have projected youth prevalence of tobacco use. It is actually smoking. That does not necessarily include smokeless.

For my colleagues, including myself, I have spoken on the fact that we must keep tobacco out of the hands of our children. It has an age limit. I would agree it has some problems on enforcement. But marijuana is illegal. It is supposed to be enforced in every community. It is supposed to be enforced in every State. Yet more kids use it than they do tobacco products.

In 1975, Congress commissioned the University of Michigan to track youth smoking rates. At that time, youth smoking was at an alltime high. However, those rates have started to come down and leveled off around 30 percent, all the way up to 1993.

For some unknown reason at the time, youth smoking rates started to increase around 1993, peaking at close to a new alltime high in 1997.

In 1998, 12th graders who said they tried cigarettes in the last 30 days was approximately 36 percent, according to the University of Michigan.

Congress did not have a good sense of why this was happening. Opponents of the tobacco industry started blaming all this on the alleged manipulation of young people by tobacco manufacturers through sophisticated marketing and advertising campaigns.

I heard a Member on the floor last night of the Senate basically blaming everything on these very creative marketing techniques. Trust me, if they

were that effective, every company would be figuring out how to adopt those techniques.

The tobacco industry has a checkered past, at best, when it comes to marketing and advertising. But what I am suggesting is, it may not have been all due to tobacco. There was another trend occurring in the 1993 to 1998 period that virtually mirrored that of youth smoking, and it was the increased use of illicit drugs by teenagers. Something much broader was happening among youths in our society during that time period. The Senate's answer to smoking rate increases was to pass a massive FDA tobacco regulation bill, the exact bill we are debating today. Congress said nothing else would work to save our kids and bring down youth smoking rates.

Senator KENNEDY made the following remarks during the 1998 Senate floor debate to emphasize the need to protect our children. I quote:

> FDA Commissioner David Kessler has called smoking a ''pediatric disease with its onset in adolescence.'' In fact, studies show that over 90 percent of the current adult smokers began to smoke before they reached the age of 18. It makes sense for Congress to do what we can to discourage young Americans from starting to smoke during these critical years. . . . Youth smoking in America has reached epidemic proportions. According to a report issued last month by the Centers for Disease Control and Prevention, smoking rates among high school students soared by nearly a third between 1991 and 1997. Among African-Americans, the rates have soared by 80 percent. More than 36 percent of high school students smoke, a 1991 year high. . . . With youth smoking at crisis levels and still increasing we cannot rely on halfway measures. Congress must use the strongest legislative tools available to reduce smoking as rapidly as possible.

Senator KENNEDY, on the Senate floor, May 19, 1998.

Of course, the Senate told the American public that passage of the massive FDA tobacco regulation bill back in 1998 contained the ''strongest legislative tools available'' to address youth smoking issue.

Congress did not pass the FDA bill we are debating today. What happened with youth smoking rates? They decreased since 1998 to current alltime lows. I am talking about record lows over a 34-year period. In 1998, we were told by some in the Senate that youth smoking rates would not come down absent a major bureaucratic expansion over tobacco at FDA. Those Senators were wrong, dead wrong.

Today, we continue the same debate over basically the same bill, and we are debating this as if nothing else has happened or changed. Obviously, something we are doing across this country is working, and it has nothing to do with what Congress is talking about doing. It has to do with the passage of the Master Settlement Agreement, advertising restrictions, awareness campaigns, and education.

None of these things are enhanced in H.R. 1256, the Kennedy bill. It is about design, not about keeping kids from smoking. CBO recently stated that if it was enacted, youth smoking would reduce, over the 10-year period, 2 percent—excuse me, 11 percent for youth, 2 percent overall. But according to the University of Michigan, youth smoking rates have declined by 5 percent over the last 5 years and 16 percent over the last 10 years.

If this is an indication of how youth smoking rates will go over the next 10 years, we will actually slow the decline by passing this bill.

Let me say that again. My colleagues do not understand. We slow the decline of youth usage by actually passing this bill. It is the University of Michigan, it is the Congressional Budget Office, all very reputable agencies.

I know I have a colleague on the floor who wants to speak. I am going to yield the floor to him. But let me remind my colleagues, we are talking about a massive expansion of regulation for the FDA, not a massive expansion of regulation over tobacco. There are a host of agencies currently that regulate tobacco. It is the most regulated product in the United States of America. Now we want to centralize that regulation into the FDA.

Let me read the FDA's mission statement:

> The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our Nation's food supply, cosmetics and products that emit radiation.

Just in the first phrase, ''protecting the public health,'' you are not protecting public health when you allow cigarettes to be sold. So the fact that we have constructed a bill that grandfathers every existing product but makes it practically impossible to bring to market reduced-risk products that allow Americans to give up the cigarettes and to move to something else, the CBO was right, it will slow the reduction in smoking rates. We do nothing for disease and death. We do more for disease and death by not passing legislation than we do by passing legislation. If the authors of this bill are, in fact, honest and the effort is to reduce youth access and youth usage, then the Members of the Senate should do nothing.

Hopefully, tonight Senator HAGAN and I will offer a substitute that brings as much regulatory authority to an entity outside the Food and Drug Administration but one under the Secretary of Health and Human Services. Why? Because I spent 15 years in Washington trying to protect the integrity and the gold standard of the FDA, so that when every American goes to bed at night and they take that prescription they got from a pharmacist prescribed by a doctor, they don't have any question as to whether, one, it is safe, or, two, it is going to work; that when they go to the hospital and all of a sudden a doctor shows them a procedure they are going to have and a medical device is involved, they are not sitting wondering: Is this going to work? Is it going to hurt me? Because the FDA has already said it is safe and effective; as we bring on this new line of biological products that are going to cure terminal illnesses that are very expensive, we are not going to do it in a way that hurts our health because the FDA's gold standard is in place; that when we go to the store and we buy food, we are going to be assured it is safe, something we haven't been able to do for the last few years—spinach contamination, salmonella in peanut butter. The list goes on and on.

Why, with an agency that is struggling to meet their core mission, would we ask them to take on a product that in legislation we say we know you cannot prove it is protecting public health or it meets safety and efficacy, but on that we want you to turn your head, we want you to ignore the core mission for this new jurisdiction we are going to give you, but for everything else, we want you to apply that gold standard, we want to ensure drug safety, device safety, food safety but not with tobacco.

To my colleagues, it is very simple. Read the bill. You won't vote for this bill. You want to reduce youth consumption of tobacco? It is real simple. We reduce it faster by doing nothing.

Again, I think there will be a substitute that all Members can vote for tonight. It accomplishes further reductions of youth usage, because we don't constrict less harmful products in the future from coming to the market. We don't lock an adult population in to only being smokers because they are addicted to nicotine. We give them options, such as Sweden gave their citizens, where they have reduced adult tobacco smoking at incredible rates because of innovative new products that deliver nicotine in a way that reduces the risk of disease and reduces the rate of death.

If the objective here is to reduce disease, to reduce death, to reduce youth usage, then I would encourage my colleagues tonight, when Senator HAGAN and I introduce the substitute, to listen very carefully and support the substitute. But at the end of the day, if your objective is to reduce youth consumption of cigarettes, in the absence of passing that substitute, it is very clear—the CBO and the University of Michigan says: Pass nothing.

Madam President, I yield the floor.

The PRESIDING OFFICER. The Senator from Oregon.

Mr. MERKLEY. Madam President, I ask unanimous consent to refer to these tobacco orb products during my speech.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. MERKLEY. Madam President, I want to start by thanking Senator DODD for his tireless advocacy on this issue. The need to regulate tobacco products has been evident for many years, and for year after year it has been impossible to accomplish this

goal. It is frankly unbelievable that while we heavily regulate the production and sale of aspirin, a product that is not addicting and not destructive, tobacco, which is addictive and is destructive, goes without regulation.

This bill will go a long way in helping to keep these addictive tobacco products out of the hands of our children. This bill gives the FDA the legal authority it needs to reduce youth smoking by preventing tobacco advertising targeting children. It provides the FDA with the authority to prevent the sale of tobacco products to minors as well as the authority to prevent the tobacco industry from misleading the public about the dangers of smoking.

Additionally, this bill takes important steps in the regulation of smokeless tobacco. We are all familiar with the dangers posed by cigarettes—the health effects have long been documented—both on users and bystanders. We are also familiar with the steps being taken in many cities and many States to rid our public areas of secondhand smoke. These actions, thankfully, have been quite successful, but they lead to a major dilemma for tobacco companies: if smoking becomes socially unacceptable, how can the industry replace the hundreds of thousands of tobacco addicts who die every year? The industry's response has been to bet heavily on smokeless tobacco products and to bet on addicting youngsters to those products.

Chewing tobacco has been around for a while, but it has its own limitations. There aren't many places—outside of this very Chamber—in the United States where you can find a spittoon. So the tobacco companies are looking for hip new smokeless tobacco products that don't require spitting and that can appeal to a new generation of children.

This picture was taken just a few blocks from this Capitol. It is of a new product called ''Snus'' that R.J. Reynolds is selling nationwide. It is a flavored, pouched tobacco product advertised as not requiring spitting. And as you can see here, it is advertised next to displays of candy and Peppermint Patties. I should note that this container was not the original designed for the Snus container. The original container was round. As reported by the Portland Oregonian last December, it came in containers similar to chewing tobacco, but teachers in schools noticed these containers in their students' pockets.

So now R.J. Reynolds has redesigned them so that teachers can't recognize that these are smokeless tobacco products in their students' pockets.

Clearly, the marketing is aimed at young people. But it gets even worse. Now R.J. Reynolds has come out with another product that they are test marketing in three cities across the country, one of which is in my home State of Oregon. Portland, OR, is a site for the test market of tobacco candy.

Tobacco candy, as you see here, also comes in what was designed to look like a cell phone in your pocket rather than a traditional can of smokeless tobacco. They have done two other things to make this product appealing, and I have a sample right here. First, they come in candy flavors. This one is euphemistically called ''fresh.'' It is a mint candy. This one is euphemistically called ''mellow.'' It is a caramel-flavored candy. So they have thrown in the candy flavoring and a really cool dispenser. And not only does the dispenser look like a cell phone—so teachers can't tell what it is—but it has a feature taken from the world of the Pez candy dispenser. You pop it open, and out pops a single tobacco tablet. You close it and shake it around, open it up again, and out pops another one. So we have three features here designed specifically to market to children: the cell phone shape, the candy flavoring, and the Pez-style dispenser.

Now, why is it tobacco companies need to market to children? It is because when adult testers try out a tobacco product, they rarely continue using it. Therefore, they rarely become a customer of a tobacco company. A teenager who tries one of these products—whose brain is still being wired and, therefore, is much more susceptible to the influence of nicotine—is much more likely to become addicted and become a lifelong customer or reliable customer. That is why the tobacco companies are marketing tobacco candy to our children.

There is no question that this tobacco candy is dangerous. The Indiana Poison Control has estimated that each tablet delivers 60 to 300 percent of the nicotine in a single cigarette. The product is addictive. The product causes cancer. And unless we pass this bill and give the FDA the authority to regulate, soon you will see this tobacco candy in a convenience store near you, and we will see more displays such as the one shown here in Portland—tobacco candy advertised right next to ice cream.

Once the companies master the technique of turning tobacco into kid-friendly candy, there is no end to the variety of products that can be turned out. Already RJR has announced they are planning to launch two new forms of tobacco candy; sticks, which look like toothpicks you suck on, and strips, which are nearly identical to breath mint strips that dissolve on your tongue.

Everywhere I go and talk about these products, people are outraged. Meanwhile, the tobacco industry and its champions are trying to justify these products as safe alternatives to smoking. That just isn't so. And that rhetoric poses a real danger to consumers who might think smokeless tobacco is harmless. In fact, this very rhetoric shows why we need to have the FDA regulating this product. In fact, the Surgeon General has determined the use of smokeless tobacco can lead to oral cancer, gum disease, heart attacks, heart disease, cancer of the esophagus, cancer of the stomach.

This is not a safe product. This is not safe tobacco. It is a product like cigarettes that causes cancer and kills. Further, it is not a method of helping smokers to quit smoking. The purpose of smokeless tobacco candy is not to help people quit tobacco products, it is designed to addict them to tobacco products. The idea that the tobacco companies would be out marketing a product designed to get people to quit using tobacco products is, quite frankly, obviously ridiculous. Unlike Nicorette or the nicotine patch, which are designed to help people quit smoking, tobaccoless candy does not help you quit and the doses do not get any lower over time.

The U.S. Public Health Service Clinical Practice Guideline notes:

> The use of smokeless tobacco products is not a safe alternative to smoking, nor is there evidence suggesting it is effective in helping smokers quit.

It is no secret these products are dangerous. Six years ago to this very day, Surgeon General Richard Carmona talked about what he called the ''public health myth'' that smokeless tobacco is a good alternative to smoking. He emphatically said that was simply not true, and I think it is worth quoting him at some length:

> I cannot conclude that the use of any tobacco product is a safer alternative to smoking. This message is especially important to communicate to young people, who may perceive smokeless tobacco as a safe form of tobacco use. Smokeless tobacco is not a safe alternative to cigarettes. Smokeless tobacco does cause cancer.

That statement is from a 2003 House hearing on tobacco harm reduction, and I ask unanimous consent, Madam President, to have printed in the RECORD the entire prepared testimony delivered that day.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

TESTIMONY BEFORE THE SUBCOMMITTEE ON COMMERCE, TRADE, AND CONSUMER PROTECTION, COMMITTEE ON ENERGY AND COMMERCE, UNITED STATES HOUSE OF REPRESENTATIVES

CAN TOBACCO CURE SMOKING? A REVIEW OF TOBACCO HARM REDUCTION

Statement of Richard H. Carmona, M.D., M.P.H., F.A.C.S., Surgeon General, U.S. Public Health Service, Acting Assistant Secretary for Health, Department of Health and Human Services

Mr. Chairman, distinguished members of the Subcommittee, thank you for the opportunity to participate in this important hearing. My name is Richard Carmona and I am the Surgeon General of the United States of America.

Let me start with a few statements that were once accepted throughout society that have now been relegated to the status of myth.

Men do not suffer from depression.

Domestic violence is a 'family' or 'private' matter.

The HIV-AIDS epidemic is of no concern to most Americans.

All of us here know that these three statements are very dangerous public health myths.

My remarks today will focus on a fourth public health myth which could have severe consequences in our nation, especially among our youth: smokeless tobacco is a good alternative to smoking. It is a myth. It is not true.

As the nation's Surgeon General, my top responsibility is to ensure that Americans are getting the best science-based information to make decisions about their health. So I very much appreciate the opportunity to come before this Subcommittee today and help refute this dangerous idea.

First, let me emphasize this:

No matter what you may hear today or read in press reports later, I cannot conclude that the use of any tobacco product is a safer alternative to smoking. This message is especially important to communicate to young people, who may perceive smokeless tobacco as a safe form of tobacco use.

Smokeless tobacco is not a safe alternative to cigarettes.

Smokeless tobacco does cause cancer.

Our nation's experience with low-tar cigarettes yields valuable lessons for the debate over smokeless tobacco.

Tobacco use is the leading preventable cause of death in the United States.

Each year, 440,000 people die of diseases caused by smoking or other form of tobacco use—that is about 20 percent of all deaths in our nation.

The office I lead as Surgeon General has long played a key role in exposing the risks of tobacco use. In 1986, the Surgeon General's Report The Health Consequences of Using Smokeless Tobacco reached four major conclusions about the oral use of smokeless tobacco:

1. Smokeless tobacco represents a significant health risk;
2. Smokeless tobacco can cause cancer and a number of non-cancerous oral conditions;
3. Smokeless tobacco can lead to nicotine addiction and dependence; and
4. Smokeless tobacco is not a safer substitute for cigarette smoking.

Recognizing these serious health consequences, Congress passed the Comprehensive Smokeless Tobacco Health Education Act in 1986. This law required the placement of Surgeon General's warnings on all smokeless tobacco products.

Mr. Chairman and Members of the Subcommittee, I respectfully submit that smokeless tobacco remains a known threat to public health just as it was when Congress acted in 1986.

Conversely, time has only brought more disease, death and destroyed lives.

The National Toxicology Program of the National Institutes of Health continues to classify smokeless tobacco as a known human carcinogen—proven to cause cancer in people.

As Surgeon General I cannot recommend use of a product that causes disease and death as a 'lesser evil' to smoking. My commitment, and that of my office, to safeguard the health of the American people demands that I provide information on safe alternatives to smoking where they exist.

I cannot recommend the use of smokeless tobacco products because there is no scientific evidence that smokeless tobacco products are both safe and effective aids to quitting smoking.

Smokers who have taken the courageous step of trying to quit should not trade one carcinogenic product for another, but instead could use Food and Drug Administration-approved methods such as nicotine gum, nicotine patches, or counseling.

While it may be technically feasible to someday create a reduced-harm tobacco product, the Institute of Medicine recently concluded that no such product exists today. When and if such a product is ever constructed, we would then have to take a look at the hard scientific data of that particular product.

Our nation's experience with low-tar, low-nicotine cigarettes is instructive to the issue at hand. Low-tar, low-nicotine cigarettes were introduced in the late 1960's and widely endorsed as a potentially safer substitute for the typical cigarette on the market at that time. Within a decade, the low-tar brands dominated the cigarette market. Many smokers switched to them for their perceived health benefits.

Unfortunately, the true health effects of these products did not become apparent for another 10 to 20 years. We now know that low-tar cigarettes not only did not provide a public health benefit, but they also may have contributed to an actual increase in death and disease among smokers.

First, many smokers switched to these products instead of quitting, which continued their exposure to the hundreds of carcinogens and other dangerous chemicals in cigarettes. Second, to satisfy their bodies' craving for nicotine, many smokers unwittingly changed the way they smoked these low-tar cigarettes: they began inhaling more deeply, taking more frequent puffs, or smoking more cigarettes per day.

In fact, we now believe that low-tar cigarettes may be responsible for an increase in a different form of lung cancer, adenocarcinoma, which was once relatively rare. This cancer is found farther down in the lungs of smokers, indicating deeper inhalations, and appears linked to a specific carcinogen particularly present in low-tar brands.

We must learn the lessons of the low-tar cigarette experience. Not only did they fall to reduce an individual's risk of disease, but they also appear to have increased population risk by delaying quitting and potentially contributing to initiation among young people. This has taught us that we must move cautiously in recommending any supposedly safer alternative for people trying to quit smoking—because now, with more knowledge and the benefit of hindsight, the science does not support early recommendations on low-tar cigarettes.

Mr. Chairman, in the interest of time I will shortly ask that the remainder of my statement and the scientific information contained in it be considered as read and made part of the record. But before I do that, I would like to ask for this Subcommittee and the Congress' help in getting the message out about the dangers of the myth of smokeless tobacco.

All of us in this room are very concerned about our nation's youth. Kids growing up today have a tough time of it. In addition to the normal struggles of puberty, many kids are facing a host of other challenges. Many, especially minority kids, must struggle to find their way in unsafe neighborhoods.

So the temptation to engage in behavior that is not healthy, and the opportunity to do so, is very hard for our young people to resist.

According to a 2000 survey by the Substance and Mental Health Services Administration (SAMHSA) (The National Household Survey on Drug Abuse), about 1 million kids from age 12–17 smoke every day. Another 2 million kids smoke occasionally.

And we know that smoking is often not a ''stand-alone'' risk behavior; it travels with others. The SAMHSA survey found that youth who were daily cigarette smokers or heavy drinkers were more likely to use illicit drugs than either daily smokers or heavy drinkers from older age groups. More than half of 12–17 year olds who were daily smokers had also used illicit drugs within the past month.

Every day, more than 2,000 kids in the U.S. will start to smoke, and more than 1,000 adults will die because of smoking. We have to get youth to stop starting. But the answer is not smokeless tobacco.

We have evidence to suggest that instead of smokeless tobacco being a less dangerous alternative to smoking, just as smoking is a gateway to other drugs, smokeless tobacco is a gateway to smoking.

So we must redouble our efforts to get our youth to avoid tobacco in all forms.

We have some real work to do on the ''culture'' of smokeless tobacco, which is glamorized by some sports stars. Chicago Cub Sammy Sosa, who has made a public commitment to avoiding smokeless tobacco, is a great example for kids. Past baseball great Joe Garagiola is now Chairman of the National Spit Tobacco Education program, and regularly lectures young players against the dangers of smokeless tobacco.

As Members of Congress, you can lead by example too, not just in legislation, but in your own lives. I encourage you to avoid tobacco in all its forms. Do not fall for the myth—a very dangerous public health myth—that smokeless tobacco is preferable to smoking. Do not let America's youth fall for it, either.

From the perspective of individual risk, the cumulative effect on smokers of switching to smokeless tobacco is simply not known. But we clearly know that use of smokeless tobacco has serious health consequences. Overall, smokeless tobacco products have been classified as a known human carcinogen. And limited scientific data indicate that former smokers who switch to smokeless tobacco may not have as great a decrease in lung cancer risks as quitters who do not use smokeless tobacco.

From the perspective of population risk, there are even more unanswered questions. Even if there was some decreased risk for smokers who switch to smokeless tobacco, that benefit may be more than offset by increased exposure of the overall population to this known carcinogen.

The marketing of smokeless tobacco as a potentially safer substitute for cigarettes could lead to:

More smokers switching to smokeless tobacco instead of quitting tobacco use completely;

A rise in the number of lifetime smokeless tobacco users if more youth begin using smokeless tobacco;

A rise in the number of cigarette smokers as a result of more youth starting to use smokeless tobacco and then switching to cigarette use; and

Some former smokers returning to using tobacco if they believe that smokeless tobacco is a less hazardous way to consume tobacco.

Concerns about youth initiation are especially troubling. The scientific evidence is clear that use of smokeless tobacco is a gateway to cigarette use. Young people may be especially attracted to smokeless tobacco if they perceive it to be safer than cigarettes. Studies show that more than one in five teenage males have used smokeless tobacco, with age 12 being the median age of first use. Surveys also show that more than two in five teenagers who use smokeless tobacco daily also smoke cigarettes at least weekly. Finally, independent research and tobacco company documents show that youth are encouraged to experiment with low-nicotine starter products and subsequently graduate to higher-level nicotine brands or switch to cigarettes as their tolerance for nicotine increases.

Finally, we simply do not have enough scientific evidence to conclude that any tobacco product, Including smokeless tobacco,

is a means of reducing the risks of cigarette smoking. At this time, any public health recommendation that positions smokeless tobacco as a safer substitute for cigarettes or as a quitting aid would be premature and dangerous. With the memory of our experience with low-tar cigarettes fresh in our minds, we must move extremely cautiously before making any statement or endorsement about the potential reduced risk of any tobacco product.

Finally, my strong recommendation as Surgeon General is a call for sound evidence about tobacco products and their individual and population based health effects. We need more research. We need to know more about the risks to individuals of switching from smoking to smokeless; and we need to know more about the risks to the entire population of a promotion campaign that would position smokeless tobacco as a safer substitute for smoking.

Until we have this science base, we must convey a consistent and uncompromised message: there is no safe form of tobacco use.

Thank you. I would be happy to answer any questions.

Mr. MERKLEY. Madam President, it is a travesty that R.J. Reynolds can launch an addictive carcinogenic candy targeted at children with no review by the Food and Drug Administration. Nicorette—designed to help you quit smoking—went to the FDA for approval, but caramel tobacco candy or mint tobacco candy—designed to hook kids on tobacco—is on the shelves in Portland, OR, right now with zero oversight.

This bill will finally bring some transparency and common sense to the regulation of tobacco. Finally, the FDA will be able to address the single greatest public health menace in our Nation. I am pleased that this bill does include an amendment that Senator BROWN and I authored to require the Tobacco Advisory Committee to expedite the review of tobacco candy. I look forward to passing this bill and to keeping tobacco candy from store shelves before the industry succeeds in hooking a whole new generation of our children.

Madam President, I yield the floor, and I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The bill clerk proceeded to call the roll.

Mr. REED. Madam President, I ask unanimous consent the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. REED. Madam President, I rise today in support of the Family Smoking Prevention and Tobacco Control Act, but first, I would like to take a moment to recognize the outstanding leadership of Chairman KENNEDY on this important public health issue. This is not the first time he has ushered a bill on this topic from committee to the Senate floor. I am confident that my colleagues, in recognition of the tremendous, hazardous effects that tobacco has on children, adolescents, adults, and seniors, will join me in fulfilling one of chairman KENNEDY's wishes, and mine, of finally seeing this bill signed into law.

I would also like to thank Senator DODD for his dedication in carrying out the aggressive schedule of the HELP Committee set forth by the chairman so we can bring this legislation to the floor.

As a cosponsor of this legislation, I firmly believe that we cannot afford to wait another day for it to be enacted. This is not the first time that I have risen to speak on the importance of regulating the sale of tobacco products, but I am hopeful that with this legislation we will take a giant leap toward eradicating the use of nicotine, by discouraging our youth from ever lighting-up, and chip away at skyrocketing smoking-related healthcare costs.

Every year that passes, and this legislation is not enacted, another 4,700 children in Rhode Island try a cigarette for the first time—that amounts to 1,400 children in my State alone becoming regular, daily smokers each year. These new smokers become part of the 8.6 million individuals nationwide suffering from smoking-caused illnesses; they become part of the 400,000 deaths every year attributed to tobacco use. We can and must do more to curb the use of this very serious and deadly poison. This is a public health emergency that demands action.

Over the years, the tobacco industry has been confronted with opportunities to do the right thing—to be honest about the health effects of tobacco or even the intended targets of various marketing campaigns. In every instance they passed up that opportunity and actively fought to continue alluring generation after generation to use tobacco products.

I would like to use the time that I have today to walk through some of those occasions in an attempt to demonstrate how important the Family Smoking Prevention and Tobacco Control Act is to the American people, not only to our health, but to our economic prosperity.

In 1994, while I was in the House of Representatives, seven executives from the tobacco industry took an oath before a House committee that they would tell the truth about tobacco. In their statements and responses to questions from members on the committee, all seven individuals stated that they believed nicotine was not addictive, and that new marketing practices were not designed to reach younger and younger age groups, below the legal smoking age of 18.

In order to support these claims, the executives cited research councils and institutes. But these statements were contrary to what many public health officials were saying, and what I believed. This further obscured the notion that smoking was a direct cause of disease.

A total of 46 States—including my own—States in which the majority of my colleagues represent—then proceeded to call their bluff, one lawsuit at a time.

Through these cases, the American people learned that the lies and deceit of the tobacco industry extended far beyond that of a Congressional hearing room. The suits unearthed that the tobacco industry had established and funded the councils and institutes claiming tobacco was not a health hazard; and had internal documents stating that No. 1, nicotine is addictive; No. 2, smoking is a habit of addiction; and No. 3, that in order to continue to prosper, cigarettes must be marketed to younger and younger age groups—below the legal smoking age of 18.

The tobacco industry settled these lawsuits. The agreement, totaling nearly $206 billion, was ordered to be distributed to the States in an effort to recoup Medicaid dollars spent on smoking-related health care costs. While $206 billion seems like a lot to you and me, this amount of money only accounts for approximately 7 years of the Medicaid budgets of the 46 States.

The fact that the industry did settle should have been a clear sign that tobacco production and marketing needs to be regulated. Unfortunately, around the same time that the settlement occurred, the Supreme Court narrowly ruled—on a 5-to-4 margin—that the FDA did not have such authority to regulate their products. The tobacco industry continued to aggressively market tobacco products.

Nearly 10 years later, this past December, the Supreme Court upheld that tobacco firms could, in fact, be charged at the State level with deceptive advertising practices of cigarettes. We have on the one hand, no regulation; on the other hand, the possibility of State enforcement.

These two Supreme Court decisions further complicate the message received by Americans regarding the use, marketing and distribution of tobacco. In essence, the industry could be held liable for certain advertising practices, but direct, regulatory oversight of those practices does not exist. Appropriate guidelines do not exist. With this bill, we have the opportunity to ensure that guidelines are established.

To add yet another layer to this debate, only 2 weeks ago, the U.S. District Court of Appeals for the District of Columbia ruled that the tobacco industry falsely advertised ''light'' and ''low-tar'' cigarettes under the guise that they were less dangerous than other products. This ruling comes after 10 years from the date the suit was originally filed—10 years too late to prevent 10,000 Rhode Island children beginning to regularly use tobacco. Had we enacted the Family Smoking Prevention and Tobacco Control Act, or a similar version of this legislation, years ago, we could have prevented some of those in my State and across the country from ever smoking. Instead, the debate has dragged on for 10 years.

Unfortunately, this debate will continue to drag on. The tobacco industry has already publicly stated that it will

continue to argue the decision that was recently rendered. Rather than taking the tortuous, time-consuming and very expensive path of taking the case through litigation, I think we have to give the FDA the authority to regulate tobacco products.

We have the opportunity before us to put an end to the courtroom drama. With the Family Smoking Prevention and Tobacco Control Act, we can give the FDA the authority to regulate tobacco, restrict illegal advertising practices targeting children, prevent the unlawful sale of tobacco to our Nation's youth, and strengthen warning labels.

With this legislation, everyone wins. The tobacco industry would have clear guidance on advertising practices which could help them avoid lengthy litigation; young people will not be targeted by aggressive tobacco media campaigns; and the public health crisis caused by tobacco use—which costs the American people in health care dollars, in lost productivity, and in loss of loved ones—tremendous prices—would hopefully begin to fade.

In preparation for our discussion, I looked back at some of the past statements that I have made in support of regulating tobacco—and one sticks out in my mind: the tobacco industry has worked hard to earn the trust of the American people.

We must try to win that trust back. We must empower the FDA to regulate tobacco in order to rein in the use of tobacco by children, control the access that our children have to tobacco, and warn the American public about its dangers.

The Senate is finally once again on the path to having a meaningful debate about our Nation's health care system. It is my hope that this debate will result in appropriate, high quality health care coverage and access for every American. Of course, we hope to do all of this at the lowest possible cost.

If we are serious about reforming our health care system, why wait? Smoking-related health care costs are skyrocketing. Today the average cost of a pack of cigarettes in the country is about $5 but the social cost is much more.

Every year, the public and private health care expenditures caused by smoking total approximately $100 billion, and $100 billion in lost productivity. These are staggering totals.

I will repeat: we literally cannot afford to wait another day for this legislation to be enacted.

We have the opportunity to begin charting a new course today. With this bill, we will begin to chip away at health care costs, steer our youth away from smoking, and pave the way for a healthier future for our Nation.

I look forward to working with my colleagues to enact this important piece of legislation and set forth on this new path for a healthier and more prosperous America.

I yield the floor and suggest the absence of a quorum.

The PRESIDING OFFICER (Mrs. HAGAN). The clerk will call the roll.

The legislative clerk proceeded to call the roll.

Mr. SANDERS. I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. SANDERS. Madam President, I am very pleased that we are finally taking up this very important legislation. Regulating tobacco through the FDA is an essential part of addressing public health issues related to tobacco use, and I fully support this long overdue legislation. The cost of smoking is estimated at $96 billion a year in health care costs. The human toll is even more appalling: 440,000 smoking-related deaths per year. Tobacco is responsible for one-third of all cancer deaths in the United States each year, and tobacco use is the most preventable cause of death in the country.

There are many important provisions in this bill, but this issue is primarily about our children. It is appalling that in Vermont, one in every six high school students smokes cigarettes, and nationally 20 percent—one in every five high school students—smoke. Every day, about 3,600 children between 12 and 17 years of age smoke their first cigarette; 1,100 of them will become regular smokers, and 300 of those will ultimately die from this habit. That is condemning over 100,000 kids every year to a certain early death caused by tobacco. No wonder that 70 percent of voters strongly support FDA having the authority to regulate tobacco.

Make no mistake, tobacco marketing and marketing to kids is big business. The tobacco industry spends about $36 million every day marketing and advertising its addictive products in the United States. That is over $13 billion a year. The multinational corporations that market tobacco are not spending that kind of money if they don't expect a big return. Some of these ads are not just trying to get older addicted smokers to switch brands, they are marketing to girls and young women to get them to start smoking and they are marketing to teenage boys to get them to start smoking. They are adding candy flavors to get young people to start smoking.

That our Nation's most vulnerable are subjected to these kinds of marketing campaigns of multimillion-dollar profit companies is a disgrace and an outrage. Can one imagine a company trying to addict our young people to a habit which will prematurely kill them? I am not quite sure what kind of morality exists on the part of people who do this. We are talking about an industry where the largest company, Philip Morris, brought in $18.5 billion in revenue in 2007 from their U.S. business alone and over $64 billion in total revenues internationally. The tobacco industry spent nearly $28 million lobbying Congress in 2008, and from 1998 to 2006, they spent over $248 million to prevent Congress from acting to protect the children and the citizens of our country from this addictive practice. Given these figures and the fact that profit margins are estimated at 46 cents per pack for Philip Morris, I cannot understand any argument against legislation to regulate the marketing, advertising, and product standards of cigarettes and other tobacco products.

Tobacco has been considered more addictive than heroin. Let me repeat: Tobacco has been considered more addictive than heroin. In fact, there are a number of anecdotal stories of former heroin addicts who were able to kick their heroin habit but not their tobacco habit. It was just too hard to quit tobacco compared to heroin. Imagine that.

Tobacco companies are adding nicotine and other chemicals to their products to make these products even more addictive. And they are not regulated. Nobody regulates them. They can add whatever they want whenever they want. So we have multinational corporate executives in three-piece suits making huge amounts in compensation packages based on selling a killing and addictive product to the American people and to our children. We should be very clear when we take a look at these CEOs and understand that they are nothing more than high-priced and high-paid drug pushers. This Congress has spoken out repeatedly against those horrendous people, the lowest of the low, who are trying to get our kids into heroin and other drugs. We should look at these CEOs in the same way and say to them: How dare you try to sell addictive products to our kids, get them hooked into smoking cigarettes, and force them to end their lives prematurely and, in many cases, very painfully.

While one major part of this issue is stopping tobacco use before it starts, Congress will also need to take up the issue of cessation. About 70 percent of all smokers say they want to quit smoking, but tobacco is so addictive that even the most motivated may try to quit eight or nine times before they are able to do so. I look forward to working with my colleagues in the Senate to address what I see as an addiction that leaves hard-working people struggling to make ends meet with limited choices in terms of cessation programs. What we have to do as a nation—and I know it is outside the scope of this particular bill—is to make it as easy as possible for anyone in America who wants help in order to stop smoking and kicking the habit to be able to do so. We are not there right now. Sometimes it is complicated. Sometimes it is expensive. Sometimes people do not know how to access cessation programs. But I think that is a goal we must strive for.

Studies have shown smoking has become even more concentrated among populations with lower incomes and with less education. Why do low-income people smoke? Medical research

shows that being poor is, needless to say, extremely stressful. And as anyone who has ever been addicted to tobacco knows, being anxious, being stressful makes you reach for a cigarette.

We have a lot of work in front of us. I think this bill is a very good step forward. The bottom line is, this Congress has to, through the FDA, regulate tobacco. Our goal has to be for these companies to stop pushing their dangerous and addictive product onto our people, especially our kids. Our goal has to be to come up with programs to make it as easy as possible for people to get off their addiction.

So we have a lot of work in front of us. I think this bill is a very good step forward.

Having said that, Madam President, I yield the floor and suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

Mr. FEINGOLD. Madam President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

(The remarks of Mr. FEINGOLD pertaining to the introduction of S. 1173 are located in today's RECORD under ''Statements on Introduced Bills and Joint Resolutions.'')

Mr. FEINGOLD. Madam President, I yield the floor, and I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mr. UDALL of New Mexico. Madam President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. UDALL of New Mexico. Madam President, I rise to support the Family Smoking Prevention and Tobacco Control Act, and I wish to start by thanking Senator KENNEDY and all those who have fought for this legislation over the years.

Watching this debate, I can't help but think of the movie ''Groundhog Day.'' In that movie, Bill Murray has to live the same day over and over. Like him, I have been here before. We have all been here before.

The FDA first attempted to regulate tobacco products in August 1996, almost 13 years ago. In 2000, a narrow majority on the Supreme Court ruled that the Congress had not given the FDA authority to regulate tobacco. But even as the Court struck down the FDA rules, it noted that tobacco poses ''one of the most troubling public health problems facing our Nation today.''

Immediately after that decision, this body considered legislation to provide the needed authority. That legislation was introduced by the Senator from Rhode Island and our senior Senator from New Mexico. They argued that the FDA regulation of tobacco was ''long overdue.'' They pointed out that every day we delayed, more kids would start smoking and more citizens would face disease and death. That was almost a decade ago.

Since the FDA first tried to regulate tobacco, more than 20.6 million American kids smoked their first cigarette, and more than 2.6 million of those kids will die because they did. Almost $1 trillion has been spent on health care costs associated with smoking, and 4.6 million Americans have lost their lives to cigarettes.

We do not know how many young people would not be addicted today if these companies had been prevented from advertising their products to our children. We do not know how many cases of lung cancer and heart disease could have been prevented if tobacco companies had not boosted nicotine levels and marketed light cigarettes as if these cigarettes weren't killers. We don't know how many lives were lost while Congress failed to act. But we do know that number is too high—much too high.

I first became involved with this issue when I was New Mexico's attorney general. In May of 1997, we joined a lawsuit that would eventually involve 46 States and 6 territories. In some ways, this lawsuit was like any other. My client, the State of New Mexico, had lost thousands of lives and billions of dollars because of the defendant. Our suit simply demanded restitution and damages.

But on a broader level, the tobacco cases were unprecedented. We were responding to a threat that impacts every American. The suit began in Mississippi and it spread to almost every State, regardless of politics or geography. We were addressing a national problem because the Congress had failed to act.

In 1998, we negotiated a Master Settlement Agreement that was an important step forward. But we knew there was more to be done. Some have claimed the settlement makes FDA regulation of the tobacco industry unnecessary. As somebody who helped negotiate that agreement, let me tell you that nothing could be further from the truth.

The settlement was not intended as a substitute for adequate Federal regulation. In fact, the agreement originally called for FDA regulation as an integral part of efforts to protect the public. The National Association of Attorneys General recently filed an amicus brief saying the settlement has not stopped tobacco companies from marketing to kids.

In fact, tobacco company memos demonstrate that their business depends on recruiting what they call ''replacement smokers.'' Companies used to strategize about how to attract customers as young as 13, and evidence suggests this strategy has not changed. Even after the 1998 settlement agreement, one tobacco company noted, ''market renewal is almost entirely from 18-year-old smokers.'' They do not say they are targeting minors. That would be illegal. But somebody is going to have to explain to me how you can focus your business model on 18-year-olds without marketing to 17-year-olds.

When I came to Congress after my service as an AG, I strongly supported FDA regulation of tobacco. I knew then the settlement did not provide the kind of flexibility needed to effectively control tobacco industry actions. Since the settlement was signed, the tobacco companies have shown us they will evade it at every opportunity. On May 22, the DC Circuit Court of Appeals affirmed the 2006 ruling that found tobacco companies guilty of racketeering and fraud. The original ruling contained 1,300 pages describing tobacco company efforts to endanger the public health and to cover up their activities. Many of these actions were taken after the settlement agreement.

The court found the tobacco companies ''began to evade and at times even violate the settlement agreement's prohibitions almost immediately after signing the agreement.'' After disbanding a research program, according to the terms of the agreement, the companies initiated a new research program with the same office, the same board, and even the same phone numbers.

Given the obvious dangers of tobacco products and the behavior of the tobacco company executives over the years, why isn't this product already regulated by the FDA? This question was answered implicitly by the Supreme Court in 2000, and the answer is instructive. The Court found that tobacco, unlike other FDA-regulated drugs, has no health benefits. In other words, tobacco is too unhealthy to be regulated.

Whatever you think of that ruling, it poses a serious question. Should an agency that regulates Tylenol be unable to regulate a substance that kills 440,000 Americans every year—more than—and think about this for a minute—more than alcohol, AIDs, car crashes, illegal drugs, murders, and suicides combined? Tobacco kills more than all those combined. Is it possible that one of the world's most deadly addictive substances should be immune from the rules that govern almost every other addictive substance that can be legally sold in this country?

Some of those who have spoken on this bill have pointed out the FDA cannot solve the most significant problem with tobacco—that when used as directed, it kills the user. But the FDA can stop tobacco companies from adding ingredients that make their products more addictive and more deadly. It can stop them from lying to consumers about the health impact of their products, and it can stop them from marketing to our children. In

fact, the FDA is particularly qualified to do these things.

As I was preparing to come to the floor today, I got an e-mail from one of my constituents in Hobbs, NM, and she reminded me why this bill is so important. She had received an e-mail from a tobacco company. The company thought she was one of their customers, and they asked her to send me a form e-mail opposing this legislation. She forwarded their e-mail, and at the beginning of the e-mail she wrote:

> They strongly urged me to copy the following message to you and to vote against it. What they don't know is I don't smoke. But my 12 and 7-year-olds do because they have to go visit their dad, who smokes around them. Not only do they get a lot of secondhand smoke, but my oldest one idolizes her dad and will probably end up smoking because of him. So by all means, pass the bill.

Congress has waited too long to protect this woman and her children. It is time to get this done.

In ''Groundhog Day,'' Bill Murray wakes up to a different day when he finally does the right thing. I am hoping we will all wake up after this vote to a new day—a day when our citizens have the health protections they should expect from their government. I would ask you to join me in supporting this commonsense legislation.

I yield the floor.

The PRESIDING OFFICER. The Senator from Wyoming.

Mr. ENZI. Madam President, I yield 45 minutes postcloture time to Senator BURR.

The PRESIDING OFFICER. The Senator from North Carolina.

Mr. BURR. Madam President, let me say to my colleague, who had his constituent send him a letter and who served in an incredibly effective fashion as State attorney general and who was involved in the MSA, the MSA was very clear. States extorted—that is what I call it—money from the tobacco companies to pay for health care costs. That money that was part of the Master Settlement Agreement was laid out on behalf of the tobacco industry to address the health care costs in those States but also to provide the resources so those States could, in fact, do cessation programs for adults to stop smoking.

What is our experience in the country relative to the recommendations given by the Centers for Disease Control to those States in terms of what they ought to spend on programs to get individuals to stop smoking? Well, in the State of New Mexico, they have done very well. They have actually spent 44 percent of what the CDC suggested they spend.

But I think you would also find it shocking to know that the prevalence of marijuana usage in that State is 1 percent higher than the prevalence of smoking by youth. The prevalence of youth marijuana usage is 1 percent higher than the prevalence of smoking cigarettes by youth. In addition to that, I might add that the prevalence of alcohol among the youth there is almost double what the usage is of smoking or the prevalence of marijuana usage.

There are two objectives to regulating differently an industry that is currently the most regulated industry in America, and the sponsors of this bill have stated it numerous times: No. 1, to reduce youth usage; No. 2, to reduce disease and death. That is the public health component, and I agree totally with it. But I think what we have to look at is the experience of what is happening today and what the assessments are of the bill that is being considered that would grant FDA jurisdiction of this product.

Today, the Centers for Disease Control says smoking is being reduced annually by 2 to 4 percent. The Congressional Budget Office has looked at the Kennedy bill and assessed that over the next 10 years the bill would reduce consumption by smokers at 2 percent. Let me say that again. Currently, doing nothing—not spending billions of dollars, not giving new authorities to the FDA—we reduce smoking by 2 to 4 percent per year. But if we put this bill into effect—at $787 million annually—and we give the FDA authority and jeopardize the gold standard of the agency which approves drugs and biologics, medical devices and food safety, we are actually not going to reduce smoking usage as much as if we did nothing.

Why is that? This is very important because you will hear me talk over the next several days about reduced-risk products. Reduced-risk products are products that deliver the nicotine needed for the addiction but reduce the risk of disease and death because it may be moved from smoking products to smokeless products. The truth is, under the Kennedy bill, we basically eliminate any product that wasn't marketed in February of 2007—over 2 years. We have put a marker in the bill that says if there is a product in the marketplace that was not sold in February of 2007, it can't be sold any more. But if it is a product that was sold before February 2007, the FDA can't change it one bit. It is grandfathered in.

So what is the CBO's assessment? What the Kennedy bill does is it grandfathers every cigarette that was on the market 2½ years ago and it doesn't allow the FDA to change it in any way. The only thing it does is to increase the warning label. I stated on the floor earlier today that if putting a warning label on it reduces the usage of cigarettes, I am willing to do it today. I will cosponsor it with anybody. The truth is, what this bill does is it locks in these products; therefore, it eliminates the choices adults have to try to get off of cigarettes and move to a reduced-risk product.

My colleague pointed to the Supreme Court ruling on the tobacco industry, and he was partially correct. He just didn't tell the whole story. The whole story was the Court said, in 1998, when the FDA Modernization Act was written and passed and signed into law, Congress opened the entirety of the FDA Act and had the opportunity to give the FDA tobacco jurisdiction and chose at the time not to do it. That was 11 years ago; 11 years ago, the FDA Modernization Act was passed. I was the lead sponsor of that bill, writing that bill in the House of Representatives. It took 2½ years to construct it. Every Member believed that the gold standard of the FDA was so important that we never lost focus on the fact that we had to maintain the integrity of the mission statement of the FDA. But no Member of Congress ever attempted to extend jurisdiction over tobacco to the FDA because they were concerned at the time that to do that would lessen that gold standard at the FDA.

How can you tell an agency that has a regulatory responsibility to protect the safety and effectiveness of those products they regulate that we want you to do it on drugs and biologics and medical devices, but we don't want you to do it on this new product of tobacco? The risk and concerns and fears at the time were that this might diminish the effectiveness of the FDA.

What has happened in 11 years? For 11 years, we have had a steady decrease in smokers. Now we are going to adopt a bill that potentially locks us into just the products in 2007. Why have we had a reduction? Because new reduced-risk products have come to the marketplace. We ought to continue to bring new reduced-risk products to the marketplace. Unfortunately, this bill does not do that. As a matter of fact, in section 910 of this bill, a so-called new tobacco product would not be marketed unless these three things were met: No. 1, it can show the marketing is appropriate for the protection of public health; No. 2, the increased likelihood that existing users of tobacco products will stop using such products; and No. 3, the likelihood that those not using such products will not start.

Let's take the first requirement and put it into English. Before a company could market a new tobacco product, it would have to show that its use is appropriate for the protection of public health. Who in the world can show that the use of a tobacco product is appropriate for public health? It is impossible. In other words, this new tobacco product—be it a cigarette, raw tobacco, perhaps an alternative tobacco product—the companies would have to show that this new product is appropriate for the protection of public health. Somebody is going to have to explain to me how a cigarette can be appropriate for the protection of public health. It cannot be done. Therein lies why I grandfathered products before 2007.

Even if by some miracle the inventer could show a product was appropriate for the protection of public health, this would only meet a third of the qualifications for a new product to come to

market. It would also have to show that the product will make smokers or those using chewing tobacco less likely to smoke or chew and will prevent new people from starting. Again, somebody will have to show me how you can provide an example of a tobacco product currently for sale that would satisfy these standards: it discourages people from smoking, and it deters young people from starting. The bill's manager, the author of the bill, could not share with us exactly how you accomplish that.

How does one go about assembling the data that is needed for new products when, in fact, you cannot actually ask consumers about a product that has yet to have an application approved. It is a catch-22. It sounds good.

Let me highlight another problem with the bill as it relates to harm reduction. You heard me discuss harm-reduction products or products that are less harmful. These are not found in H.R. 1256.

I am sure my colleagues are aware that the legislation would ban several products not sold in 2007. One of the products is a product called snus. We have seen the can. It is a Swedish smokeless tobacco, it is pasteurized, and it doesn't require one to spit. It is a tool that in Sweden has been used to get people off of cigarettes. Yes, it is still the use of tobacco products, but it meets the threshold of diminishing the risk of death and disease. Some suggest because there is a wintergreen and there is a spice, that this is attractive to kids. That is not the case. If that were the case, we would see wintergreen marijuana, because the usage or preference among youth is higher. The truth is, that has nothing to do with it. As I understand it, the product does not require the burning of tobacco. It does not require the actual smoking of tobacco. It generates no secondhand smoke. It will not affect the children near a user. According to the research done by a host of reputable scientists and public health organizations, use of this product instead of cigarettes can actually reduce death and disease associated with smoking. Why would you ban this product if the pretext of passing this bill is to reduce the risk of death and disease? You would not. But we eliminate the ability for this product to come to market in the future, and that which is at market today we ban from the market. In other words, it is clear that snus is far less dangerous than cigarettes, and it would be appropriate for the protection of public health because it eliminates secondhand smoke, it moves people away from smoking cigarettes. It would meet much of the standard of the bill, but the legislation still mandates that the manufacturer of snus demonstrate that snus will not encourage nonusers to start.

Again, I am not sure how you communicate with the general public—which is strictly prohibited in the bill until you have an approved application. If you need to communicate with the public in order to understand whether the product would cause nonusers to start for a reduced product approval application but you cannot communicate with consumers until you have an approved application, how would you ever get approval under section 911? The devil is in the details. In fact, you cannot communicate, but you have to communicate to be able to pass the third threshold of allowing the product to come to the marketplace.

So it is disingenuous to suggest that this bill is for the purposes of reducing death and disease when, in fact, those things that are proven to reduce death and disease have strictly been forbidden. And in the case of those that are at market today, they would be pulled from the marketplace.

It would be fair to say that what we are doing is freezing the marketplace for cigarettes and chewing tobacco. In 2007, I raised the issue with the HELP Committee because this same bill was brought up. The answer I was told then was that it may be difficult to bring a reduced-risk product to market. Bringing a reduced-exposure product to market is much simpler. So I said: Let's take a look at it. Maybe a cigarette with less benzene or nitrosamines can work, so I read the reduced-exposure portion of section 911.

The first part of the reduced-exposure language reads that in the absence of conducting a 20- to 25-year study on tobacco products, if you can show a reduction in a harmful constituent in the product, you can classify it as reduced exposure. That seems reasonable.

Then, in addition, those little pesky words pop up: ''additional findings.'' The reduced-exposure language states that you must show how the product would actually be used by consumers. Once again, catch-22—you can't talk to consumers until you have an approved application. You can't show how the product is going to be used by consumers unless you can talk to consumers. Therefore, there is no such thing as reduced exposure.

The bottom line? The bill that is being considered to give FDA jurisdiction brings no new harm reduction to tobacco users in America. It does to smokers exactly what the bill states, it locks in place all the cigarettes that were sold prior to February 1, 2007. Any of the reduced-risk product that has been introduced in over 2½ years automatically goes off the market, and the pathway through FDA for any new technology that might not burn tobacco or that might use tobacco in a different way that enables somebody to quit smoking and reduces death and disease—there is no pathway for it to happen because there is no way to communicate with the public until you have an application, and a part of the application process means you have to communicate with the public to meet the test that has been designed.

You know what this is typical of what the American people think about Congress, that we say one thing and we do something else. That is exactly what we are doing here.

I will offer a substitute with Senator HAGAN tonight, I believe. That substitute will bring full regulatory authority to an entity to regulate this industry. I am not up here saying we cannot regulate it better than we do today. It is the most regulated product in America. It is regulated by more agencies than any product that is sold today. Can we do it more extensively? Sure. Can we have better warning labels? Absolutely. Can we be graphic in our description of what these products cost? Certainly. But the question is, Where is it more appropriate to do the regulation?

I suggest that creating a new entity under the Secretary of Health and Human Services, where they have full authority to regulate this product, to limit its advertising, to eliminate its advertising, is a more appropriate place than to give it to the FDA, where their mission statement is to prove the safety and efficacy of all products they regulate, but they can never do it on tobacco products; to put it under the same guidance of the Secretary of Health and Human Services, who also oversees the FDA.

What is so magical about putting this at the FDA? I will tell you, because they have attempted to do it for 10 years. It is because when you put it there, over time you will be able to outlaw this product—or you think.

I go back to this chart from the CDC, the Centers for Disease Control, where in 48 out of 50 States the prevalence of youth marijuana usage is higher than the prevalence of youth smoking. Don't think just because you outlaw it you are going to reduce this country's youth usage. As a matter of fact, you may find out you have increased youth access.

The way to do it is to take the money the manufacturers gave to the States and use the money to provide the education, to provide the cessation programs, to provide the reduced-use products that will allow individuals to get off cigarettes and go to something that really does reduce death and disease. But if you pass the Kennedy bill, that is not what we are doing. What we are doing is we are locking in forever the 21 or 22 percent of the American people who are going to smoke. In fact, the Centers for Disease Control said that if we do nothing, by 2016 we will reduce, from 21 or 22 percent, the smoking rate in America to 15.9 percent. We will actually reduce it over 6 percentage points by doing nothing.

Yet we are getting ready, if we don't support the substitute, to lock in a measure that assures us indefinitely into the future that 21 or 22 percent of the country will choose cigarettes as their means of tobacco usage. It means we will continue the rate of death and disease. We may look back and say: But we picked the strongest regulatory agency that we could to be in charge of

the regulation of this product. Tell that to a patient waiting for a lifesaving drug and the reviewer who was reviewing the application was moved over to the tobacco section, because this new responsibility they had made them take senior reviewers and get them over because they had to regulate this product from day one. Tell the individual in America who is harmed because of a medical device that should have never been approved but got through the system because the gold standard of safety and efficacy was not adhered to at FDA because they were asked to turn to tobacco and not prove that public health was important on this product and, therefore, new reviewers looked at it and said: We don't have to be 100 percent accurate on devices. Or the biologic companies, when they see a delay in the approval of an application, that actually invest billions of dollars to bring a lifesaving biologic to the marketplace that ends a terminal or chronic illness, what if this product doesn't come because of what we do?

These are questions we should be asking ourselves. The American people deserve us to fully vet this. But in 2 days of markup on this bill, when questions were asked, the answers were ignored. They were more interested in the speed with which we pass this than the accuracy of the policies that we put in place. I have tried to keep the debate since yesterday on facts. I have tried, when I made a claim, to produce the numbers. The CDC is typically a credible source. The Congressional Budget Office is usually a credible source. The University of Michigan, many have come on the floor and used it as a credible source. This is not industry hype. These are institutions that we come to the floor and use to make our claims every day. What all of them say is: Don't pass this bill. But they don't say not to do something.

Tonight Members will have an opportunity to vote for a substitute, a substitute that gives the same level of authority, that does away with advertising in total, that puts the same descriptive labels on so that people cannot only read it in plain English but see it in detail. It just doesn't put it at the FDA. Why? Because I spent 2½ years of my life trying to modernize the Food and Drug Administration through a piece of legislation we passed in 1998. Why did it take so long? Because the FDA regulates 25 cents of every dollar of our economy. When the American people go to bed at night, they know if they take a drug that was prescribed by a doctor and filled by a pharmacist, it will not hurt them. More importantly, it is probably going to help them. It will make them better. Or when they go to the hospital or the doctor's office and they use a device, they know it has been reviewed and it is safe. They know that when they go to the grocery store, there is an agency called the Food and Drug Administration that is responsible for food safety. What they buy and what they eat is actually not going to kill them.

Yet we have seen instances over the last 3 years where spinach is sneaked through and peanut butter is sneaked through. And as we become a more global economy, our concerns about where it is made and what they put on it mean that our review of food safety has to be as stringent as everything else. The FDA is struggling today. The biggest mistake we could make is to give them another product and say, regulate this, and don't regulate it based upon the same standards you do everything else. But that is what we are doing.

If you want to reduce youth access, youth usage, if you want to reduce death and disease, vote for the substitute tonight. Reject the base bill. If we do that, we will have successfully done our job. If, in fact, we fall prey to jeopardizing the gold standard of the FDA, mark my words, this body will be back at some point fixing a mistake they made.

My only hope today is that there won't be an American who loses their life by the actions we have taken. I am willing to concede that if the FDA gets the jurisdiction, the authority to regulate this industry, we will miss the opportunity to take a lot of Americans off of cigarettes and move them to other products, other products that are better for their health and not as likely to kill them. The statistics say that that will happen. Ask yourself, knowing that, is it worth risking that you might change the gold standard at the FDA, that you might lower the bar for drug or device approval, that we might actually slip on food safety. I am not sure the risk is worth it.

This is about our kids. Vote for the substitute. This is about the status quo. This is about letting an outside group have a win that has fought this for 10 years because they are in some battle with an industry.

Is it worth it for us to give them a win versus the American people? I don't think so. I encourage my colleagues to support the substitute tonight. Reject the base bill.

I yield the floor and suggest the absence of a quorum.

The ACTING PRESIDENT pro tempore. The clerk will call the roll.

The bill clerk proceeded to call the roll.

Mr. DURBIN. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

Mr. DURBIN. Mr. President, pending before the Senate now is consideration of a bill that would dramatically change the way we regulate tobacco and tobacco products in America. This is an issue which has meant a lot to me during the course of my time in the House and in the Senate.

Many years ago—over 20 years ago—I offered an amendment which was the first successful attempt to regulate tobacco. I should say, earlier efforts at warning labels go back many years. But this was the first successful attempt to regulate the use of tobacco product.

What we did 20 years ago was suggest that the old days and the old ways of allowing people to smoke on airplanes had to change. Some of us are old enough to remember those days when you would make a reservation to fly on an airplane and you would tell them whether you wanted to sit in the smoking on nonsmoking section—as if there was any difference. For the most part, if you happen to be seated, at least, in the last seat of the nonsmoking section, you might as well be smack dab in the middle of the smoking section.

So we decided to eliminate smoking on airplanes. That was an amendment I offered in the House of Representatives over 20 years ago. It had the opposition of the tobacco lobby and the opposition of all the political leadership in the House of Representatives—Democrats and Republicans. They all opposed it for a variety of different reasons. But we called it anyway, and the amendment was successful. What it taught me was that Members of Congress are members of the largest frequent flyer club in America. We spend more time on airplanes than most. If there is something we want to change, it affects us personally. And this did.

So Democrats and Republicans came forward, and we started a trend which I think has been very beneficial for this country because once I passed that amendment, Senator FRANK LAUTENBERG of New Jersey took it up here in the Senate. He successfully passed it. We worked together to eventually eliminate smoking on airplanes, and the American people noticed. They liked it. They reached an obvious and rational conclusion: If secondhand smoke is dangerous in an airplane, then it is also dangerous in a train, in a bus, in an office, in a school, in a hospital, in a restaurant. Of course, the dominoes just kept falling. As they fell, there were more and more restrictions on smoking in public-type places.

So there were many things still to be done, and we started thinking about the obvious need for change. We knew we were up against one of the most powerful lobbies on Capitol Hill with the tobacco lobby. Not only were they very wealthy, with a lot of revenue from the sale of their product, but they also had ingratiated themselves to many Members of Congress of both parties. They did it in obvious ways: in contributing to campaigns. They were a major factor in some districts where they either manufactured their product or tobacco was grown. But they also befriended many Members of Congress, providing charitable contributions to hometown charities for Members of the House and Senate. It went a long way to build up good will and to convince Members of Congress to oppose any other changes when it came to tobacco regulation.

Well, there were things we knew needed to be done. You see, each day in America, 3,000 to 4,000 children start smoking for the first time—3,000 to 4,000 a day. During the course of that decisionmaking, about a third or a fourth of them will decide to stick with it. They will stick with it long enough that the nicotine chemical in the cigarette creates a craving and satisfies an addiction which is tough to break.

Oh, I have seen people walk away from a lifetime of smoking in a few days. But I have also seen people struggling for their entire lives trying to break that smoking habit—patches notwithstanding and hypnosis and all those things. For a lot of people, it is a very hard thing to do.

The tobacco companies know if they are going to have 400,000 of their customers die each year, they have to replace them with children. If people wait until they are 18 years old or 21 years old, they are likely to be smart enough not to start smoking, but if you are 12 or 13, it is an adventure. It is something that is forbidden, and it shows that you are just like a grownup, and kids try it.

The tobacco companies know that. Although they deny it, they market to kids. They sell their products in a way that appeals to children, hoping that teenagers and even younger will start taking up this tobacco habit because it is not only cool, it tastes good. The advertising is appealing. Tobacco companies spend over $13 billion a year promoting their products and many of those marketing efforts are directed right at our kids.

Mr. BROWN. Mr. President, would the assistant majority leader yield for a moment?

Mr. DURBIN. I would be happy to.

Mr. BROWN. Mr. President, I wanted to reemphasize the words of the assistant majority leader for a moment because I was walking through and heard his comments about tobacco companies' efforts to get children addicted.

As the assistant majority leader said, more than 1,000 Americans a day—400,000 a year—die from tobacco-related illnesses. I remember 15 years ago sitting in the House Energy and Commerce Health Subcommittee listening to tobacco executives talk to us about a whole host of things that they weren't exactly truthful about. But from the point Senator DURBIN makes that 400,000 Americans die a year from tobacco-related illnesses, it is clear that what the tobacco companies know they have to do is they have to replenish their customers. They have to find more than 1,000 new customers a day. They don't go to our age group. They do not go to 50-year-olds and 60-year-olds or 40-year-olds or even 30-year-olds; they go to the people the age of the pages sitting in front of us. They go to teenagers. Those are the people whom they know they must addict to replenish their customer base, if you will. That is why this legislation is so important and why the efforts of the assistant majority leader over the last 20 years, as a Member of the House and Senate, are so important, the victories he has had such as stopping smoking on airplanes and all of those other places. This legislation is extraordinarily important.

I yield back to the assistant majority leader.

Mr. DURBIN. Mr. President, I thank my colleague from Ohio for joining in. He certainly recalls those infamous hearings in the House of Representatives when the tobacco company executives stood up and ceremoniously testified under oath that nicotine was not addictive. That, I think, was the beginning of the end of the tobacco lobby in Washington, DC. Everyone knew that they were, at best, misleading and, at worst, just plain lying to the American people. When it came to their advertising, they denied for years that kids were their targets. They said it hadn't been the case.

Then one can take a look at some of the tobacco companies' internal documents that came out during the course of lawsuits, and let me tell my colleagues some of the things they found.

The Lorillard Tobacco Company was quoted as saying: ''The base of our business is the high school student.''

Philip Morris, in their internal documents, said: ''Today's teenager is tomorrow's potential regular customer.''

U.S. Tobacco: ''Cherry Skoal is for somebody who likes the taste of candy, if you know what I'm saying.'' I think I know what they are saying.

R.J. Reynolds, in an internal document, said:

> Many manufacturers have ''studied'' the 14–20 market in hopes of uncovering the ''secret'' of the instant popularity some brands enjoy to the almost exclusion of others. . . . creating a ''fad'' in this market can be a great bonanza.

So make no mistake about it. We know. We all know. Tobacco companies have directed their ad campaigns and their recruitment at our children. I have said it before; it bears repeating. I have never met a parent who has said to me, I got the greatest news last night. My daughter came home and announced she had started smoking.

I have never heard that. I don't think I ever will. Most parents know that is a bad decision and one that can be fatal.

Cigarette companies claim they have finally stopped intentionally marketing to kids and targeting youth in their research and in their promotions, but they continue to advertise cigarettes in ways that reach these populations. They continue to make products that appeal to kids.

For example, take a look at this one on this chart. This is a product called Liquid Zoo. The packaging is powerful, and the cigarettes come in fun flavors: Coconut cigarettes. How about that one? Vanilla cigarettes. Strawberry cigarettes. Liquid Zoo offers these. It is almost as if you are going into an ice cream store, which most kids like to do, because you are offering the flavors they will find in the ice cream.

Look at the Sweet Dreams and Chocolate Dreams cigarettes over here; again, a variety of kid-friendly flavors. This time, the cigarettes themselves, if you will notice down here, are pastel colors to make them even more appealing to children. Not only are these cigarettes designed to appeal to kids, but the tobacco companies buy the ads in magazines that teenagers read and try to draw them to their brands through advertising.

Here is a familiar one: Camel. Look at this ad for Camel cigarettes that ran in Rolling Stone Magazine, Cosmopolitan, and Vogue in 2004 and 2005. You can see from this ad it is appealing. These packages are designed in ways to appeal to young people, and the advertising as well. It took 39 State attorneys general to get on the tobacco companies' case before they finally agreed to stop marketing these cigarettes.

So what is next? Well, until we pass this legislation, it is inevitable that these tobacco companies will dream up another way to market their product to the kids.

This bill before us will make a difference. For the first time we are going to get serious about this. Tobacco products are one of the few, and maybe the only, products in America that go unregulated. You can't sell food or medicine in America without the Food and Drug Administration, or even the U.S. Department of Agriculture, taking a look at it. I will concede they don't inspect every package of food you will find in the store, but they have an overall responsibility to make sure that that product is safe for Americans to consume. But tobacco is an exception. Tobacco is not regulated. Tobacco is not inspected. They somehow manage to wiggle their way somewhere between food and drugs, saying, Oh, we are not a food product, and we are definitely not a drug product you would find in a pharmacy. But we know better. Even though it is an odd way to deliver a chemical—a drug—tobacco delivers nicotine and a lot of other chemicals as well. So even though they were successful in Congress for decades exempting themselves from coverage and inspection by the Food and Drug Administration, this bill is going to change that.

Senator TED KENNEDY is recovering from cancer, a brain tumor he has been fighting for many months now, and we all wish him the very best. He was the one who pushed this bill. He is the one who believed that the Food and Drug Administration should regulate tobacco products. I am sorry he can't be on the floor, because I would like to give him a big shout-out for the years he put into this effort. But we are here, and we have a chance to pass this legislation.

Here is what the bill does. It prohibits the colorful and alluring images in advertising that these tobacco companies shamelessly use to appeal to

children. This bill also limits ads to only black-and-white text in newspapers and magazines with significant young readership, and in stores that are accessible to children. It makes it harder for them to reach out to these kids and to dazzle them with their artwork and all of their images. It bans outdoor advertising near schools and playgrounds so kids won't be standing, waiting to go into school, looking up at a billboard suggesting that after school, you better get a pack of cigarettes. It ends incentives to buy cigarettes by prohibiting free giveaways with the purchase of tobacco products, and it finally puts a stop to tobacco sponsorship of sports and entertainment events.

I wish to tell my colleagues that most of us know the warnings that have been on cigarette packages for more than 40 years have outlived their usefulness. Does anybody notice them anymore? They put them on the sides of packages. They are really routine. Folks don't pay attention.

Well, we are going to change that. We are going to have much more effective warning labels on these products. This bill requires large, clearly visible warning labels at least covering half of the front and half of the back of the package of cigarettes. These labels will have large text and graphics displaying the dangers of smoking. Some people say, Why waste your time warning people? They know it already. Maybe they do. Maybe they need to be reminded. But we have an obligation as a government, as a people, to do everything we can to discourage this deadly addiction.

We are also going to require much larger warning labels in print ads for products. Some of these pictures I have shown my colleagues, you almost need a magnifying glass to find the Surgeon General's warning, which sadly has gone ignored too often. We are going to improve that by requiring that warning messages take up at least 20 percent of any advertisement they have in a magazine or on a billboard.

Study after study shows that advertising can influence young buyers. We certainly want to influence them to make a healthy decision when it comes to tobacco. This bill makes critical changes to limit kids' exposure to tobacco ads, and we know that is going to prevent kids from trying cigarettes and getting addicted.

One of the things we do in this bill as well is finally tell those who buy tobacco products what they are buying. If you believe a cigarette is just tobacco leaves ground up and put into a paper cylinder, you have missed the point. Those cigarettes are loaded with chemicals, not just the obvious naturally occurring nicotine but added nicotine to increase the addiction of smokers, as well as other chemicals which they think will make the taste of tobacco more appealing and will in some ways help the new smoker get through that first two or three cigarettes where they might be coughing. They are trying to make it a smooth transition from ordinary breathing to breathing with tobacco smoke, so they load up the cigarettes with these chemicals.

If you go in and buy a box of macaroni at the store and take a look at the side of the package, you will see the contents. What is that macaroni made of? It will have 6 or 8 or 10 different things and a nutrition labeling box. If you pick up one of these packs of cigarettes and look for the ingredients, what is included in that cigarette, you won't find it. Why the exception? Because the tobacco lobby made sure there was an exception. They don't want you to know what is in that little paper cylinder of tobacco. Now that is going to change. This bill before us is going to give the Food and Drug Administration the authority to require disclosure of ingredients so that consumers know what they are getting into, and, of course, in the process, give us information we need to find out what kind of dangerous, toxic chemicals are being added to cigarettes. Those listening may say, Well, this Senator is getting carried away calling them toxic chemicals. In fact, they are. They are toxic, and they are carcinogenic, they are dangerous, and they make that smoking experience even more hazardous for the people who are involved in it. Don't we owe that warning to consumers across America? Don't we owe it to our kids? Shouldn't we try to protect the American people from the dangers that are associated with the No. 1 preventable cause of death in America today, tobacco-related illness?

This bill has been a long time coming. Some of us have been battling this tobacco industry for two decades, and more. Now we have a chance to do something. We had a press conference earlier with Senator CHRIS DODD of Connecticut, and he has kind of picked up this standard and is carrying it for Senator KENNEDY, who is the inspiration for most of us when it comes to this issue. Senator DODD just completed the Credit Card Reform Act a couple of weeks ago, a measure we have been trying to bring to the Senate floor for 25 years. He successfully guided it through. Here he is back 2 weeks later with an issue that has been waiting in the wings for at least 10 or 20 years. I salute Senator DODD for his extraordinary leadership on these two historic issues.

Senator LAUTENBERG, my colleague when it came to banning smoking on airplanes, was at the press conference. Senator JACK REED of Rhode Island, who has always been stalwart when it comes to this issue, was there. I said at the press conference: I wonder if 20 years from now, a child or grandchild of one of these Senators will come up and say Granddad, explain to me. You mean you actually sold these cigarettes with warning labels people couldn't read and they didn't have to disclose their ingredients, and they could sell them to kids and they could advertise to kids? You mean that actually happened? Well, it is happening right now, and unless we pass this bill, it will continue to happen. Unless we pass this bill, 1,000 of our children today and every single day will start smoking and start an addiction which will lead to the deaths of at least one out of three. That is the reality. We can face our responsibility here, pass this bill on a bipartisan basis and say to America, it took a long time, but this Congress of the United States of America has finally put the public health of the people we represent ahead of the tobacco lobby.

Mr. President, I yield the floor and suggest the absence of a quorum.

The ACTING PRESIDENT pro tempore. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

Mr. BOND. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER (Mr. MERKLEY). Without objection, it is so ordered.

Mr. BOND. Mr. President, I ask unanimous consent that I may be permitted to proceed as in morning business for up to 12 minutes.

The PRESIDING OFFICER. Without objection, it is so ordered.

NORTH KOREA

Mr. BOND. Mr. President, East Asia is a very interesting and challenging area. There are tremendous opportunities. We have great friends there. The potential for trade and better relations continues to grow in many ways, and there are many good things that are happening that we need to pursue in that part of the world, but they are also coupled with some immense challenges. There are some real problems there. Unfortunately, we were reminded of one of those key challenges most recently; that is, North Korea.

One of the world's most secretive societies, North Korea has increased its isolation from the rest of the world by continuing to pursue its nuclear ambitions, along with its missile capability potentially to deliver those weapons.

As one of the countries still under Communist rule, Supreme Leader Kim Jong-il heads a rigid, state-controlled system where no dissent is tolerated. Its destroyed economy has suffered from natural disasters, poor planning, and a failure to keep up with its burgeoning neighbors—China and South Korea.

North Korea, officially named the ''Democratic People's Republic of Korea''—and that in itself is an oxymoron—maintains one of the world's largest armies, but the standards of training, the discipline, and the equipment are reported to be very poor.

The Korean war ended with the armistice of 1953. But when one visits the demilitarized zone, as I did in March of 2006, the tension of the zone feels as if

the war has done anything but end. The north has recently fueled the tension by launching six short-range missiles, renouncing the 1953 armistice, and threatening continued attacks on South Korea.

After 15 years of negotiations, bilateral and multilateral talks, and a state of affairs worse than when we started, it is time for tougher action, barring all-out war. We hear people say: We want to talk with them, we want to negotiate with them, we need to pass a resolution. The bottom line, as we say in the old country music song: We need a little less talk and a lot more action. Talk has not gotten the job done. We need action.

A key to the successful resolution of this difficult situation is our good friend China. China provides as much as 90 percent of the north's energy, 40 percent of its food. Like Russia, it has used its Security Council veto, regrettably, against attempts to isolate Pyongyang. Without its support, its poor neighbor would struggle to survive. And it appears that the North Koreans may be exhausting Beijing's patience. Recent nuclear tests, last month's rocket launch, increasing threats, and the suspected restarting of the Yongbyon nuclear plant have reignited debate about how best to deal with this very troublesome neighbor. Beijing was swift to slap down the recent nuclear test. I hope that was the final straw for China.

We need China to play a constructive leadership role and support the Security Council resolution in toughening existing sanctions and implementing them. When you look at the sanctions that have been applied to Iran, sanctions should be applied to North Korea that are at least as tough if not tougher than those on Iran. After all, it is North Korea that has actually tested and detonated a nuclear weapon and fired missiles over Japan and throughout the region. And the North Koreans' continued sabre-rattling could lead to proliferation in the region and alter balances of power. Our friends there may not be willing to see a nuclear North Korea unchecked and unbridled, posing threats to them. We do not need to put our allies and friends in a position where they believe they must have a nuclear counterweight.

After 15 years of happy-talk and discouraging attempts during the last months of the Bush administration to turn the six-party talks into two-party talks, the time for tougher action is way overdue. My personal opinion was the two-party negotiations last fall were a tragic mistake. Obviously, they did not stop what has happened since.

North Korea poses security and humanitarian challenges to the world and particularly to China's core interests. China's ability to contain North Korea is critical in demonstrating it will provide leadership on the world stage, but it is certainly not fair to ask China to handle it all. This is the world's problem, and I believe we can work together with China and our critical allies in Japan and South Korea to defuse this situation.

South Korea's President Lee Myung-bak, unlike his predecessor, has embraced the United States instead of North Korea. He has embraced working constructively within the six-party framework and with the United States, and we certainly ought not to be getting into bilateral negotiations. The six-party talks at the minimum are absolutely essential.

South Korea is one of our most important security partners in the region. I was proud last year to support the United States-Korea Defense Cooperation Enhancement Act to strengthen this important alliance. We must take the next step and approve the United States-Korea Free Trade Agreement to further strengthen our economic and strategic partnership. It is in our interest, their interest, and the interest of peace and prosperity in the region.

Japan is steadily increasing the role it is playing in international security affairs. We must continue to support these initiatives. Japan and the United States work very closely together on the AEGIS missile defense system, and robust support for ballistic missile defense is now more important than ever.

We have seen that these countries have the ability to shoot off missiles. We used to think we have mutually assured destruction. We feared the only place that would be sending missiles at us might be the former Soviet Union. That ain't so. North Korea has shown its ability, and others are working on it.

But we have made progress. According to the head of the Missile Defense Agency, LTG Patrick O'Reilly, the United States has fine-tuned its ability to shoot down long-range missiles launched by North Korea, based on a trio of tests mimicking such an attack. At a recent conference at the National Defense University, he went on to say:

> We have made adjustments to give ourselves even higher confidence, even though we intercepted three out of three times in that scenario.

General O'Reilly, in response to a question, said the U.S. ability to hit a specific spot on a target missile had improved ''dramatically'' during the tests. ''So, do I think it is likely that you're going to intercept if somebody launches out there?'' He said, ''Yes, I do. And the basis is those three tests and what we know about the threat. . . .''

I can tell you that President Obama was fully engaged, working with our National Security Council, to be able to use the resources we have at our disposal should a North Korean missile launch have threatened the United States or other of our close allies or our interests. I congratulate him on that. I applaud him for having that in place and being willing to use what was necessary. But unfortunately—and I don't understand why, with the threats we have—President Obama's defense budget reduced funding for more ground-based interceptors in Alaska and California. It scaled back funding for the airborne laser interceptor and canceled further research and development for multiple kill vehicles—all of this at a time when North Korea is increasing its sabre-rattling and Iran is showing no signs of reducing its program and continues to issue threats to Israel and its neighbors in the Middle East.

When I visited Israel in December, I went over to talk about intelligence. They only wanted to talk about one thing. They needed missile defense—short-range, medium-range, long-range—because they are looking at weapons coming in, missiles coming into them: short range, potentially ultimately long range. To protect our allies and Israel, we are working with them on the Arrow and certain other programs that I am proud to support that give them that defense, but they are in a position where they are subject to attack, not only from long-range and medium-range missiles but very short-range missiles, and we have to provide them that kind of capability.

I hope my colleagues will reconsider the proposed cuts to ballistic missile defense. It is a threat that is here, it is now, it is threatening our allies and, yes, possibly, even the United States.

As far as North Korea goes, in addition, I have recently agreed to cosponsor Senator BROWNBACK's North Korea Sanctions Act. The legislation would require the Secretary of State to relist North Korea as a state sponsor of terrorism. This requirement could be waived by Presidential certification as provided for in the bill. But we were able to hurt North Korea significantly when we imposed sanctions on the bank, the Bank of Asia, which was handling their transfer of funds. But in a very unfortunate, misguided effort to try to win the friendship of North Korea, we took off those sanctions last year. That was a mistake.

This is a challenging area. It is one in which I hope others will pay great attention, and I look forward, when the budgets come before us, to talking about the need for ballistic missile defense. We are seeing that threat. It is being visited on a daily basis on our allies in Israel. It is no time to back away from the tremendous technology we have that could protect us, our allies, and our interests around the world.

I yield the floor and suggest the absence of a quorum.

The PRESIDING OFFICER (Mr. BURRIS). The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mr. BURR. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. BURR. Mr. President, while the Senate is in consideration of a bill to regulate tobacco, I think it is extremely important that Members of

the body understand that tobacco is not an unregulated industry today. Let me preface this by saying that I am not proposing that we do not do something additionally in the Senate. I think we can regulate more effectively. But what I have put up—I know it is hard for the Presiding Officer to see—is the current regulatory structure of the tobacco industry in America. It shows every Federal agency that currently has a regulatory jurisdiction over tobacco: Department of Transportation, Department of Treasury, Department of Commerce, Department of Justice, the Executive Office of the President, Department of Health and Human Services, Department of Education, Department of Labor, General Services Administration—the GSA—the Department of Veterans Affairs, Federal Trade Commission, Department of Agriculture, the Environmental Protection Agency, the U.S. Postal Service, and the Department of Defense. These are all Federal agencies that currently, today, regulate the product of tobacco. For any person to come to the floor of the Senate and claim that there is not sufficient regulation of this industry right now is ludicrous. As a matter of fact, this is the most regulated product sold in the United States of America currently.

The proposal Senator KENNEDY has introduced is a proposal that concentrates all the regulation of tobacco in the Food and Drug Administration, an agency that was created for the sole purpose, by its mission statement, of approving the safety and efficacy of drugs, biologics, medical devices, cosmetics, products that emit radiation, and responsibility for food safety.

We are going to shift from all these Federal agencies and all the flowcharts underneath them of different aspects of regulation currently for the tobacco industry, and we will concentrate this in the Food and Drug Administration. It probably makes a lot of sense from the standpoint of consolidation, but what I want my colleagues to understand is that this truly today is the most regulated product sold in America, when we look at the expanse of the regulatory framework that exists today.

The authors of the bill have suggested we have to allow the FDA to have jurisdiction because there should be two objectives. One is to reduce death and disease, and the other is to reduce youth usage of tobacco products. These are two goals I embrace wholeheartedly.

Let me share this chart. It starts with a product I consider to be the base: 100 percent of these products presents a health risk. What is the product? Nonfiltered cigarettes. I know the President of the Senate probably remembers when all his friends smoked nonfiltered cigarettes. The truth is, we probably still have some friends who do it today. The continuum of risk goes down in the next category, filtered cigarettes. The industry introduced filtered cigarettes at some point, probably before I was born. The risk is only reduced by 10 percent. It meant it was 10 percent less likely to have a risk involved in it. But still, clearly, 90 percent of users having the risk is pretty unacceptable.

Then we go to a category that never hit the market, except for experimentally through market testing. That was tobacco-heated cigarettes, a product that didn't actually burn tobacco, but it had a ceramic disk in the front that glowed and got hot. As that hot air was pulled through the tobacco, the nicotine was extracted and delivered, but the product never burned. It never created secondhand smoke. In fact, it never had any smoke that actually was emitted afterward. Whatever was emitted was a vapor, and it dissipated.

Then we have a new category called electronic cigarettes, a fascinating product, rather expensive. It actually runs off a battery. It extracts the nicotine and delivers it into the system in a totally different way than the tobacco-heated cigarette. But, clearly, we see that in two new iterations, we have gone from 100 percent risk to 90 percent risk to 45 percent risk and now, with this new electronic cigarette, to a risk of less than 20 percent. One would say, moving from here to here from the standpoint of risk is an advantageous opportunity for people who use nonfiltered cigarettes. If we could get them over here, we have reduced the risk of death, and we have reduced the risk of disease.

Let me move out to the next category, which is smokeless tobacco, U.S. smokeless tobacco. I need to draw the distinction because globally there are new types of smokeless tobacco. But U.S. smokeless tobacco all of a sudden reduces the risk to 10 percent. We have gone from 100 percent to 10 percent. We have reduced by 90 percent the risk presented by the use of tobacco products. Now we move to the next category, which is probably hard to see. I would equate this to about 2 or 3 percent risk. This is Swedish smokeless snus, a pasteurized product. It is actually spitless. It can be swallowed because of the pasteurization. But, again, products that deliver the nicotine need to allow somebody to go from a nonfiltered product all the way over here to a U.S. smokeless or to a Swedish smokeless. We have now gone from 100 percent risk to 2 or 3 percent risk.

Now a new category, not even on the market, a category already targeted as a product that should not be: dissolvable tobacco, a product that dissolves in the mouth. That delivers what this person needs over here from the standpoint of being addicted to nicotine but puts the category of risk somewhere down in the 1 percent category. As innovation has taken place, we have allowed the opportunity for people to come off products that had 100 percent risk down to products that reduce the risk by 99 percent. Then we have therapeutics, such as gum and patches and lozenges, that have minimal risk and pharmaceutical products that allow people to actually either reduce or quit the habit of tobacco usage.

When we look at the goal of a tobacco bill—and the authors have said the goal is to reduce disease, death, and youth usage—I ask the Presiding Officer, if you reduce from 100 percent the risk to 10 percent for U.S. smokeless or 2 percent for Swedish smokeless, does that embrace the spirit or intent of what the author of the bill is trying to do? I say yes. But what I have to share with my colleagues is this category that is at 2 percent, under the current bill being considered, would be banned. Why? Because of an arbitrary date that they have chosen to say if the product wasn't sold in the United States before February of 2002, then this product is not allowed to stay on the marketplace.

My point is, if the authors say the objective of the legislation is to reduce the risk, as you reduce the risk, you reduce the likelihood of disease, the severity of death, isn't this the category we would like more smokers to move to? I think the answer is obviously yes. We would like to move people away. We would like to reduce the health cost. We would like to reduce death. If we can do that by bringing this new age of products to the marketplace, this is beneficial to everybody. It makes a lot of sense.

That is not what the legislation does. I have spent this day coming to the floor trying to emphasize with my colleagues that what the legislation does is grandfathers two categories, nonfiltered cigarettes and filtered cigarettes. It says these are the only products that will be allowed to stay on the market. It means the 20 percent of Americans who currently have chosen to smoke, hopefully adults, are not locked into these categories from the standpoint of choice. Yet in Sweden, they created this new product, and they have had a massive movement of people from these two categories to this category. This is not something I have made up. The data is there to show.

The authors of the bill would suggest we allow this product to be created, but there are three thresholds they have to meet. The three thresholds they have set are absurd. Let me focus on the third threshold. They suggest that the manufacturer would have to prove this product wouldn't be used by a nontobacco user. For you to accumulate data to know whether a nontobacco user would be interested in using this product, you would have to go out and present the product to them and explain it before they could comment on whether they would be inclined to want to try it. But the bill forbids any communication about a product that hasn't been approved. So I ask, how do we get a product approved if the threshold is to tell them what the likelihood is of people who haven't used tobacco products using it, if you can't talk to people who haven't used

tobacco products about using the product because the product hasn't been approved?

In Washington we call this a quite crafty way of making a claim but reversing in the bill the ability to use it. In essence, the bill that is under consideration creates these two categories indefinitely and says: It is OK if we have 20 percent of the American people who choose to use those products. Hopefully, over time, more adults won't choose to use them. We are willing to accept that 20 percent are using them, and they are going to die or have severe disease.

If that is the case, then how can you come out and claim that this is a public health bill, that we are going to pass this bill because of the responsibilities we have to public health?

Since 1998, smoking rates in America have dropped from approximately 23.5 percent to 19.5 percent. The Centers for Disease Control and Prevention, the agency that many come to the floor and quote with great frequency because of their expertise, says if the Senate does nothing, if we don't pass a piece of legislation, by 2016, the rate of smokers in America will drop to 15.7 percent. But if we look at the Congressional Budget Office that has had an opportunity to see the Kennedy bill, they estimate the Kennedy bill will reduce smoking 2 percent over the next 10 years. Meaning in 2019, the rate will fall from 19.5 percent to 17.5 percent. You get where I am going? By giving the FDA regulatory authority, we are going to increase by over 2.5 percent the number of smokers in the country than if we did nothing. That doesn't make much sense, does it?

Let me explain. When we lock in these two categories and we eliminate the ability for somebody who is a smoker to find one of these products to move to, we have now locked in the category of smokers. When we explain it to somebody, it makes tremendous sense. The question is, Why would we do this? I expect Sweden to be up here arguing that this is the right strategy. Yet Sweden is the one that is the most progressive. Why? Because they are truly focused on the health of Swedes. The fact that we claim that we are doing this because of death and disease isn't true. We are doing this because 10 years ago somebody wanted to do something punitive to an industry. As a matter of fact, the date that is set in the Kennedy bill is February 2007, meaning if the product wasn't sold before 2007, it is banned from the marketplace. Why did they use February 2007? Because they wouldn't even change the bill they passed out of committee in 2007 to reflect 2009, which is the current date. There was so little attention paid to this piece of legislation that they didn't even go through to purge the date and change it. They printed the same page of the bill they had last time.

I have said several times throughout, the only thing I ask Members to do before they vote on this bill is to read it. I don't think that is too much to ask. If they read the bill, they will never vote for it. If they read the bill, they will understand that, one, this makes a lot of sense. But, two, remember, when I went over the current regulatory structure, I didn't mention the Food and Drug Administration. I did mention the Department of Health and Human Services. As we go down this flowchart of things under the HHS, there is no FDA. We are choosing an agency of the Federal Government that has never regulated tobacco. How can that possibly make sense? Maybe if you claimed you were going to put it at the Centers for Disease Control, they actually have some responsibility within the framework currently of regulating tobacco. But not the FDA. We may have taken the only piece of the Federal Government that doesn't currently have any jurisdictional responsibilities to regulate tobacco, and we are giving them 100 percent of the requirement to regulate tobacco.

The truth is, we don't need the FDA to do it. We can do it by creating a new entity under the Secretary of HHS, the same person who is over the FDA today, and we would suggest doing that by creating a new center. That new center would be responsible to regulate in total tobacco products throughout the industry.

It is a Harm Reduction Center. Think about that: Harm Reduction Center. Let me go back to this chart: The continuum of risk. If the objective is to reduce death and disease, then you have to drive the risk down. To drive the risk down, you have to bring less harmful products to the marketplace. So you have two choices. You have a bill that will do that through creating a Harm Reduction Center that regulates with all the authority the FDA has or you can choose the Kennedy bill, which basically isolates these two categories of 100 percent risk and 90 percent risk; and you put that into statute that the FDA cannot touch products that are over here, as shown on the chart, but, more importantly, you structure it in a way that the FDA could never approve any new products that are less harmful.

The Harm Reduction Center actually has two responsibilities. One, it is to regulate the entire tobacco industry and, two, to facilitate smokers moving over to lower risk options because we want to reduce the harm that potentially can be caused.

I am going to speak later tonight, as I offer this substitute, which I hope every Member will take the opportunity to read on behalf of Senator HAGAN and myself. I am sure we will both speak tonight and throughout the day tomorrow as we get ready to have a vote. It is my hope Members will take the opportunity to review the substitute.

Let me put Members on notice right now, some will come to the floor and claim: Well, this is a substitute that the HELP Committee considered and they rejected it 12 to 8, 13 to 8—I cannot remember exactly what it was. Let me put Members on notice before they come down here and make claims on it, it is not the same bill. It is not the same substitute. I am sure staff now is going to scramble to figure out what is in this new bill.

We listened to criticism. Where we thought we could better the bill, we did that. The fact is, there are still going to be Members who come and make claims tonight, tomorrow—before this is all settled—that are not accurate. I put them on notice now: I will come to the floor and expose exactly what you say.

This is not a debate where we are going to use the charts we had 10 years ago and say they are relevant today. This is not a debate where we are going to have information that was produced in 1990 for an issue we are discussing and debating in 2009. It is not right to do that to the American people.

In concluding—because I see my colleague is here wanting to speak—I pointed out earlier that in 1998 the industry made a massive payment to the 50 States of this country. It was called the Master Settlement Agreement, MSA. Mr. President, $280 billion that the industry, over a fixed period of time, was paying out to States. It was for two purposes: No. 1, to subsidize health care costs—the Medicaid costs in States—that might have been from the direct cause of tobacco usage; and, No. 2, so States would have the resources they needed to create cessation programs so people would move from this category, as shown on the chart, to this category or quit tobacco use all together.

I came to the floor yesterday—and I will say for the purposes of the Presiding Officer in the Senate, who is from Illinois—CDC made recommendations to every State to do this every year: How much of the money they got that year should be used for cessation programs.

Well, in Illinois, Illinois devoted 6.1 percent of what the CDC recommended for cessation programs to cessation programs—6.1 percent. Mr. President, 19.9 percent of the youth in Illinois have a prevalence to smoking—way too high. In Illinois, though, 43.7 percent have a prevalence to alcohol use. In Illinois, 20.3 percent have a prevalence of marijuana use. I am not picking on the Presiding Officer of the Senate, and I am certainly not picking on Illinois. I will have used all 50 States before this is over with.

As I said, one of the shocking things to me, as I explored this chart, was that I found that, I believe it was, 48 out of the 50 States have higher youth prevalence in marijuana use than of smoking.

Well, some are going to claim the reason you have to give FDA jurisdiction over this is because the age limitation of 18 is not working, that youth are getting products. Well, you know

what. There is no age where it is legal to buy marijuana, especially for youth. Yet in 48 out of 50 States, the prevalence of marijuana usage is higher than the prevalence of smoking.

Do not believe for a minute you are going to construct a regulatory regimen here that is going to take a product that is legal to people over 18 and it is going to allow a framework where people under 18 are not going to get it, when a higher percentage of them can get a product that is illegal for everybody in America.

I might also say to the Presiding Officer, his State is not the lowest from the standpoint of the percentage they chose of the CDC recommendation to devote to cessation programs. As a matter of fact, one State had a commitment of 3.7 percent.

Now, $280 billion—paid for by the tobacco industry to cover health care costs and cessation programs—I would suggest to you, if the States had all spent 100 percent of what the CDC told them they needed to spend, we would not be here talking about the regulation of the tobacco industry because cessation programs would have worked and the rate of 19.6 percent today of smokers would have reduced drastically.

I would remind you that the CDC says, if we do nothing, by 2016, we reduce the rate to 15.7 percent of the American people. But when CBO looked at the Kennedy bill, they said, in 10 years, in 2019, the Kennedy bill would reduce smoking to 17.5 percent. If we do nothing, we get to 15.7 percent. If we pass this bill, we get to 17.5 percent. If the objective is to have less smokers, the answer is: Do nothing.

But tonight, sometime around 6 o'clock, Senator HAGAN and I will come to the floor not to suggest to our colleagues that we do nothing but to suggest to our colleagues we do the right thing, that we find the appropriate place to put regulation, that we give it the same teeth the FDA has, that we give them the ability not just to have black-and-white print advertising—such as the Kennedy bill does—I suggest in my substitute we eliminate print advertising, we do away with it in total.

We do not worry about whether Vogue magazine, which is typically bought by an adult woman, might be looked at by a teenage girl. If we just eliminate print advertising, we do not have that problem. The Kennedy Bill limits it to black and white. We ban it in total.

If Members will take the opportunity to read both bills—to read the substitute, to read the base bill—they will find out we are actually more expansive from the standpoint of regulation. We actually accomplish the task of reducing disease and death. I believe, by some of the things we do, we actually reduce the amount of youth usage, such as by eliminating print ads.

But there is a big difference. I do not turn it over to the FDA. I do not do that for a selfish reason—purely selfish. I spent 2½ years, 15 years ago, when I got to the U.S. House of Representatives, where I was tasked by the chairman of the Energy and Commerce Committee to write a bill that modernized the Food and Drug Administration. It took 2½ years to do. It was signed into law in 1998.

We opened the entirety of the Food and Drug Administration and revamped all the ways it worked to make sure we could reach new efficiencies in the approval of lifesaving drugs, biologics, which were new, devices. We spent a meticulous amount of time going through this with one goal in mind: Do not lower the gold standard the American people have come to expect through the FDA; do not lower the standard an applicant has to reach so we can assure the safety and efficacy of the products we regulate.

Well, I thought that was important, and in 1998 it became law. And you know what. When we had the entirety of the FDA bill open to every Member of the House and the Senate, no Member of Congress offered an amendment to give the FDA authority over tobacco because they knew, at the time, the integrity of the FDA was more important than who controlled it from a regulatory standpoint. They did not want to jeopardize the integrity of what the FDA core mission was.

But here now, 11 years later—I might also say, the Supreme Court ruled in a court case that the FDA did not have jurisdiction over tobacco. The reason they chose was, in 1998, the Congress opened the FDA Act and did not give FDA authority. Therefore, it was not the intent of Congress for FDA to have authority.

So those who claim this is part of the FDA—should have been, always would be—it is not the case. Because Members of Congress had the opportunity and did not do it. Why? Because of the integrity of the Food and Drug Administration. Why in the world would we have changed, in 11 years, to where we would risk the gold standard of drug approval, of biologic approval, of medical devices approval? Why would we risk at a time where, every year for the past 3 years, we have had an issue on food safety—we have had salmonella in peanut butter; we have had tainted spinach; we have had imported products that have killed Americans; and the FDA is the agency responsible for the regulation of food safety—why would we dump on an agency today that is struggling to meet their core mission of food safety a new product such as tobacco?

Why would we take an agency, such as the FDA, that regulates 25 cents of every $1 of the U.S. economy, and say: You know what. You have never regulated tobacco before, but we would like you to do it now. We would like you to take senior reviewers who are approving lifesaving applications for drugs, and we would like you to move them over to the tobacco area.

What else can they do? You cannot go out in the world and find people automatically at the FDA who have ever regulated tobacco. So they are going to take their most senior folks. What does that mean? The likelihood is, we are going to wait longer for that lifesaving drug. We are not going to reduce health care costs because chronic disease is not going to have new therapies because the applications will not be acted on. Heaven forbid we do this and all of a sudden somebody dies as a result of an FDA reviewer who looked at it and said: Well, you know, I know our core mission is to prove the safety and efficacy of all the products we regulate—with the exception of tobacco because you cannot prove it is safe and effective—so if I am going to turn my head on tobacco, maybe I will turn my head on this medical device because it does not look too bad, and all of a sudden somebody dies from it.

This is a huge mistake for the Senate to do. I urge my colleagues: Read the bill. You will not vote for it. Read the substitute, it will supply the sufficient amount of regulation to an industry that can be better regulated, should be better regulated—more importantly, a substitute that goes much further from the standpoint of reducing youth usage of tobacco, which gets at the heart of death and disease.

In fact, the substitute is the only bill that accomplishes what the authors of the current base bill suggest is the reason we are debating this issue. This chart I have in the Chamber proves it. It does it in the most visual of ways. If we do not allow these products to come, you have now locked it into this. That is not what the authors suggest is the objective.

I urge my colleagues, tonight, when given the opportunity, listen intently, read the bills. Tomorrow, when you are given an opportunity to vote, vote for the substitute. Do not support the base bill.

Mr. President, I yield the floor.

The PRESIDING OFFICER. The Senator from Alabama.

Mr. SESSIONS. Mr. President, I wish to express my appreciation to Senator BURR for his hard work on this issue. He is one of our most able Members. I think the fundamental premise of the study that showed his bill will reduce smoking more than the bill on the floor, the Kennedy bill, is something that should give us pause. I know they have worked very hard on it. He has worked very hard on it, and I hope my colleagues will avail themselves of his suggestion to read it—both bills—and make a judgment on what they think is best for the country.

UNPRECEDENTED BUDGET DEFICITS

Mr. President, the unprecedented budget deficits we see today are creating fears of a surge in bond interest yields and a fall in the U.S. credit rating. I wish to talk about that. I have talked about it previously. But I would repeat my fundamental assertion that nothing comes from nothing, nothing

ever could, as Julie Andrews said. Debts must be paid, and they will be paid one way or the other. Either somebody is going to lose—either you are going to print money and inflate the money or you are going to pay back the debt with interest to whomever will loan you the money to fund the debt. We are moving into a decade of the most unprecedented deficits in the history of our country. Nothing has ever been seen like it before. It is irresponsible. We have not discussed it enough. It is breathtaking to people who examine it.

The estimated deficit for fiscal year 2009, the one we are in, ending September 30, is expected to be $1.84 trillion. That is a lot of money. That number dwarfs even the $500 billion maximum, inflation-adjusted deficit—nearly the same dollars to dollars—during World War II. It was only $500 billion in World War II. So this year, the deficit is projected to be 12.9 percent of the gross domestic product. In 1 year, the deficit will be 12.9 percent of the gross domestic product of the United States of America. That is a level not seen since World War II.

David Walker, the former Comptroller General of the United States—that is what we call the Government Accountability Office—has been speaking out for a number of years on deficits. He criticized President Bush for deficits. He continues now to speak out since he has left government. He has concluded that the United States of America is in danger of losing our AAA credit rating. He points out that the cost of insuring U.S. Government debt has risen so much that it recently cost more to buy protection on U.S. debt than debt issued by McDonald's Corporation. That is his statement. In fact, a Wall Street Journal editorial in March noted that the insurance rate for U.S. Government bonds rose 700 percent to 100 basis points between March of 2008 and March of 2009. That means in this past month of March, it costs $10,000 to insure $1 million in Treasury bonds. Who would think you would have to get insurance to guarantee the payment of U.S. Treasury bonds? As of May 28, that insurance cost had fallen to 45 basis points, but that is still more than three times what it was in March of 2008, just a year ago. Not only that, as of May 28, the cost of insuring our government's debt is higher than that of France and Germany.

Mr. Walker goes on to note that the United States has had a AAA credit rating since 1917. Furthermore, he states that given the current national debt and deficit, the United States may not deserve the AAA rating we have today. That is a warning. I hope that is not so. I hope we don't see a reduction of our AAA rating, which has a real impact in how much we have to pay to borrow money, and we are borrowing a lot. But I think this man deserves hearing. This is a serious commentator on American deficits and debt.

So the idea he has proposed is not farfetched. In fact, the Standard & Poor's—S&P—a few weeks ago lowered its outlook on Great Britain's debt. They put it on a negative outlook. While the United Kingdom is keeping its AAA rating for now, the Wall Street Journal notes that the negative outlook that S&P has found is a precursor to a downgrade. They also note that Japan's debt, in fact, has already been downgraded to AA2 from AAA. So the question is, are we next?

Not only is our credit rating in danger, but it is costing more and more to borrow. This is very important. While it may appear to be a separate problem, I think it is related to us spending more and borrowing too much. The yield on the 10-year Treasury bond, which rises with the increased government debt and expectations of inflation, has surged 54 percent this year, from 2.4 percent to 3.7 percent as of yesterday. It was 3.2 percent 2 weeks ago. Yesterday it was 3.7 percent. That is a significant surge.

So let me say it this way, and to repeat: We will borrow this year a record amount of money. Not only that, over the next 10 years, we will continue to borrow at unprecedented rates. We are borrowing because we are spending more than we take in—a lot more than we take in—and nothing comes from nothing.

How do we spend more than we take in, in taxes? How do we do it? We borrow the money. How do we borrow the money? We sell Treasury bills. We ask people to take their money out of their bank account and buy U.S. Treasury bills. We have had an unusual situation with interest rates being low, because people were so afraid if they bought stock or private bonds, that companies may go bankrupt, and they were interested in buying government bonds, Treasury bonds, presumably the most secure bonds in the world. So we have had a bargain and we have been taking advantage of it. But all of a sudden now we are beginning to see a surge in these interest rates, because people are thinking: Well, if I don't get a 3-percent return when I buy a Treasury bill, and inflation next year is 5 percent, and my money is tied up for 10 years, I am losing 2 percent a year. I am not gaining money; I am losing money. The world looks at it like that. The Chinese and people in Saudi Arabia who have excess wealth and bought Treasury bills are looking at this too and they are demanding higher interest rates. That is why it is going up. That means each year we will pay a larger percentage of the tax money we take in to pay interest on the debt than we would have if that had not been the case.

I am told that this rampant rise in Treasury rates is the talk of Wall Street. How has it happened? Net debt sales; that is, the net sales of Treasury bills and the borrowing the government has done, increased from $332 billion last year to $1.555 billion this year. That is a lot. That is almost five times. When you put too much of a product on the market, things happen, and people start demanding better returns. Two weeks ago, Barron's reported as big news that the U.S. Department of Treasury bond yields could top 4 percent this year. And it seems, since it already hit 3.7 percent yesterday, that we may get there sooner than Barron's even anticipated.

So how does all this stack up with what the President estimated when he submitted his budget earlier this year? His budget estimated an average yield on Treasury bonds at 2.8 percent for the entire year. We already hit 3.7, and Barron's said we are going to hit 4, so we are ahead of Barron's schedule already. So the 10-year Treasury bill is increasing, and hopefully, it won't surge out of reason. Some are worried about that. It does look like it may well reach that 4 percent or more this year. That is bad news for American taxpayers.

So we are like the credit cardholder. When interest rates go up, it costs us more. When the interest rates on Treasury bills go up, we have to pay more to get people to loan us money so we can spend it. I guess it is fair to say we have only ourselves to blame.

Even if you took the President's assumptions, interest on the debt is supposed to be $170 billion this year. So this Nation will pay on the debt we already have accumulated $170 billion in interest this year. That is a lot of money. We spend $40 billion on the Federal highway program. We spend less than $100 billion on Federal aid to education in America. We are already spending, and will spend this year, $170 billion on interest, on debt we have run up before. That equals $1,435 per household. That is a lot of money, $1,435. By 2019, according to the Congressional Budget Office, our own Budget Office's evaluation of what the President's budget is going to be, 10 years from now, the interest on the debt will not be $170 billion; it will be $800 billion. That would be $3,433 per household, more than twice the current debt interest payment that each household in America is to incur. Why? Because we are spending too much. We are spending money we don't have. We spent $800 billion on a stimulus package. We are spending $700 billion on the TARP Wall Street bailout. Our increase in spending for the underlying Federal budget this year, the nondefense, the discretionary spending was a 9-percent increase. That is huge, many times the rate of inflation, a 9-percent baseline increase. Most of my colleagues know that if you increase spending, or have an interest rate of 7 percent, your money will double in 10 years. So at 9 percent, in less than 10 years, the amount of our spending would double; entire government spending in 8 or 9 years would be doubled. That is why we are running up debt. But the most troubling thing is, it is going to continue.

We have heard the President say, I am worried about this. We are going to

have to talk about this in the future. Have you heard that? Oh, yes. This is a big problem. We are going to have to do something about it in the future. Well, the future is becoming now. The budget that he submitted to us didn't do anything about it in the future. Let me be frank with my colleagues. The budget this year, the deficit this year the President projected would be $1.76 trillion. That has already been proven to be low. They are now estimating $1.84 trillion in 1 year. And they project it dropping down to maybe $500 billion in 3 or 4 years, assuming the economy is growing well. But over the 10 years, in the tenth year of his budget deficit, the annual deficit in the tenth year, is over $1 trillion. And over the 10 years, the average deficits from the President's own submitted budget would be almost $1 trillion a year, and the highest deficit prior to this we have ever had was $455 billion last year. So this is averaging almost twice, really twice the highest deficit we have ever had.

The President has said, correctly, that these trends are unsustainable. He recognizes that. He also said, according to Bloomberg at a townhall meeting in New Mexico on May 14, that current deficit spending is unsustainable. He warned of skyrocketing interest rates for consumers if the United States continues to finance government by borrowing from other countries. So I agree with him on that, but it is time to start doing something.

China remains the biggest foreign holder of United States debt in Treasuries, and Prime Minister Wen Jiabao stated in March that China is worried about its investments.

Not only that, but yields are currently rising despite an extremely unusual move by the Federal Reserve to directly purchase Treasury bonds. So the U.S. Federal Reserve—our banking gurus—have decided they will take money and purchase U.S. Treasury bonds to keep the interest rates from going up so fast, because there are not enough people out there to buy them all, I suggest. It holds the interest rates down somewhat.

The Fed has not done anything like this since the 1960s. It is very unusual. Even then, it was a much smaller operation. They announced a $300 billion purchase plan in March and have made $100 billion in purchases so far. If those purchases are not carefully managed, they could lead to inflation down the road; there is no doubt about it. Not only that, but the Fed could get stuck with sizable losses if the yield on those Treasury bills continues to rise.

According to Barron's, if rates rise 1 percentage point, it could lead to a $140 billion loss for the Fed in that deal of purchasing these bonds. That is $140 billion. The Federal highway spending in America is $40 billion. This is a huge sum of money.

Let's look at the deficit and debt that are driving our interest rates higher as part of his detailed budget released in May. The President raised his estimate of a deficit from $1.75 trillion to $1.84 trillion. I ask, do we remember that at that same time when the President released his budget, he also released a plan that was going to show that he was committed to frugality, and it would supposedly save $17 billion? Remember that? Some people had to laugh at it, really. It was pretty amazing. There were these numbers out there, and he announced this frugality package to save $17 billion. It wasn't clearly understood, in my view, how insignificant that was, because at the same time they were announcing saving $17 billion, the reaccounting of the projected deficit for this very fiscal year jumped $90 billion. So it dwarfed the $17 billion in spending cuts that were announced at that time. So we had a $17 billion efficiency project, which remains to be seen whether it will be successful, and the total deficit expectation jumped $90 billion.

The President's budget proposes to take us to a debt level of 82 percent of GDP by 2019. In 2019, the amount of debt, in the country at that point would amount to 82 percent of our entire gross domestic product in America. That is a level not seen since 1946, at the height of World War II. The difference between now and then, of course, is that that was during a war. It was widely known that those expenditures were temporary, and when the war was over, they would end; and, in fact, they did.

However, today, the President is projecting deficits averaging nearly $1 trillion as far as the eye can see, with no projections to show them drop, or be reduced. It has been popular to complain that, well, President Bush had deficits—and he did. I criticized him for that, and I think he could have done a better job. His highest deficit was $455 billion. This year's deficit will be $1.8 trillion, and they will average $900 billion over the next 10 years. Not 1 year in the next 10 years, according to the President's own budget, will his deficit be as low as the highest deficit President Bush had, which was $455 billion. Even as a percentage of the total gross domestic product, it is astounding. President Bush's deficits averaged 3.2 percent of GDP. President Obama's budget, over the next 10 years, will average 7.3 percent of GDP each year—twice what President Bush's averaged.

I am worried that we are not getting the kind of bang for our buck that we hoped to get. We got an $800 billion stimulus package that was supposed to go out there and build infrastructure and create jobs now. It was money that had to be spent in a hurry. The truth is, though, that most of that money is not going to be spent until after 2010. It takes time to get that money out. The CBO estimated that $162 billion of the $311 billion now appropriated won't be spent until 2011, or later—not to mention that there is no evidence of the government ever taxing and spending its way out of a recession. That is not, historically speaking, proven to work.

Christina Romer, the Chairman of President Obama's Council of Economic Advisers, wrote about this in 1992, in a paper titled ''What Ended the Great Depression?'' in the 1930s. She concluded:

> Nearly all of the observed recovery of the U.S. economy prior to 1942 was due to monetary expansion [from gold inflows].

She gives almost no credit to the increased spending that occurred.

Another report with Ms. Romer's name on it, one that the President's economic team put out this January—and she is the head of the team—was titled ''The Job Impact of the American Recovery and Reinvestment Plan.'' It estimates that the $800 billion stimulus package will lower the unemployment rate and create 3.6 million new jobs, and it includes a chart. The chart, if you look at it today—and it has been examined by others, such as Greg Mankiw, Chairman of the Council of Economic Advisers—it shows that their projected unemployment rate, without the stimulus package—that rate would hit a certain level. Now that we have had the $800 billion stimulus package, what does it show? That we are trending, on unemployment, exactly where they projected the unemployment rate would be if there were no stimulus package at all.

Indeed, if you look at the numbers, very little of it has gotten out of there, and you can see how little was stimulative, or job creating, or how much of it was spent on things it should not have be spent on. Indeed, this Senate rejected and failed to adopt my amendment that would have said at least the employers who hired people with this money ought to run the E-Verify system to make sure the people they hire are here legally in America and are entitled to work. That wasn't even part of it.

Unemployment continues to go up. It was 8.9 percent in May, and a lot of people think it may hit 10 percent. I hope not, but I think it is likely to continue above 9 percent, which is higher than what was projected, for sure.

I say all this to point out that some of the brilliant thinkers in our country believe we had to do all this; if we had not, the country would sink into the ocean. We could have this problem and that problem. But the testimony we had in the Budget Committee from the Congressional Budget Office, whose numbers have held up pretty well so far, and they are basically hired by the Democratic majority here, but they are nonpartisan and do a good job. They projected only a slight difference in unemployment, if you had a stimulus package—only slightly better than if you didn't have one at all. But, more importantly, they concluded that over 10 years, the stimulus package, if we passed it, would have a net negative effect on the economy. It should help some in the 2 or 3 years from the moneys being pumped out—it has to help some out soon.

But the crowding out of private borrowing, the interest that will have to be paid on the debt over the 10-year period, will mean that the economy will be less healthy at the end of 10 years than if we hadn't had the bailout package or stimulus package at all, which confirms my view that nothing comes from nothing. There is no free lunch. Debts have to be repaid. You cannot create something out of thin air. If you spend something today and you have resources today to spend today, and you took them from tomorrow, they are not going to be there tomorrow. Somebody is going to have a greater burden to carry—our young people—than if we hadn't taken their money and spent it today.

I have to say that I am not happy about this. I am worried about it. I do believe deficits matter. People who say deficits don't matter—and some Republicans used to say that—what planet are they from? Of course, deficits matter. You can cover them up, the Fed can help, and smart monetary policy and spending policies may make a difference here and there, but in the long run, it drives you down, and we have to be serious about it. I hope as time goes by, we can work together in a bipartisan way to try to establish some control over our spending.

Just Monday, GM went into bankruptcy. We already have $20 billion in Federal Government money going into General Motors prior to bankruptcy, and the White House plans to add another $30 billion. That is a substantial additional investment. This is what the numbers show. First, the White House said we are going to be out of GM and get our money back in 5 years. That is their goal, right? You heard that we are going to get the money back. But the Wall Street Journal has calculated this, and they have said for the Federal Government to get their money back out of GM, they would have to sell their stock, and GM's market cap, the total value of their stock, would have to reach a value of $80 billion. So to get our money back in 5 years, the market cap or value of GM stock would have to total $80 billion. Let me remind you that at its peak, in 2000, the highest GM ever got as a market cap was $56 billion. Their current market cap is less than $1 billion—$441 million dollars. It goes beyond rationality to believe that in 5 years—or maybe ever—we are going to get our money back out of GM. I am worried about that.

That is one more example of the kind of spending we are doing, and the money is being spent in a way that is not controlled. How does the Secretary of the Treasury decide how much money to give? And to what corporation? What about suppliers of GM? What about automobile dealers, who are losing their shirts and going into bankruptcy? Nobody bailed them out.

Somewhere along the way, it has been decided that we need to do this. It should have been done according to the established constitutionally-approved reorganization policies of bankruptcy. The U.S. Government could have put some money into GM in an effective way, I think, and had a positive benefit. But just to pour the money in, as we have, in an unprincipled way, is not good.

I will repeat one more time my concern about the unlawful way, the unprecedented way, in which this money is allocated.

The money comes from the TARP, the Wall Street bailout. I opposed it because I thought the language was too broad, but even I didn't know it was this broad. But we were told if we passed the TARP bill, Secretary Paulson and the Treasury Department would buy toxic assets. He was specifically asked at a House committee meeting whether he would buy stock in banks. He said: No. His goal was to get the money flowing again in the financial markets, and we had to do something about the financial markets. Senators were eventually convinced, and it was rammed through here in the very shortest period of time—in a panic, really. A week had not gone by when he had decided to buy stock and not buy toxic assets, not to buy toxic mortgages. As time has gone by, that same money is used to buy stock in what was once a private corporation.

I think this is unbelievable. There are no hearings on where the money is going. There is no public ability to understand what kind of justification these banks, GM, or Chrysler had to put forward to receive billions of dollars from the taxpayers. It was all done basically in secret, as far as I can understand. They are telling the company they have to do this and that and firing the CEO and all of those kinds of things that have been occurring. I don't think the American people are happy with that. The American people are very concerned—I believe they are rightly concerned—because we are doing some things that have never been done in the history of our Republic. It is not healthy.

I hope that somehow we can get our footing again, get our balance, and return to the tried-and-true principles that made this country great.

I yield the floor.

The PRESIDING OFFICER. The Senator from Utah.

HEALTH CARE

Mr. BENNETT. Mr. President, we have just heard from the President of the United States with respect to an effort to get a bipartisan health care plan. I have been to the White House summit on health care. I have heard the President speak directly to this issue. I applaud him in his effort to make sure we deal with this problem intelligently, and I accept at face value his desire that it be done in a bipartisan manner.

But as we have this discussion about doing this in a bipartisan manner, it all ultimately comes down to one sticking point that seems to be firmly established in the President's position and firmly established in the position of those who sit on this side of the aisle. At the moment, that sticking point seems to be irreconcilable. I want to talk about it in direct terms so that we understand what it is we are talking about and those who listen will understand why those of us who are Republicans are determined to stand firm on this point.

This is the point: Shall there be a public plan, a government-run option in the choices that are available to people with respect to health care?

Along with Senator WYDEN of Oregon, I have cosponsored the Healthy Americans Act, which is determined to create as many options as possible, to create a wide range of choices for Americans to make with respect to their health care.

We recognize we are going to have to change the tax laws in order to give people control over their own health care dollars. Right now, health care is the only part of the economy where the individual receiving the goods or services does not control the money that pays for the goods or services. So it is obvious that you will not have market forces available in that circumstance. If the individual who is receiving the goods or services controls the money that pays for the goods or services, he or she will make a different choice than if someone else is controlling the money. But in health care, somebody else makes the choice, and that is why the core function of the Healthy Americans Act, which Senator WYDEN and I are cosponsoring, says individuals should be in control of their own money and we should have as many choices as possible so that individuals can go out in the market.

There will be competing forces. Competition brings prices down. Competition creates new opportunities. Competition fills niche markets. We believe all of that will happen if we have this degree of choice.

When we have had this conversation with officials of the administration, they don't disagree. As a matter of fact, many officials of the administration have said to me: We really like what you are doing with Senator WYDEN, and we applaud you, Senator BENNETT, for reaching out in a bipartisan way to try to solve this problem. But we just have one additional factor we would like to add to your bill. We would like to say that as a backup, as a final option, we want a government-run plan to be there as one of the available choices, just in case none of the others work. That is, as I say, the sticking point here.

I have said to members of the administration: If we end up with a government-run plan as one of the options in my bill, I will vote against my own bill.

The government-run option will change the playing field, will ultimately drive out all of the other choices because the government is in a position to subsidize it. The government is in a position to make it more

attractive than anything else and thereby gain the blessing of the voters because the voters will say: The government took care of those greedy companies that would otherwise make me pay this, that, or the other. Here, the government choice is cheaper; isn't it wonderful that the government is looking out for me? Ultimately, we would end up with a government plan, single payer for the whole country.

I know there are many of my friends on the other side of the aisle who want that, and they are very open about it and very direct about it. They say a number of things. They say the government plan is cheaper, the government plan provides health care for everybody, the government plan is fairer, and that is what we ought to have.

I wish to spend a little time talking about the experience of those countries that have adopted that attitude. If I may be personal and give my own example before I get into the statistics, I will tell you about a situation when I was living in Great Britain and had a medical problem. I won't bore you, Mr. President, with the details of the problem, simply that I went to a doctor in Scotland to see if anything should be done. The doctor first signed me up because under the British system a doctor—this shows how long ago it was, but the system has not changed—got a shilling a week for every patient he signed up on his list. So immediately he wanted to sign me up so he would get that shilling for having me there, which would be a decimal of a pound today rather than that old designation.

Once he had me signed up, as I say, he examined me. He said: Yes, you do need treatment. And he gave me a piece of paper that would allow me to go to the Edinburgh Royal Infirmary, where I was to see a surgeon. So I went to the Edinburgh Royal Infirmary and sat there for most of the day before a doctor could finally see me.

The doctor saw me and checked me out and said: Yes, indeed, you should be scheduled for surgery.

I said: Fine. I have a schedule. Can you give me some idea when the surgery will be so I can arrange my affairs to be available?

He said: My guess would be 9 months.

I said: I am going to be returning to the United States in less than 9 months, so I guess we can just forget this.

I communicated that to my father, who was in the United States, and he said: I don't think so. Can you get a surgeon who would operate on you right away?

So I inquired and I was told: Yes, you can get a private surgeon, but the private surgeon cannot take the health care system dollars or pounds. He is outside of it. If he stays in private practice, he cannot participate in the national health system at all.

I said: OK, that is fine.

My father said: I will pay it. Where can you go?

I went to the private surgeon and, yes, he had a practice where he took only patients who were outside of the health plan. He looked at it and said: Yes, you need surgery.

I said: All right. When?

He said: Will Wednesday be soon enough?

This was on a Monday.

I said: All right.

We went into a private hospital. It was separated from the national health service. He performed the surgery. I paid him cash, got the thing taken care of, and finished my time in Great Britain with that particular problem solved.

I would like to think that was only the case back when I was younger, but I find it is still the case, not only in Great Britain but in other countries that have this kind of problem.

Let me share a few statistics with you of what happens with respect to this single-payer system.

One of the things we are told by those who support single payers is that the outcomes in these other countries are really not any different than they are in America, that we are paying far more in America and the outcomes are basically the same. The statistic they usually use in order to prove that America is not any better is life expectancy and infant mortality. They say as a country, our life expectancy is not that much better than anybody else's and our infant mortality rate is as high or higher than other countries. Shame on us, we are not getting good health care that we are paying for.

Life expectancy is tied in very many cases to either ethnic or geographic locations. The life expectancy, for example, in Utah, where the behavior is a little different than it is in some other places, is substantially higher and has little or nothing to do with the health care. It has to do with the culture in Utah that causes people to behave in a healthier lifestyle.

Let's go beyond this broad-brush approach and look at some specifics.

The largest international study to date has found that the 5-year survival rate for all types of cancer among both men and women is higher in the United States than in Europe. Isn't that a statistic showing that we are getting a better result in America than in Europe? A cancer survival rate is not something that is due to the geography of where you are born. If you are born in the inner city, that has something to do with infant mortality rates, or if you live in a healthy environment, that has something to do with life expectancy. Cancer survival rate has to do with health care, and the health care in the United States is better than it is in Europe and has produced a higher survival rate for both men and women.

In Britain, there are one-fourth as many CT scanners per capita as there are in the United States and one-third as many MRIs. If we think the CT scanner and the MRI produce a better result in terms of health care, we want to be in the United States. We do not want to be in one of these single-payer, government plans of the kind President Obama wants as an option destroying the other options and choices there would be if we pass the Healthy Americans Act.

The rate for treating kidney failure—dialysis or transplants—is five times higher in the United States for patients between the ages of 45 and 84 and nine times higher for patients 85 years and older. Again, there is a personal interest here because members of my family have kidney disease. I want them in the United States with the kind of system we have where they do not have to wait and they do not have to worry about government regulations. I want them here where it is five times better than it is in Europe with respect to kidney disease.

Right now, nearly 1.8 million Britons are waiting for hospital or outpatient treatments at any given time—1.8 million waiting in the circumstance that I described in my own situation. In 2002 to 2004, dialysis patients waited an average of 16 days for permanent blood vessel access in the United States, or 20 days in Europe, and 62 days in Canada.

We often hear about the benefits of being in Canada. I have constituents who come from Canada, who have moved to Utah. Every time this comes up, they come to me and say: Senator, whatever you do, do not give us the Canadian system. Whatever you do, make sure that America doesn't go in the direction the Canadians have gone.

Let me give you some examples to demonstrate why that is good advice. This is one that broke out in the debate in the Canadian Parliament. A woman by the name of Emily Morely, in March of 2006, was informed by her doctor that her cancer had spread and she needed to see an oncologist, and then she was told: You will not be able to get an appointment for months. Well, if my cancer is spreading, I don't want to wait months for an appointment. Her family raised a ruckus, they called the local newspaper, a petition was signed by her neighbors demanding she get care, and then, in response to that, the government got her to a specialist. Once again, in the government, you respond to the voters. If you are getting bad publicity in the press, or the voters don't like what you are doing: Oh, let's take her to a specialist. So she got to a specialist and he told her she had only 3 months to live.

Well, she at least had time to put her affairs in order. Had she not had the intervention of her family and her neighbors, it is quite likely she would have died before even seeing an oncologist for the first time.

But let's go to another example that may be even closer to home to the legislators. A member of Parliament in Canada, Belinda Stronach, strongly supports the Canadian health care system, and she would object to this kind of argument that the Canadian health care system isn't very good. But where did she go when she was diagnosed with

cancer in 2007? She went to California and paid for the treatment out of pocket. Even a member of Parliament who supports the Canadian system recognized that the government plan didn't work for her. And with her own health at risk, she came to America and took advantage of what we offer here.

There is the case of the mother in Calgary, Alberta who was expecting quadruplets. I am the father of twins, and they came as a great surprise. Quadruplets is something I am not sure we could handle, and certainly they would require very good facilities to deal with a pregnancy that produces quadruplets. She is in Albert, Canada, and she is flown to Great Falls, MT, to deliver the quadruplets. Great Falls, MT, is not thought of as one of the great centers of health care excellence in the United States. Yet the facilities in this small town in Montana were better than any facility available anywhere in Alberta.

These are the examples of a government-run plan and because people who are getting the service don't control the money the government plan can end up focusing on overall cost control to the detriment of the people who are trying to access it. I don't think ultimately the American voters, having gotten used to the access that they currently have—being used to the idea that they do not have to wait—would ultimately tolerate a government plan.

My consult to President Obama and to my colleagues here in the Senate is to slow down a little. We are talking about restructuring 18 percent of the entire economy. We spend 18 percent of our GDP on health care. I agree absolutely that it is long past time that we addressed this issue; that we rationalize the challenge; and that we do things that make it far more effective.

As I have spent the last 3 or so years working with Senator WYDEN to try to understand the problem and fashion the Healthy Americans Act in a way that will solve the problem, I have discovered a great truth that I didn't realize before, and that is this: The greatest cost control factor in health care is quality. The best health care is the cheapest health care. And it has been achieved in those places that have focused on quality first and the patient first, and it has not involved any government intervention.

Dartmouth has done a study and told us the three cities in the United States where you get the best health care. They are Seattle, WA; Rochester, MN; and Salt Lake City, UT. I take some pride in that fact. And then the Dartmouth study goes on to say that if every American got his or her health care in Salt Lake City, UT, it would not only be the best in the United States, it would be one-third cheaper than the national average.

Those are the kinds of examples we should be focusing on and learning from, and then doing our best to write legislation that would support that. Slow down. We are not going to understand this in time for any artificial deadline set for some political agenda. I understand the sense of urgency that the Obama administration feels on this issue, and I share the idea that now is the time to address it. This is the Congress in which we should pass it. But I don't think setting a deadline to say it must be done in July, when we are talking about 18 percent of GDP, is that persuasive.

We can examine these alternatives a little more carefully than the present deadline will allow us to do. We can say: All right, why is quality the best cost control, and does our bill create the kinds of incentives and rewards focused on quality that will produce that result, instead of saying: Whatever else you do, you have to have a government option in there. You have to have a government plan that can compete with all the rest of this, and thus set us up for the kind of situation where we would move as a nation to imitate Great Britain or Canada or the others that have produced the kinds of examples I have talked about here.

So I am more than willing and I am anxious to work with President Obama and his administration, to work with my friends across the aisle. I have worked with Senator WYDEN for these past 3-plus years to try to fashion an intelligent solution. But I repeat what I said at the beginning: The sticking point in this entire debate is the demand on the part of the Obama administration that the final product have within it a government plan as one of the options. And if that happens, I vote against my own bill. If that happens, I do everything I can to say no. Because I am convinced if that happens, we end up with a situation where there is only one option that survives.

One of my colleagues has described this, I think, quite well. He says: Having a government plan as one of the options is a little like taking an elephant into a room full of mice and then saying: All right, this is a roomful of animals, let's let them compete. And as the elephant walks around the room, pretty soon there aren't any mice left. A government plan is the elephant in the room.

Those of us who want to solve this problem intelligently say: Let's learn from the examples of those people who have adopted a single-payer system. Let us realize that the American experiment in health care produces better outcomes in all of the areas I have outlined. And as politicians, let's realize that the American voter will never stand for the kind of rationing by delay that seems to have crept into every other system. Let's take our time to do it right. There is a bipartisan consensus to get it done. We can work together and make that accomplishment, if we are not quite so insistent that the government plan ultimately is the only way to go.

Mr. President, I yield the floor, and I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mr. DODD. Mr. President, I ask unanimous consent the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

The 30 hours postcloture under rule XXII has expired. The question is on agreeing to the motion to proceed to H.R. 1256.

The motion was agreed to.

FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT

The PRESIDING OFFICER. The Senator from Connecticut is recognized.

Mr. DODD. Mr. President, I ask unanimous consent the only amendments in order today after the amendment is offered by myself, Senator DODD, the HELP Committee substitute amendment, be the Lieberman amendment re: TSP, and the substitute amendment of Senators BURR AND HAGAN.

The PRESIDING OFFICER. Is there objection?

Without objection, it is so ordered.

ORDER FOR RECESS

Mr. DODD. Mr. President, I now ask unanimous consent the Senate stand in recess from 6 p.m. to 6:30 p.m. My intention would be to address for a few minutes some comments and then would defer to others who may want to speak until we recess at 6 p.m.

The PRESIDING OFFICER. Without objection, it is so ordered.

The clerk will report the bill.

The assistant legislative clerk read as follows:

A bill (H.R. 1256) to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes.

Mr. DODD. Mr. President, I rise to offer an amendment in the nature of a substitute to H.R. 1256.

As I understand it from the leadership, while there will be some comments I will make this evening, briefly, about the substitute, and others may have some comments to make before the evening concludes, there will be no votes this evening. The leadership has notified us of that, so colleagues ought to be aware there will be no votes at all this evening.

If I could, I wish to take a few minutes to describe the substitute amendment, and I will yield the floor to others who want to talk before the 6 p.m. hour arrives and others who may come back around 6:30 to make some additional comments.

AMENDMENT NO. 1247

The PRESIDING OFFICER. The clerk will report the amendment.

The assistant legislative clerk read as follows.

The Senator from Connecticut [Mr. DODD] proposes an amendment numbered 1247.

Mr. DODD. I ask unanimous consent the reading of the amendment be dispensed with.

The PRESIDING OFFICER. Without objection, it is so ordered.

(The amendment is printed in today's RECORD under ''Text of Amendments.'')

Mr. DODD. Mr. President, this substitute amendment represents the work of the Committee on Health, Education, Labor and Pensions, which was reported out of our committee by a vote of 15 to 8 prior to the Memorial Day recess. In this substitute we have included some very important changes as a result of good work by my friend and colleague from Wyoming, Senator ENZI. I thank him and thank his staff, as well as the majority staff, for their work in reaching agreement on this amendment. It was important to my colleague from Wyoming that we improve the language on civil monetary penalties on companies that violate the law, and I agree with those suggestions. Senator ENZI also made clear, and I agree with him, that we need to make sure that over time, Congress and the public need to understand how this bill is being implemented, so we have enhanced the reporting requirements on the Food and Drug Administration and called on the General Accountability Office to make a study of the bill's implementation.

These are strong provisions and I appreciate very much the diligence of my colleague from Wyoming, his work, and the work of his staff as well.

Otherwise, the substitute would still give the Food and Drug Administration the authority to regulate the tobacco industry and put in place very tough provisions for families that, for far too long, have been absent when it comes to how cigarettes are marketed to America's children.

We cannot afford to wait any longer. Every day we delay, as I have said over and over, another 3,000 to 4,000 children across our country—as they did today and will again tomorrow, will again every single day—3,000 to 4,000 of our young people are ensnared by the tobacco companies that target them with impunity as they try smoking for the very first time. Those numbers are incredible; 3,000 to 4,000 every single day take that first cigarette, begin that process. Almost a third to a quarter of them will actually become addicted. Roughly a third of that number will die, in many cases prematurely, because of that process that starts today with 3,000 to 4,000 children.

A thousand of these children become addicted. Of these addicted, a third, as I said, will die eventually of smoking-related diseases. Absent any action by this Congress, more than 6 million children alive today will die from smoking, including more than 76,000 people in my own State of Connecticut.

The purpose of this historic public health legislation is very simple. It is to protect America's children and to give them the longer, healthier future they deserve. This is a cry from parents as well, including parents who smoke. As I said earlier, parents who smoke, if all of them could be here in this Chamber today and have the privilege that I have to have a microphone attached to my pocket here to talk about this, as smokers, would plead that their children never ever begin this habit. If they could wish anything, they would wish their children would avoid this deadly habit. So it is not just those who do not smoke or those who are offended by it or those who are worried about the health implications. I don't know of anybody who wants to see a young child begin the habit of smoking.

Yet for almost 10 years we have been unable to get this bill passed—almost 10 years of effort, led by our colleague from Massachusetts, Senator KENNEDY, who has tried over and over to get this legislation up and to get it adopted by both Chambers.

For the benefit of our colleagues, they should know this Chamber has adopted legislation, but at the time we did, the other body didn't. Candidly, the other body has acted as well, but when they did, we did not. So we have had this kind of circus going on over the last 8 or 10 years, where when the Senate acted, the House didn't; then the House acted but the Senate didn't. We are on the cusp of both Chambers acting and a President who will sign this bill into law to make a difference for the millions of people who have been adversely affected by this subject matter.

I also want to address some of the points our opponents of the bill have been saying about the legislation. Let me be clear. The Food and Drug Administration is absolutely the right agency for this job. It is the one Federal agency with the necessary scientific expertise, regulatory experience, and public health mission to do the job. No other agency of government is able to do all three of these.

Many others can do good work, but they can't do all three. They don't have the scientific expertise, they don't have the regulatory experience, and they don't have the public health mission that the Food and Drug Administration does.

The FDA regulates food, drugs, cosmetics, even pet food, but they do not regulate tobacco. They can regulate what your cat has and what your dog has but not what your child starts today, the 3,000 to 4,000 who do. We have been able to get that done so your pets are OK, but your child may not be because of our failure over the years to make sure tobacco will be regulated by the FDA. Tobacco, we know, is the most dangerous consumer product sold in the United States, or anywhere in the world for that matter. Yet it is currently exempted from oversight by the agency that regulates virtually every other product that Americans consume.

Some have said this bill will drain precious resources away from the FDA. In fact, what we have done with this bill ensures that the Food and Drug Administration is given adequate resources to perform its new tobacco product responsibilities without taking any resources from its other important activities. We do this by setting up a special division within the FDA to do just this job and we allocate specific resources, collected as user fees, to fund the very efforts we are seeking to accomplish. So all of the other functions the FDA does are not going to be adversely affected because of what we have written into this bill. The legislation does this, as I said, by assessing user fees on the companies and the cost of regulating tobacco is paid entirely by these user fees.

Some have also suggested that we should not act because States have squandered the funding provided in the Master Settlement Agreement on smoking and tobacco products. Some States have, and we do not defend their actions. But this is not a reason for inaction now, when we can protect as many children as we will with the adoption of this legislation.

Furthermore, while the 1998 Master Settlement Agreement on tobacco between the States and the tobacco industry was a very positive step, it simply did not go far enough. In order to protect the public and to prevent and reduce smoking, especially among children and kids, tobacco products must be regulated by the Food and Drug Administration. Since the Master Settlement Agreement was signed, marketing expenditures by the tobacco industry have reached record levels. The industry spends $13 billion a year—$13 billion a year—to market their products to America's children.

This bill would restrict the tobacco industry's ability to market to children. Mr. President, 400,000 people die every year from tobacco-related illnesses. That is more than die from alcohol abuse, automobile accidents, violent crime, illegal drugs, and suicide. All of them combined do not equal the number of deaths caused by tobacco products and by cigarettes. In order to make up those loss numbers, the industry targets the youngest of our citizens, our children. They do it with a $13 billion appropriation to go out and actually solicit the children to become addicted to these products.

Let me be clear that despite what some have claimed, this bill does not grandfather any existing tobacco products. In fact, this legislation will finally allow the Food and Drug Administration to take action on these products that have had special protection for decades. For the very first time, the FDA will have the broad authority to require changes in existing tobacco products and make them less risky or less addictive.

Some opponents have sought to downplay the significant impact of this bill. The Congressional Budget Office has estimated that the bill will reduce adult smoking by 2 percent over 10

years. This is true. But what opponents do not tell us is that a 2-percent decline in adult smoking is about 900,000 fewer adult smokers. That is not insignificant, almost a million people. That 2 percent sounds small, but when you translate it into actual numbers, it is somewhere in the neighborhood of 900,000 to a million people. More importantly, opponents leave out the fact that, according to the Congressional Budget Office, this bill would reduce youth smoking by 11 percent. Such a decline would save the lives of some 700,000 children from premature smoking-related deaths.

For adults to quit smoking is hard. I could be a personal witness to this, having been a smoker. I can tell my colleagues how hard it is to quit. People I know try every day and fail. It is hard. It is a very addictive product. So as a former smoker, I know what this is like and how hard it can be for people to break this habit. But 90 percent of the adults who smoke started as kids. They started as children. If we can break that link with children so that they don't begin this deadly habit, then we can start saving lives. And if lives don't impress you, how about money? It is billions of dollars we spend every year as part of our health care costs. A lot of those don't die but end up being sick or ill for years in a very debilitated fashion as a result of smoking-related products, particularly cigarettes.

In a few days, we are going to be dealing with health care. There is a lot of division here about what we ought to do on health care. One subject matter we are not divided on is prevention. To avoid chronic illnesses, the best way is to prevent them from happening in the first place. If we thought we could make a dent of even 100,000 lives, what about 200,000 lives because we made a difference in the number of children who started this deadly habit each year? What better way to begin the debate about prevention than going after the one cause, the self-inflicted wound that we impose on ourselves because of smoking habits? That is self-infliction that we do. We know it kills. We know what damage it does. Here we have the ability in a few days, maybe, or less, to actually do something in a meaningful way that has never, ever happened before. Cat food, pet food, dog food get regulated by the FDA, and finally tobacco will, tobacco and cigarettes.

Passing this bill will be a historic victory for our Nation's health, helping parents protect their children, as every parent across the country tonight would pray and hope their child would never begin this deadly habit. Their Federal Government is now going to be of some assistance. We are going to provide for these products the same kinds of protections we do for animals in terms of what they eat every night in your homes. We will now say the same kind of protection ought to be afforded to your children. Parents deserve peace of mind when it comes to how dangerous tobacco products are marketed. With this legislation, that is precisely what we will give them.

I commend my colleagues in this Chamber who over the years have voted, when they have had the opportunity, to implement this legislation. I thank immensely our colleague from Massachusetts, Senator KENNEDY. I thank Mike DeWine of Ohio, who is no longer with us as a Member. He was Senator KENNEDY's partner on this issue, as were HENRY WAXMAN and TOM DAVIS on the House side. This has had bipartisan support. Tonight, our friend from Massachusetts is at home recovering from his own struggle with illness. But he may be watching at this hour. We want him to know how grateful we are to him for his undying efforts to make this bill a reality.

I thank MIKE ENZI. MIKE cares deeply about this issue. He gets passionate about a lot of subject matters, but this is one where I have seen the most passion by my colleague from Wyoming. He can tell his own personal stories of what he has witnessed over the years. While he may have some problems with this particular proposal, he has no problem with the idea that we ought to be cutting back and making significant inroads in children beginning this deadly habit.

Our substitute is a bipartisan effort to bring together these ideas and once and for all to do something in a way that will make a difference in the lives of millions of people in this country and hopefully one day around the world as well. This habit is not confined to our own Nation. We can't legislate for the world, but we can legislate for ourselves, to say to America's parents that tonight and over the next day or so we will make a huge difference, I believe, in their children's lives by limiting the ability of this industry to appeal and market directly to their children. That is what this bill does.

I yield the floor.

The PRESIDING OFFICER. The Senator from North Carolina.

AMENDMENT NO. 1246 TO AMENDMENT NO. 1247

Mr. BURR. Mr. President, I ask unanimous consent to call up an amendment in the nature of a substitute, No. 1246, and ask for its immediate consideration.

The PRESIDING OFFICER. The clerk will report.

The assistant legislative clerk read as follows:

The Senator from North Carolina [Mr. BURR], for himself and Mrs. HAGAN, proposes an amendment numbered 1246 to amendment No. 1247.

Mr. BURR. I ask unanimous consent that reading of the amendment be dispensed with.

The PRESIDING OFFICER. Without objection, it is so ordered.

(The amendment is printed in today's RECORD under ''Text of Amendments.'')

Mr. BURR. Mr. President, let me say it is shocking that the argument as to why we should do this is because the Food and Drug Administration regulates cat and dog food, what we have just heard. The truth is, the FDA regulates every pharmaceutical product, every medical device, every biological product, lifesaving drugs, chronic disease, treatments, therapies. It is in charge of food safety, of products that emit radiation. It is the gold standard of the world from the standpoint of the approval and assurance of safety and efficacy of things Americans take that are prescribed by doctors and filled by pharmacists. They know when they go home, they can take it because it is safe and effective. Now we are talking about giving that same agency a product for which they can't prove safety and efficacy—their core mission statement for every product they regulate. They will have to turn their head on tobacco because it kills. It causes disease. It isn't safe. This makes no sense.

What the substitute does is create a tobacco harm reduction center. It locates it at the Department of Health and Human Services, under the Secretary—the same Secretary who oversees the Food and Drug Administration.

Within that tobacco harm reduction center, it gives the authority to the center to regulate all cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and other tobacco products that are deemed by the Secretary to be necessary for regulation. We don't lessen the regulation of this industry. As a matter of fact, as Members have an opportunity to hear tomorrow about this substitute amendment, we increase the regulatory authority. We do it under the same guidance of the Secretary of Health and Human Services. We define what adulterated and misbranded tobacco products are. We give the tobacco harm reduction center the ability to pull products directly from the market and to prevent those products from going to market. Misbranded product would be a label that is false or misleading, labels that don't contain all the information, are not in compliance with section 109, and tobacco or ingredients are not disclosed. It requires tobacco manufacturers to submit extensive lists of ingredients, substances, compounds, and additives by brand style to the tobacco harm reduction center. It requires the center to determine and make public a list of harmful constituents, including smoke constituents and by brand styles. It requires annual registration and submission of additional information by the manufacturers to the center. It requires establishment of tobacco product design standards and establishes tar and nicotine ceilings for cigarettes. It eliminates candy and fruit descriptors on cigarette advertising and marketing. It gives the center the authority to remove tobacco products from interstate commerce if such products pose an unreasonable risk of substantial harm to public health.

This is about public health. The objective of any bill should be to reduce

youth usage, to reduce disease, to reduce death. If we put it in the FDA, we grandfather a tremendous amount of smoking products, but we don't allow a pathway for new, less harmful products to reach the marketplace. In our case, we allow reduced-risk products to come but under the supervision, the direction of the harm reduction center.

It requires all tobacco manufacturers of imported tobacco products to establish and maintain records, make reports, provide information as the Secretary requests, not as we prescribe. It requires premarket approval of new combustible tobacco products before entering interstate commerce. It bans the use of such descriptions as ''light,'' ''ultra-light,'' and ''low tar'' on packaging, advertising, and marketing of cigarettes. It requires testing and reporting of all tobacco product constituents, ingredients, additives, including smoke constituents and by brand styles. It creates a scientific advisory committee of 19 people. It establishes a new warning label that communicates the health risk of cigarettes, with placement for cigarettes on the front of the packaging. It requires ingredient disclosures and other information on all tobacco packaging. It has the graphic warning labels required. It establishes new warning labels that communicate the health risks of smokeless tobacco. It requires ingredient disclosure and information on tobacco products. The list goes on and on.

The authors of the base bill and the substitute that has been offered in its place suggest that they do a better job of making sure that youth don't access tobacco products. That is just wrong. Every State sets an age limit. One bill does not police the process more than the other.

The one thing this substitute does, this amendment in the nature of a substitute, is we ban print advertising except in a publication that is an industry publication. So every general print ad, every general print publication, a publication that a mom might buy but a teenager might look at, we eliminate advertising. What does the base bill do? It limits it to black-and-white advertising.

Don't come to the floor and suggest one does a better job than this substitute. When you ban advertising, you have banned the ability to market to the youth. When you ban descriptors and other items such as candy and fruit descriptors, we do that as effectively, we just do it through a harm reduction center. Why? Because it is under the same leadership of the Secretary of HHS.

I don't want to jeopardize the gold standard of the FDA. I don't want to compromise the gold standard that it has to meet the test of safety and efficacy so the American people have trust in products. We jeopardize that when we give the FDA this mission.

Some will claim the FDA is the only one that can do it. As I showed before, there is the regulatory chart for tobacco today in the United States. Every Federal agency is listed up here, including HHS. FDA has no current jurisdiction. They have no expertise to regulate tobacco.

It is the most regulated product sold in America today. But I am not on the floor arguing that this is enough. We can do better. We can consolidate that regulation. We can build on the strengths of all of these underneath the heads. But to add FDA is a huge mistake.

We just got faxed to us the endorsement of this substitute amendment, No. 1246, by the American Association of Public Health Physicians. The Association of Public Health Physicians endorses the Burr-Hagan amendment. All of a sudden, health care entities are looking at these two bills, and they are saying: The amendment in the nature of a substitute, No. 1246, actually does accomplish what is best for public health. And public health physicians are willing to put their name on it.

We are going to have an opportunity tomorrow to talk at length about what is in the substitute. My colleague, Senator HAGAN, cosponsor of this bill, will have an opportunity to address it either tonight or tomorrow. I look forward to the opportunity to do that.

I yield the floor.

RECESS

The PRESIDING OFFICER. Under the previous order, the Senate stands in recess until 6:30 p.m.

Thereupon, at 6 p.m., the Senate recessed until 6:30 p.m. and reassembled when called to order by the Presiding Officer (Mr. BENNET.)

FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT—Continued

Mr. ENZI. Mr. President, I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

Mr. LAUTENBERG. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. LAUTENBERG. Mr. President, basic instinct in humankind directs so much attention to the well-being of our children. We do it in various ways. Now you see it creeping into better nutrition. We see it in our attention to environmental conditions, to global climate change. We see it in our attention to deal with violent behavior against children. We do whatever we can to protect our kids, to protect them and do whatever it takes to do what we can to make sure they grow up healthy, they have long lives.

One of the ways we can be effective is to protect our kids against addiction. I use the word deliberately. ''Addiction'' immediately conjures up a view of drugs—prescription drugs, prohibited drugs. We are not talking about that addiction. I am talking about a serious addiction, an addiction to tobacco—to tobacco—that has such a devastating effect on the people who smoke and often on those who are around the people who smoke.

We heard from Senator DODD earlier about what happens from smoking. It kills more than 400,000 Americans each and every year. Many of them are of younger ages. In addition to the lethal dose, there is that kind of attack on health that disables people—emphysema, conditions that affect the heart, all kinds of things. We know lung cancer is among the most dangerous.

Senator DURBIN, who was a Member of the House at the time, and I decided to take up the fight against big tobacco and their powerful special interests more than 20 years ago when we wrote the law banning smoking on airplanes. We stood up to big tobacco because smoking on airplanes was so unhealthful. We learned the dangers of secondhand smoke. Many of the people who were cabin attendants were subjected to terrible respiratory discomfort and danger.

As a matter of fact, there was a study that was done, and it said even those who never smoked—people who worked in the cabin of the airplane—would show nicotine in their body fluids weeks after they had worked a trip. That is how pervasive this was. But big tobacco fought back. They fought back ferociously. They unleashed their forces. Money flowed to protect their addicted clientele and to keep them there. They brought phony science and high-paid lobbyists to squash this assault on behalf of public health. They had phony experts testify to Congress, up here on television, saying unashamedly that there was no evidence that secondhand smoke was dangerous, even though they knew in the tobacco companies. In the 1930s they learned that nicotine was so addictive and that it would continue to help them earn enormous profits. We fought back, and we succeeded in banning smoking on airplanes. It was a tough fight because of all of the misinformation that the industry spread. That then started a smoke-free revolution, and it did change the world culture on tobacco.

Some years later I authored a law that banned smoking in buildings that provided services to children, any building that had Federal funds. It could have been a library, a clinic, a daycare center; whatever it was, there was no smoking allowed in those buildings, except if it was in a separate room that ventilated directly to the outside. They fought us on that, but the people won. It is as clear to me today as it was then that this industry has not earned the trust to regulate itself. That is a plea they make, but no one believes they mean it.

Ten years ago, I was able to gather unpublished, internal reports by the tobacco industry showing that so-called

''light'' and ''low-tar'' cigarettes were a poor disguise of the true harm that these cigarettes brought. The cigarette makers were seducing smokers into thinking that these cigarettes were a healthier choice than those previously generally sold.

Real government oversight was essential to protect the public, especially our young, from this deadly product. As we know, since the 1980s, the tobacco industry has continued to engage in one sophisticated marketing campaign after another to get youngsters addicted to nicotine—just get them started and they are yours—even though selling and marketing cigarettes to children is generally against the law. It is our obligation, our responsibility to end the recruitment of kids as the next generation of smokers.

If there was ever any doubt about how effective and real this unlawful marketing is, just consider that more than 3 million young people—people who are under the age of 18—in our society are smokers. What is more, currently 3,500 kids every day try smoking. That, for many, is the first step to a life of addiction.

When I served in the Army, we were given an emergency pack in case we got in trouble, in case we were isolated from our units, and the emergency pack had some food, including a high-nutrition chocolate bar, but it also had four cigarettes in a little sleeve. Everybody got cigarettes free, even if you didn't use them before. The temptation to use them then was great, and it was right down the addiction alley.

The legislation we are talking about now that is being debated in this Chamber would finally grant some supervision and give a Federal agency—the Food and Drug Administration—the authority to regulate the tobacco industry. The bill, very simply, would give the FDA jurisdiction over the content and the marketing of tobacco products, and more explicit warning labels would be required. President Obama supports this effort, and it is now our turn and our obligation to safeguard families and children by passing this critical bill.

The legislation would give us more and better information about cigarettes. The fact is that we still don't know a cigarette's exact contents. That means 40 million Americans—the number of people in this country who are addicted to smoking—burn and inhale a product whose real ingredients are a mystery. Think about it. We see evidence of the fact that these people are typically locked in a vice, a vice so embarrassing that they sneak into hallways, they stand outside in a huddle in the rain, or in all kinds of weather conditions, whatever they are, to get the puffs on cigarettes. I know people who work in the Capitol here whom I see frequently going down the hall to get outside in inclement weather. Why? To smoke. So we have a situation we can't deal with. We have to understand what is in these products. The real ingredients are a mystery. To lead so many Americans on a dangerous path to a debilitating disease, and often lethal, is not simply wrong, it is the definition of negligence. If this legislation is successful, the FDA would monitor the content of cigarettes and could call for the reduction or removal of the toxic substances.

FDA oversight would also ensure that cigarette makers don't deceive Americans through trick advertising and promotional campaigns. History has proven how untrustworthy the tobacco companies are. Just think: More than 20 percent of twelfth graders said they have smoked in the last 30 days—20 percent of kids in the twelfth grade, typically 16, 17, 18 years old, have had a cigarette in the last 30 days.

For years, we have set our sights on getting the FDA to regulate cigarettes. Why? To protect our kids. No other government agency is as qualified to get this job done. In fact, one out of every five products that Americans purchase is regulated by the FDA. They watch over all kinds of things. Now they are looking at chemicals that are in products that very small children have contact with. The agency currently oversees prescription drugs, over-the-counter medicines, and medical devices, and it already regulates a number of well-known nicotine delivery products, such as the Nicorette gum and the patch.

For the last 45 years, ever since the Surgeon General's office began issuing warnings about cigarettes, big tobacco has used every tactic imaginable, including sham organizations, influential lobbyists, and powerful lawyers, to avoid public scrutiny. It is time to make big tobacco accountable to the public. It is time to make it accountable so that we can protect our children from the danger that kills more than 400,000 Americans every year.

I, too, was a smoker at one time, until over 30 years ago. Many times I thought about quitting, but the temptation to light up was always there and overcame any decision that could persuade me to stop from lighting up and taking a few drags. What happened? One night after dinner my third daughter, who was about 7 or 8—she was in maybe second grade—said, Daddy, why are you smoking? I said, well, because it makes me feel relaxed. It feels good when I am doing it after I have eaten. This little kid looked at me and she said, Daddy, today in school we learned that if you smoke, you get a black box in your throat. She was 7 years old. She said, I love you and I don't want you to have a black box in your throat. That convinced me. Within days I had my last cigarette.

I will close with another hideous reminder about the woman who appeared in front of one of my committees. She had already had an operation on her esophagus, I think, but in her throat, she actually had a hole in her throat. She admitted that despite the fact that she had essentially lost her voice box, she still smoked through the hole in her throat. She said her doctor got angry with her when after this serious surgery she was asking for a cigarette. The hold on people is almost unbreakable. But we can do our part here in the Senate if we pass this bill.

I ask my colleagues to vote yes on this legislation. It is good for your constituents, it is good for your families, it is good for America's financial well-being. We spend over $100 billion a year as a result of premature death and disability from tobacco use.

With that, I yield the floor and note the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

Mrs. HAGAN. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER (Mr. BEGICH). Without objection, it is so ordered.

Mrs. HAGAN. Mr. President, we are going to hear a lot this week about how the Family Smoking Prevention and Smoking Control Act is going to prevent youth from taking up smoking. I fully support that goal. I think all of us do. I don't think anybody here believes that smoking among our Nation's youth isn't a problem. Every day, over 3,500 youth in our country try their first cigarette and another thousand become regular daily smokers. Clearly, we must do something to deter our children from smoking.

As I mentioned yesterday, this bill before us goes much further than that. It grants the FDA extremely broad authority to take action that it considers to be in the interest of public health. I reiterate that is an interesting standard—especially when you consider that cigarettes, when used as intended, are a dangerous, unhealthy product. This bill puts the FDA in an impossible situation.

My colleague from North Carolina, Senator BURR, is offering a sensible alternative to the bill before us that focuses on reducing tobacco use among our Nation's youth. I joined Senator BURR in supporting this alternative because I believe it balances the need to curb teenage smoking while protecting tobacco farmers and, in turn, North Carolina's families. Similar to the Family Smoking Prevention and Tobacco Control Act, this alternative would be financed through user fees assessed on tobacco manufacturers.

While the bill before us today would place additional burdens on the already overtaxed FDA, our alternative instead creates the Tobacco Regulatory Agency—a Federal agency within the Department of Health and Human Services dedicated solely to regulating the manufacture, marketing, and use of tobacco products.

Unlike the Family Smoking Prevention and Tobacco Control Act, this alternative bill has a smoking-cessation

component which would require the administrator to develop recommendations to reduce smoking and reduce the harm of tobacco use.

The alternative contains language similar to the amendment I offered in the committee to ensure that the technology is available to meet the standards and that the Tobacco Regulatory Agency does not have the authority to regulate tobacco growers. In fact, the alternative explicitly states that the new Tobacco Regulatory Agency would not have authority over the actual tobacco growers and tobacco cooperatives. It takes this protection one step further by prohibiting any changes to traditional farming practices, including standard cultivation practices, the curing process, seed composition, tobacco type, fertilization, soil, record keeping, or any other requirement affecting farming practices.

The alternative also prescribes requirements for cigarette and smokeless tobacco labels and warnings, and it requires the administrator of the new agency to publicly disclose the ingredients in each brand of tobacco.

Finally, as I mentioned, this alternative requires some thoughtful changes that will reduce teen smoking rates. It prohibits fruits and candy branding on cigarettes. None of us want that. It also reduces the utilization of any character cartoons in advertisements. It prohibits providing any free samples, sponsoring sports events, and any advertising on television and radio in order to sell cigarettes. Stiff penalties are imposed for distributing tobacco products to minors and for minors possessing tobacco products.

Again, I think this alternative offers a better approach to curb teen smoking. It helps adults to quit smoking, and it ensures that the Federal Government can adequately regulate tobacco and protect the 12,000 tobacco farmers and 65,700 employees in tobacco-related industries in North Carolina.

Finally, I say this to my colleagues. I have no doubt they would view an amendment to this bill supported by two Senators from North Carolina with suspicion. But if they will look at the amendment that Senator BURR has offered, I think they will agree this is a serious amendment that actually addresses the issues with which this underlying bill purports to deal. I hope my colleagues will consider the Burr amendment with an open mind.

Mr. UDALL of Colorado. Mr. President, I am here to add my voice to the strong bipartisan support for the bill before us today. I also thank Senator TED KENNEDY for his tireless effort to shepherd its success. While this legislation is long overdue, I think it is especially timely and appropriate that we have the opportunity to see it signed into law in the midst of a historic health reform debate.

We have known for some time that one of the biggest obstacles we face in reforming our broken health care system is the nearly exponential rise in health care costs. An enormous contributor to these costs is the price tag for treating chronic disease and preventable illness, particularly the pulmonary disorders and throat and lung cancer that come with smoking.

What better way to help lower health care costs and promote wellness and prevention than by going after the No. 1 cause of preventable death and disease in this country? Coloradans currently pay taxes to cover over $1 billion per year in smoking and tobacco-driven costs. That is nearly $600 per Colorado household.

As we are struggling to find ways to pay for a revamped health care system that provides quality care to everyone who needs it, let's have part of that pay-for be this bill by preventing millions of American children and teens from becoming addicted to a product that is really a one-way ticket to disease, cancer, and many times death.

While I have been disturbed by so many of the sobering facts, figures, and statistics we have heard throughout this debate, there is one in particular that I think really drives home the underlying issue here: 90 percent of current adult smokers were addicted by the age of 18.

That means that, in order to maintain its bottom line, big tobacco isn't finding new customers in our age range. The only way for them to continue making big profits is to target what they have, in the past, deemed ''their base'': our children. As a father, it terrifies me to know that tobacco companies view our children as ''replacement smokers.''

As tobacco companies continue to find more creative ways to get kids to join their customer base through deceptive marketing and other tactics, parents must continue to educate their children about the dangers of smoking. But we can give them a helping hand by ensuring that youth magazines aren't full of colorful ads tailored specifically to make them the new generation of smokers—tailored to encourage addiction. We can help them by ensuring that the convenience store across the street from their kids' high school doesn't have an advertised ''back-to-school'' special on newly introduced fruit-flavored tobacco products, displayed prominently next to their shelves of gum and candy products. As we have heard from my colleagues who have spoken before me, practices like these have been documented, and they are horribly unacceptable.

In addition to many important tools this legislation would give to the FDA to protect children and consumers, this bill will allow the agency to restrict tobacco advertising, especially to children; prevent sales to youth; improve and strengthen warning labels on products; prevent misleading marketing and misrepresentation; regulate and remove many of the hazardous chemicals and ingredients used to make tobacco products more addictive—and many times more deadly.

Because this bill is, at its root, about people, I would like to share the story of a Coloradan who knew firsthand the effects of cigarette smoke and spent many years fighting to keep kids safe.

First diagnosed with throat cancer in 2002, David Hughes was a musician, Colorado outdoorsman and cave explorer, father, and husband. Having begun his smoking habit as a teenager, he quit cigarettes upon diagnosis and bravely endured 70 radiation treatments, chemotherapy, and successful surgery. Feeling as if he had a new lease on life, David went back to school and started a woodworking business, spent even more time with his wife Kathy and son Nathan, and volunteered with the Loveland Alliance on Smoking and Health to fight for smoke-free air for his family and community. He worked especially hard to keep cigarettes out of the hands of children, knowing firsthand the lifelong addiction that can come from being exposed to tobacco early on.

Unfortunately, 4 years later, the cancer returned—this time to his lungs—eventually taking his life on June 4, 2008, but not without a spirited fight fueled by an infectiously positive attitude and love for his family and friends.

David's wife Kathy has called 2009 her and Nathan's year of ''adventurous recovery.'' I hope getting this bill signed into law will help, if even in just a small way, give them the energy to continue their adventure and give them the peace of mind of knowing that their father and husband's powerful advocacy on behalf of this cause will help prevent other families from experiencing similar heartache and loss.

David's story underscores the importance of this legislation to real people and the affect it can have on real lives.

The time to act on this bill is now. The idea for the Family Smoking Prevention and Tobacco Control Act has been around for over a decade, and the provisions contained in this version have been debated and polished by countless capable policymakers. The FDA is the only agency that combines the scientific know-how and regulatory authority to get the job done. This bill is fiscally responsible and fully paid for through user fees to tobacco companies.

Given the current rate of tobacco use, it is estimated that 92,000 Colorado kids alive in my home State today could ultimately die of smoking. While the long-term goal is to shrink this figure to zero, let's pass this legislation this week and put a significant dent in such an overwhelming and unacceptable number.

Mr. President, I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mr. SCHUMER. Mr. President, I ask unanimous consent the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

AMENDMENT NO. 1256 TO AMENDMENT NO. 1247

(Purpose: To modify provisions relating to Federal employees retirement)

Mr. SCHUMER. Mr. President, under the previous order, on behalf of Senator LIEBERMAN, I call up his amendment, which is at the desk.

The PRESIDING OFFICER. Without objection, the clerk will report.

The assistant legislative clerk read as follows:

The Senator from New York [Mr. SCHUMER], for Mr. LIEBERMAN, for himself, Ms. COLLINS, Mr. AKAKA, and Mr. VOINOVICH, proposes an amendment numbered 1256 to amendment No. 1247.

(The amendment is printed in today's RECORD under ''Text of Amendments.'')

MORNING BUSINESS

Mr. SCHUMER. I ask unanimous consent that the Senate proceed to a period of morning business with Senators permitted to speak for up to 10 minutes each.

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMENDING NONCOMMISSIONED OFFICERS

Mr. REID. Mr. President, I rise today in recognition of the Army's 234th anniversary. On June 14, 2009, the Army celebrates its 234th year of courageous and noble service to the people of the United States of America.

The Army has designated 2009 as ''The Year of the Noncommissioned Officer,'' in recognition of the dedicated and selfless service of noncommissioned officers, known as the ''Backbone of the Army,'' throughout the Nation's history. Our country nation owes a debt of gratitude to those noncommissioned officers who have defended our country and freedom worldwide, serving in harm's way across the globe to defend freedom and secure the peace for the American people. It is fitting that we should pay special tribute to the Army's noncommissioned officer corps on the 234th anniversary of the Army's establishment in 1775.

At Fort Lewis, WA, home of the I Corps, known as ''America's Corps,'' noncommissioned officers are observing the Army's birthday while preparing for deployment into harm's way, training for future service to the Nation, and upholding the high standards of our armed services.

It is my desire to thank and honor those courageous, dedicated and selfless men and women. I am grateful for the Army's outstanding corps of noncommissioned officers at Fort Lewis, WA, under the direction of COL Cynthia Murphy, Garrison Commander, and Command Sergeant MAJ Matthew Barnes, for their role in defending our Nation and serving its people as the keepers of the Army's high standards, the trainers and maintainers who make our Army the greatest force for good across the globe, and the heart and soul of our fighting forces at home and abroad. They are truly the ''Backbone of the Army.''

150TH ANNIVERSARY OF VIRGINIA CITY, NV

Mr. REID. Mr. President, I rise today in honor of a very historic event—this Saturday marks the 150th anniversary of the founding of Virginia City, NV. Many Americans know Virginia City from the old TV show ''Bonanza,'' but this city also played an extremely important role in the history of the United States in the second half of the 19th century.

Virginia City's roots as a mining town began in 1850 as the '49ers traveled through on their way to California. Men often stopped in this area to practice their gold-mining skills but never found much of value until 1859 when Peter O'Riley and Patrick McLaughlin found some gold in the dirt. Henry Comstock passed by shortly after and talked his way into a share of what would later be named after him: the Comstock Lode. For several months, they mined the earth, tossing aside buckets full of ''blue stuff'' that got in the way of only a small amount of gold. Out of curiosity, they sent away a sample of this blue stuff to be tested, and it turned out to be made up of three-fourths silver ore. News spread quickly, and by the following spring, 10,000 men had arrived hoping to make their fortune.

This silver lode proved more difficult to mine than the gold in California, and mines collapsed before they could reach much of the ore. American ingenuity persevered, however, and a whole list of new technologies were developed that would be used in mines across the country. In no time, the ground below Virginia City was crisscrossed with mines, and the city itself was a boom town full of boarding houses and saloons. The official value of all the gold and silver taken out of the Comstock between 1859 and 1882 is over $300 million. These riches helped Nevada in its effort to become an independent territory and then its own State in 1864.

Virginia City also produced some of America's great historical figures. George Hearst made his fortune in Nevada before founding the newspaper empire he became famous for, and Samuel Clemens first used the name ''Mark Twain'' while writing for the local paper, the Territorial Enterprise.

Today, Virginia City has a population of less than a tenth of what it had at its peak in the 1870s. However, it remains a vibrant community and an outstanding monument to the Wild West. The millions of tourists who visit Virginia City each year can stroll the wooden sidewalks, explore old mines, pan for gold, and watch the annual international camel and ostrich races. I am happy I will be able to celebrate this historic anniversary in Virginia City, and I am proud to recognize the city's achievements today.

CHANGES TO S. CON. RES. 13

Mr. CONRAD. Mr. President, section 311(a) of S. Con. Res. 13, the 2010 budget resolution, permits the chairman of the Senate Budget Committee to adjust the allocations of a committee or committees, the aggregates, and other appropriate levels in the resolution for legislation that authorizes the Food and Drug Administration to regulate products and assess user fees on manufacturers and importers of those products to cover the cost of the regulatory activities. Additionally, section 307 of S. Con. Res. 13 permits the chairman to adjust the allocations of a committee or committees, aggregates, and other appropriate levels in the resolution for legislation that, among other things, reduces or eliminates the offset between the survivor benefit plan annuities and veterans' dependency and indemnity compensation. The adjustments under both reserve funds are contingent on the legislation not increasing the deficit over either the period of the total of fiscal years 2009 through 2014 or the period of the total of fiscal years 2009 through 2019.

I find that the amendment in the nature of a complete substitute to H.R. 1256, the Family Smoking Prevention and Tobacco Control Act, contains language that fulfills the conditions of the deficit-neutral reserve funds for the Food and Drug Administration and America's veterans and wounded servicemembers. Therefore, pursuant to sections 311(a) and 307, I am adjusting the aggregates in the 2010 budget resolution, as well as the allocation to the Senate Health, Education, Labor, and Pensions Committee.

I ask unanimous consent that the following revisions to S. Con. Res. 13 be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

CONCURRENT RESOLUTION ON THE BUDGET FOR FISCAL YEAR 2010—S. CON. RES. 13; REVISIONS TO THE CONFERENCE AGREEMENT PURSUANT TO SECTION 311 DEFICIT-NEUTRAL RESERVE FUND FOR THE FOOD AND DRUG ADMINISTRATION AND SECTION 307 DEFICIT-NEUTRAL RESERVE FUND FOR AMERICA'S VETERANS AND WOUNDED SERVICEMEMBERS

[In billions of dollars]

Section 101	
(1)(A) Federal Revenues:	
FY 2009	1,532.571
FY 2010	1,653.722
FY 2011	1,929.684
FY 2012	2,129.674
FY 2013	2,291.204
FY 2014	2,495.884
(1)(B) Change in Federal Revenues:	
FY 2009	0.000
FY 2010	−12.264
FY 2011	−158.947
FY 2012	−230.719
FY 2013	−224.133
FY 2014	−137.774

Section 101	
(2) New Budget Authority:	
FY 2009	3,674.397
FY 2010	2,888.696
FY 2011	2,844.909
FY 2012	2,848.114
FY 2013	3,012.188
FY 2014	3,188.874
(3) Budget Outlays: FY2009	
FY 2009	3,358.510
FY 2010	3,003.315
FY 2011	2,968.399
FY 2012	2,882.772
FY 2013	3,019.399
FY 2014	3,174.863

CONCURRENT RESOLUTION ON THE BUDGET FOR FISCAL YEAR 2010—S. CON. RES. 13; REVISIONS TO THE CONFERENCE AGREEMENT PURSUANT TO SECTION 311 DEFICIT-NEUTRAL RESERVE FUND FOR THE FOOD AND DRUG ADMINISTRATION AND SECTION 307 DEFICIT-NEUTRAL RESERVE FUND FOR AMERICA'S VETERANS AND WOUNDED SERVICEMEMBERS

[In millions of dollars]

Current Allocation to Senate Health, Education, Labor, and Pensions Committee:	
FY 2009 Budget Authority	−22,436
FY 2009 Outlays	−19,058
FY 2010 Budget Authority	4,487
FY 2010 Outlays	1,526
FY 2010–2014 Budget Authority	50,349
FY 2010–2014 Outlays	44,474
Adjustments:	
FY 2009 Budget Authority	0
FY 2009 Outlays	0
FY 2010 Budget Authority	0
FY 2010 Outlays	0
FY 2010–2014 Budget Authority	17
FY 2010–2014 Outlays	17
Revised Allocation to Senate Health, Education, Labor, and Pensions Committee:	
FY 2009 Budget Authority	−22,436
FY 2009 Outlays	−19,058
FY 2010 Budget Authority	4,487
FY 2010 Outlays	1,526
FY 2010–2014 Budget Authority	50,366
FY 2010–2014 Outlays	44,491

FURTHER CHANGES TO S. CON. RES. 13

Mr. CONRAD. Mr. President, section 401(c)(5) of S. Con. Res. 13, the 2010 budget resolution, permits the chairman of the Senate Budget Committee to adjust the section 401(b) discretionary spending limits, budgetary aggregates, and allocations pursuant to section 302(a) of the Congressional Budget Act of 1974 for the aggregate difference for discretionary appropriations in 2010 and related outlays between the Congressional Budget Office's reestimate of the President's budget and the Office of Management and Budget's original estimate of such policies.

On May 29, the Congressional Budget Office released its reestimate of the President's request for discretionary appropriations. Based on that reestimate, I am revising both the discretionary spending limits and the allocation to the Senate Committee on Appropriations for discretionary budget authority and outlays. As specified by section 401(c)(5), the adjustment reflects the aggregate difference in budget authority in 2010 between the CBO reestimate and the original OMB estimate of the President's request for discretionary spending, as well as the related outlays. For 2010, I am revising the amount of budget authority by $3.766 billion and the amount of outlays by $2.355 billion. In addition, I am similarly adjusting the budgetary aggregates consistent with section 401(c)(5) of S. Con. Res. 13. In addition to the 2010 adjustments in budget authority and outlays, I am adjusting outlays in fiscal years 2011 through 2014 to reflect further changes in outlays that result from the adjustment in budget authority in 2010.

I ask unanimous consent that the following revisions to S. Con. Res. 13 be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

CONCURRENT RESOLUTION ON THE BUDGET FOR FISCAL YEAR 2010—S. CON. RES. 13; REVISIONS TO THE CONFERENCE AGREEMENT PURSUANT TO SECTION 401(c)(5)—REVISED APPROPRIATIONS FOR FISCAL YEAR 2010

[In billions of dollars]

Section 101	
(1)(A) Federal Revenues:	
FY 2009	1,532.571
FY 2010	1,653.722
FY 2011	1,929.684
FY 2012	2,129.674
FY 2013	2,291.204
FY 2014	2,495.884
(1)(B) Change in Federal Revenues:	
FY 2009	0.000
FY 2010	−12.264
FY 2011	−158.947
FY 2012	−230.719
FY 2013	−224.133
FY 2014	−137.774
(2) New Budget Authority:	
FY 2009	3,674.397
FY 2010	2,892.462
FY 2011	2,844.909
FY 2012	2,848.114
FY 2013	3,012.188
FY 2014	3,188.874
(3) Budget Outlays:	
FY 2009	3,358.510
FY 2010	3,005.670
FY 2011	2,969.115
FY 2012	2,883.130
FY 2013	3,019.578
FY 2014	3,174.976

CONCURRENT RESOLUTION ON THE BUDGET FOR FISCAL YEAR 2010—S. CON. RES. 13; REVISIONS TO THE CONFERENCE AGREEMENT PURSUANT TO SECTION 401(c)(5) TO THE ALLOCATION OF BUDGET AUTHORITY AND OUTLAYS TO THE SENATE APPROPRIATIONS COMMITTEE AND THE SECTION 401(b) SENATE DISCRETIONARY SPENDING LIMITS

In millions of dollars	Initial allocation limit	Adjustment	Revised allocation limit
FY 2009 Discretionary Budget Authority	1,480,686	0	1,480,686

CONCURRENT RESOLUTION ON THE BUDGET FOR FISCAL YEAR 2010—S. CON. RES. 13; REVISIONS TO THE CONFERENCE AGREEMENT PURSUANT TO SECTION 401(c)(5) TO THE ALLOCATION OF BUDGET AUTHORITY AND OUTLAYS TO THE SENATE APPROPRIATIONS COMMITTEE AND THE SECTION 401(b) SENATE DISCRETIONARY SPENDING LIMITS—Continued

In millions of dollars	Initial allocation limit	Adjustment	Revised allocation limit
FY 2009 Discretionary Outlays	1,247,230	0	1,247,230
FY 2010 Discretionary Budget Authority	1,082,255	3,766	1,086,021
FY 2010 Discretionary Outlays	1,304,885	2,355	1,307,240

CLEAN WATER RESTORATION ACT

Mr. BARRASSO. Mr. President, we all know that one word can make a world of a difference, especially in Washington. Some are advocating for the removal of the word ''navigable'' from the Clean Water Restoration Act. Doing so would give the government control over all wet areas in the country. In this case, one word will send common sense soaring out the window.

It snows in Wyoming. When the snow melts, it often leaves large puddles on ranches and farms across the State.

The Federal Government should not be regulating mud puddles.

This proposal will be detrimental to Wyoming's farmers and ranchers. We have been living out here for a long time quite successfully without the ''helpful hand'' of Washington.

A recent article printed in the June edition of the Wyoming Farm Bureau Federation's newspaper, ''Wyoming Agriculture'' really hit home. I recommend my colleagues read the article by Kerin Clark. I believe it is an accurate reflection of the feelings of Wyoming farmers and ranchers on this issue. I ask unanimous consent that it be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

What's in one word?

Deletion of ''navigable'' from CWA would have far-reaching consequences

Federal control of a ditch or grass waterway that is only filled with water after a rainstorm. Sound outlandish? Not, if the term ''navigable'' is deleted from the Clean Water Act and that is just what proponents of the Clean Water Restoration Act (CWRA) are pushing to do.

''This proposal, if passed, would clearly define intrastate waters as waters of the United States and give control to areas that only have water during rainfall events,'' Don Parrish, American Farm Bureau Federation (AFBF) Senior Director, Regulatory Relations, stated. ''It is clearly the largest expansion of the Clean Water Act since it was passed in 1972.''

The deletion of the term ''navigable'' from the Clean Water Act could have grave consequences for Wyoming water.

''Under both proposals the sponsors make it explicit they intend to roll-back the Supreme Court decision in SWANCC which gives the opportunity for agencies to regulate intrastate water,'' Parrish continued.

''Both bills also intend to roll-back the Supreme Court decision in Rapanos,'' He explained. ''This was about ephemerals a loosely defined set of waters, what the Corp of Engineers and EPA define as only having water

in them during and after a precipitation event.''

''What is water and what is a ditch is hard to ascertain,'' He continued. ''It is extremely broad and goes beyond what the Supreme Court has allowed.''

According to Parrish, the implications of rolling back these two Supreme Court rulings are many including: 1) All intrastate waters and all water confined and retained completely on the property of a single owner would be federalized; 2) the use of all water, if linked to economic and commerce would be federalized; 3) Any areas that have flowing water only during, and for a short duration after, precipitation events would be treated as ''waters of the U.S.''; 4) the agencies would be allowed to use any and all economic activity involving water, including the production of agricultural and forestry products, as the hook for federal regulatory reach; and 5) environmental activists would have the ability to sue landowners or the agencies to expand Federal jurisdiction.

The proposals would allow the Corp of Engineers and the Environmental Protection Agency to use the broadest possible regulatory reach of federal waters. ''It probably even reaches the preverbal western water hole'' Parrish stated. ''If cattle drink from the water hole and then rancher sell those cattle out-of-state to be finished and that could be an economic hook for federal regulation of that water.''

In a May 2009 Field and Stream article, passage of the Clean Water Restoration Act is listed as one of the five crucial goals sportsmen must work toward right now. ''Sportsmen need to understand what the implications are for landowning and not just shooting ducks,'' Parrish continued. ''Farmers and ranchers have to make a living working the land and this legislation will make it harder to do that. Thus, keeping the land in open spaces and providing habitat for wildlife and birds would be even harder.''

The American Farm Bureau Federation opposes the Clean Water Restoration Act because it is an expansion of federal jurisdiction.

''Farmers and ranchers do good things for the environment, we support the Clean Water Act,'' Parrish concluded. ''But removing the term ''navigable'' from the CWA gives total control to the federal government and leaves little or no authority for the states and owners of private property.''

HONORING OUR ARMED FORCES

SENIOR AIRMAN ASHTON L.M. GOODMAN

Mr. BAYH. Mr. President, I rise today with a heavy heart to honor the life of SA Ashton L. M. Goodman, from Indianapolis, IN. Ashton was 21 years old when she lost her life on May 26, 2009, from injuries sustained from a bomb attack near Bagram Air Field, Afghanistan. She was a member of the 43rd Logistics Readiness Squadron, Pope Air Force Base, NC.

Today, I join Ashton's family and friends in mourning her death. Ashton will forever be remembered as a loving daughter, sister, and friend to many. She is survived by her mother, Vicki Goodman; father and stepmother, Mark and Chasity Goodman; brother, Levi Goodman; grandmother, Lois Kammers; aunt, Yvonne Chapman; stepsisters, Amber and Michelle Jefferies; half-sisters, Brianna and Courtney Goodman; and a host of other friends and relatives.

Ashton joined the Air Force in 2006, following her graduation from Indianapolis's Warren Central High School. She served as a driver for the Air Force in Afghanistan, working with the Panshir Provincial Reconstruction Team, a unit that rebuilds roads and schools in Afghanistan. Ashton, who loved animals, was training to be a biologist. In high school, she worked at a local pet store and was active in the Zoo Teen Club, a student group that volunteers at the Indianapolis Zoo. She was also a member of the Japan Club.

While we struggle to express our sorrow over this loss, we can take pride in the example Ashton set as a soldier. Today and always, she will be remembered by family and friends as a true American hero, and we cherish the legacy of her service and her life.

As I search for words to do justice to this valiant fallen soldier, I recall President Abraham Lincoln's words as he addressed the families of soldiers who died at Gettysburg: ''We cannot dedicate, we cannot consecrate, we cannot hallow this ground. The brave men, living and dead, who struggled here, have consecrated it, far above our poor power to add or detract. The world will little note nor long remember what we say here, but it can never forget what they did here.'' This statement is just as true today as it was nearly 150 years ago, as we can take some measure of solace in knowing that Ashton's heroism and memory will outlive the record of the words here spoken.

It is my sad duty to enter the name of Ashton L. M. Goodman in the official Record of the U.S. Senate for her service to this country and for her profound commitment to freedom, democracy, and peace. I pray that Ashton's family can find comfort in the words of the prophet Isaiah who said, ''He will swallow up death in victory; and the Lord God will wipe away tears from off all faces.''

May God grant strength and peace to those who mourn, and may God be with all of you, as I know He is with Ashton.

NOMINATION OF REGINA McCARTHY

Mr. LAUTENBERG. Mr. President, I rise today to speak in support of Regina McCarthy, President Obama's nominee to be Assistant Administrator of the Environmental Protection Agency for Air and Radiation. Ms. McCarthy has decades of experience administering environmental programs at the state level under both Democratic and Republican administrations. Her qualifications are unquestionable, and her confirmation will help move our country toward a safer environment and a healthier economy.

We are at a critical point in the history of our Nation and indeed our planet. New science appears seemingly every month showing the danger posed by climate change. Already this year, new peer-reviewed studies revealed that the Arctic will likely be ice-free in the summer as early as 2012— not 2050, as predicted by the Nobel Prize-winning Intergovernmental Panel on Climate Change—IPCC—in 2007. Another peer-reviewed study in the Proceedings of the National Academy of Sciences showed that global emissions, if they continue at current rates, would increase global temperatures by 12 degrees Fahrenheit by the end of the century. This is on the extreme high end of temperature projections by the IPCC. Finally, two new studies found that ice melt from Antarctica and Greenland will likely raise sea levels by five to six feet by the end of the century, far above the two feet predicted by the IPCC, which did not consider melting from those two sources.

Regina McCarthy will be on the front lines of our Nation's battle to stabilize the climate. The office she will manage is responsible for improving air quality and reducing the greenhouse gas emissions that cause global warming.

Congress must act quickly to place strong, science-based limits on emissions, and force polluters to pay to clean up the damage they have done to our environment and our health. We must do so in a way that creates jobs, allows businesses and individuals to save money through efficiency, and pulls the country out of this recession and into a clean energy future.

The coal and oil industries are powerful, and are spending billions of dollars fighting the science and fighting any policies that would break their stranglehold on our Nation's energy policy. In the first 3 months of this year alone, the oil and gas industry spent $37.3 million to lobby the Federal Government. That is money that could be going toward cleaning up their operations. Instead it goes toward impeding our progress toward a clean energy jobs bill to stop climate change.

Despite those obstacles, the House has reported legislation out of committee and we are working toward a bill in the Environment and Public Works Committee. However, as Congress works toward comprehensive legislation, our planet cannot afford to wait to begin reducing emissions. That's why President Obama's EPA recently found that greenhouse gases are pollutants under the Clean Air Act. This will allow the EPA to use existing authority to regulate some of the largest sources of greenhouse gases, such as power plants, refineries, and automobiles.

Just as the EPA does not use the Clean Air Act to regulate small sources of air pollution such as residential buildings, churches, or hospitals for pollutants like smog and soot, it will not regulate these sources for greenhouse gases. Our economy grew rapidly as we dramatically reduced emissions of air pollutants under the Clean Air Act, and I am certain we can use the Clean Air Act to reduce greenhouse gases while creating clean energy jobs and reviving our economy.

Ms. McCarthy is supremely qualified to succeed in that task. Throughout her 25 years of experience at the State level, she has proven to be practical and intelligent in her approach to protecting the environment. She most recently served as the commissioner for the Connecticut Department of Environmental Protection—DEP—and was appointed to this post by Republican Governor M. Jodi Rell in December 2004. Prior to serving in this capacity, Ms. McCarthy worked on environmental issues for 20 years at the State and local level in Massachusetts. She served as the deputy secretary of operations for the Massachusetts Office of Commonwealth Development, a ''super Secretariat'' that coordinates policies and programs of that state's environmental, transportation, energy and housing agencies. She was appointed to this position by then-Governor Mitt Romney.

Ms. McCarthy is known for her active role as Connecticut DEP commissioner in promoting the Regional Greenhouse Gas Initiative, RGGI, a cooperative initiative by 10 Northeastern States, including New Jersey, to implement a cap-and-trade program for greenhouse gas emissions from powerplants. That experience will serve her well when she is tasked with implementing the climate legislation that Congress must—and will—pass.

Our planet cannot wait any longer for lower emissions from cars and power plants, American workers cannot wait any longer for clean energy jobs, and our economy cannot wait any longer for the technological innovations and improved efficiency that will lay the groundwork for lasting, sustainable prosperity. Confirming Regina McCarthy will let her get to work cleaning up our environment, and we in the Senate will begin the work of passing a bill that makes polluters pay, creates clean energy jobs, and revives our economy.

SRI LANKA

Mr. FEINGOLD. Mr. President, last month Sri Lanka saw an end to the longstanding military conflict between the Liberation Tigers of Tamil Eelam, the LTTE, and the Sri Lankan Government. In the immediate days that followed the end of fighting, President Mahinda Rajapaksa delivered a speech to his nation's parliament which formally marked the conclusion of an armed conflict that has escalated since January, but stretches back over 26 years.

This tragic war has claimed the lives of over 70,000 Sri Lankans, displaced hundreds of thousands, and seen systematic and brutal atrocities committed by both sides. Over the last 5 months, as the conflict intensified, it drew increasing and unprecedented attention from the international community. Nevertheless, obtaining a clear picture of this conflict, especially the situation of the estimated 290,000 people living in internally displaced persons camps, has been obscured by the Sri Lankan Government's severe restrictions on access for media, international observers, and humanitarian aid workers. If we are to see a sustainable solution to this conflict over the long term, it is vital that the Sri Lankan Government remove these restrictions now and allow access to all independent actors.

I was pleased that President Rajapaksa acknowledged that Sri Lanka must not accept a military solution as the ultimate solution. As we have seen in conflicts around the world, a military ceasefire will not hold if the underlying causes that led to this conflict are not addressed. The fundamental grievances of the Tamil minority have been overshadowed, distorted, and in some cases silenced by the severe tactics of the LTTE, who since 1997 have been designated by the United States as a terrorist organization. The LTTE claimed to be the voice of the Tamil people, and yet their commitment to both indiscriminate and targeted violence, as well as reports from the last days of fighting that they used Tamil civilians as human shields, would indicate otherwise. If we are to see legitimate reconciliation in Sri Lanka, the grievances of the Tamil minority must be seen as distinct from the violence of the LTTE and addressed thoroughly and justly.

I urge President Rajapaksa to take steps now to demonstrate a serious commitment to a political solution, the rule of law, and most importantly, to genuinely addressing the needs of the Tamil people. At the same time, in proportion to the passion and effort with which the world's diplomats have demanded peace and respect for civilians throughout this conflict, donor countries must remain actively engaged and dedicated to helping bring about a lasting resolution to this decades-old conflict.

I am especially concerned about issues surrounding resettlement. In the wake of this conflict, land mines line those roads which still exist and cover farmers' fields in northern Sri Lanka. Schools, hospitals, roads, homes, and businesses have been damaged and in some cases completely destroyed. Some 290,000 internally displaced people languish in squalid humanitarian camps the safe and voluntary return of whom must be a top priority for postconflict recovery. The Sri Lankan Government must not shirk its responsibility to help these people return to their homes swiftly and safely. The international community, too, can provide assistance to help these people return home safely or seek other lasting solutions. The U.S. government should join with its international partners to coordinate demining efforts, work with the Sri Lankan government to develop and rebuild infrastructure, and ensure that those who have been displaced are able to reclaim the land that is rightfully theirs.

These events are critical steps in the right direction in a long and complicated history. If we seek to address this conflict comprehensively, we must learn from past setbacks and help identify new opportunities for the people of Sri Lanka. It will not be easy, but on behalf of all the innocent civilians whose lives have been caught in the crossfire of this conflict, we must support this opportunity to finally achieve lasting and long awaited peace in Sri Lanka.

U.N. KENYA REPORT

Mr. FEINGOLD. Mr. President, this week the U.N. Special Rapporteur, Mr. Philip Alston, has released his final report on extrajudicial, summary or arbitrary executions in Kenya. His report states that, despite significant investigative work, no concrete steps have been taken to prosecute perpetrators of the violence after Kenya's December 2007 election. It also finds that both the Sabaot Land Defense Forces—SLDF—and the Kenyan government's security forces engaged in widespread brutality in Mount Elgon, including torture and unlawful killings. These alleged abuses have not been seriously investigated by the police or the military. Finally, the report concludes that the police in Kenya continue to carry out extrajudicial killings and that death squads continue to exist within the police to assassinate high-profile suspected criminals.

The report makes a number of detailed recommendations for how Kenya can address these problems, beginning with the replacement of the existing police commissioner and a clear public order that extrajudicial killings will not be tolerated, then followed by a comprehensive reform of the police. In addition, the report calls for the attorney general to resign and for the Kenyan government to take steps to reduce corruption and incompetence in the judiciary. With regard to the post-election violence, the report calls for the Kenyan government to establish a special tribunal to seek accountability for persons bearing the greatest responsibility for the violence after the elections. And with regard to the killings in Mount Elgon, the report calls on the government to immediately set up an independent commission to investigate human rights abuses, including those committed by the SLDF.

I urge the Obama administration to issue a strong response to the release of the Special Rapporteur's final report and press for the implementation of these recommendations. I was pleased that Assistant Secretary Carson traveled earlier this month to Nairobi as part of his first trip to Africa following his confirmation. He met with government leaders there and delivered a strong message of concern. This was an important step. It must now be followed by concrete actions that both support reforms and press for individuals found guilty of killings and

kleptocracy to be held accountable. To that end, I noted with interest that the President's budget request included increased military assistance for Kenya. Such assistance may be justified, but before we provide it, we need to make sure that steps are being taken by the Kenyan government to investigate past abuses and stop continuing ones. We need to ensure that U.S. taxpayer dollars do not enable a pattern of impunity in Kenya's security forces.

For some time I have worried about the very real possibility that political instability in Kenya could worsen and that armed conflict could return if these underlying rule of law problems are not addressed. That backsliding would be tragic, not least because Kenya is an extremely important country for the stability of the Horn of Africa and east Africa. Moreover, it is a country with vast potential that has been and continues to be a leader on the African continent. The United States, given our longstanding and historic partnership with Kenya must step up to the plate and work to ensure Kenya achieves its full potential. We can begin by ensuring the U.N. Special Rapporteur's report serves as a guide and a catalyst for needed reforms and renewed progress.

REMEMBERING TIANANMEN SQUARE

Mr. KAUFMAN. Mr. President, tomorrow marks 20 years since China's crackdown on democracy advocates in Tiananmen Square that resulted in an estimated 700 deaths of innocent civilians. Unfortunately, this represents a mere estimate of the senseless loss of life because the Chinese government has not been transparent in disclosing what happened at Tiananmen Square, and has actively suppressed reporters, protestors, and medical personnel who may have provided a firsthand account. Twenty years later, this suppression continues in the form of government-led crack downs on New Media sources, such as blogs, Twitter, and social networking sites including Facebook, where state censors target internet service providers in an attempt to control the free flow of information.

As we solemnly mark 20 years since Tiananmen Square, it is critical to highlight the ongoing limitations on human rights and freedom of the press in China. This Tuesday, a column was published in the Washington Post by Dan Southerland, the former China bureau chief, which did just that. I ask unanimous consent that this important editorial be printed in the RECORD.

There being no objection, the material was orderd to be printed in the RECORD, as follows:

TIANANMEN: DAYS TO REMEMBER

Two years ago I met a Chinese student who was entering graduate school in the United States. I told her I had been in Beijing during ''6–4,'' the Chinese shorthand for the massacre of June 4, 1989.

''What are you talking about?'' she asked.

At first I thought she might not have understood my Chinese, but it soon became clear that ''June 4'' meant nothing to her. I probably shouldn't have been surprised.

In the 20 years since that day in 1989 when Chinese troops opened fire on unarmed civilians near Tiananmen Square, Chinese censors have managed to erase all mention of that tragedy from the country's textbooks and state-run media.

But for me, Tiananmen is impossible to forget. As Beijing bureau chief for The Post, I covered the student demonstrations that began in mid-April, tried to track a murky power struggle among top Chinese leaders and managed a small team of young, Chinese-speaking American reporters.

What I remember best was the sudden openness of many Beijing citizens of all professions. They were inspired by throngs of students calling for political reform, media freedom and an end to ''official profiteering.''

People I believed to be Communist Party supporters were suddenly telling me what they really thought. Some who had been silent in the past even debated politics on street corners. In early May, Chinese journalists petitioned for the right to report openly on the Tiananmen protests, which on May 17 swelled to more than a million people marching in the capital. Journalists from all the leading Chinese newspapers, including the People's Daily, the mouthpiece of the Communist Party, joined in. Their slogan was ''Don't force us to lie.''

For a brief period, Chinese journalists were allowed to report objectively on the student protests. But this press freedom was short-lived and ended May 20 with the imposition of martial law and the entry of the People's Liberation Army into Beijing.

At first, Beijing residents manning makeshift barriers blocked the troops. But late on the evening of June 3, tanks, armored personnel carriers and soldiers firing automatic weapons broke through to the square.

The death toll quickly became a taboo subject for Chinese media.

Chinese doctors and nurses who had openly sided with students on the square, and who had allowed reporters into operating rooms to view the wounded, came under pressure to conceal casualty figures.

One brave doctor at a hospital not far from Tiananmen Square led me and a colleague to a makeshift morgue, where we saw some 20 bullet-riddled bodies laid out on a cement floor. I later learned that the doctor was ''disciplined'' for allowing us to view that scene.

A Chinese journalist I considered a friend tried to convince me that government estimates of fewer than 300 killed were correct and that these included a large number of military and police casualties. I later learned from colleagues of his that this journalist was working for state security.

After comparing notes with others, my guess was that the actual death toll was at least 700, and that most of those killed were ordinary Beijing residents.

It's almost incredible that the Chinese government has succeeded for so long in covering up a tragedy of this magnitude.

But for those who closely monitor the continued repression of civil liberties in China—and the government's stranglehold on news deemed ''sensitive''—it's not surprising.

Chinese authorities continue to intimidate reporters, block Web sites and jam broadcasts of outside news organizations. China is the world's leading jailer of journalists and cyber-dissidents. Chinese youths are among the most Web-savvy in the world. But Chinese search engines, chat and blog applications, as well as Internet service providers, are equipped with filters that block out certain keywords incorporated in a blacklist that is continually updated.

China's censorship is multipronged, sometimes heavy-handed and sometimes sophisticated, allowing debate on some issues and shutting it down on others, such as Tiananmen.

Censors hold online service providers and Internet cafe owners responsible for the content that users read and post. A small blogging service will usually err on the side of caution rather than lose its license because of a debate about June 4.

Lines that cannot be crossed shift from time to time, leaving citizens uncertain and therefore prone to self-censorship.

The good news is that the blackout isn't complete. We know from Radio Free Asia's call-in shows that some younger Chinese know just enough about Tiananmen to want to learn more. I work with several Chinese broadcasters who were students in Beijing on June 4. Many of them saw more than I did. And they are here to remind me—and many Chinese—of a history we should never forget.

ADDITIONAL STATEMENTS

COMMENDING LUCIA MOCZ

• Mr. AKAKA. Mr. President, I congratulate Mililani High School senior Lucia Mocz for winning the third place Addiction Science Award at this year's Intel International Science and Engineering Fair, ISEF. With over 1,500 students participating from more than 50 countries, the Intel ISEF is the world's largest science competition for high school students. The awards were presented by the National Institute on Drug Abuse—NIDA—at a ceremony on May 14, 2009.

I wish to acknowledge Lucia's technical skill, innovation, and creativity in creating her winning project. Lucia's computer science project, ''Complex Evaluation of Danger and Tranquility in Urban Settings: An Immunocomputing Intelligence Approach,'' used an artificial intelligence algorithm to generate highly detailed maps correlating indicators of danger and tranquility in the urban region of her hometown. While there are medical and behavioral science awards given by various public and private agencies, this is the first series of awards given exclusively for projects that advance addiction science.

However, this young woman could not have achieved what she has done without the additional support and knowledge of science and social issues provided by her teachers. I commend the teachers at Mililani High School, who played a role in Lucia's success. Their dedication to instructing, nourishing and inspiring the next generation of professionals is exemplary. Her family is recognized as well for their commitment, sacrifice, and support that all helped to encourage and instill the important values that led to her award.

I would also like to note NIDA Director Dr. Nora D. Volkow's comments that ''our judges recognized a provocative strategy that could one day help

us better understand how the built environment relates to patterns of drug abuse . . . This approach nicely mirrors the multidimensionality of the many factors known to influence the risk and consequences of drug abuse in our communities.''

I encourage Lucia to continue to study and follow her passions for applied science and social issues. I wish nothing but the best for the her and her family and wish her continued success as she faces the challenges of college and beyond.●

COMMENDING DR. NANCY ZIMPHER

● Mr. BROWN. Mr. President, today I honor the accomplishments of Dr. Nancy Zimpher, president of the University of Cincinnati. For the last 5 years, Dr. Zimpher has served the university, its students, and the Cincinnati community, and she will soon leave to become the chancellor of the State University of New York.

An Ohio native, President Zimpher earned her academic credentials at the Ohio State University and has devoted her professional life to improving higher education for America's young people. In 2003, she became the 25th president, and the first woman to lead the University of Cincinnati. Shortly after her arrival, UC embarked on a comprehensive strategic plan to transform the University of Cincinnati into one of the nation's top research universities. Dr. Zimpher's work resulted in a significant increase in the graduation rate along with nearly a 10-percent increase in university enrollment.

During her tenure at UC, President Zimpher has been highly engaged on the national and regional level regarding education policy. As chair of the Coalition of Urban Serving Universities, Dr. Zimpher was heavily involved in issues surrounding the reauthorization of the Higher Education Act and was a strong advocate for issues facing urban research universities.

I have had the opportunity to work closely with Dr. Zimpher on issues relating to workforce development. Dr. Zimpher served on the host committee of our inaugural Ohio College Presidents' Conference, where she was instrumental in forming partnerships between universities and employers. One of Dr. Zimpher's greatest achievements at UC was the founding of Strive, a Cincinnati-northern Kentucky collaborative focused on college access and success. This partnership involves higher education institutions in the Cincinnati region, urban P–12 school districts in Cincinnati and northern Kentucky, as well as business, civic, and nonprofit organizations. As President Obama has recognized through the creation of the Promise Neighborhoods initiative, these types of partnerships are essential to the health of urban communities like Cincinnati.

The State of Ohio, the city of Cincinnati, and the university are grateful to President Zimpher for her service. I am confident the university will continue to grow and increase in national stature because of her hard work and leadership. I wish her the best in her new position at SUNY and I know that we will continue to work together in the future.●

MESSAGES FROM THE PRESIDENT

Messages from the President of the United States were communicated to the Senate by Mrs. Neiman, one of his secretaries.

EXECUTIVE MESSAGES REFERRED

As in executive session the Presiding Officer laid before the Senate messages from the President of the United States submitting sundry nominations which were referred to the appropriate committees.

(The nominations received today are printed at the end of the Senate proceedings.)

MESSAGE FROM THE HOUSE

At 4:06 p.m., a message from the House of Representatives, delivered by Mrs. Cole, one of its reading clerks, announced that the House has passed the following bills and joint resolution, in which it requests the concurrence of the Senate:

H.R. 325. An act to amend the Reclamation Wastewater and Groundwater Study and Facilities Act to authorize the Secretary of the Interior to participate in the Avra/Black Wash Reclamation and Riparian Restoration Project.

H.R. 689. An act to interchange the administrative jurisdiction of certain Federal lands between the Forest Service and the Bureau of Land Management, and for other purposes.

H.R. 1120. An act to amend the Reclamation Wastewater and Groundwater Study and Facilities Act to authorize the Secretary of the Interior to participate in the Central Texas Water Recycling and Reuse Project, and for other purposes.

H.R. 1280. An act to modify a land grant patent issued by the Secretary of the Interior.

H.R. 1380. An act to establish a grant program for automated external defibrillators in elementary and secondary schools.

H.R. 1393. An act to amend the Lower Rio Grande Valley Water Resources Conservation and Improvement Act of 2000 to authorize additional projects and activities under that Act, and for other purposes.

H.R. 1662. An act to amend the Child Care and Development Block Grant Act of 1990 to require child care providers to provide to parents information regarding whether such providers carry current liability insurance.

H.R. 2330. An act to direct the Secretary of the Interior to carry out a study to determine the suitability and feasibility of establishing Camp Hale as a unit of the National Park System.

H.R. 2430. An act to direct the Secretary of the Interior to continue stocking fish in certain lakes in the North Cascades National Park, Ross Lake National Recreation Area, and Lake Chelan National Recreation Area.

H. J. Res. 40. Joint resolution to honor the achievements and contributions of Native Americans to the United States, and for other purposes.

MEASURES REFERRED

The following bills were read the first and the second times by unanimous consent, and referred as indicated:

H.R. 325. An act to amend the Reclamation Wastewater and Groundwater Study and Facilities Act to authorize the Secretary of the Interior to participate in the Avra Black Wash Reclamation and Riparian Restoration Project; to the Committee on Energy and Natural Resources.

H.R. 689. An act to interchange the administrative jurisdiction of certain Federal lands between the Forest Service and the Bureau of Land Management, and for other purposes; to the Committee on Energy and Natural Resources.

H.R. 1120. An act to amend the Reclamation Wastewater and Groundwater Study and Facilities Act to authorize the Secretary of the Interior to participate in the Central Texas Water Recycling and Reuse Project, and for other purposes; to the Committee on Energy and Natural Resources.

H.R. 1280. An act to modify a land grant patent issued by the Secretary of the Interior; to the Committee on Energy and Natural Resources.

H.R. 1380. An act to establish a grant program for automated external defibrillators in elementary and secondary schools; to the Committee on Health, Education, Labor, and Pensions.

H.R. 1393. An act to amend the Lower Rio Grande Valley Water Resources Conservation and Improvement Act of 2000 to authorize additional projects and activities under that Act, and for other purposes; to the Committee on Energy and Natural Resources.

H.R. 1662. An act to amend the Child Care and Development Block Grant Act of 1990 to require child care providers to provide to parents information regarding whether such providers carry current liability insurance; to the Committee on Health, Education, Labor, and Pensions.

H.R. 2330. An act to direct the Secretary of the Interior to carry out a study to determine the suitability and feasibility of establishing Camp Hale as a unit of the National Park System; to the Committee on Energy and Natural Resources.

H.R. 2430. An act to direct the Secretary of the Interior to continue stocking fish in certain lakes in the North Cascades National Park, Ross Lake National Recreation Area, and Lake Chelan National Recreation Area; to the Committee on Energy and Natural Resources.

MEASURES DISCHARGED

The following bill was discharged from the Committee on Commerce, Science, and Transportation by unanimous consent, and referred as indicated:

S. 1144. A bill to improve transit services; including in rural States; to the Committee on Banking, Housing, and Urban Affairs.

EXECUTIVE AND OTHER COMMUNICATIONS

The following communications were laid before the Senate, together with accompanying papers, reports, and documents, and were referred as indicated:

EC–1754. A communication from the Chief of Publications and Regulations, Internal

Revenue Service, Department of the Treasury, transmitting, pursuant to law, the report of a rule entitled ''Guidance Necessary to Facilitate Business Election Filing; Finalizing Controlled Group Qualification Rules'' ((RIN1545–BF25)(TD 9451)) received in the Office of the President of the Senate on May 27, 2009; to the Committee on Finance.

EC–1755. A communication from the Chief of Publications and Regulations Branch, Internal Revenue Service, Department of the Treasury, transmitting, pursuant to law, the report of a rule entitled ''Application of Sections 7702 and 7702A to Life Insurance Contracts that Mature after Age 100'' (Notice 2009–47) received in the Office of the President of the Senate on May 27, 2009; to the Committee on Finance.

EC–1756. A communication from the Chief of Publications and Regulations, Internal Revenue Service, Department of Treasury, transmitting, pursuant to law, the report of a rule entitled ''Tier 1 Issue—Section 965 Foreign Earnings Repatriation Directive #3'' (LMSB–4–0409–017) received in the Office of the President of the Senate on May 27, 2009; to the Committee on Finance.

EC–1757. A communication from the Chief of Publications and Regulations, Internal Revenue Service, Department of the Treasury, transmitting, pursuant to law, the report of a rule entitled ''Section 42.—Low-Income Housing Credit'' (Notice 2009–44) received in the Office of the President of the Senate on May 27, 2009; to the Committee on Finance.

EC–1758. A communication from the Chief of Publications and Regulations, Internal Revenue Service, Department of the Treasury, transmitting, pursuant to law, the report of a rule entitled ''Treatment of Certain Employer-Owned Life Insurance Contracts'' (Notice 2009–48) received in the Office of the President of the Senate on May 27, 2009; to the Committee on Finance.

EC–1759. A communication from the Chief of Publications and Regulations, Internal Revenue Service, Department of the Treasury, transmitting, pursuant to law, the report of a rule entitled ''Tier 1 Issue—International Hybrid Instrument Transactions'' (LMSB–4–0509–122) received in the Office of the President of the Senate on May 27, 2009; to the Committee on Finance.

EC–1760. A communication from the Assistant General Counsel of the Division of Regulatory Services, Office of Postsecondary Education, Department of Education, transmitting, pursuant to law, the report of a rule entitled ''Interim Final Regulations—Student Assistance General Provisions; Teacher Education Assistance for College and Higher Education (TEACH) Grant Program; Federal Pell Grant Program; Academic Competitiveness Grant Program and National Science and Mathematics Access to Retain Talent Grant Program'' (RIN1840–AC96) received in the Office of the President of the Senate on May 26, 2009; to the Committee on Health, Education, Labor, and Pensions.

EC–1761. A communication submitted jointly by the Chairman and the General Counsel, National Labor Relations Board, transmitting, pursuant to law, the Semi-Annual Report of the Inspector General for the period from October 1, 2008 through March 31, 2009; to the Committee on Homeland Security and Governmental Affairs.

EC–1762. A communication from the Acting Administrator, General Services Administration transmitting, pursuant to law, the Semi-Annual Report of the Inspector General for the period from October 1, 2008 through March 31, 2009; to the Committee on Homeland Security and Governmental Affairs.

EC–1763. A communication from the Secretary, Federal Maritime Commission, transmitting, pursuant to law, the Semi-Annual Report of the Inspector General for the period from October 1, 2008 through March 31, 2009; to the Committee on Homeland Security and Governmental Affairs.

EC–1764. A communication from the Secretary of Energy, transmitting, pursuant to law, the Semi-Annual Report of the Inspector General for the period from October 1, 2008 through March 31, 2009; to the Committee on Homeland Security and Governmental Affairs.

EC–1765. A communication from the Administrator, Environmental Protection Agency, transmitting, pursuant to law, the Semi-Annual Report of the Inspector General for the period from October 1, 2008 through March 31, 2009; to the Committee on Homeland Security and Governmental Affairs.

EC–1766. A communication from the Chairman, National Credit Union Administration, transmitting, pursuant to law, the Semi-Annual Report of the Inspector General for the period from October 1, 2008 through March 31, 2009; to the Committee on Homeland Security and Governmental Affairs.

EC–1767. A communication from the Director of Legislative Affairs, Office of the Director of National Intelligence, transmitting, pursuant to law, a report relative to action on a nomination for the position of Associate Director of National Intelligence and Chief Information Officer, received in the Office of the President of the Senate on May 27, 2009; to the Select Committee on Intelligence.

EC–1768. A communication from the Staff Director, U.S. Commission on Civil Rights, transmitting, pursuant to law, a report relative to the Commission's recent appointment of members to the Connecticut Advisory Committee; to the Committee on the Judiciary.

EC–1769. A communication from the Assistant Secretary, Bureau of Legislative Affairs, Department of State, transmitting, pursuant to the Arms Export Control Act, the certification of a manufacturing license agreement for the export of technical data, defense services, and defense articles for the manufacture and support of the S–70B(SH–60J/K) Helicopters, parts and support equipment in the amount of $100,000,000 or more with Japan; to the Committee on Foreign Relations.

EC–1770. A communication from the Assistant Secretary, Bureau of Legislative Affairs, Department of State, transmitting, pursuant to the Arms Export Control Act, the certification of a proposed manufacturing license agreement for the export of technical data, defense services, and defense articles for the manufacture of the AN/APG–63(V)1 Radar System Retrofit Kits in the amount of $100,000,000 or more with Japan; to the Committee on Foreign Relations.

EC–1771. A communication from the Assistant Secretary, Bureau of Legislative Affairs, Department of State, transmitting, pursuant to the Arms Export Control Act, the certification of a proposed manufacturing license agreement for the export of technical data, defense services, and defense articles for the manufacture and support of the S–70A(UH–60J) Helicopters, parts and support equipment in the amount of $100,000,000 or more with Japan; to the Committee on Foreign Relations.

EC–1772. A communication from the Assistant Secretary, Bureau of Legislative Affairs, Department of State, transmitting, pursuant to the Arms Export Control Act, the certification of a proposed license agreement for the export of defense articles and defense services in the amount of $50,000,000 or more with the United Kingdom, Germany, Netherlands, Sweden, Luxembourg, Belgium, France, and Kazakhstan; to the Committee on Foreign Relations.

EC–1773. A communication from the Assistant Secretary, Bureau of Legislative Affairs, Department of State, transmitting, pursuant to the Arms Export Control Act, the certification of a proposed manufacturing license agreement for the export of technical data, defense services, and defense articles in the amount of $50,000,000 or more with Canada; to the Committee on Foreign Relations.

EC–1774. A communication from the Assistant Secretary, Bureau of Legislative Affairs, Department of State, transmitting, pursuant to the Arms Export Control Act, the certification of a proposed manufacturing license agreement for the manufacture of significant military equipment abroad and the export of defense services and defense articles in the amount of $50,000,000 or more with Mexico; to the Committee on Foreign Relations.

EC–1775. A communication from the Assistant Secretary, Bureau of Legislative Affairs, Department of State, transmitting, pursuant to the Arms Export Control Act, the certification of a proposed technical assistance agreement for the export of technical data, and defense services articles in the amount of $50,000,000 or more with Mexico; to the Committee on Foreign Relations.

EC–1776. A communication from the Assistant Secretary, Bureau of Legislative Affairs, Department of State, transmitting, pursuant to the Arms Export Control Act, the certification of a proposed technical assistance agreement for the export of technical data, defense services, and defense articles in the amount of $50,000,000 or more with the United Kingdom, Russia, Germany, Netherlands, Sweden, Luxembourg, Belgium, France, and Kazakhstan; to the Committee on Foreign Relations.

EC–1777. A communication from the Assistant Secretary, Bureau of Legislative Affairs, Department of State, transmitting, pursuant to the Arms Export Control Act, the certification of a proposed manufacturing license agreement for the manufacture of significant military equipment abroad and the export of technical data, defense services, and defense articles in the amount of $50,000,000 or more with the United Arab Emirates; to the Committee on Foreign Relations.

EC–1778. A communication from the Assistant Secretary, Bureau of Legislative Affairs, Department of State, transmitting, pursuant to the Arms Export Control Act, the certification of a proposed technical assistance agreement for the export of technical data, defense services, and defense articles in the amount of $50,000,000 or more with Iraq, the United Kingdom, the United Arab Emirates; to the Committee on Foreign Relations.

EC–1779. A communication from the Assistant Secretary, Bureau of Legislative Affairs, Department of State, transmitting, pursuant to the Arms Export Control Act, the certification of a proposed manufacturing license agreement for the manufacture of significant military equipment abroad with Mexico; to the Committee on Foreign Relations.

EC–1780. A communication from the Assistant Secretary, Bureau of Legislative Affairs, Department of State, transmitting, pursuant to the Arms Export Control Act, the certification of a proposed manufacturing license agreement for the manufacture of significant military equipment abroad with Israel; to the Committee on Foreign Relations.

EC–1781. A communication from the Assistant Secretary, Bureau of Legislative Affairs, Department of State, transmitting, pursuant to the Arms Export Control Act, the certification of a proposed manufacturing license agreement for the manufacture of significant military equipment abroad with Japan; to the Committee on Foreign Relations.

EC–1782. A communication from the Assistant Secretary, Legislative Affairs, Department of State, transmitting, pursuant to

law, a report relative to provisions of Section 7072 of the Foreign Operations, and Related Programs Appropriations Act, 2009, as they relate to restrictions on assistance to the central government of Serbia; to the Committee on Foreign Relations.

EC–1783. A communication from the Assistant Secretary, Legislative Affairs, Department of State, transmitting, pursuant to law, a report relative to the status of the Government of Cuba's compliance with the United States-Cuba September 1994 ''Joint Communique'' and on the treatment of persons returned to Cuba in accordance with the United States-Cuba May 1995 ''Joint Statement''; to the Committee on Foreign Relations.

EC–1784. A communication from the Assistant Secretary, Legislative Affairs, Department of State, transmitting, pursuant to law, a report relative to Suspending Prohibitions on Certain Sales and Leases Under the Anti-Economic Discrimination Act of 1994 with regards to Kuwait, Lebanon, Libya, Qatar, Saudi Arabia, the United Arab Emirates, and Yemen; to the Committee on Foreign Relations.

EC–1785. A communication from the Assistant Legal Adviser for Treaty Affairs, Department of State, transmitting, pursuant to the Case-Zablocki Act, 1 U.S.C. 112b, as amended, the report of the texts and background statements of international agreements, other than treaties (List 2009–0068—2009–0073); to the Committee on Foreign Relations.

EC–1786. A communication from the Deputy Assistant Administrator of Diversion Control, Drug Enforcement Administration, Department of Justice, transmitting, pursuant to law, the report of a rule entitled ''Schedules of Controlled Substances: Placement of Lacosamide into Schedule V'' (Docket Number DEA–325) received in the Office of the President of the Senate on June 3, 2009; to the Committee on the Judiciary.

INTRODUCTION OF BILLS AND JOINT RESOLUTIONS

The following bills and joint resolutions were introduced, read the first and second times by unanimous consent, and referred as indicated:

By Mr. REID:

S. 1166. A bill to amend the Internal Revenue Code of 1986 to allow taxpayers to designate part or all of any income tax refund to support reservists and National Guard members; to the Committee on Finance.

By Mr. THUNE (for himself, Mr. VITTER, Mr. BROWNBACK, Mr. ROBERTS, and Mr. INHOFE):

S. 1167. A bill to require that the Federal Government procure from the private sector the goods and services necessary for the operations and management of certain Government agencies, and for other purposes; to the Committee on Homeland Security and Governmental Affairs.

By Mr. SCHUMER:

S. 1168. A bill to authorize the acquisition and protection of nationally significant battlefields and associated sites of the Revolutionary War and the War of 1812 under the American Battlefield Protection Program; to the Committee on Energy and Natural Resources.

By Mrs. GILLIBRAND (for herself, Ms. COLLINS, Mr. CARDIN, Mr. SANDERS, Mr. BROWNBACK, and Mr. SPECTER):

S. 1169. A bill to amend title 10, United States Code, to provide for the treatment of autism under TRICARE; to the Committee on Armed Services.

By Ms. MURKOWSKI:

S. 1170. A bill to improve aviation safety in Alaska, and for other purposes; to the Committee on Commerce, Science, and Transportation.

By Mr. PRYOR (for himself, Mr. BROWNBACK, Mr. BAYH, Mr. ISAKSON, Mr. CHAMBLISS, Mr. LUGAR, and Mr. INHOFE):

S. 1171. A bill to amend title XVIII of the Social Security Act to restore State authority to waive the 35-mile rule for designating critical access hospitals under the Medicare Program; to the Committee on Finance.

By Mr. BROWN:

S. 1172. A bill to direct the Secretary of Energy to establish a grant program to facilitate the production of clean, renewable energy from municipal solid waste, and for other purposes; to the Committee on Energy and Natural Resources.

By Mr. FEINGOLD:

S. 1173. A bill to establish a demonstration project to train unemployed workers for employment as health care professionals, and for other purposes; to the Committee on Health, Education, Labor, and Pensions .

By Ms. CANTWELL (for herself, Ms. COLLINS, and Mr. WHITEHOUSE):

S. 1174. A bill to amend the Public Health Service Act and the Social Security Act to increase the number of primary care physicians and primary care providers and to improve patient access to primary care services, and for other services; to the Committee on Finance.

By Ms. CANTWELL:

S. 1175. A bill to amend the Public Utility Regulatory Policies Act of 1978 to authorize the Secretary of Energy to make loans to electric utilities to carry out projects to comply with any Federal renewable electricity standard, and for other purposes; to the Committee on Energy and Natural Resources.

By Ms. CANTWELL:

S. 1176. A bill to amend the Public Health Service Act to promote and improve the allied health professionals; to the Committee on Health, Education, Labor, and Pensions.

By Mr. KOHL (for himself and Mr. WYDEN):

S. 1177. A bill to improve consumer protections for purchasers of long-term care insurance, and for other purposes; to the Committee on Finance.

By Mr. WEBB (for himself and Mr. WARNER):

S. 1178. A bill to extend Federal recognition to the Chickahominy Indian Tribe, the Chickahominy Indian Tribe-Eastern Division, the Upper Mattaponi Tribe, the Rappahannock Tribe, Inc., the Monacan Indian Nation, and the Nansemond Indian Tribe; to the Committee on Indian Affairs.

SUBMISSION OF CONCURRENT AND SENATE RESOLUTIONS

The following concurrent resolutions and Senate resolutions were read, and referred (or acted upon), as indicated:

By Mr. INHOFE (for himself, Mr. BROWN, Mr. GRAHAM, Mr. KYL, Mr. MENENDEZ, Mr. VITTER, Mr. LIEBERMAN, Mr. COBURN, and Mr. WEBB):

S. Res. 167. A bill commending the people who have sacrificed their personal freedoms to bring about democratic change in the People's Republic of China and expressing sympathy for the families of the people who were killed, wounded, or imprisoned, on the occasion of the 20th anniversary of the Tiananmen Square Massacre in Beijing, China from June 3 through 4, 1989; to the Committee on Foreign Relations.

ADDITIONAL COSPONSORS

S. 144

At the request of Mr. KERRY, the names of the Senator from Nebraska (Mr. NELSON), the Senator from Missouri (Mr. BOND) and the Senator from Indiana (Mr. BAYH) were added as cosponsors of S. 144, a bill to amend the Internal Revenue Code of 1986 to remove cell phones from listed property under section 280F.

S. 424

At the request of Mr. LEAHY, the name of the Senator from Illinois (Mr. DURBIN) was added as a cosponsor of S. 424, a bill to amend the Immigration and Nationality Act to eliminate discrimination in the immigration laws by permitting permanent partners of United States citizens and lawful permanent residents to obtain lawful permanent resident status in the same manner as spouses of citizens and lawful permanent residents and to penalize immigration fraud in connection with permanent partnerships.

S. 451

At the request of Ms. COLLINS, the names of the Senator from South Dakota (Mr. JOHNSON), the Senator from Mississippi (Mr. COCHRAN), the Senator from Nevada (Mr. ENSIGN) and the Senator from Alaska (Mr. BEGICH) were added as cosponsors of S. 451, a bill to require the Secretary of the Treasury to mint coins in commemoration of the centennial of the establishment of the Girl Scouts of the United States of America.

S. 461

At the request of Mrs. LINCOLN, the names of the Senator from Iowa (Mr. HARKIN) and the Senator from California (Mrs. BOXER) were added as cosponsors of S. 461, a bill to amend the Internal Revenue Code of 1986 to extend and modify the railroad track maintenance credit.

S. 491

At the request of Mr. WEBB, the name of the Senator from Maryland (Ms. MIKULSKI) was added as a cosponsor of S. 491, a bill to amend the Internal Revenue Code of 1986 to allow Federal civilian and military retirees to pay health insurance premiums on a pretax basis and to allow a deduction for TRICARE supplemental premiums.

S. 535

At the request of Mr. NELSON of Florida, the name of the Senator from Washington (Mrs. MURRAY) was added as a cosponsor of S. 535, a bill to amend title 10, United States Code, to repeal requirement for reduction of survivor annuities under the Survivor Benefit Plan by veterans' dependency and indemnity compensation, and for other purposes.

S. 546

At the request of Mr. REID, the names of the Senator from California (Mrs. FEINSTEIN) and the Senator from Colorado (Mr. UDALL) were added as cosponsors of S. 546, a bill to amend title 10, United States Code, to permit certain retired members of the uniformed

services who have a service-connected disability to receive both disability compensation from the Department of Veterans Affairs for their disability and either retired pay by reason of their years of military service or Combat-Related Special Compensation.

S. 565

At the request of Mr. DURBIN, the name of the Senator from Maine (Ms. COLLINS) was added as a cosponsor of S. 565, a bill to amend title XVIII of the Social Security Act to provide continued entitlement to coverage for immunosuppressive drugs furnished to beneficiaries under the Medicare Program that have received a kidney transplant and whose entitlement to coverage would otherwise expire, and for other purposes.

S. 581

At the request of Mr. BENNET, the name of the Senator from Maryland (Mr. CARDIN) was added as a cosponsor of S. 581, a bill to amend the Richard B. Russell National School Lunch Act and the Child Nutrition Act of 1966 to require the exclusion of combat pay from income for purposes of determining eligibility for child nutrition programs and the special supplemental nutrition program for women, infants, and children.

S. 614

At the request of Mrs. HUTCHISON, the name of the Senator from Pennsylvania (Mr. CASEY) was added as a cosponsor of S. 614, a bill to award a Congressional Gold Medal to the Women Airforce Service Pilots (''WASP'').

S. 645

At the request of Mrs. LINCOLN, the name of the Senator from Colorado (Mr. UDALL) was added as a cosponsor of S. 645, a bill to amend title 32, United States Code, to modify the Department of Defense share of expenses under the National Guard Youth Challenge Program.

S. 663

At the request of Mr. NELSON of Nebraska, the names of the Senator from Florida (Mr. MARTINEZ) and the Senator from Rhode Island (Mr. REED) were added as cosponsors of S. 663, a bill to amend title 38, United States Code, to direct the Secretary of Veterans Affairs to establish the Merchant Mariner Equity Compensation Fund to provide benefits to certain individuals who served in the United States merchant marine (including the Army Transport Service and the Naval Transport Service) during World War II.

S. 718

At the request of Mr. HARKIN, the name of the Senator from Vermont (Mr. SANDERS) was added as a cosponsor of S. 718, a bill to amend the Legal Services Corporation Act to meet special needs of eligible clients, provide for technology grants, improve corporate practices of the Legal Services Corporation, and for other purposes.

S. 769

At the request of Mrs. LINCOLN, the name of the Senator from Montana (Mr. TESTER) was added as a cosponsor of S. 769, a bill to amend title XVIII of the Social Security Act to improve access to, and increase utilization of, bone mass measurement benefits under the Medicare part B program.

S. 812

At the request of Mr. BAUCUS, the names of the Senator from North Carolina (Mr. BURR) and the Senator from Georgia (Mr. ISAKSON) were added as cosponsors of S. 812, a bill to amend the Internal Revenue Code of 1986 to make permanent the special rule for contributions of qualified conservation contributions.

At the request of Mr. THUNE, his name was added as a cosponsor of S. 812, supra.

S. 823

At the request of Ms. SNOWE, the name of the Senator from Idaho (Mr. RISCH) was added as a cosponsor of S. 823, a bill to amend the Internal Revenue Code of 1986 to allow a 5-year carryback of operating losses, and for other purposes.

S. 832

At the request of Mr. NELSON of Florida, the name of the Senator from Maine (Ms. SNOWE) was added as a cosponsor of S. 832, a bill to amend title 36, United States Code, to grant a Federal charter to the Military Officers Association of America, and for other purposes.

S. 837

At the request of Mr. BROWNBACK, the name of the Senator from Missouri (Mr. BOND) was added as a cosponsor of S. 837, a bill to require that North Korea be listed as a state sponsor of terrorism, to ensure that human rights is a prominent issue in negotiations between the United States and North Korea, and for other purposes.

S. 891

At the request of Mr. BROWNBACK, the name of the Senator from Maryland (Mr. CARDIN) was added as a cosponsor of S. 891, a bill to require annual disclosure to the Securities and Exchange Commission of activities involving columbite-tantalite, cassiterite, and wolframite from the Democratic Republic of Congo, and for other purposes.

S. 934

At the request of Mr. HARKIN, the names of the Senator from Hawaii (Mr. INOUYE), the Senator from Michigan (Mr. LEVIN), the Senator from North Dakota (Mr. DORGAN), the Senator from Vermont (Mr. SANDERS), the Senator from Wisconsin (Mr. FEINGOLD), the Senator from Massachusetts (Mr. KERRY) and the Senator from Delaware (Mr. CARPER) were added as cosponsors of S. 934, a bill to amend the Child Nutrition Act of 1966 to improve the nutrition and health of schoolchildren and protect the Federal investment in the national school lunch and breakfast programs by updating the national school nutrition standards for foods and beverages sold outside of school meals to conform to current nutrition science.

S. 950

At the request of Mrs. LINCOLN, the name of the Senator from Hawaii (Mr. INOUYE) was added as a cosponsor of S. 950, a bill to amend title XVIII of the Social Security Act to authorize physical therapists to evaluate and treat Medicare beneficiaries without a requirement for a physician referral, and for other purposes.

S. 982

At the request of Mr. SPECTER, his name was added as a cosponsor of S. 982, a bill to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products.

S. 1023

At the request of Mr. DORGAN, the names of the Senator from South Dakota (Mr. JOHNSON) and the Senator from South Carolina (Mr. GRAHAM) were added as cosponsors of S. 1023, a bill to establish a non-profit corporation to communicate United States entry policies and otherwise promote leisure, business, and scholarly travel to the United States.

S. 1026

At the request of Mr. CORNYN, the names of the Senator from Oklahoma (Mr. COBURN), the Senator from Kansas (Mr. BROWNBACK), the Senator from Georgia (Mr. ISAKSON) and the Senator from Connecticut (Mr. LIEBERMAN) were added as cosponsors of S. 1026, a bill to amend the Uniformed and Overseas Citizens Absentee Voting Act to improve procedures for the collection and delivery of marked absentee ballots of absent overseas uniformed service voters, and for other purposes.

S. 1048

At the request of Mr. HARKIN, the name of the Senator from Illinois (Mr. BURRIS) was added as a cosponsor of S. 1048, a bill to amend the Federal Food, Drug, and Cosmetic Act to extend the food labeling requirements of the Nutrition Labeling and Education Act of 1990 to enable customers to make informed choices about the nutritional content of standard menu items in large chain restaurants.

S. 1064

At the request of Mr. LIEBERMAN, the name of the Senator from Wisconsin (Mr. FEINGOLD) was added as a cosponsor of S. 1064, a bill to amend the American Recovery and Reinvestment Act of 2009 to provide for enhanced State and local oversight of activities conducted under such Act, and for other purposes.

S. 1066

At the request of Mr. SCHUMER, the name of the Senator from Montana (Mr. TESTER) was added as a cosponsor of S. 1066, a bill to amend title XVIII of the Social Security Act to preserve access to ambulance services under the Medicare program.

S. 1067

At the request of Mr. FEINGOLD, the name of the Senator from Maryland (Mr. CARDIN) was added as a cosponsor

of S. 1067, a bill to support stabilization and lasting peace in northern Uganda and areas affected by the Lord's Resistance Army through development of a regional strategy to support multilateral efforts to successfully protect civilians and eliminate the threat posed by the Lord's Resistance Army and to authorize funds for humanitarian relief and reconstruction, reconciliation, and transitional justice, and for other purposes.

S. 1076

At the request of Mr. MENENDEZ, the name of the Senator from Pennsylvania (Mr. CASEY) was added as a cosponsor of S. 1076, a bill to improve the accuracy of fur product labeling, and for other purposes.

S. 1103

At the request of Mr. VITTER, the name of the Senator from Arizona (Mr. KYL) was added as a cosponsor of S. 1103, a bill to amend the Help America Vote Act of 2002 to establish standards for the distribution of voter registration application forms and to require organizations to register with the State prior to the distribution of such forms.

S. 1113

At the request of Mr. PRYOR, the name of the Senator from Louisiana (Mr. VITTER) was added as a cosponsor of S. 1113, a bill to amend title 49, United States Code, to direct the Secretary of Transportation to establish and maintain a national clearinghouse for records related to alcohol and controlled substances testing of commercial motor vehicle operators, and for other purposes.

S. 1121

At the request of Mr. HARKIN, the name of the Senator from Massachusetts (Mr. KENNEDY) was added as a cosponsor of S. 1121, a bill to amend part D of title V of the Elementary and Secondary Education Act of 1965 to provide grants for the repair, renovation, and construction of elementary and secondary schools, including early learning facilities at the elementary schools.

S. 1147

At the request of Mr. KOHL, the names of the Senator from New York (Mrs. GILLIBRAND) and the Senator from New York (Mr. SCHUMER) were added as cosponsors of S. 1147, a bill to prevent tobacco smuggling, to ensure the collection of all tobacco taxes, and for other purposes.

S. 1148

At the request of Mr. GRASSLEY, the names of the Senator from Kansas (Mr. BROWNBACK) and the Senator from Nebraska (Mr. JOHANNS) were added as cosponsors of S. 1148, a bill to amend the Clean Air Act to modify a provision relating to the renewable fuel program.

S. CON. RES. 14

At the request of Mr. BARRASSO, the name of the Senator from Kansas (Mr. ROBERTS) was added as a cosponsor of S. Con. Res. 14, a concurrent resolution supporting the Local Radio Freedom Act.

S. RES. 71

At the request of Mr. WYDEN, the name of the Senator from Maryland (Mr. CARDIN) was added as a cosponsor of S. Res. 71, a resolution condemning the Government of Iran for its state-sponsored persecution of the Baha'i minority in Iran and its continued violation of the International Covenants on Human Rights.

S. RES. 142

At the request of Mr. ENZI, the names of the Senator from Nebraska (Mr. JOHANNS), the Senator from Kansas (Mr. ROBERTS) and the Senator from Idaho (Mr. RISCH) were added as cosponsors of S. Res. 142, a resolution designating July 25, 2009, as ''National Day of the American Cowboy''.

AMENDMENT NO. 1229

At the request of Mr. VITTER, his name was added as a cosponsor of amendment No. 1229 intended to be proposed to H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes.

At the request of Mr. DORGAN, the names of the Senator from Iowa (Mr. GRASSLEY) and the Senator from Wisconsin (Mr. FEINGOLD) were added as cosponsors of amendment No. 1229 intended to be proposed to H.R. 1256, supra.

STATEMENTS ON INTRODUCED BILLS AND JOINT RESOLUTIONS

By Mr. REID:

S. 1166. A bill to amend the Internal Revenue Code of 1986 to allow taxpayers to designate part or all of any income tax refund to support reservists and National Guard members; to the Committee on Finance.

Mr. REID. Mr President, I rise today to introduce legislation to help reduce the financial burden placed on our Reserve and National Guard troops and their families. More than a quarter of a million have deployed in support of operations in Iraq and Afghanistan, and we must make it a priority to honor their service at home.

Nevada alone has more than three thousand Guards men and women, and a thousand Reservists—many of whom work full-time jobs when they are not on active duty. Since September 11th, our National Guard and Reserve Troops have significantly increased their deployments beyond what had been forecasted, advertised or expected. They have continued their engagements around the globe while still responding to historic callouts in support of disaster relief.

In our Democracy, we enjoy the luxury of an all-volunteer military force. Yet in volunteering, many of our Citizen-Soldiers are financially penalized for their service. Far too frequently, when a Service Member is mobilized in service to their state or our nation, they suffer a financial burden in the reduced pay received while mobilized. A National Guard medic might earn much less while he or she is deployed in Afghanistan than they did working a full-time job in a Nevada hospital. This legislation gives American taxpayers the option of contributing money to help our military families to make up for wages lost during a deployment.

The bill I am introducing today allows Americans to designate all or a portion of their income tax refunds to the Reserve Income Replacement Program. The Program is a compensation that must be paid to all eligible Service Members when they incur a loss in monthly income as a result of a mobilization. The funds that volunteers donate will be transferred from the Treasury Department to this program, which was developed specifically to provide payments to eligible members of the National Guard and Reserve who are involuntary serving on active-duty and who are experiencing a monthly active-duty income differential of more than $50. In 2007, the IRS issued 106 million refunds that totaled $246 billion with the average refund coming in at $2,342. Even a small percentage of this amount could make a significant difference in the lives of these reservist and National Guard families.

The financial stress of deployments during a recession has placed enormous pressures on our National Guard and Reserve Service Members and their families. Many of these members are returning from war only to find their businesses facing extreme difficulty. This bill would not only assist the Guard with monetary resources, but it would also rightfully focus more attention on the financial struggles that our brave and dedicated citizen Soldiers and Airmen undertake in defense of our country. With this legislation, we can show them that their service is not taken for granted.

Mr. President, I ask unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the text of the bill was ordered to be printed in the RECORD, as follows:

S. 1166

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Voluntary Support for Reservists and National Guard Members Act''.

SEC. 2. DESIGNATION OF OVERPAYMENTS TO SUPPORT RESERVISTS AND NATIONAL GUARD MEMBERS.

(a) DESIGNATION.—Subchapter A of chapter 61 of the Internal Revenue Code of 1986 is amended by adding at the end the following new part:

''PART IX—DESIGNATION OF OVERPAYMENTS TO RESERVE INCOME REPLACEMENT PROGRAM

''Sec. 6097. Designation.

"SEC. 6097. DESIGNATION.

''(a) IN GENERAL.—In the case of an individual, with respect to each taxpayer's return for the taxable year of the tax imposed by chapter 1, such taxpayer may designate that a specified portion (not less than $5) of any overpayment of tax for such taxable year be paid over to the Reserve Income Replacement Program (RIRP) under section 910 of title 37, United States Code.

''(b) MANNER AND TIME OF DESIGNATION.—A designation under subsection (a) may be made with respect to any taxable year only at the time of filing the return of the tax imposed by chapter 1 for such taxable year. Such designation shall be made in such manner as the Secretary prescribes by regulations except that such designation shall be made either on the first page of the return or on the page bearing the taxpayer's signature.

''(c) OVERPAYMENTS TREATED AS REFUNDED.—For purposes of this title, any portion of an overpayment of tax designated under subsection (a) shall be treated as—

''(1) being refunded to the taxpayer as of the last date prescribed for filing the return of tax imposed by chapter 1 (determined without regard to extensions) or, if later, the date the return is filed, and

''(2) a contribution made by such taxpayer on such date to the United States.''.

(b) TRANSFERS TO RESERVE INCOME REPLACEMENT PROGRAM.—The Secretary of the Treasury shall, from time to time, transfer to the Reserve Income Replacement Program (RIRP) under section 910 of title 37, United States Code, the amounts designated under section 6097 of the Internal Revenue Code of 1986, under regulations jointly prescribed by the Secretary of the Treasury and the Secretary of Defense.

(c) CLERICAL AMENDMENT.—The table of parts for subchapter A of chapter 61 of the Internal Revenue Code of 1986 is amended by adding at the end the following new item:

''PART IX. DESIGNATION OF OVERPAYMENTS TO RESERVE INCOME REPLACEMENT PROGRAM''.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2009.

By Mr. PRYOR (for himself, Mr. BROWNBACK, Mr. BAYH, Mr. ISAKSON, Mr. CHAMBLISS, Mr. LUGAR, and Mr. INHOFE):

S. 1171. A bill to amend title XVIII of the Social Security Act to restore State authority to waive the 35–mile rule for designating critical access hospitals under the Medicare Program; to the Committee on Finance.

Mr. PRYOR. Mr. President, I rise today to introduce legislation with Senators BROWNBACK, BAYH, ISAKSON, and CHAMBLISS. The Critical Access Flexibility Act of 2009 will return to States the flexibility needed to help preserve local hospitals that serve rural communities.

Hospitals are often the largest employers in rural America. They provide much needed jobs and are facing serious financial difficulties during this economic downturn. Without immediate relief, many small hospitals are at serious risk of closure, job loss, or reductions in patient services. Rural areas most often have sicker, older, and poorer populations. In these difficult times, it is crucial that we protect hospitals serving our rural communities.

A Critical Access Hospital, CAH, is a hospital that is certified to receive cost-based reimbursement from Medicare. The reimbursement that CAHs receive is intended to improve their financial performance and thereby reduce hospital closures. CAHs are certified under a different set of Medicare conditions of participation that are more flexible than those used for acute care hospitals. In order for a hospital to be classified as a CAH, it must meet a number of conditions including a distance requirement that it must be 35 miles away from the nearest hospital. Prior to enactment of the 2003 Medicare Modernization Act, MMA, hospitals that were designated as ''necessary providers'' by a State could be exempt from the distance requirement.

I am joining with Senators BROWNBACK, BAYH, and ISAKSON today to introduce legislation that restores a state's authority to waive the mileage requirements if all other requirements are met and the State designates the facility as a necessary provider. Existing requirements that cannot be waived include requiring that CAHs be nonprofit or public hospitals in a rural area, offer 24-hour emergency room services, and have no more than 25 acute care inpatient beds.

There are at least two communities in my State where changing conditions are threatening small town hospitals, and restoring the flexibility for States to make exemptions for the distance requirement would help residents of these communities continue to be able to receive necessary medical care from a local hospital. I know from talking to my colleagues in the Senate and to health care providers that this is the case throughout rural America. In recent years, there have been legislative efforts for single hospitals to be singled out and granted an exemption to the distance requirement. I believe the best way to address this problem is to have a uniform national policy that gives States the flexibility they need.

I want to thank Senators BROWNBACK, BAYH, ISAKSON, and CHAMBLISS for their work, leadership and support on this very important legislation, and I urge the rest of my colleagues to support this effort.

By Mr. FEINGOLD:

S. 1173. A bill to establish a demonstration project to train unemployed workers for employment as health care professionals, and for other purposes; to the Committee on Health, Education, Labor, and Pensions.

Mr. FEINGOLD. Mr. President, today I introduce the Community-Based Health Care Retraining Act, which would amend the Workforce Investment Act to help communities with both significant job losses and shortages in the health care professions create programs to retrain displaced workers for high-demand health care jobs. I have introduced similar legislation in the past to help workers who are displaced from the manufacturing and service sectors.

In light of the state of our economy and the tremendous increase in unemployment across this country, I have tried to broaden the bill to cover workers from all sectors. According to the Department of Labor, in the last year the number of unemployed people in the United States has increased by 6 million. In April alone, private sector employment fell by 539,000, bringing the unemployment rate to 8.9 percent. In my home State of Wisconsin, the unemployment rate is up to 8.8 percent.

In Wisconsin, we have seen the loss of many manufacturing jobs, including at the idled General Motors automobile assembly plant in my hometown of Janesville, and in Kenosha, where Chrysler recently announced that the Kenosha Chrysler plant will cease production in 2010. But these large factories are just the tip of the iceberg. Some small manufacturing businesses are also going out of business in communities around Wisconsin, and others are struggling to survive.

In addition, the economic troubles in the last few years have permeated other industries besides manufacturing, including construction, business, and also the retail industry.

The people in my State are facing tough economic challenges, but they are meeting them head-on. Wisconsin has a determined workforce that is a tremendous asset as we look to rebuild this economy. These talented, hard-working people are ready, willing, and able to work, and Congress should be doing more to help connect them with jobs in growing industries.

That is exactly what I am proposing to do as I introduce this Community-Based Health Care Retraining Act. This bill will help more dislocated workers find jobs in the growing health care industry. My bill would create $25 million in grants to help workforce development boards in our communities identify health care job openings and train people for these positions. This bill is also paid for, so it won't increase the deficit. This bill is a small step toward two critically important goals: helping the hard-working Americans whose jobs have disappeared and providing all Americans with the health care they deserve.

The Community-Based Health Care Retraining Act puts control in the hands of the local communities. It allows local workforce development boards to partner with institutions of higher education and other community leaders to design programs that can retrain dislocated workers for jobs in the health care industry. Allowing the local workforce boards and their partners to apply for the grant funds and design the programs means that each community can use the funds differently to address the specific needs it faces. Particularly in such challenging economic times, I think a one-size-fits-all approach will not work; communities know best about the resources they need to run an efficient program. I believe the Federal programs should be flexible enough to allow partnerships to tailor the programs to meet the needs of individual communities.

For years, despite limited resources and increases in demand for their services, our workforce development boards have worked tirelessly to retrain workers for new employment. These boards are a tremendous asset for local economies, bringing together members of the labor, business, education, and other communities to ensure that the boards are doing their best to provide the most valuable services and training. In Wisconsin, workforce development boards are leading the way in finding innovative solutions to retraining workers for new careers on shoestring budgets. I look forward to the long overdue reauthorization of the Workforce Investment Act this year and to the opportunity to provide better support for these boards.

I wish to take this time to commend the leaders of these boards in Wisconsin and across the country for their dedication and hard work. Workforce development agencies in Wisconsin have already been training people for health care jobs. But in these difficult times, we have to do more to support our communities in these efforts. We must do our best to ensure that communities across the country have the resources they need to help employ more dislocated workers.

As we face the challenge of helping Americans who lose jobs, we must look to industries that continue to grow and demand more workers. As many of my colleagues know, there is, in fact, a real shortage of health care workers in the United States. Congress continues to fund programs that address nursing shortages and recently provided stimulus funds for health care retraining, but we need to develop longer term and wider ranging programs. Shortages of health care professionals of all sorts pose a real threat to the health of our communities by impacting access to timely, high-quality health care.

As Congress looks forward to reforming our Nation's health care system, we must also ensure that there are enough trained professionals to provide services. According to the Bureau of Labor Statistics, we are going to need an additional 700,000 nursing aides, home health aides, and other health professionals in long-term care before the year 2016.

This bill will help provide communities with the resources they need to run retraining programs for the health professions.

Partnerships funded by the legislation will be able to use these funds for a variety of purposes, including for implementing training programs, providing tuition assistance, providing transportation assistance, and also to increase capacity for existing training programs that are already working but could use more resources.

We must ensure we are doing what we can to train laid-off Americans into fields such as health care that continue to demand more workers, and this Community-Based Health Care Retraining Act takes a small but important step toward that goal.

Mr. President, I ask unanimous consent that the text of the bill and a list of supporters be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

S. 1173

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Community-Based Health Care Retraining Act''.

SEC. 2. HEALTH PROFESSIONS TRAINING DEMONSTRATION PROJECT.

Section 171 of the Workforce Investment Act of 1998 (29 U.S.C. 2916) is amended by adding at the end the following:

''(f) HEALTH PROFESSIONS TRAINING DEMONSTRATION PROJECT.—

''(1) DEFINITIONS.—In this subsection:

''(A) COVERED COMMUNITY.—The term 'covered community' means a community or region—

''(i) that has experienced a significant percentage decline in rates of employment; and

''(ii)(I) that is determined by the Secretary of Health and Human Services (in consultation with the medical community) to be an area with a shortage of health care professionals described in subparagraph (C)(i); or

''(II) that is underserved by the health care structure, such as a rural community, a community with a significant minority population, or a community for which an applicant can otherwise demonstrate need for increased training for health care professionals.

''(B) COVERED WORKER.—The term 'covered worker' means an individual who—

''(i)(I) has been terminated or laid off, or who has received a notice of termination or layoff;

''(II)(aa) is eligible for or has exhausted entitlement to unemployment compensation; or

''(bb) has been employed for a duration sufficient to demonstrate, to the appropriate entity at a one-stop center referred to in section 134(c), attachment to the workforce, but is not eligible for unemployment compensation due to insufficient earnings or having performed services for an employer that were not covered under a State unemployment compensation law; and

''(III) is unlikely to return to a previous industry or occupation;

''(ii)(I) has been terminated or laid off, or has received a notice of termination or layoff, as a result of any permanent closure of, or any substantial layoff at, a plant, facility, or enterprise; or

''(II) is employed at a facility at which the employer has made a general announcement that such facility will close within 180 days; or

''(iii) is an incumbent worker employed in a health care profession, and whose training will provide an opportunity for employment of other individuals by increasing—

''(I) the number of instructors serving the covered community; or

''(II) the number of vacant positions in the covered community.

''(C) HEALTH CARE PROFESSIONAL.—The term 'health care professional'—

''(i) means an individual who is involved with—

''(I) the delivery of health care services, or related services, pertaining to—

''(aa) the identification, evaluation, management, and prevention of diseases, disorders, or injuries; or

''(bb) home-based or community-based long-term care;

''(II) the delivery of dietary and nutrition services;

''(III) the delivery of dental services; or

''(IV) rehabilitation and health systems management; and

''(ii) includes individuals in health care professions for which there is a shortage in the community involved, as determined by the Secretary of Health and Human Services (in consultation with the medical community) or as otherwise demonstrated by the applicant.

''(D) TRIBAL COLLEGE OR UNIVERSITY.—The term 'tribal college or university' means a Tribal College or University, as defined in section 316(b) of the Higher Education Act of 1965 (20 U.S.C. 1059c(b)).

''(2) ESTABLISHMENT OF PROJECT.—In accordance with subsection (b), the Secretary shall establish and carry out a health professions training demonstration project.

''(3) GRANTS.—In carrying out the project, the Secretary, after consultation with the Secretary of Health and Human Services, shall make grants to eligible entities to pay for the Federal share of the cost of enabling the entities to carry out programs in covered communities to train covered workers for employment as health care professionals (referred to in this subsection as 'training programs'). The Secretary shall make each grant in an amount of not less than $100,000 and not more than $500,000, and each such grant shall be for a period of 5 years.

''(4) ELIGIBLE ENTITIES.—Notwithstanding subsection (b)(2)(B), to be eligible to receive a grant under this subsection to carry out a training program in a covered community, an entity shall be a partnership that consists of—

''(A) a local workforce investment board established under section 117 that is serving the covered community; and

''(B) an institution of higher education, as defined in sections 101 and 102 of the Higher Education Act of 1965 (20 U.S.C. 1001, 1002), in partnership with at least 1 of the following:

''(i) A health clinic or hospital.

''(ii) A home-based or community-based long-term care facility or program.

''(iii) A health care facility administered by the Secretary of Veterans Affairs.

''(iv) A tribal college or university.

''(v) A labor organization, or an industry or industry group.

''(vi) A local economic development entity serving the covered community.

''(vii) A joint labor-management partnership.

''(5) APPLICATIONS.—To be eligible to receive a grant under this subsection, an entity shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require, including, at a minimum—

''(A) a proposal to use the grant funds to establish or expand a training program in order to train covered workers for employment as health care professionals, including information that demonstrates the long-term viability of the training program beyond the period of the grant;

''(B) information demonstrating the need for the training and support services to be provided through the training program;

''(C) information describing the manner in which the entity will expend the grant funds, and the activities to be carried out with the funds;

''(D) information demonstrating that the entity meets the requirements of paragraph (4);

''(E) with respect to training programs carried out by the applicant, information—

''(i) on the graduation rates of the training programs involved;

''(ii) on the retention measures carried out by the applicant;

''(iii) on the length of time necessary to complete the training programs of the applicant; and

''(iv) on the number of qualified covered workers that are refused admittance into the training programs because of lack of capacity; and

''(F) a description of how the applicant has engaged all relevant stakeholders, including the health care industry to be served by the training program, local labor organizations and other workforce groups, and local industry, in the design of the training program to be served with grant funds.

''(6) SELECTION.—In making grants under paragraph (3), the Secretary, after consultation with the Secretary of Health and Human Services, shall—

''(A) consider the information submitted by the eligible entities under paragraph (5)(E);

''(B) select—

''(i) eligible entities submitting applications that meet such criteria as the Secretary of Labor determines to be appropriate; and

''(ii) among such entities, the eligible entities serving the covered communities with the greatest need for the grants and the greatest potential to benefit from the grants; and

''(C) give preference to eligible entities—

''(i) submitting applications to serve covered workers who have been terminated or laid off or have received a notice of termination or layoff from a manufacturing, service, or construction industry, or another industry with significant decline in employment as determined by the Secretary; and

''(ii) with a demonstrated history of similar and successful partnerships with State boards or local boards, institutions of higher education (as defined in paragraph (4)(B)), industry groups, and labor organizations.

''(7) USE OF FUNDS.—

''(A) IN GENERAL.—An entity that receives a grant under this subsection shall use the funds made available through the grant for training and support services that meet the needs described in the application submitted under paragraph (5), which may include—

''(i) implementing training programs for covered workers;

''(ii) providing support services for covered workers participating in the training programs, such as—

''(I) providing tuition assistance;

''(II) establishing or expanding distance education programs;

''(III) providing transportation assistance; or

''(IV) providing child care; or

''(iii) increasing capacity, subject to subparagraph (B), at an educational institution or training center to train individuals for employment as health professionals, such as by—

''(I) expanding a facility, subject to subparagraph (B);

''(II) expanding course offerings;

''(III) hiring faculty;

''(IV) providing a student loan repayment program for the faculty;

''(V) establishing or expanding clinical education opportunities;

''(VI) purchasing equipment, such as computers, books, clinical supplies, or a patient simulator; or

''(VII) conducting recruitment.

''(B) LIMITATION.—Any such grant funds that are used to expand facilities may only be used to rent or modernize existing facilities, not to build additional facilities. The entity shall use not less than 50 percent of the grant funds to carry out activities described in clause (i) or (ii) of subparagraph (A), unless the entity demonstrates, in the application submitted under paragraph (5), a need to spend more than 50 percent of the grant funds on activities described in subparagraph (A)(iii).

''(8) FEDERAL SHARE.—

''(A) IN GENERAL.—The Federal share of the cost described in paragraph (3) shall be—

''(i) for the first year of the grant period, 95 percent;

''(ii) for the second such year, 85 percent;

''(iii) for the third such year, 75 percent;

''(iv) for the fourth such year, 65 percent; and

''(v) for the fifth such year, 55 percent.

''(B) NON-FEDERAL SHARE.—The eligible entity shall provide the non-Federal share of the cost in cash or in kind, fairly evaluated, including plant, equipment, or services.

''(9) EVALUATION.—

''(A) IN GENERAL.—Under the Secretary's existing authority under section 172, not more than 1 percent of the funds provided under this subsection shall be used for evaluation of the training programs described in paragraph (3). Eligible entities receiving grants under this section shall use not more than 1 percent of the grant funds for purposes of evaluation or documentation of the training programs.

''(B) CONTENTS.—In conducting an evaluation under subparagraph (A), an eligible entity shall provide data detailing the success of the training program carried out by the entity under paragraph (3), including—

''(i) information on the number and percentage of participating covered workers who complete a training program, including those who earn a degree or certificate through such training programs;

''(ii) information on the rate of employment of covered workers who have completed the training program;

''(iii) an assessment of how well the needs of the health care community were addressed by the training program; and

''(iv) any other data determined to be relevant by the entity to demonstrate the success of the training program.

''(C) REPORT.—The Secretary shall compile the information resulting from the evaluation or documentation conducted under subparagraph (A), and shall submit a report to Congress containing the information.

''(10) FUNDING.—Of the amounts appropriated to, and available at the discretion of, the Secretary or the Secretary of Health and Human Services for programmatic and administrative expenditures, a total of $25,000,000 shall be used to establish and carry out the demonstration project described in paragraph (2) in accordance with this subsection.''.

Service Employees International Union (SEIU), Wisconsin Hospital Association, Wisconsin Workforce Development Association, University of Wisconsin System, Southwest Wisconsin Workforce Development Board, Workforce Development Board of South Central Wisconsin, Moraine Park Technical College, Gundersen Lutheran, American Health Care Association, South Central AHEC, Rural Wisconsin Health Cooperative, National Rural Recruitment and Retention Network (3RNet), American Indian Higher Education Consortium, Wisconsin Indianhead Technical College, Madison Area Technical College, Wisconsin Community Action Program Association (WISCAP), UMOS, Fox Valley Technical College, Columbia County Economic Development Corporation, Lakeshore Technical College, Western Technical College, Workforce Connections Inc., Blackhawk Technical College, Mid-State Technical College, Northeast Wisconsin Technical College, Southwest Technical College, Chippewa Valley Technical College, Northcentral Technical College, Gateway Technical College.

By Ms. CANTWELL (for herself, Ms. COLLINS, and Mr. WHITEHOUSE):

S. 1174. A bill to amend the Public Health Service Act and the Social Security Act to increase the number of primary care physicians and primary care providers and to improve patient access to primary care services, and for other services; to the Committee on Finance.

Ms. CANTWELL. Mr. President, I rise today to introduce the Preserving Patient Access to Primary Care Act of 2009, together with my colleagues from Maine, Senator SUSAN COLLINS, and from Rhode Island, Senator SHELDON WHITEHOUSE. As we set about the urgently important business of health care reform, we will be hearing a lot about the uninsured. But there is another urgent problem in our health care system: the underserved. We must address both problems as we set about reforming the health care system.

It does you little good to have health care insurance if the nearest primary care physician is hundreds of miles away.

This bipartisan proposal sets out a multifaceted approach to supporting and expanding our primary care workforce as well as enhancing the coordination of care within our health care system. I am grateful for the input and collaboration of key health-care stakeholders in Washington state that has helped make this legislation possible. In my state, we know it is possible to both increase health care quality while also lowering costs, all within an integrated system that places a priority on expanding our primary care workforce and protecting patients' relationships with their doctors.

A dramatic increase in the primary care physician workforce will be needed. My legislation not only addresses the needs of those individuals to whom health insurance coverage will be extended but also of those who are currently insured but who live in areas underserved by our current health care system.

I believe we can address this problem by adopting long overdue reforms to improve pay levels for primary care providers while also taking measures to ensure an adequate primary care workforce, particularly in rural areas. As more Americans gain health care coverage, the experts estimate there will be a shortage of 46,000 primary care physicians available to care for the influx of patients by the year 2025. As the need grows, the number of medical students choosing primary care is rapidly dwindling.

Detailed studies from the Center for Evaluative Clinical Sciences at Dartmouth and the Commonwealth Fund found that populations with ready access to primary care physicians realize improved health outcomes, reduced mortality, lower utilization of health care resources, and lower overall costs of care. Yet despite what we know, all across this country, we are failing to realize the benefits of primary care and

a system of having a primary care physician coordinate a patient's health care needs. This bill includes several key provisions aimed at achieving a high quality, more comprehensive integrated health system.

Specific provisions include: scholarship and loan repayment opportunities for primary care providers who serve in areas with critical shortages of primary care services. New residency positions for primary care with a focus on more opportunities to train in ambulatory care settings—including community in health centers. Increased reimbursements for primary care providers. Medicare payments for care coordination services, and bonus payments to providers who serve as integrated patient-centered medical homes. Improved access to primary care for seniors by eliminating copayments for preventives care services in Medicare.

I look forward to working with my colleagues in the Senate to ensure we make the necessary investments in our primary care workforce. Mr. President, I ask unanimous consent that the text of the bill and letters of support be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

S. 1174

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Preserving Patient Access to Primary Care Act of 2009''.

(b) TABLE OF CONTENTS.—The table of contents is as follows:

Sec. 1. Short title; table of contents.
Sec. 2. Findings.
Sec. 3. Definitions.

TITLE I—MEDICAL EDUCATION

Sec. 101. Recruitment incentives.
Sec. 102. Debt forgiveness, scholarships, and service obligations.
Sec. 103. Deferment of loans during residency and internships.
Sec. 104. Educating medical students about primary care careers.
Sec. 105. Training in a family medicine, general internal medicine, general geriatrics, general pediatrics, physician assistant education, general dentistry, and pediatric dentistry.
Sec. 106. Increased funding for National Health Service Corps Scholarship and Loan Repayment Programs.

TITLE II—MEDICAID RELATED PROVISIONS

Sec. 201. Transformation grants to support patient centered medical homes under Medicaid and CHIP.

TITLE III—MEDICARE PROVISIONS

Subtitle A—Primary Care

Sec. 301. Reforming payment systems under Medicare to support primary care.
Sec. 302. Coverage of patient centered medical home services.
Sec. 303. Medicare primary care payment equity and access provision.
Sec. 304. Additional incentive payment program for primary care services furnished in health professional shortage areas.
Sec. 305. Permanent extension of floor on Medicare work geographic adjustment under the Medicare physician fee schedule.
Sec. 306. Permanent extension of Medicare incentive payment program for physician scarcity areas.
Sec. 307. HHS study and report on the process for determining relative value under the Medicare physician fee schedule.

Subtitle B—Preventive Services

Sec. 311. Eliminating time restriction for initial preventive physical examination.
Sec. 312. Elimination of cost-sharing for preventive benefits under the Medicare program.
Sec. 313. HHS study and report on facilitating the receipt of Medicare preventive services by Medicare beneficiaries.

Subtitle C—Other Provisions

Sec. 321. HHS study and report on improving the ability of physicians and primary care providers to assist Medicare beneficiaries in obtaining needed prescriptions under Medicare part D.
Sec. 322. HHS study and report on improved patient care through increased caregiver and physician interaction.
Sec. 323. Improved patient care through expanded support for limited English proficiency (LEP) services.
Sec. 324. HHS study and report on use of real-time Medicare claims adjudication.
Sec. 325. Ongoing assessment by MedPAC of the impact of medicare payments on primary care access and equity.
Sec. 326. Distribution of additional residency positions.
Sec. 327. Counting resident time in outpatient settings.
Sec. 328. Rules for counting resident time for didactic and scholarly activities and other activities.
Sec. 329. Preservation of resident cap positions from closed and acquired hospitals.
Sec. 330. Quality improvement organization assistance for physician practices seeking to be patient centered medical home practices.

TITLE IV—STUDIES

Sec. 401. Study concerning the designation of primary care as a shortage profession.
Sec. 402. Study concerning the education debt of medical school graduates.
Sec. 403. Study on minority representation in primary care.

SEC. 2. FINDINGS.

Congress makes the following findings:

(1) Approximately 21 percent of physicians who were board certified in general internal medicine during the early 1990s have left internal medicine, compared to a 5 percent departure rate for those who were certified in subspecialties of internal medicine.

(2) The number of United States medical graduates going into family medicine has fallen by more than 50 percent from 1997 to 2005.

(3) In 2007, only 88 percent of the available medicine residency positions were filled and only 42 percent of those were filled by United States medical school graduates.

(4) In 2006, only 24 percent of third-year internal medicine resident intended to pursue careers in general internal medicine, down from 54 percent in 1998.

(5) Primary care physicians serve as the point of first contact for most patients and are able to coordinate the care of the whole person, reducing unnecessary care and duplicative testing.

(6) Primary care physicians and primary care providers practicing preventive care, including screening for illness and treating diseases, can help prevent complications that result in more costly care.

(7) Patients with primary care physicians or primary care providers have lower health care expenditures and primary care is correlated with better health status, lower overall mortality, and longer life expectancy.

(8) Higher proportions of primary care physicians are associated with significantly reduced utilization.

(9) The United States has a higher ratio of specialists to primary care physicians than other industrialized nations and the population of the United States is growing faster than the expected rate of growth in the supply of primary care physicians.

(10) The number of Americans age 65 and older, those eligible for Medicare and who use far more ambulatory care visits per person as those under age 65, is expected to double from 2000 to 2030.

(11) A decrease in Federal spending to carry out programs authorized by title VII of the Public Health Service Act threatens the viability of one of the programs used to solve the problem of inadequate access to primary care.

(12) The National Health Service Corps program has a proven record of supplying physicians to underserved areas, and has played an important role in expanding access for underserved populations in rural and inner city communities.

(13) Individuals in many geographic areas, especially rural areas, lack adequate access to high quality preventive, primary health care, contributing to significant health disparities that impair America's public health and economic productivity.

(14) About 20 percent of the population of the United States resides in primary medical care Health Professional Shortage Areas.

SEC. 3. DEFINITIONS.

(a) GENERAL DEFINITIONS.—In this Act:

(1) CHRONIC CARE COORDINATION.—The term ''chronic care coordination'' means the coordination of services that is based on the Chronic Care Model that provides on-going health care to patients with chronic diseases that may include any of the following services:

(A) The development of an initial plan of care, and subsequent appropriate revisions to such plan of care.

(B) The management of, and referral for, medical and other health services, including interdisciplinary care conferences and management with other providers.

(C) The monitoring and management of medications.

(D) Patient education and counseling services.

(E) Family caregiver education and counseling services.

(F) Self-management services, including health education and risk appraisal to identify behavioral risk factors through self-assessment.

(G) Providing access by telephone with physicians and other appropriate health care professionals, including 24-hour availability of such professionals for emergencies.

(H) Management with the principal nonprofessional caregiver in the home.

(I) Managing and facilitating transitions among health care professionals and across settings of care, including the following:

(i) Pursuing the treatment option elected by the individual.

(ii) Including any advance directive executed by the individual in the medical file of the individual.

(J) Information about, and referral to, hospice care, including patient and family caregiver education and counseling about hospice care, and facilitating transition to hospice care when elected.

(K) Information about, referral to, and management with, community services.

(2) CRITICAL SHORTAGE HEALTH FACILITY.—The term ''critical shortage health facility'' means a public or private nonprofit health facility that does not serve a health professional shortage area (as designated under section 332 of the Public Health Service Act), but that has a critical shortage of physicians (as determined by the Secretary) in a primary care field.

(3) PHYSICIAN.—The term physician has the meaning given such term in section 1861(r)(1) of the Social Security Act.

(4) PRIMARY CARE.—The term ''primary care'' means the provision of integrated, high-quality, accessible health care services by health care providers who are accountable for addressing a full range of personal health and health care needs, developing a sustained partnership with patients, practicing in the context of family and community, and working to minimize disparities across population subgroups.

(5) PRIMARY CARE FIELD.—The term ''primary care field'' means any of the following fields:

(A) The field of family medicine.

(B) The field of general internal medicine.

(C) The field of geriatric medicine.

(D) The field of pediatric medicine

(6) PRIMARY CARE PHYSICIAN.—The term ''primary care physician'' means a physician who is trained in a primary care field who provides first contact, continuous, and comprehensive care to patients.

(7) PRIMARY CARE PROVIDER.—The term ''primary care provider'' means—

(A) a nurse practitioner; or

(B) a physician assistant practicing as a member of a physician-directed team;

who provides first contact, continuous, and comprehensive care to patients.

(8) PRINCIPAL CARE.—The term ''principal care'' means integrated, accessible health care that is provided by a physician who is a medical subspecialist that addresses the majority of the personal health care needs of patients with chronic conditions requiring the subspecialist's expertise, and for whom the subspecialist assumes care management, developing a sustained physician-patient partnership and practicing within the context of family and community.

(9) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

(b) PRIMARY MEDICAL CARE SHORTAGE AREA.—

(1) IN GENERAL.—In this Act, the term ''primary medical care shortage area'' or ''PMCSA'' means a geographic area with a shortage of physicians (as designated by the Secretary) in a primary care field, as designated in accordance with paragraph (2).

(2) DESIGNATION.—To be designated by the Secretary as a PMCSA, the Secretary must find that the geographic area involved has an established shortage of primary care physicians for the population served. The Secretary shall make such a designation with respect to an urban or rural geographic area if the following criteria are met:

(A) The area is a rational area for the delivery of primary care services.

(B) One of the following conditions prevails within the area:

(i) The area has a population to full-time-equivalent primary care physician ratio of at least 3,500 to 1.

(ii) The area has a population to full-time-equivalent primary care physician ratio of less than 3,500 to 1 and has unusually high needs for primary care services or insufficient capacity of existing primary care providers.

(C) Primary care providers in contiguous geographic areas are overutilized.

(c) MEDICALLY UNDERSERVED AREA.—

(1) IN GENERAL.—In this Act, the term ''medically underserved area'' or ''MUA'' means a rational service area with a demonstrable shortage of primary healthcare resources relative to the needs of the entire population within the service area as determined in accordance with paragraph (2) through the use of the Index of Medical Underservice (referred to in this subsection as the ''IMU'') with respect to data on a service area.

(2) DETERMINATIONS.—Under criteria to be established by the Secretary with respect to the IMU, if a service area is determined by the Secretary to have a score of 62.0 or less, such area shall be eligible to be designated as a MUA.

(3) IMU VARIABLES.—In establishing criteria under paragraph (2), the Secretary shall ensure that the following variables are utilized:

(A) The ratio of primary medical care physicians per 1,000 individuals in the population of the area involved.

(B) The infant mortality rate in the area involved.

(C) The percentage of the population involved with incomes below the poverty level.

(D) The percentage of the population involved age 65 or over.

The value of each of such variables for the service area involved shall be converted by the Secretary to a weighted value, according to established criteria, and added together to obtain the area's IMU score.

(d) PATIENT CENTERED MEDICAL HOME.—

(1) IN GENERAL.—In this Act, the term ''patient centered medical home'' means a physician-directed practice (or a nurse practitioner directed practice in those States in which such functions are included in the scope of practice of licensed nurse practitioners) that has been certified by an organization under paragraph (3) as meeting the following standards:

(A) The practice provides patients who elect to obtain care through a patient centered medical home (referred to as ''participating patients'') with direct and ongoing access to a primary or principal care physician or a primary care provider who accepts responsibility for providing first contact, continuous, and comprehensive care to the whole person, in collaboration with teams of other health professionals, including nurses and specialist physicians, as needed and appropriate.

(B) The practice applies standards for access to care and communication with participating beneficiaries.

(C) The practice has readily accessible, clinically useful information on participating patients that enables the practice to treat such patients comprehensively and systematically.

(D) The practice maintains continuous relationships with participating patients by implementing evidence-based guidelines and applying such guidelines to the identified needs of individual beneficiaries over time and with the intensity needed by such beneficiaries.

(2) RECOGNITION OF NCQA APPROVAL.—Such term also includes a physician-directed (or nurse-practitioner-directed) practice that has been recognized as a medical home through the Physician Practice Connections—patient centered Medical Home (''PPC–PCMH'') voluntary recognition process of the National Committee for Quality Assurance.

(3) STANDARD SETTING AND QUALIFICATION PROCESS FOR MEDICAL HOMES.—The Secretary shall establish a process for the selection of a qualified standard setting and certification organization—

(A) to establish standards, consistent with this subsection, to enable medical practices to qualify as patient centered medical homes; and

(B) to provide for the review and certification of medical practices as meeting such standards.

(4) TREATMENT OF CERTAIN PRACTICES.—Nothing in this section shall be construed as preventing a nurse practitioner from leading a patient-centered medical home so long as—

(A) all of the requirements of this section are met; and

(B) the nurse practitioner is acting consistently with State law.

(e) APPLICATION UNDER MEDICARE, MEDICAID, PHSA, ETC.—Unless otherwise provided, the provisions of the previous subsections shall apply for purposes of provisions of the Social Security Act, the Public Health Service Act, and any other Act amended by this Act.

TITLE I—MEDICAL EDUCATION

SEC. 101. RECRUITMENT INCENTIVES.

Title VII of the Higher Education Act of 1965 (20 U.S.C. 1133 et seq.) is amended by adding at the end the following:

"PART F—MEDICAL EDUCATION RECRUITMENT INCENTIVES

"SEC. 786. MEDICAL EDUCATION RECRUITMENT INCENTIVES.

''(a) IN GENERAL.—The Secretary is authorized to award grants or contracts to institutions of higher education that are graduate medical schools, to enable the graduate medical schools to improve primary care education and training for medical students.

''(b) APPLICATION.—A graduate medical school that desires to receive a grant under this section shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

''(c) USES OF FUNDS.—A graduate medical school that receives a grant under this section shall use such grant funds to carry out 1 or more of the following:

''(1) The creation of primary care mentorship programs.

''(2) Curriculum development for population-based primary care models of care, such as the patient centered medical home.

''(3) Increased opportunities for ambulatory, community-based training.

''(4) Development of generalist curriculum to enhance care for rural and underserved populations in primary care or general surgery.

''(d) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $50,000,000 for each of the fiscal years 2010 through 2012.''.

SEC. 102. DEBT FORGIVENESS, SCHOLARSHIPS, AND SERVICE OBLIGATIONS.

(a) PURPOSE.—It is the purpose of this section to encourage individuals to enter and continue in primary care physician careers.

(b) AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT.—Part D of title III of the Public Health Service Act (42 U.S.C. 254b et seq.) is amended by adding at the end the following:

"Subpart XI—Primary Care Medical Education

"SEC. 340I. SCHOLARSHIPS.

''(a) IN GENERAL.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall

award grants to critical shortage health facilities to enable such facilities to provide scholarships to individuals who agree to serve as physicians at such facilities after completing a residency in a primary care field (as defined in section 3(a)(5) of the Preserving Patient Access to Primary Care Act of 2009).

''(b) SCHOLARSHIPS.—A health facility shall use amounts received under a grant under this section to enter into contracts with eligible individuals under which—

''(1) the facility agrees to provide the individual with a scholarship for each school year (not to exceed 4 school years) in which the individual is enrolled as a full-time student in a school of medicine or a school of osteopathic medicine; and

''(2) the individual agrees—

''(A) to maintain an acceptable level of academic standing;

''(B) to complete a residency in a primary care field; and

''(C) after completing the residency, to serve as a primary care physician at such facility in such field for a time period equal to the greater of—

''(i) one year for each school year for which the individual was provided a scholarship under this section; or

''(ii) two years.

''(c) AMOUNT.—

''(1) IN GENERAL.—The amount paid by a health facility to an individual under a scholarship under this section shall not exceed $35,000 for any school year.

''(2) CONSIDERATIONS.—In determining the amount of a scholarship to be provided to an individual under this section, a health facility may take into consideration the individual's financial need, geographic differences, and educational costs.

''(3) EXCLUSION FROM GROSS INCOME.—For purposes of the Internal Revenue Code of 1986, gross income shall not include any amount received as a scholarship under this section.

''(d) APPLICATION OF CERTAIN PROVISIONS.—The provisions of subpart III of part D shall, except as inconsistent with this section, apply to the program established in subsection (a) in the same manner and to the same extent as such provisions apply to the National Health Service Corps Scholarship Program established in such subpart.

''(e) DEFINITIONS.—In this section:

''(1) CRITICAL SHORTAGE HEALTH FACILITY.—The term 'critical shortage health facility' means a public or private nonprofit health facility that does not serve a health professional shortage area (as designated under section 332), but has a critical shortage of physicians (as determined by the Secretary) in a primary care field.

''(2) ELIGIBLE INDIVIDUAL.—The term 'eligible individual' means an individual who is enrolled, or accepted for enrollment, as a full-time student in an accredited school of medicine or school of osteopathic medicine.

''SEC. 340J. LOAN REPAYMENT PROGRAM.

''(a) PURPOSE.—It is the purpose of this section to alleviate critical shortages of primary care physicians and primary care providers.

''(b) LOAN REPAYMENTS.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall establish a program of entering into contracts with eligible individuals under which—

''(1) the individual agrees to serve—

''(A) as a primary care physician or primary care provider in a primary care field; and

''(B) in an area that is not a health professional shortage area (as designated under section 332), but has a critical shortage of primary care physicians and primary care providers (as determined by the Secretary) in such field; and

''(2) the Secretary agrees to pay, for each year of such service, not more than $35,000 of the principal and interest of the undergraduate or graduate educational loans of the individual.

''(c) SERVICE REQUIREMENT.—A contract entered into under this section shall allow the individual receiving the loan repayment to satisfy the service requirement described in subsection (a)(1) through employment in a solo or group practice, a clinic, a public or private nonprofit hospital, or any other appropriate health care entity.

''(d) APPLICATION OF CERTAIN PROVISIONS.—The provisions of subpart III of part D shall, except as inconsistent with this section, apply to the program established in subsection (a) in the same manner and to the same extent as such provisions apply to the National Health Service Corps Scholarship Program established in such subpart.

''(e) DEFINITION.—In this section, the term 'eligible individual' means—

''(1) an individual with a degree in medicine or osteopathic medicine; or

''(2) a primary care provider (as defined in section 3(a)(7) of the Preserving Patient Access to Primary Care Act of 2009).

''SEC. 340K. LOAN REPAYMENTS FOR PHYSICIANS IN THE FIELDS OF OBSTETRICS AND GYNECOLOGY AND CERTIFIED NURSE MIDWIVES.

''(a) PURPOSE.—It is the purpose of this section to alleviate critical shortages of physicians in the fields of obstetrics and gynecology and certified nurse midwives.

''(b) LOAN REPAYMENTS.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall establish a program of entering into contracts with eligible individuals under which—

''(1) the individual agrees to serve—

''(A) as a physician in the field of obstetrics and gynecology or as a certified nurse midwife; and

''(B) in an area that is not a health professional shortage area (as designated under section 332), but has a critical shortage of physicians in the fields of obstetrics and gynecology or certified nurse midwives (as determined by the Secretary), respectively; and

''(2) the Secretary agrees to pay, for each year of such service, not more than $35,000 of the principal and interest of the undergraduate or graduate educational loans of the individual.

''(c) SERVICE REQUIREMENT.—A contract entered into under this section shall allow the individual receiving the loan repayment to satisfy the service requirement described in subsection (a)(1) through employment in a solo or group practice, a clinic, a public or private nonprofit hospital, or any other appropriate health care entity.

''(d) APPLICATION OF CERTAIN PROVISIONS.—The provisions of subpart III of part D shall, except as inconsistent with this section, apply to the program established in subsection (a) in the same manner and to the same extent as such provisions apply to the National Health Service Corps Scholarship Program established in such subpart.

''(e) DEFINITION.—In this section, the term 'eligible individual' means—

''(1) a physician in the field of obstetrics and gynecology; or

''(2) a certified nurse midwife.

''SEC. 340L. REPORTS.

''Not later than 18 months after the date of enactment of this section, and annually thereafter, the Secretary shall submit to Congress a report that describes the programs carried out under this subpart, including statements concerning—

''(1) the number of enrollees, scholarships, loan repayments, and grant recipients;

''(2) the number of graduates;

''(3) the amount of scholarship payments and loan repayments made;

''(4) which educational institution the recipients attended;

''(5) the number and placement location of the scholarship and loan repayment recipients at health care facilities with a critical shortage of primary care physicians;

''(6) the default rate and actions required;

''(7) the amount of outstanding default funds of both the scholarship and loan repayment programs;

''(8) to the extent that it can be determined, the reason for the default;

''(9) the demographics of the individuals participating in the scholarship and loan repayment programs;

''(10) the justification for the allocation of funds between the scholarship and loan repayment programs; and

''(11) an evaluation of the overall costs and benefits of the programs.

''SEC. 340M. AUTHORIZATION OF APPROPRIATIONS.

''To carry out sections 340I, 340J, and 340K there are authorized to be appropriated $55,000,000 for fiscal year 2010, $90,000,000 for fiscal year 2011, and $125,000,000 for fiscal year 2012, to be used solely for scholarships and loan repayment awards for primary care physicians and primary care providers.''.

SEC. 103. DEFERMENT OF LOANS DURING RESIDENCY AND INTERNSHIPS.

(a) LOAN REQUIREMENTS.—Section 427(a)(2)(C)(i) of the Higher Education Act of 1965 (20 U.S.C. 1077(a)(2)(C)(i)) is amended by inserting ''unless the medical internship or residency program is in a primary care field (as defined in section 3(a)(5) of the Preserving Patient Access to Primary Care Act of 2009)'' after ''residency program''.

(b) FFEL LOANS.—Section 428(b)(1)(M)(i) of the Higher Education Act of 1965 (20 U.S.C. 1078(b)(1)(M)(i)) is amended by inserting ''unless the medical internship or residency program is in a primary care field (as defined in section 3(a)(5) of the Preserving Patient Access to Primary Care Act of 2009)'' after ''residency program''.

(c) FEDERAL DIRECT LOANS.—Section 455(f)(2)(A) of the Higher Education Act of 1965 (20 U.S.C. 1087e(f)(2)(A)) is amended by inserting ''unless the medical internship or residency program is in a primary care field (as defined in section 3(a)(5) of the Preserving Patient Access to Primary Care Act of 2009)'' after ''residency program''.

(d) FEDERAL PERKINS LOANS.—Section 464(c)(2)(A)(i) of the Higher Education Act of 1965 (20 U.S.C. 1087dd(c)(2)(A)(i)) is amended by inserting ''unless the medical internship or residency program is in a primary care field (as defined in section 3(a)(5) of the Preserving Patient Access to Primary Care Act of 2009)'' after ''residency program''.

SEC. 104. EDUCATING MEDICAL STUDENTS ABOUT PRIMARY CARE CAREERS.

Part C of title VII of the Public Health Service Act (42 U.S.C. 293k) is amended by adding at the end the following:

''SEC. 749. EDUCATING MEDICAL STUDENTS ABOUT PRIMARY CARE CAREERS.

''(a) IN GENERAL.—The Secretary shall award grants to eligible State and local government entities for the development of informational materials that promote careers in primary care by highlighting the advantages and rewards of primary care, and that encourage medical students, particularly students from disadvantaged backgrounds, to become primary care physicians.

''(b) ANNOUNCEMENT.—The grants described in subsection (a) shall be announced through a publication in the Federal Register and

through appropriate media outlets in a manner intended to reach medical education institutions, associations, physician groups, and others who communicate with medical students.

''(c) ELIGIBILITY.—To be eligible to receive a grant under this section an entity shall—

''(1) be a State or local entity; and

''(2) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

''(d) USE OF FUNDS.—

''(1) IN GENERAL.—An entity shall use amounts received under a grant under this section to support State and local campaigns through appropriate media outlets to promote careers in primary care and to encourage individuals from disadvantaged backgrounds to enter and pursue careers in primary care.

''(2) SPECIFIC USES.—In carrying out activities under paragraph (1), an entity shall use grants funds to develop informational materials in a manner intended to reach as wide and diverse an audience of medical students as possible, in order to—

''(A) advertise and promote careers in primary care;

''(B) promote primary care medical education programs;

''(C) inform the public of financial assistance regarding such education programs;

''(D) highlight individuals in the community who are practicing primary care physicians; or

''(E) provide any other information to recruit individuals for careers in primary care.

''(e) LIMITATION.—An entity shall not use amounts received under a grant under this section to advertise particular employment opportunities.

''(f) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, such sums as may be necessary for each of fiscal years 2010 through 2013.''.

SEC. 105. TRAINING IN A FAMILY MEDICINE, GENERAL INTERNAL MEDICINE, GENERAL GERIATRICS, GENERAL PEDIATRICS, PHYSICIAN ASSISTANT EDUCATION, GENERAL DENTISTRY, AND PEDIATRIC DENTISTRY.

Section 747(e) of the Public Health Service Act (42 U.S.C. 293k) is amended by striking paragraph (1) and inserting the following:

''(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there is authorized to be appropriated $198,000,000 for each of fiscal years 2010 through 2012.''.

SEC. 106. INCREASED FUNDING FOR NATIONAL HEALTH SERVICE CORPS SCHOLARSHIP AND LOAN REPAYMENT PROGRAMS.

(a) IN GENERAL.—There is authorized to be appropriated $332,000,000 for the period of fiscal years 2010 through 2012 for the purpose of carrying out subpart III of part D of title III of the Public Health Service Act (42 U.S.C. 254l et seq.). Such authorization of appropriations is in addition to the authorization of appropriations in section 338H of such Act (42 U.S.C. 254q) and any other authorization of appropriations for such purpose.

(b) ALLOCATION.—Of the amounts appropriated under subsection (a) for the period of fiscal years 2010 through 2012, the Secretary shall obligate $96,000,000 for the purpose of providing contracts for scholarships and loan repayments to individuals who—

(1) are primary care physicians or primary care providers; and

(2) have not previously received a scholarship or loan repayment under subpart III of part D of title III of the Public Health Service Act (42 U.S.C. 254l et seq.).

TITLE II—MEDICAID RELATED PROVISIONS

SEC. 201. TRANSFORMATION GRANTS TO SUPPORT PATIENT CENTERED MEDICAL HOMES UNDER MEDICAID AND CHIP.

(a) IN GENERAL.—Section 1903(z) of the Social Security Act (42 U.S.C. 1396b(z)) is amended—

(1) in paragraph (2), by adding at the end the following new subparagraph:

''(G) Methods for improving the effectiveness and efficiency of medical assistance provided under this title and child health assistance provided under title XXI by encouraging the adoption of medical practices that satisfy the standards established by the Secretary under paragraph (2) of section 3(d) of the Preserving Patient Access to Primary Care Act of 2009 for medical practices to qualify as patient centered medical homes (as defined in paragraph (1) of such section).''; and

(2) in paragraph (4)—

(A) in subparagraph (A)—

(i) in clause (i), by striking ''and'' at the end;

(ii) in clause (ii), by striking the period at the end and inserting ''; and''; and

(iii) by inserting after clause (ii), the following new clause:

''(iii) $25,000,000 for each of fiscal years 2010, 2011, and 2012.''; and

(B) in subparagraph (B), by striking the second and third sentences and inserting the following: ''Such method shall provide that 100 percent of such funds for each of fiscal years 2010, 2011, and 2012 shall be allocated among States that design programs to adopt the innovative methods described in paragraph (2)(G), with preference given to States that design programs involving multipayers (including under title XVIII and private health plans) test projects for implementation of the elements necessary to be recognized as a patient centered medical home practice under the National Committee for Quality Assurance Physicians Practice Connection-PCMH module (or any other equivalent process, as determined by the Secretary).''.

(b) EFFECTIVE DATE.—The amendments made by this section take effect on October 1, 2010.

TITLE III—MEDICARE PROVISIONS

Subtitle A—Primary Care

SEC. 301. REFORMING PAYMENT SYSTEMS UNDER MEDICARE TO SUPPORT PRIMARY CARE.

(a) INCREASING BUDGET NEUTRALITY LIMITS UNDER THE PHYSICIAN FEE SCHEDULE TO ACCOUNT FOR ANTICIPATED SAVINGS RESULTING FROM PAYMENTS FOR CERTAIN SERVICES AND THE COORDINATION OF BENEFICIARY CARE.—Section 1848(c)(2)(B) of the Social Security Act (42 U.S.C. 1395w–4(c)(2)(B)) is amended—

(1) in clause (ii)(II), by striking ''(iv) and (v)'' and inserting ''(iv), (v), and (vii)''; and

(2) by adding at the end the following new clause:

''(vii) INCREASE IN LIMITATION TO ACCOUNT FOR CERTAIN ANTICIPATED SAVINGS.—

''(I) IN GENERAL.—Effective for fee schedules established beginning with 2010, the Secretary shall increase the limitation on annual adjustments under clause (ii)(II) by an amount equal to the anticipated savings under parts A, B, and D (including any savings with respect to items and services for which payment is not made under this section) which are a result of payments for designated primary care services and comprehensive care coordination services under section 1834(m) and the coverage of patient centered medical home services under section 1861(s)(2)(FF) (as determined by the Secretary).

''(II) MECHANISM TO DETERMINE APPLICATION OF INCREASE.—The Secretary shall establish a mechanism for determining which relative value units established under this paragraph for physicians' services shall be subject to an adjustment under clause (ii)(I) as a result of the increase under subclause (I).

''(III) ADDITIONAL FUNDING AS DETERMINED NECESSARY BY THE SECRETARY.—In addition to any funding that may be made available as a result of an increase in the limitation on annual adjustments under subclause (I), there shall also be available to the Secretary, for purposes of making payments under this title for new services and capabilities to improve care provided to individuals under this title and to generate efficiencies under this title, such additional funds as the Secretary determines are necessary.''.

(b) SEPARATE MEDICARE PAYMENT FOR DESIGNATED PRIMARY CARE SERVICES AND COMPREHENSIVE CARE COORDINATION SERVICES.—

(1) IN GENERAL.—Section 1834 of the Social Security Act (42 U.S.C. 1395m) is amended by adding at the end the following new subsection:

''(n) PAYMENT FOR DESIGNATED PRIMARY CARE SERVICES AND COMPREHENSIVE CARE COORDINATION SERVICES.—

''(1) IN GENERAL.—The Secretary shall pay for designated primary care services and comprehensive care coordination services furnished to an individual enrolled under this part.

''(2) PAYMENT AMOUNT.—The Secretary shall determine the amount of payment for designated primary care services and comprehensive care coordination services under this subsection.

''(3) DOCUMENTATION REQUIREMENTS.—The Secretary shall propose appropriate documentation requirements to justify payments for designated primary care services and comprehensive care coordination services under this subsection.

''(4) DEFINITIONS.—

''(A) COMPREHENSIVE CARE COORDINATION SERVICES.—The term 'comprehensive care coordination services' means care coordination services with procedure codes established by the Secretary (as appropriate) which are furnished to an individual enrolled under this part by a primary care provider or principal care physician.

''(B) DESIGNATED PRIMARY CARE SERVICES.—The term 'designated primary care service' means a service which the Secretary determines has a procedure code which involves a clinical interaction with an individual enrolled under this part that is inherent to care coordination, including interactions outside of a face-to-face encounter. Such term includes the following:

''(i) Care plan oversight.

''(ii) Evaluation and management provided by phone.

''(iii) Evaluation and management provided using internet resources.

''(iv) Collection and review of physiologic data, such as from a remote monitoring device.

''(v) Education and training for patient self management.

''(vi) Anticoagulation management services.

''(vii) Any other service determined appropriate by the Secretary.''.

(2) EFFECTIVE DATE.—The amendment made by this section shall apply to items and services furnished on or after January 1, 2010.

SEC. 302. COVERAGE OF PATIENT CENTERED MEDICAL HOME SERVICES.

(a) IN GENERAL.—Section 1861(s)(2) of the Social Security Act (42 U.S.C. 1395x(s)(2)) is amended—

(1) in subparagraph (DD), by striking ''and'' at the end;

(2) in subparagraph (EE), by inserting ''and'' at the end; and

(3) by adding at the end the following new subparagraph:

''(FF) patient centered medical home services (as defined in subsection (hhh)(1));''.

(b) DEFINITION OF PATIENT CENTERED MEDICAL HOME SERVICES.—Section 1861 of the Social Security Act (42 U.S.C. 1395x) is amended by adding at the end the following new subsection:

''Patient Centered Medical Home Services

''(hhh)(1) The term 'patient centered medical home services' means care coordination services furnished by a qualified patient centered medical home.

''(2) The term 'qualified patient centered medical home' means a patient centered medical home (as defined in section 3(d) of the Preserving Patient Access to Primary Care Act of 2009).''.

(c) MONTHLY FEE FOR PATIENT CENTERED MEDICAL HOME SERVICES.—Section 1848 of the Social Security Act (42 U.S.C. 1395w–4) is amended by adding at the end the following new subsection:

''(p) MONTHLY FEE FOR PATIENT CENTERED MEDICAL HOME SERVICES.—

''(1) MONTHLY FEE.—

''(A) IN GENERAL.—Not later than January 1, 2012, the Secretary shall establish a payment methodology for patient centered medical home services (as defined in paragraph (1) of section 1861(hhh)). Under such payment methodology, the Secretary shall pay qualified patient centered medical homes (as defined in paragraph (2) of such section) a monthly fee for each individual who elects to receive patient centered medical home services at that medical home. Such fee shall be paid on a prospective basis.

''(B) CONSIDERATIONS.—The Secretary shall take into account the results of the Medicare medical home demonstration project under section 204 of the Medicare Improvement and Extension Act of 2006 (42 U.S.C. 1395b–1 note; division B of Public Law 109–432) in establishing the payment methodology under subparagraph (A).

''(2) AMOUNT OF PAYMENT.—

''(A) CONSIDERATIONS.—In determining the amount of such fee, subject to paragraph (3), the Secretary shall consider the following:

''(i) The clinical work and practice expenses involved in providing care coordination services consistent with the patient centered medical home model (such as providing increased access, care coordination, disease population management, and education) for which payment is not made under this section as of the date of enactment of this subsection.

''(ii) Ensuring that the amount of payment is sufficient to support the acquisition, use, and maintenance of clinical information systems which—

''(I) are needed by a qualified patient centered medical home; and

''(II) have been shown to facilitate improved outcomes through care coordination.

''(iii) The establishment of a tiered monthly care management fee that provides for a range of payment depending on how advanced the capabilities of a qualified patient centered medical home are in having the information systems needed to support care coordination.

''(B) RISK-ADJUSTMENT.—The Secretary shall use appropriate risk-adjustment in determining the amount of the monthly fee under this paragraph.

''(3) FUNDING.—

''(A) IN GENERAL.—The Secretary shall determine the aggregate estimated savings for a calendar year as a result of the implementation of this subsection on reducing preventable hospital admissions, duplicate testing, medication errors and drug interactions, and other savings under this part and part A (including any savings with respect to items and services for which payment is not made under this section).

''(B) FUNDING.—Subject to subparagraph (C), the aggregate amount available for payment of the monthly fee under this subsection during a calendar year shall be equal to the aggregate estimated savings (as determined under subparagraph (A)) for the calendar year (as determined by the Secretary).

''(C) ADDITIONAL FUNDING.—In the case where the amount of the aggregate actual savings during the preceding 3 years exceeds the amount of the aggregate estimated savings (as determined under subparagraph (A)) during such period, the aggregate amount available for payment of the monthly fee under this subsection during the calendar year (as determined under subparagraph (B)) shall be increased by the amount of such excess.

''(D) ADDITIONAL FUNDING AS DETERMINED NECESSARY BY THE SECRETARY.—In addition to any funding made available under subparagraphs (B) and (C), there shall also be available to the Secretary, for purposes of effectively implementing this subsection, such additional funds as the Secretary determines are necessary.

''(4) PERFORMANCE-BASED BONUS PAYMENTS.—The Secretary shall establish a process for paying a performance-based bonus to qualified patient centered medical homes which meet or achieve substantial improvements in performance (as specified under clinical, patient satisfaction, and efficiency benchmarks established by the Secretary). Such bonus shall be in an amount determined appropriate by the Secretary.

''(5) NO EFFECT ON PAYMENTS FOR EVALUATION AND MANAGEMENT SERVICES.—The monthly fee under this subsection shall have no effect on the amount of payment for evaluation and management services under this title.''.

(d) COINSURANCE.—Section 1833(a)(1) of the Social Security Act (42 U.S.C. 1395l(a)(1)) is amended—

(1) by striking ''and'' before ''(W)''; and

(2) by inserting before the semicolon at the end the following: '', and (X) with respect to patient centered medical home services (as defined in section 1861(hhh)(1)), the amount paid shall be (i) in the case of such services which are physicians' services, the amount determined under subparagraph (N), and (ii) in the case of all other such services, 80 percent of the lesser of the actual charge for the service or the amount determined under a fee schedule established by the Secretary for purposes of this subparagraph''.

(e) EFFECTIVE DATE.—The amendments made by this section shall apply to services furnished on or after January 1, 2012.

SEC. 303. MEDICARE PRIMARY CARE PAYMENT EQUITY AND ACCESS PROVISION.

(a) IN GENERAL.—Section 1848 of the Social Security Act (42 U.S.C. 1395w–4), as amended by section 302(c), is amended by adding at the end the following new subsection:

''(q) PRIMARY CARE PAYMENT EQUITY AND ACCESS.—

''(1) IN GENERAL.—Not later than January 1, 2010, the Secretary shall develop a methodology, in consultation with primary care physician organizations and primary care provider organizations, the Medicare Payment Advisory Commission, and other experts, to increase payments under this section for designated evaluation and management services provided by primary care physicians, primary care providers, and principal care providers through 1 or more of the following:

''(A) A service-specific modifier to the relative value units established for such services.

''(B) Service-specific bonus payments.

''(C) Any other methodology determined appropriate by the Secretary.

''(2) INCLUSION OF PROPOSED CRITERIA.—The methodology developed under paragraph (1) shall include proposed criteria for providers to qualify for such increased payments, including consideration of—

''(A) the type of service being rendered;

''(B) the specialty of the provider providing the service; and

''(C) demonstration by the provider of voluntary participation in programs to improve quality, such as participation in the Physician Quality Reporting Initiative (as determined by the Secretary) or practice-level qualification as a patient centered medical home.

''(3) FUNDING.—

''(A) DETERMINATION.—The Secretary shall determine the aggregate estimated savings for a calendar year as a result of such increased payments on reducing preventable hospital admissions, duplicate testing, medication errors and drug interactions, Intensive Care Unit admissions, per capita health care expenditures, and other savings under this part and part A (including any savings with respect to items and services for which payment is not made under this section).

''(B) FUNDING.—The aggregate amount available for such increased payments during a calendar year shall be equal to the aggregate estimated savings (as determined under subparagraph (A)) for the calendar year (as determined by the Secretary).

''(C) ADDITIONAL FUNDING AS DETERMINED NECESSARY BY THE SECRETARY.—In addition to any funding made available under subparagraph (B), there shall also be available to the Secretary, for purposes of effectively implementing this subsection, such additional funds as the Secretary determines are necessary.''.

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to services furnished on or after January 1, 2010.

SEC. 304. ADDITIONAL INCENTIVE PAYMENT PROGRAM FOR PRIMARY CARE SERVICES FURNISHED IN HEALTH PROFESSIONAL SHORTAGE AREAS.

(a) IN GENERAL.—Section 1833 of the Social Security Act (42 U.S.C. 1395l) is amended by adding at the end the following new subsection:

''(x) ADDITIONAL INCENTIVE PAYMENTS FOR PRIMARY CARE SERVICES FURNISHED IN HEALTH PROFESSIONAL SHORTAGE AREAS.—

''(1) IN GENERAL.—In the case of primary care services furnished on or after January 1, 2010, by a primary care physician or primary care provider in an area that is designated (under section 332(a)(1)(A) of the Public Health Service Act) as a health professional shortage area as identified by the Secretary prior to the beginning of the year involved, in addition to the amount of payment that would otherwise be made for such services under this part, there also shall be paid (on a monthly or quarterly basis) an amount equal to 10 percent of the payment amount for the service under this part.

''(2) DEFINITIONS.—In this subsection:

''(A) PRIMARY CARE PHYSICIAN; PRIMARY CARE PROVIDER.—The terms 'primary care physician' and 'primary care provider' have the meaning given such terms in paragraphs (6) and (7), respectively, of section 3(a) of the Preserving Patient Access to Primary Care Act of 2009.

''(B) PRIMARY CARE SERVICES.—The term 'primary care services' means procedure codes for services in the category of the Healthcare Common Procedure Coding System, as established by the Secretary under section 1848(c)(5) (as of December 31, 2008 and as subsequently modified by the Secretary) consisting of evaluation and management services, but limited to such procedure codes

in the category of office or other outpatient services, and consisting of subcategories of such procedure codes for services for both new and established patients.

''(3) JUDICIAL REVIEW.—There shall be no administrative or judicial review under section 1869, 1878, or otherwise, respecting the identification of primary care physicians, primary care providers, or primary care services under this subsection.''.

(b) CONFORMING AMENDMENT.—Section 1834(g)(2)(B) of the Social Security Act (42 U.S.C. 1395m(g)(2)(B)) is amended by adding at the end the following sentence: ''Section 1833(x) shall not be taken into account in determining the amounts that would otherwise be paid pursuant to the preceding sentence.''.

SEC. 305. PERMANENT EXTENSION OF FLOOR ON MEDICARE WORK GEOGRAPHIC ADJUSTMENT UNDER THE MEDICARE PHYSICIAN FEE SCHEDULE.

Section 1848(e)(1)(E) of the Social Security Act (42 U.S.C. 1395w–4(e)(1)(E)) is amended by striking ''and before January 1, 2010,''.

SEC. 306. PERMANENT EXTENSION OF MEDICARE INCENTIVE PAYMENT PROGRAM FOR PHYSICIAN SCARCITY AREAS.

Section 1833(u) of the Social Security Act (42 U.S.C. 1395l(u)) is amended—

(1) in paragraph (1)—

(A) by inserting ''or on or after July 1, 2009'' after ''before July 1, 2008''; and

(B) by inserting ''(or, in the case of services furnished on or after July 1, 2009, 10 percent)'' after ''5 percent''; and

(2) in paragraph (4)(D), by striking ''before July 1, 2008'' and inserting ''before January 1, 2010''.

SEC. 307. HHS STUDY AND REPORT ON THE PROCESS FOR DETERMINING RELATIVE VALUE UNDER THE MEDICARE PHYSICIAN FEE SCHEDULE.

(a) STUDY.—The Secretary shall conduct a study on the process used by the Secretary for determining relative value under the Medicare physician fee schedule under section 1848(c) of the Social Security Act (42 U.S.C. 1395w–4(c)). Such study shall include an analysis of the following:

(1)(A) Whether the existing process includes equitable representation of primary care physicians (as defined in section 3(a)(6)); and

(B) any changes that may be necessary to ensure such equitable representation.

(2)(A) Whether the existing process provides the Secretary with expert and impartial input from physicians in medical specialties that provide primary care to patients with multiple chronic diseases, the fastest growing part of the Medicare population; and

(B) any changes that may be necessary to ensure such input.

(3)(A) Whether the existing process includes equitable representation of physician medical specialties in proportion to their relative contributions toward caring for Medicare beneficiaries, as determined by the percentage of Medicare billings per specialty, percentage of Medicare encounters by specialty, or such other measures of relative contributions to patient care as determined by the Secretary; and

(B) any changes that may be necessary to reflect such equitable representation.

(4)(A) Whether the existing process, including the application of budget neutrality rules, unfairly disadvantages primary care physicians, primary care providers, or other physicians who principally provide evaluation and management services; and

(B) any changes that may be necessary to eliminate such disadvantages.

(b) REPORT.—Not later than 12 months after the date of enactment of this Act, the Secretary shall submit to Congress a report containing the results of the study conducted under subsection (a), together with recommendations for such legislation and administrative action as the Secretary determines appropriate.

Subtitle B—Preventive Services

SEC. 311. ELIMINATING TIME RESTRICTION FOR INITIAL PREVENTIVE PHYSICAL EXAMINATION.

(a) IN GENERAL.—Section 1862(a)(1)(K) of the Social Security Act (42 U.S.C. 1395y(a)(1)(K)) is amended by striking ''more than'' and all that follows before the comma at the end and inserting ''more than one time during the lifetime of the individual''.

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to services furnished on or after January 1, 2010.

SEC. 312. ELIMINATION OF COST-SHARING FOR PREVENTIVE BENEFITS UNDER THE MEDICARE PROGRAM.

(a) DEFINITION OF PREVENTIVE SERVICES.—Section 1861(ddd) of the Social Security Act (42 U.S.C. 1395w(dd)) is amended—

(1) in the heading, by inserting ''; Preventive Services'' after ''Services'';

(2) in paragraph (1), by striking ''not otherwise described in this title'' and inserting ''not described in subparagraphs (A) through (N) of paragraph (3)''; and

(3) by adding at the end the following new paragraph:

''(3) The term 'preventive services' means the following:

''(A) Prostate cancer screening tests (as defined in subsection (oo)).

''(B) Colorectal cancer screening tests (as defined in subsection (pp)).

''(C) Diabetes outpatient self-management training services (as defined in subsection (qq)).

''(D) Screening for glaucoma for certain individuals (as described in subsection (s)(2)(U)).

''(E) Medical nutrition therapy services for certain individuals (as described in subsection (s)(2)(V)).

''(F) An initial preventive physical examination (as defined in subsection (ww)).

''(G) Cardiovascular screening blood tests (as defined in subsection (xx)(1)).

''(H) Diabetes screening tests (as defined in subsection (yy)).

''(I) Ultrasound screening for abdominal aortic aneurysm for certain individuals (as described in subsection (s)(2)(AA)).

''(J) Pneumococcal and influenza vaccine and their administration (as described in subsection (s)(10)(A)).

''(K) Hepatitis B vaccine and its administration for certain individuals (as described in subsection (s)(10)(B)).

''(L) Screening mammography (as defined in subsection (jj)).

''(M) Screening pap smear and screening pelvic exam (as described in subsection (s)(14)).

''(N) Bone mass measurement (as defined in subsection (rr)).

''(O) Additional preventive services (as determined under paragraph (1)).''.

(b) COINSURANCE.—

(1) GENERAL APPLICATION.—

(A) IN GENERAL.—Section 1833(a)(1) of the Social Security Act (42 U.S.C. 1395l(a)(1)), as amended by section 302, is amended—

(i) in subparagraph (T), by striking ''80 percent'' and inserting ''100 percent'';

(ii) in subparagraph (W), by striking ''80 percent'' and inserting ''100 percent'';

(iii) by striking ''and'' before ''(X)''; and

(iv) by inserting before the semicolon at the end the following: '', and (Y) with respect to preventive services described in subparagraphs (A) through (O) of section 1861(ddd)(3), the amount paid shall be 100 percent of the lesser of the actual charge for the services or the amount determined under the fee schedule that applies to such services under this part''.

(2) ELIMINATION OF COINSURANCE FOR SCREENING SIGMOIDOSCOPIES AND COLONOSCOPIES.—Section 1834(d) of the Social Security Act (42 U.S.C. 1395m(d)) is amended—

(A) in paragraph (2)—

(i) in subparagraph (A), by inserting '', except that payment for such tests under such section shall be 100 percent of the payment determined under such section for such tests'' before the period at the end; and

(ii) in subparagraph (C)—

(I) by striking clause (ii); and

(II) in clause (i)—

(aa) by striking ''(i) IN GENERAL.—Notwithstanding'' and inserting ''Notwithstanding'';

(bb) by redesignating subclauses (I) and (II) as clauses (i) and (ii), respectively, and moving such clauses 2 ems to the left; and

(cc) in the flush matter following clause (ii), as so redesignated, by inserting ''100 percent of'' after ''based on''; and

(B) in paragraph (3)—

(i) in subparagraph (A), by inserting '', except that payment for such tests under such section shall be 100 percent of the payment determined under such section for such tests'' before the period at the end; and

(ii) in subparagraph (C)—

(I) by striking clause (ii); and

(II) in clause (i)—

(aa) by striking ''(i) IN GENERAL.—Notwithstanding'' and inserting ''Notwithstanding''; and

(bb) by inserting ''100 percent of'' after ''based on''.

(3) ELIMINATION OF COINSURANCE IN OUTPATIENT HOSPITAL SETTINGS.—

(A) EXCLUSION FROM OPD FEE SCHEDULE.—Section 1833(t)(1)(B)(iv) of the Social Security Act (42 U.S.C. 1395l(t)(1)(B)(iv)) is amended by striking ''and diagnostic mammography'' and inserting '', diagnostic mammography, and preventive services (as defined in section 1861(ddd)(3))''.

(B) CONFORMING AMENDMENTS.—Section 1833(a)(2) of the Social Security Act (42 U.S.C. 1395l(a)(2)) is amended—

(i) in subparagraph (F), by striking ''and'' after the semicolon at the end;

(ii) in subparagraph (G)(ii), by adding ''and'' at the end; and

(iii) by adding at the end the following new subparagraph:

''(H) with respect to preventive services (as defined in section 1861(ddd)(3)) furnished by an outpatient department of a hospital, the amount determined under paragraph (1)(W) or (1)(X), as applicable;''.

(c) WAIVER OF APPLICATION OF DEDUCTIBLE.—The first sentence of section 1833(b) of the Social Security Act (42 U.S.C. 1395l(b)) is amended—

(1) in clause (1), by striking ''items and services described in section 1861(s)(10)(A)'' and inserting ''preventive services (as defined in section 1861(ddd)(3))'';

(2) by inserting ''and'' before ''(4)''; and

(3) by striking '', (5)'' and all that follows up to the period at the end.

SEC. 313. HHS STUDY AND REPORT ON FACILITATING THE RECEIPT OF MEDICARE PREVENTIVE SERVICES BY MEDICARE BENEFICIARIES.

(a) STUDY.—The Secretary, in consultation with provider organizations and other appropriate stakeholders, shall conduct a study on—

(1) ways to assist primary care physicians and primary care providers (as defined in section 3(a)) in—

(A) furnishing appropriate preventive services (as defined in section 1861(ddd)(3) of the Social Security Act, as added by section 312) to individuals enrolled under part B of title XVIII of such Act; and

(B) referring such individuals for other items and services furnished by other physicians and health care providers; and

(2) the advisability and feasability of making additional payments under the Medicare program to physicians and primary care providers for—

(A) the work involved in ensuring that such individuals receive appropriate preventive services furnished by other physicians and health care providers; and

(B) incorporating the resulting clinical information into the treatment plan for the individual.

(b) REPORT.—Not later than 12 months after the date of enactment of this Act, the Secretary shall submit to Congress a report containing the results of the study conducted under subsection (a), together with recommendations for such legislation and administrative action as the Secretary determines appropriate.

Subtitle C—Other Provisions

SEC. 321. HHS STUDY AND REPORT ON IMPROVING THE ABILITY OF PHYSICIANS AND PRIMARY CARE PROVIDERS TO ASSIST MEDICARE BENEFICIARIES IN OBTAINING NEEDED PRESCRIPTIONS UNDER MEDICARE PART D.

(a) STUDY.—The Secretary, in consultation with physician organizations and other appropriate stakeholders, shall conduct a study on the development and implementation of mechanisms to facilitate increased efficiency relating to the role of physicians and primary care providers in Medicare beneficiaries obtaining needed prescription drugs under the Medicare prescription drug program under part D of title XVIII of the Social Security Act. Such study shall include an analysis of ways to—

(1) improve the accessibility of formulary information;

(2) streamline the prior authorization, exception, and appeals processes, through, at a minimum, standardizing formats and allowing electronic exchange of information; and

(3) recognize the work of the physician and primary care provider involved in the prescribing process, especially work that may extend beyond the amount considered to be bundled into payment for evaluation and management services.

(b) REPORT.—Not later than 12 months after the date of enactment of this Act, the Secretary shall submit to Congress a report containing the results of the study conducted under subsection (a), together with recommendations for such legislation and administrative action as the Secretary determines appropriate.

SEC. 322. HHS STUDY AND REPORT ON IMPROVED PATIENT CARE THROUGH INCREASED CAREGIVER AND PHYSICIAN INTERACTION.

(a) STUDY.—The Secretary, in consultation with appropriate stakeholders, shall conduct a study on the development and implementation of mechanisms to promote and increase interaction between physicians or primary care providers and the families of Medicare beneficiaries, as well as other caregivers who support such beneficiaries, for the purpose of improving patient care under the Medicare program. Such study shall include an analysis of—

(1) ways to recognize the work of physicians and primary care providers involved in discussing clinical issues with caregivers that relate to the care of the beneficiary; and

(2) regulations under the Medicare program that are barriers to interactions between caregivers and physicians or primary care providers and how such regulations should be revised to eliminate such barriers.

(b) REPORT.—Not later than 12 months after the date of enactment of this Act, the Secretary shall submit to Congress a report containing the results of the study conducted under subsection (a), together with recommendations for such legislation and administrative action as the Secretary determines appropriate.

SEC. 323. IMPROVED PATIENT CARE THROUGH EXPANDED SUPPORT FOR LIMITED ENGLISH PROFICIENCY (LEP) SERVICES.

(a) ADDITIONAL PAYMENTS FOR PRIMARY CARE PHYSICIANS AND PRIMARY CARE PROVIDERS.—Section 1833 of the Social Security Act (42 U.S.C. 1395l), as amended by section 304, is amended by adding at the end the following new subsection:

''(y) ADDITIONAL PAYMENTS FOR PROVIDING SERVICES TO INDIVIDUALS WITH LIMITED ENGLISH PROFICIENCY.—

''(1) IN GENERAL.—In the case of primary care providers' services furnished on or after January 1, 2010, to an individual with limited English proficiency by a provider, in addition to the amount of payment that would otherwise be made for such services under this part, there shall also be paid an appropriate amount (as determined by the Secretary) in order to recognize the additional time involved in furnishing the service to such individual.

''(2) JUDICIAL REVIEW.—There shall be no administrative or judicial review under section 1869, 1878, or otherwise, respecting the determination of the amount of additional payment under this subsection.''.

(b) NATIONAL CLEARINGHOUSE.—Not later than 180 days after the date of enactment of this Act, the Secretary shall establish a national clearinghouse to make available to the primary care physicians, primary care providers, patients, and States translated documents regarding patient care and education under the Medicare program, the Medicaid program, and the State Children's Health Insurance Program under titles XVIII, XIX, and XXI, respectively, of the Social Security Act.

(c) GRANTS TO SUPPORT LANGUAGE TRANSLATION SERVICES IN UNDERSERVED COMMUNITIES.—

(1) AUTHORITY TO AWARD GRANTS.—The Secretary shall award grants to support language translation services for primary care physicians and primary care providers in medically underserved areas (as defined in section 3(c)).

(2) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Secretary to award grants under this subsection, such sums as are necessary for fiscal years beginning with fiscal year 2010.

SEC. 324. HHS STUDY AND REPORT ON USE OF REAL-TIME MEDICARE CLAIMS ADJUDICATION.

(a) STUDY.—The Secretary shall conduct a study to assess the ability of the Medicare program under title XVIII of the Social Security Act to engage in real-time claims adjudication for items and services furnished to Medicare beneficiaries.

(b) CONSULTATION.—In conducting the study under subsection (a), the Secretary consult with stakeholders in the private sector, including stakeholders who are using or are testing real-time claims adjudication systems.

(c) REPORT.—Not later than January 1, 2011, the Secretary shall submit to Congress a report containing the results of the study conducted under subsection (a), together with recommendations for such legislation and administrative action as the Secretary determines appropriate.

SEC. 325. ONGOING ASSESSMENT BY MEDPAC OF THE IMPACT OF MEDICARE PAYMENTS ON PRIMARY CARE ACCESS AND EQUITY.

The Medicare Payment Advisory Commission, beginning in 2010 and in each of its subsequent annual reports to Congress on Medicare physician payment policies, shall provide an assessment of the impact of changes in Medicare payment policies in improving access to and equity of payments to primary care physicians and primary care providers. Such assessment shall include an assessment of the effectiveness, once implemented, of the Medicare payment-related reforms required by this Act to support primary care as well as any other payment changes that may be required by Congress to improve access to and equity of payments to primary care physicians and primary care providers.

SEC. 326. DISTRIBUTION OF ADDITIONAL RESIDENCY POSITIONS.

(a) IN GENERAL.—Section 1886(h) of the Social Security Act (42 U.S.C. 1395ww(h)) is amended—

(1) in paragraph (4)(F)(i), by striking ''paragraph (7)'' and inserting ''paragraphs (7) and (8)'';

(2) in paragraph (4)(H)(i), by striking ''paragraph (7)'' and inserting ''paragraphs (7) and (8)''; and

(3) by adding at the end the following new paragraph:

''(8) DISTRIBUTION OF ADDITIONAL RESIDENCY POSITIONS.—

''(A) ADDITIONAL RESIDENCY POSITIONS.—

''(i) REDUCTION IN LIMIT BASED ON UNUSED POSITIONS.—

''(I) IN GENERAL.—The Secretary shall reduce the otherwise applicable resident limit for a hospital that the Secretary determines had residency positions that were unused for all 5 of the most recent cost reporting periods ending prior to the date of enactment of this paragraph by an amount that is equal to the number of such unused residency positions.

''(II) EXCEPTION FOR RURAL HOSPITALS AND CERTAIN OTHER HOSPITALS.—This subparagraph shall not apply to a hospital—

''(aa) located in a rural area (as defined in subsection (d)(2)(D)(ii));

''(bb) that has participated in a voluntary reduction plan under paragraph (6); or

''(cc) that has participated in a demonstration project approved as of October 31, 2003, under the authority of section 402 of Public Law 90–248.

''(ii) NUMBER AVAILABLE FOR DISTRIBUTION.—The number of additional residency positions available for distribution under subparagraph (B) shall be an amount that the Secretary determines would result in a 15 percent increase in the aggregate number of full-time equivalent residents in approved medical training programs (as determined based on the most recent cost reports available at the time of distribution). One-third of such number shall only be available for distribution to hospitals described in subclause (I) of subparagraph (B)(ii) under such subparagraph.

''(B) DISTRIBUTION.—

''(i) IN GENERAL.—The Secretary shall increase the otherwise applicable resident limit for each qualifying hospital that submits an application under this subparagraph by such number as the Secretary may approve for portions of cost reporting periods occurring on or after the date of enactment of this paragraph. The aggregate number of increases in the otherwise applicable resident limit under this subparagraph shall be equal to the number of additional residency positions available for distribution under subparagraph (A)(ii).

''(ii) DISTRIBUTION TO HOSPITALS ALREADY OPERATING OVER RESIDENT LIMIT.—

''(I) IN GENERAL.—Subject to subclause (II), in the case of a hospital in which the reference resident level of the hospital (as defined in clause (ii)) is greater than the otherwise applicable resident limit, the increase in the otherwise applicable resident limit

under this subparagraph shall be an amount equal to the product of the total number of additional residency positions available for distribution under subparagraph (A)(ii) and the quotient of—

''(aa) the number of resident positions by which the reference resident level of the hospital exceeds the otherwise applicable resident limit for the hospital; and

''(bb) the number of resident positions by which the reference resident level of all such hospitals with respect to which an application is approved under this subparagraph exceeds the otherwise applicable resident limit for such hospitals.

''(II) REQUIREMENTS.—A hospital described in subclause (I)—

''(aa) is not eligible for an increase in the otherwise applicable resident limit under this subparagraph unless the amount by which the reference resident level of the hospital exceeds the otherwise applicable resident limit is not less than 10 and the hospital trains at least 25 percent of the full-time equivalent residents of the hospital in primary care and general surgery (as of the date of enactment of this paragraph); and

''(bb) shall continue to train at least 25 percent of the full-time equivalent residents of the hospital in primary care and general surgery for the 10-year period beginning on such date.

In the case where the Secretary determines that a hospital no longer meets the requirement of item (bb), the Secretary may reduce the otherwise applicable resident limit of the hospital by the amount by which such limit was increased under this clause.

''(III) CLARIFICATION REGARDING ELIGIBILITY FOR OTHER ADDITIONAL RESIDENCY POSITIONS.—Nothing in this clause shall be construed as preventing a hospital described in subclause (I) from applying for additional residency positions under this paragraph that are not reserved for distribution under this clause.

''(iii) REFERENCE RESIDENT LEVEL.—

''(I) IN GENERAL.—Except as otherwise provided in subclause (II), the reference resident level specified in this clause for a hospital is the resident level for the most recent cost reporting period of the hospital ending on or before the date of enactment of this paragraph, for which a cost report has been settled (or, if not, submitted (subject to audit)), as determined by the Secretary.

''(II) USE OF MOST RECENT ACCOUNTING PERIOD TO RECOGNIZE EXPANSION OF EXISTING PROGRAM OR ESTABLISHMENT OF NEW PROGRAM.—If a hospital submits a timely request to increase its resident level due to an expansion of an existing residency training program or the establishment of a new residency training program that is not reflected on the most recent cost report that has been settled (or, if not, submitted (subject to audit)), after audit and subject to the discretion of the Secretary, the reference resident level for such hospital is the resident level for the cost reporting period that includes the additional residents attributable to such expansion or establishment, as determined by the Secretary.

''(C) CONSIDERATIONS IN REDISTRIBUTION.—In determining for which hospitals the increase in the otherwise applicable resident limit is provided under subparagraph (B) (other than an increase under subparagraph (B)(ii)), the Secretary shall take into account the demonstrated likelihood of the hospital filling the positions within the first 3 cost reporting periods beginning on or after July 1, 2010, made available under this paragraph, as determined by the Secretary.

''(D) PRIORITY FOR CERTAIN AREAS.—In determining for which hospitals the increase in the otherwise applicable resident limit is provided under subparagraph (B) (other than an increase under subparagraph (B)(ii)), the Secretary shall distribute the increase to hospitals based on the following criteria:

''(i) The Secretary shall give preference to hospitals that submit applications for new primary care and general surgery residency positions. In the case of any increase based on such preference, a hospital shall ensure that—

''(I) the position made available as a result of such increase remains a primary care or general surgery residency position for not less than 10 years after the date on which the position is filled; and

''(II) the total number of primary care and general surgery residency positions in the hospital (determined based on the number of such positions as of the date of such increase, including any position added as a result of such increase) is not decreased during such 10-year period.

In the case where the Secretary determines that a hospital no longer meets the requirement of subclause (II), the Secretary may reduce the otherwise applicable resident limit of the hospital by the amount by which such limit was increased under this paragraph.

''(ii) The Secretary shall give preference to hospitals that emphasizes training in community health centers and other community-based clinical settings.

''(iii) The Secretary shall give preference to hospitals in States that have more medical students than residency positions available (including a greater preference for those States with smaller resident-to-medical-student ratios). In determining the number of medical students in a State for purposes of the preceding sentence, the Secretary shall include planned students at medical schools which have provisional accreditation by the Liaison Committee on Medical Education or the American Osteopathic Association.

''(iv) The Secretary shall give preference to hospitals in States that have low resident-to-population ratios (including a greater preference for those States with lower resident-to-population ratios).

''(E) LIMITATION.—

''(i) IN GENERAL.—Except as provided in clause (ii), in no case may a hospital (other than a hospital described in subparagraph (B)(ii)(I), subject to the limitation under subparagraph (B)(ii)(III)) apply for more than 50 full-time equivalent additional residency positions under this paragraph.

''(ii) INCREASE IN NUMBER OF ADDITIONAL POSITIONS AVAILABLE FOR DISTRIBUTION.—The Secretary shall increase the number of full-time equivalent additional residency positions a hospital may apply for under this paragraph if the Secretary determines that the number of additional residency positions available for distribution under subparagraph (A)(ii) exceeds the number of such applications approved.

''(F) APPLICATION OF PER RESIDENT AMOUNTS FOR PRIMARY CARE AND NONPRIMARY CARE.—With respect to additional residency positions in a hospital attributable to the increase provided under this paragraph, the approved FTE resident amounts are deemed to be equal to the hospital per resident amounts for primary care and nonprimary care computed under paragraph (2)(D) for that hospital.

''(G) DISTRIBUTION.—The Secretary shall distribute the increase to hospitals under this paragraph not later than 2 years after the date of enactment of this paragraph.''.

(b) IME.—

(1) IN GENERAL.—Section 1886(d)(5)(B)(v) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(B)(v)), in the second sentence, is amended—

(A) by striking ''subsection (h)(7)'' and inserting ''subsections (h)(7) and (h)(8)''; and

(B) by striking ''it applies'' and inserting ''they apply''.

(2) CONFORMING PROVISION.—Section 1886(d)(5)(B) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(B)) is amended by adding at the end the following clause:

''(x) For discharges occurring on or after the date of enactment of this clause, insofar as an additional payment amount under this subparagraph is attributable to resident positions distributed to a hospital under subsection (h)(8)(B), the indirect teaching adjustment factor shall be computed in the same manner as provided under clause (ii) with respect to such resident positions.''.

SEC. 327. COUNTING RESIDENT TIME IN OUTPATIENT SETTINGS.

(a) D–GME.—Section 1886(h)(4)(E) of the Social Security Act (42 U.S.C. 1395ww(h)(4)(E)) is amended—

(1) by striking ''under an approved medical residency training program''; and

(2) by striking ''if the hospital incurs all, or substantially all, of the costs for the training program in that setting'' and inserting ''if the hospital continues to incur the costs of the stipends and fringe benefits of the resident during the time the resident spends in that setting''.

(b) IME.—Section 1886(d)(5)(B)(iv) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(B)(iv)) is amended—

(1) by striking ''under an approved medical residency training program''; and

(2) by striking ''if the hospital incurs all, or substantially all, of the costs for the training program in that setting'' and inserting ''if the hospital continues to incur the costs of the stipends and fringe benefits of the intern or resident during the time the intern or resident spends in that setting''.

(c) EFFECTIVE DATES; APPLICATION.—

(1) IN GENERAL.—Effective for cost reporting periods beginning on or after July 1, 2009, the Secretary of Health and Human Services shall implement the amendments made by this section in a manner so as to apply to cost reporting periods beginning on or after July 1, 2009.

(2) APPLICATION.—The amendments made by this section shall not be applied in a manner that requires reopening of any settled hospital cost reports as to which there is not a jurisdictionally proper appeal pending as of the date of the enactment of this Act on the issue of payment for indirect costs of medical education under section 1886(d)(5)(B) of the Social Security (42 U.S.C. 1395ww(d)(5)(B))Act or for direct graduate medical education costs under section 1886(h) of such Act (42 U.S.C. 1395ww(h)).

SEC. 328. RULES FOR COUNTING RESIDENT TIME FOR DIDACTIC AND SCHOLARLY ACTIVITIES AND OTHER ACTIVITIES.

(a) GME.—Section 1886(h) of the Social Security Act (42 U.S.C. 1395ww(h)), as amended by section 327(a), is amended—

(1) in paragraph (4)(E)—

(A) by designating the first sentence as a clause (i) with the heading ''IN GENERAL'' and appropriate indentation and by striking ''Such rules'' and inserting ''Subject to clause (ii), such rules''; and

(B) by adding at the end the following new clause:

''(ii) TREATMENT OF CERTAIN NONHOSPITAL AND DIDACTIC ACTIVITIES.—Such rules shall provide that all time spent by an intern or resident in an approved medical residency training program in a nonhospital setting that is primarily engaged in furnishing patient care (as defined in paragraph (5)(K)) in non-patient care activities, such as didactic conferences and seminars, but not including research not associated with the treatment or diagnosis of a particular patient, as such

time and activities are defined by the Secretary, shall be counted toward the determination of full-time equivalency.'';

(2) in paragraph (4), by adding at the end the following new subparagraph:

''(I) In determining the hospital's number of full-time equivalent residents for purposes of this subsection, all the time that is spent by an intern or resident in an approved medical residency training program on vacation, sick leave, or other approved leave, as such time is defined by the Secretary, and that does not prolong the total time the resident is participating in the approved program beyond the normal duration of the program shall be counted toward the determination of full-time equivalency.''; and

(3) in paragraph (5), by adding at the end the following new subparagraph:

''(M) NONHOSPITAL SETTING THAT IS PRIMARILY ENGAGED IN FURNISHING PATIENT CARE.—The term 'nonhospital setting that is primarily engaged in furnishing patient care' means a nonhospital setting in which the primary activity is the care and treatment of patients, as defined by the Secretary.''.

(b) IME DETERMINATIONS.—Section 1886(d)(5)(B) of such Act (42 U.S.C. 1395ww(d)(5)(B)), as amended by section 326(b), is amended by adding at the end the following new clause:

''(xi)(I) The provisions of subparagraph (I) of subsection (h)(4) shall apply under this subparagraph in the same manner as they apply under such subsection.

''(II) In determining the hospital's number of full-time equivalent residents for purposes of this subparagraph, all the time spent by an intern or resident in an approved medical residency training program in non-patient care activities, such as didactic conferences and seminars, as such time and activities are defined by the Secretary, that occurs in the hospital shall be counted toward the determination of full-time equivalency if the hospital—

''(aa) is recognized as a subsection (d) hospital;

''(bb) is recognized as a subsection (d) Puerto Rico hospital;

''(cc) is reimbursed under a reimbursement system authorized under section 1814(b)(3); or

''(dd) is a provider-based hospital outpatient department.

''(III) In determining the hospital's number of full-time equivalent residents for purposes of this subparagraph, all the time spent by an intern or resident in an approved medical residency training program in research activities that are not associated with the treatment or diagnosis of a particular patient, as such time and activities are defined by the Secretary, shall not be counted toward the determination of full-time equivalency.''.

(c) EFFECTIVE DATES; APPLICATION.—

(1) IN GENERAL.—Except as otherwise provided, the Secretary of Health and Human Services shall implement the amendments made by this section in a manner so as to apply to cost reporting periods beginning on or after January 1, 1983.

(2) DIRECT GME.—Section 1886(h)(4)(E)(ii) of the Social Security Act, as added by subsection (a)(1)(B), shall apply to cost reporting periods beginning on or after July 1, 2009.

(3) IME.—Section 1886(d)(5)(B)(xi)(III) of the Social Security Act, as added by subsection (b), shall apply to cost reporting periods beginning on or after October 1, 2001. Such section, as so added, shall not give rise to any inference on how the law in effect prior to such date should be interpreted.

(4) APPLICATION.—The amendments made by this section shall not be applied in a manner that requires reopening of any settled hospital cost reports as to which there is not a jurisdictionally proper appeal pending as of the date of the enactment of this Act on the issue of payment for indirect costs of medical education under section 1886(d)(5)(B) of the Social Security Act or for direct graduate medical education costs under section 1886(h) of such Act.

SEC. 329. PRESERVATION OF RESIDENT CAP POSITIONS FROM CLOSED AND ACQUIRED HOSPITALS.

(a) GME.—Section 1886(h)(4)(H) of the Social Security Act (42 U.S.C. Section 1395ww(h)(4)(H)) is amended by adding at the end the following new clauses:

''(vi) REDISTRIBUTION OF RESIDENCY SLOTS AFTER A HOSPITAL CLOSES.—

''(I) IN GENERAL.—Subject to the succeeding provisions of this clause, the Secretary shall, by regulation, establish a process under which, in the case where a hospital with an approved medical residency program closes on or after the date of enactment of the Balanced Budget Act of 1997, the Secretary shall increase the otherwise applicable resident limit under this paragraph for other hospitals in accordance with this clause.

''(II) PRIORITY FOR HOSPITALS IN CERTAIN AREAS.—Subject to the succeeding provisions of this clause, in determining for which hospitals the increase in the otherwise applicable resident limit is provided under such process, the Secretary shall distribute the increase to hospitals located in the following priority order (with preference given within each category to hospitals that are members of the same affiliated group (as defined by the Secretary under clause (ii)) as the closed hospital):

''(aa) First, to hospitals located in the same core-based statistical area as, or a core-based statistical area contiguous to, the hospital that closed.

''(bb) Second, to hospitals located in the same State as the hospital that closed.

''(cc) Third, to hospitals located in the same region of the country as the hospital that closed.

''(dd) Fourth, to all other hospitals.

''(III) REQUIREMENT HOSPITAL LIKELY TO FILL POSITION WITHIN CERTAIN TIME PERIOD.—The Secretary may only increase the otherwise applicable resident limit of a hospital under such process if the Secretary determines the hospital has demonstrated a likelihood of filling the positions made available under this clause within 3 years.

''(IV) LIMITATION.—The aggregate number of increases in the otherwise applicable resident limits for hospitals under this clause shall be equal to the number of resident positions in the approved medical residency programs that closed on or after the date described in subclause (I).

''(vii) SPECIAL RULE FOR ACQUIRED HOSPITALS.—

''(I) IN GENERAL.—In the case of a hospital that is acquired (through any mechanism) by another entity with the approval of a bankruptcy court, during a period determined by the Secretary (but not less than 3 years), the applicable resident limit of the acquired hospital shall, except as provided in subclause (II), be the applicable resident limit of the hospital that was acquired (as of the date immediately before the acquisition), without regard to whether the acquiring entity accepts assignment of the Medicare provider agreement of the hospital that was acquired, so long as the acquiring entity continues to operate the hospital that was acquired and to furnish services, medical residency programs, and volume of patients similar to the services, medical residency programs, and volume of patients of the hospital that was acquired (as determined by the Secretary) during such period.

''(II) LIMITATION.—Subclause (I) shall only apply in the case where an acquiring entity waives the right as a new provider under the program under this title to have the otherwise applicable resident limit of the acquired hospital re-established or increased.''.

(b) IME.—Section 1886(d)(5)(B)(v) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(B)(v)), in the second sentence, as amended by section 326(b), is amended by striking ''subsections (h)(7) and (h)(8)'' and inserting ''subsections (h)(4)(H)(vi), (h)(4)(H)(vii), (h)(7), and (h)(8)''.

(c) APPLICATION.—The amendments made by this section shall not be applied in a manner that requires reopening of any settled hospital cost reports as to which there is not a jurisdictionally proper appeal pending as of the date of the enactment of this Act on the issue of payment for indirect costs of medical education under section 1886(d)(5)(B) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(B))or for direct graduate medical education costs under section 1886(h) of such Act (42 U.S.C. 1395ww(h)).

(d) NO AFFECT ON TEMPORARY FTE CAP ADJUSTMENTS.—The amendments made by this section shall not affect any temporary adjustment to a hospital's FTE cap under section 413.79(h) of title 42, Code of Federal Regulations (as in effect on the date of enactment of this Act).

SEC. 330. QUALITY IMPROVEMENT ORGANIZATION ASSISTANCE FOR PHYSICIAN PRACTICES SEEKING TO BE PATIENT CENTERED MEDICAL HOME PRACTICES.

Not later than 90 days after the date of enactment of this Act, the Secretary of Health and Human Services shall revise the 9th Statement of Work under the Quality Improvement Program under part B of title XI of the Social Security Act to include a requirement that, in order to be an eligible Quality Improvement Organization (in this section referred to as a `QIO') for the 9th Statement of Work contract cycle, a QIO shall provide assistance, including technical assistance, to physicians under the Medicare program under title XVIII of the Social Security Act that seek to acquire the elements necessary to be recognized as a patient centered medical home practice under the National Committee for Quality Assurance's Physician Practice Connections-PCMH module (or any successor module issued by such Committee).

TITLE IV—STUDIES

SEC. 401. STUDY CONCERNING THE DESIGNATION OF PRIMARY CARE AS A SHORTAGE PROFESSION.

(a) IN GENERAL.—Not later than June 30, 2010, the Secretary of Labor shall conduct a study and submit to the Committee on Education and Labor of the House of Representatives and the Committee on Health, Education, Labor, and Pensions a report that contains—

(1) a description of the criteria for the designation of primary care physicians as professions in shortage as defined by the Secretary under section 212(a)(5)(A) of the Immigration and Nationality Act;

(2) the findings of the Secretary on whether primary care physician professions will, on the date on which the report is submitted, or within the 5-year period beginning on such date, satisfy the criteria referred to in paragraph (1); and

(3) if the Secretary finds that such professions will not satisfy such criteria, recommendations for modifications to such criteria to enable primary care physicians to be so designated as a profession in shortage.

(b) REQUIREMENTS.—In conducting the study under subsection (a), the Secretary of Labor shall consider workforce data from the Health Resources and Services Administration, the Council on Graduate Medical Education, the Association of American Medical

Colleges, and input from physician membership organizations that represent primary care physicians.

SEC. 402. STUDY CONCERNING THE EDUCATION DEBT OF MEDICAL SCHOOL GRADUATES.

(a) STUDY.—The Comptroller General of the United States shall conduct a study to evaluate the higher education-related indebtedness of medical school graduates in the United States at the time of graduation from medical school, and the impact of such indebtedness on specialty choice, including the impact on the field of primary care.

(b) REPORT.—

(1) SUBMISSION AND DISSEMINATION OF REPORT.—Not later than 1 year after the date of enactment of this Act, the Comptroller General shall submit a report on the study required by subsection (a) to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Education and Labor of the House of Representatives, and shall make such report widely available to the public.

(2) ADDITIONAL REPORTS.—The Comptroller General may periodically prepare and release as necessary additional reports on the topic described in subsection (a).

SEC. 403. STUDY ON MINORITY REPRESENTATION IN PRIMARY CARE.

(a) STUDY.—The Secretary of Health and Human Services, acting through the Administrator of the Health Resources and Services Administration, shall conduct a study of minority representation in training, and in practice, in primary care specialties.

(b) REPORT.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Administrator of the Health Resources and Services Administration, shall submit to the appropriate committees of Congress a report concerning the study conducted under subsection (a), including recommendations for achieving a primary care workforce that is more representative of the population of the United States.

AMERICAN COLLEGE OF OSTEOPATHIC FAMILY PHYSICIANS,
Arlington Heights, IL, May 21, 2009.

Hon. MARIA CANTWELL,
U.S. Senate,
Washington, DC.

DEAR SENATOR CANTWELL: On behalf of the American College of Osteopathic Family Physicians (ACOFP), I am pleased to offer you our strong support for the ''Preserving Patient Access to Primary Care Act''. This legislation lays the groundwork for a much needed boost to the primary care physician workforce through reforms of both the Medicare payment system and the graduate medical education (GME) system. The ACOFP lauds your ambitious leadership on these important issues and looks forward to helping you secure enactment of this legislation.

As you are well aware, the current Medicare physician payment system neglects to recognize the value of primary care services in the health care delivery system. Studies show that access to primary health care is associated with better health outcomes and lower health care costs. We commend you on the emphasis your legislation places on addressing payment equity among physicians by increasing payments for evaluation and management services and providing bonus payments for care coordination and other tenets central to the delivery of primary care.

The ACOFP applauds the provisions included in the ''Preserving Patient Access to Primary Care Act'' to expand the Patient Centered Medical Home (PCMH). Building upon the progress made in the current Medicare demonstration projects, your legislation would require that Medicare transition to a new payment methodology to provide monthly payments to PCMH practices that provide care coordination to Medicare beneficiaries. Additionally, grants to states for inclusion of the PCMH into Medicaid and SCHIP programs will further provide patients with on-going access to coordinated care by a physician.

Over the last decade, the population of our country has increased and grown older. Increasing access to health care coverage for all Americans is at the center of the health care reform debate. We must work to ensure that our nation's physician workforce is capable of meeting future increased demand. Central to achieving this is a strong GME system.

The current Medicare payment system in the United States neglects the value of didactic experiences, training opportunities in non-hospital settings, and voluntary physician supervision of medical residents within the GME system. The ACOFP is supportive of your efforts to create new training opportunities in non-hospital settings as well as those seeking to clarify existing regulations governing non-hospital training. Recent statistics associated with career choices of medical school graduates reveal the acute need to increase our nation's supply of family physicians. The ACOFP strongly believes that by providing experiences in non-hospital settings for resident physicians, especially those in primary care specialties, increases the likelihood that they will seek practice opportunities in those settings.

Finally, the ACOFP supports your efforts to increase the number of primary care physicians through new scholarship and loan forgiveness programs. We recognize that the education debt burden carried by medical school graduates discourages students from seeking careers in public health service, seeking careers in family practice or practicing in underserved areas. According to the American Association of Colleges of Osteopathic Medicine (AACOM), the average osteopathic medical school graduate has a debt load of $168,031. Further, the average first year medical resident stipend is $44,747. Scholarships and loan forgiveness for physicians who agree to practice primary care medicine in underserved areas would allow medical school graduates to pursue careers in medical specialties based upon their individual career interests rather than their financial obligations, while additionally addressing geographic disparities in access to care.

Again, thank you for your leadership on this important legislation. The ACOFP and our members stand ready to assist you in securing enactment of this important legislation.

Respectfully,

JAN D. ZIEREN,
ACOFP President.

MAY 20, 2009.

Hon. MARIA CANTWELL,
U.S. Senate,
Washington, DC.

DEAR SENATOR CANTWELL: I am writing on behalf of the American Nurses Association (ANA) to applaud your efforts to address the shortage of primary care providers by introducing the Preserving Patient Access to Primary Care Act of 2009. ANA strongly supports this legislation because it recognizes the integral role nurses and nurse practitioners play in the delivery of primary care and helps bring the focus of our health care system back where it belongs—on the patient and the community.

The American Nurses Association is the only full-service national association representing the interests of 2.9 million registered nurses (RNs). Through our 51 constituent nursing associations, we represent RNs across the nation in all educational and practice settings. ANA believes that a health care system that is patient-centered, comprehensive, accessible, and delivers quality care for all is something that should not be a partisan or political issue.

The Preserving Patient Access to Primary Care Act of 2009 would provide scholarship and loan repayment opportunities for primary care providers who serve in areas with critical shortages of primary care services. Secondly, the bill would increase Medicare reimbursements for primary care providers, and provide Medicare payments for care coordination services, and monthly payments to practices which serve as patient centered medical homes. Moreover, the Preserving Patient Access to Primary Care Act of 2009 aims to support an interdisciplinary model in which providers, physicians and nurses, are able to practice collaboratively and to the full extent of their education and licensure on behalf of the patient.

The American Nurses Association is proud to support this legislation and we look forward to working with you and others in the health care community to ensure that your vision of strengthening primary care becomes reality.

Sincerely,

ROSE GONZALEZ,
Director, Government Affairs,
American Nurses Association.

AMERICAN OSTEOPATHIC ASSOCIATION,
Washington, DC, May 20, 2009.

Hon. MARIA CANTWELL,
U.S. Senate,
Washington, DC.

Hon. SUSAN COLLINS,
U.S. Senate,
Washington, DC.

DEAR SENATORS CANTWELL AND COLLINS: On behalf of the American Osteopathic Association (AOA) and the 64,000 osteopathic physicians it represents, I am pleased to inform you of our strong support for the ''Preserving Patient Access to Primary Care Act.'' We believe your legislation would provide a critical boost to the primary care physician workforce through innovative changes to the Medicare payment structure and graduate medical education system, among other reforms. The AOA commends your leadership on these important issues and we are committed to assisting you in securing enactment of this legislation.

We applaud the emphasis your legislation places upon improving primary care through alternative payment mechanisms. As you know, the Medicare physician payment system is fundamentally flawed and fails to recognize the value of primary care services in achieving savings through prevention and care coordination. Studies indicate that income disparities have a significant negative impact on the choice of primary care as a career. The ''Preserving Patient Access to Primary Care Act'' would promote payment equity for primary care physicians by increasing payments for evaluation and management services and providing bonus payments for other important primary services. The AOA appreciates your foresight and recognition of the long-term savings that will be realized through increased access to primary care.

The AOA strongly supports an expansion of the Patient Centered Medical Home (PCMH) through the Medicare demonstration project and grants to states for inclusion of PCMH models in their Medicaid and SCHIP programs. Your legislation provides a monthly primary care management fee for physicians who are designated the health home of a Medicare beneficiary and provide continuous

medical care. This policy is consistent with the principles of the patient-centered medical home as envisioned by the AOA. The PCMH payment policy contained in this legislation accounts for the considerable practice expenses involved in comprehensive care coordination and facilitates widespread adoption of the medical home. The AOA strongly supports this move toward a model of health care delivery that is based on an ongoing personal relationship with a physician.

Over the past 10 years our population has increased and aged, and to ensure that our nation's physician workforce is capable of meeting increased demand, we must begin to educate and train a larger cadre of physicians now. A strong graduate medical education (GME) system capable of providing training opportunities across specialties and geographic regions is central to building the physician workforce. However, these institutions are currently confronted with fierce competition from private markets, increasing costs and shrinking federal support. In addition to increasing residency training programs to meet the needs of our growing population, this legislation would appropriately permit Direct Graduate Medical Education (DGME) and Indirect Medical Education (IME) reimbursement for didactic educational activities and allow hospitals to count the time residents spend providing patient care in outpatient settings. The AOA strongly supports these provisions.

Finally, the AOA strongly supports your efforts to address the burden of the educational debt carried by many young physicians that may discourage them from seeking careers in public health service, practicing in underserved areas, or seeking careers in primary care specialties. The average osteopathic medical school graduate has a debt load of $168,031 and the average first year medical resident stipend is $44,747, making student debt a significant hardship throughout a physician's training. By providing scholarships and loan forgiveness for primary care physicians who agree to practice in underserved areas, this legislation would address geographic disparities in access to care and allow medical school graduates to pursue training opportunities in medical specialties based upon their individual career interests and talents versus their financial obligations.

Today, one in five medical students in the United States is enrolled in a college of osteopathic medicine. The current colleges of osteopathic medicine, and those set to open in the future, are located in regions that historically have had limited access to physician services. The location of current and future colleges of osteopathic medicine reflects the osteopathic profession's commitment to rural and underserved communities. We believe that our graduates and their patients will benefit greatly from the primary care policies and programs in this legislation.

Again, thank you for introducing this important legislation. The AOA and our members stand ready to assist you in promoting primary care and securing enactment of the ''Preserving Patient Access to Primary Care Act.''

Sincerely,

CARLO J. DIMARCO,
President.

By Mr. KOHL (for himself and Mr. WYDEN):

S. 1177. A bill to improve consumer protections for purchasers of long-term care insurance, and for other purposes; to the Committee on Finance.

Mr. KOHL. Mr. President, I rise today to express my support for the Confidence in Long-Term Care Insurance Act of 2009. With America aging at an unprecedented rate, and with the high and rising costs of caring for a loved one, the financing of long-term care must be addressed if we are going to get health care costs under control. I am proud to be an original cosponsor of this bill. I wish to also thank my colleague Senator WYDEN for his leadership on addressing the financing of long-term care.

We all know that long-term care is expensive. The cost of an average nursing home is nearly $75,000 per year. However, according to the Congressional Research Service, most Americans do not realize that neither Medicare nor Medicaid will cover these costs unless their household savings are nearly eliminated. States share the responsibility of providing Medicaid funding for long-term care with the federal government, and are also looking for ways to reduce their expenses. As of today, 43 states are in the process of launching ''Partnership'' programs, which provide incentives to consumers who purchase private long-term care insurance. But in the rush to ease the burden of long-term care costs on state budgets, we fear that some key concerns are being overlooked.

We have a duty to make sure these policies, which may span many decades, are financially viable. Several long-term care insurance providers have applied for TARP funds in recent months, raising questions about their solvency. In addition, many insurance companies have been raising their policyholders' monthly premiums, which can be devastating for older persons who are living on a fixed income. Many Americans living on modest or fixed incomes, who have held policies for many years, have seen premium rates double when a company encounters financial difficulties. For such consumers, the choices are stark and very limited: they can either dig deeper and pay the increased premiums, or let their policy lapse, leaving them with no coverage if they ever need care.

Last year, I was joined by several Senate and House colleagues in releasing a GAO report on whether adequate consumer protections are in place for those who purchase long-term care insurance. The report found that rate increases are common throughout the industry, and that consumer protections are uneven. While some states have adopted requirements that keep rates relatively stable, some have not, leaving consumers unprotected.

The Confidence in Long-Term Care Insurance Act takes several important steps to ensure that premiums increases are kept at a minimum, insurance agents receive adequate training, and that complaints and appeals are addressed in a timely manner. We should also make it easier for consumers to accurately compare policies from different insurance carriers, particularly with regard to what benefits are covered and whether the plan offers inflation protection. States should also have to approve materials used to market Partnership policies. The Confidence in Long-Term Care Insurance Act will institute many of these needed improvements.

In closing, I urge my colleagues to support the Confidence in Long-Term Care Insurance Act of 2009. It is estimated that two out of three Americans who reach the age of 65 will need long-term care services and supports at some point to assist them with day-to-day activities, and enable them to maintain a high-quality, independent life. Long-term care insurance is an appropriate product for many who wish to plan for a secure retirement. But we must guarantee that consumers have adequate information and protections, and that premiums won't skyrocket down the road. I thank Senator WYDEN for his commitment to ensuring we address the important issue of long-term care financing. I look forward to working with my colleagues to enact the legislation we are introducing today.

Mr. President, I ask unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the text of the bill was ordered to be printed in the RECORD, as follows:

S. 1177

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Confidence in Long-Term Care Insurance Act of 2009''.

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—NATIONAL MARKET SURVEY; MODEL DISCLOSURES AND DEFINITIONS; LTC INSURANCE COMPARE

Sec. 101. NAIC national market survey.
Sec. 102. Model disclosures and definitions.
Sec. 103. LTC Insurance Compare.

TITLE II—IMPROVED STATE CONSUMER PROTECTIONS FOR QUALIFIED LONG-TERM CARE INSURANCE CONTRACTS AND MEDICAID PARTNERSHIP POLICIES

Sec. 201. Application of Medicaid partnership required model provisions to all tax-qualified long-term care insurance contracts.
Sec. 202. Streamlined process for applying new or updated model provisions.

TITLE III—IMPROVED CONSUMER PROTECTIONS FOR MEDICAID PARTNERSHIP POLICIES

Sec. 301. Biennial reports on impact of Medicaid long-term care insurance partnerships.
Sec. 302. Additional consumer protections for Medicaid partnerships.
Sec. 303. Report to Congress regarding need for minimum annual compound inflation protection.

TITLE I—NATIONAL MARKET SURVEY; MODEL DISCLOSURES AND DEFINITIONS; LTC INSURANCE COMPARE

SEC. 101. NAIC NATIONAL MARKET SURVEY.

(a) IN GENERAL.—The Secretary shall request the NAIC to conduct biennial reviews of the national and State-specific markets

for long-term care insurance policies and to submit biennial reports to the Secretary on the results of such reviews.

(b) CONTENT.—The Secretary shall request that the biennial reviews include, with respect to the period occurring since any prior review, analysis of the following:

(1) Information on key market parameters, including the number of carriers offering long-term care insurance, and the scope of coverage offered under those policies (such as policies offering nursing-home only benefits, policies offering comprehensive coverage, and hybrid products in which long-term care benefits are present).

(2) The number of complaints received and resolved, including benefit denials.

(3) The number of policies that are cancelled (including because of having lapsed or not being renewed) and reasons for such cancellations.

(4) The number of agents trained and the content of that training, including a description of agent training standards, the extent to which competency tests are included in such standards, and the pass and fail rates associated with such tests.

(5) The number of policyholders exhausting benefits.

(6) Premium rate increases sought by carriers and the range of the amount of the increase sought.

(7) Premium rate increases that were approved and the range of the amount of increase.

(8) The number of policyholders affected by any approved premium rate increases.

(9) Requests for exceptions to State reserving or capital requirements.

(c) TIMING FOR BIENNIAL REVIEW AND REPORT.—The Secretary shall request the NAIC to—

(1) complete the initial market review under this section not later than 2 years after the date of enactment of this Act;

(2) submit a report to the Secretary on the results of the initial review not later than December 31, 2011; and

(3) complete each subsequent biennial review and submit each subsequent biennial report not later than December 31 of each second succeeding year.

(d) CONSULTATION REQUIRED.—The Secretary shall request the NAIC to consult with State insurance commissioners, appropriate Federal agencies, issuers of long-term care insurance, States with experience in long-term care insurance partnership plans, other States, representatives of consumer groups, consumers of long-term care insurance policies, and such other stakeholders as the Secretary or the NAIC determine appropriate, to conduct the market reviews requested under this section.

(e) DEFINITIONS.—In this section and section 102:

(1) LONG-TERM CARE INSURANCE POLICY.—The term ''long-term care insurance policy''—

(A) means—

(i) a qualified long-term care insurance contract (as defined in section 7702B(b) of the Internal Revenue Code of 1986); and

(ii) a qualified long-term care insurance contract that covers an insured who is a resident of a State with a qualified State long-term care insurance partnership under clause (iii) of section 1917(b)(1)(C) of the Social Security Act (42 U.S.C. 1396p(b)(1)(C)) or a long-term care insurance policy offered in connection with a State plan amendment described in clause (iv) of such section; and

(B) includes any other insurance policy or rider described in the definition of ''long-term care insurance'' in section 4 of the model Act promulgated by the National Association of Insurance Commissioners (as adopted December 2006).

(2) NAIC.—The term ''NAIC'' means the National Association of Insurance Commissioners.

(3) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

SEC. 102. MODEL DISCLOSURES AND DEFINITIONS.

(a) IN GENERAL.—The Secretary shall request the NAIC, in consultation with State health agencies as appropriate, to carry out the activities described in subsection (b).

(b) ACTIVITIES DESCRIBED.—The activities described in this subsection are the following:

(1) DEVELOP MODEL DISCLOSURES AND DEFINITIONS FOR MARKETING OF POLICIES.—To develop model language for marketing of long-term care insurance policies (including, as appropriate, language specific to qualified long-term care insurance contracts, partnership long-term care insurance policies, and such other contracts for coverage of long-term care services or benefits as the NAIC determines appropriate), that includes the following:

(A) CONSISTENT DEFINITIONS.—Consistent definitions for coverage of the various types of services and benefits provided under such policies, including institutional services, residential services with varying levels of assistance, such as assisted living, home care services, adult day services, and other types of home and community-based care, (as appropriate to describe the range of services and benefits offered under such policies in various States).

(B) CONSISTENT EXPLANATORY LANGUAGE.—Consistent language for use by issuers of such policies, and for agents selling such policies, in explaining the services and benefits covered under the policies and restrictions on the services and benefits.

(C) INFLATION PROTECTION OPTIONS.—A form that describes different inflation level options offered for long-term care insurance policies, including how policies with various levels of inflation protection compare in premium costs and benefits within 5-year time increments from 5 years through 30 years post-purchase.

(D) STANDARDIZED METHODOLOGY FOR CALCULATING INFLATION PROTECTION.—Standardized methodology for use by issuers to use to calculate inflation protection under such policies.

(2) ENFORCE.—To develop recommendations for enforcement of the model marketing disclosures and definitions, including standardized language for States to adopt to prohibit carriers from marketing policies within the State that do not meet the model marketing disclosures and definitions or the rate stability provisions under section 20 of the long-term care insurance model Act promulgated by the National Association of Insurance Commissioners (as adopted as of October 2000 and as of December 2006) and any provisions of such section adopted after December 2006.

(c) PUBLIC COMMENT.—The Secretary shall request the NAIC to allow for public comment on the work of the NAIC in carrying out the activities described in subsection (b).

SEC. 103. LTC INSURANCE COMPARE.

(a) IN GENERAL.—Section 6021(d) of the Deficit Reduction Act of 2005 (42 U.S.C. 1396p note) is amended—

(1) in paragraph (2)—

(A) in subparagraph (A)—

(i) in clause (ii), by striking ''and'' at the end;

(ii) in clause (iii), by striking the period at the end and inserting ''; and''; and

(iii) by adding at the end the following:

''(iv) establish an Internet directory of information regarding long-term care insurance, to be known as 'LTC Insurance Compare', that shall include the following:

''(I) Comparison tools to assist consumers in evaluating long-term care insurance policies (as defined in subparagraph (D)) with different benefits and features.

''(II) State-specific information about the long-term care insurance policies marketed in a State, including the following:

''(aa) Whether a State has promulgated rate stability provisions for all issuers of long-term care insurance policies and how the rate stability standards work.

''(bb) The rating history for issuers selling long-term care insurance policies in the State for at least the most recent preceding 5 years.

''(cc) The policy documents for each such policy marketed in the State.

''(III) Links to State information regarding long-term care under State Medicaid programs (which may be provided, as appropriate, through Internet linkages to the websites of State Medicaid programs) that includes the following:

''(aa) The medical assistance provided under each State's Medicaid program for nursing facility services and other long-term care services (including any functional criteria imposed for receipt of such services, as reported in accordance with section 1902(a)(28)(D) of the Social Security Act) and any differences from benefits and services offered under long-term care insurance policies in the State and the criteria for triggering receipt of such benefits and services.

''(bb) If the State has a qualified State long-term care insurance partnership under section 1917(b)(1)(C)(iii) of the Social Security Act, information regarding how and when an individual with a partnership long-term care insurance policy who is receiving benefits under the policy should apply for medical assistance for nursing facility services or other long-term care services under the State Medicaid program and information regarding about how Medicaid asset protection is accumulated over time under such policies.''; and

(B) by adding at the end the following:

''(C) CURRENT INFORMATION.—The Secretary of Health and Human Services shall ensure that, to the greatest extent practicable, the information maintained in the National Clearinghouse for Long-Term Care Information, including the information required for LTC Insurance Compare, is the most recent information available.

''(D) LONG-TERM CARE INSURANCE POLICY DEFINED.—In subparagraph (A)(iv), the term 'long-term care insurance policy' means a qualified long-term care insurance contract (as defined in section 7702B(b) of the Internal Revenue Code of 1986), a qualified long-term care insurance contract that covers an insured who is a resident of a State with a qualified State long-term care insurance partnership under clause (iii) of section 1917(b)(1)(C) of the Social Security Act (42 U.S.C. 1396p(b)(1)(C)) or a long-term care insurance policy offered in connection with a State plan amendment described in clause (iv) of such section, and includes any other insurance policy or rider described in the definition of 'long-term care insurance' in section 4 of the model Act promulgated by the National Association of Insurance Commissioners (as adopted December 2006).'';

(2) by redesignating paragraph (3) as paragraph (4)

(3) in paragraph (4), (as so redesignated), by inserting '', and $5,000,000 for each of fiscal years 2011 through 2013'' after ''2010''; and

(4) by inserting after paragraph (2) the following:

''(3) CONSULTATION ON LTC INSURANCE COMPARE.—The Secretary of Health and Human Services shall consult with the National Association of Insurance Commissioners and the entities and stakeholders specified in

section 101(d) of the Confidence in Long-Term Care Insurance Act of 2009 in designing and implementing the LTC Insurance Compare required under paragraph (2)(A)(iv).''.

(b) MEDICAID STATE PLAN REQUIREMENT TO SUBMIT NURSING FACILITY SERVICES FUNCTIONAL CRITERIA DATA.—Section 1902(a)(28) of the Social Security Act (42 U.S.C. 1396a(a)(28)) is amended—

(1) in subparagraph (C), by striking ''and'' after the semicolon;

(2) in subparagraph (D)(iii), by adding ''and'' after the semicolon; and

(3) by inserting after subparagraph (D)(iii), the following new subparagraph:

''(E) for the annual submission of data relating to functional criteria for the receipt of nursing facility services under the plan (in such form and manner as the Secretary shall specify);''.

(c) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided in paragraph (2), the amendments made by this section take effect on the date of enactment of this Act.

(2) EXTENSION OF EFFECTIVE DATE FOR STATE LAW AMENDMENT.—In the case of a State plan under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) which the Secretary of Health and Human Services determines requires State legislation or State regulation in order for the plan to meet the additional requirements imposed by the amendments made by subsection (b), the State plan shall not be regarded as failing to comply with the requirements of such title solely on the basis of its failure to meet these additional requirements before the first day of the first calendar quarter beginning after the close of the first regular session of the State legislature that begins after the date of enactment of this Act. For purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of the session is considered to be a separate regular session of the State legislature.

TITLE II—IMPROVED STATE CONSUMER PROTECTIONS FOR QUALIFIED LONG-TERM CARE INSURANCE CONTRACTS AND MEDICAID PARTNERSHIP POLICIES

SEC. 201. APPLICATION OF MEDICAID PARTNERSHIP REQUIRED MODEL PROVISIONS TO ALL TAX-QUALIFIED LONG-TERM CARE INSURANCE CONTRACTS.

(a) IN GENERAL.—Section 7702B(g)(1) of the Internal Revenue Code of 1986 (relating to consumer protection provisions) is amended—

(1) in subparagraph (A), by inserting ''(but only to the extent such requirements do not conflict with requirements applicable under subparagraph (B)),'' after ''paragraph (2)'',

(2) by redesignating subparagraphs (B) and (C) as subparagraphs (C) and (D), respectively, and

(3) by inserting after subparagraph (A), the following new subparagraph:

''(B) the requirements of the model regulation and model Act described in section 1917(b)(5) of the Social Security Act,''.

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to contracts issued after the date of enactment of this Act.

SEC. 202. STREAMLINED PROCESS FOR APPLYING NEW OR UPDATED MODEL PROVISIONS.

(a) SECRETARIAL REVIEW.—

(1) TAX-QUALIFIED POLICIES.—

(A) 2000 AND 2006 MODEL PROVISIONS.—Not later than 3 months after the date of enactment of this Act, the Secretary of the Treasury, in consultation with the Secretary of Health and Human Services, shall review the model provisions specified in subsection (c)(1) for purposes of determining whether updating any such provisions for a provision specified in section 7702B(g)(2) of the Internal Revenue Code of 1986, or the inclusion of any such provisions in such section, for purposes of an insurance contract qualifying for treatment as a qualified long-term care insurance contract under such Code, would improve consumer protections for insured individuals under such contracts.

(B) SUBSEQUENT MODEL PROVISIONS.—Not later than 3 months after model provisions described in paragraph (2) or (3) of subsection (c) are adopted by the National Association of Insurance Commissioners, the Secretary of the Treasury, in consultation with the Secretary of Health and Human Services, shall review the model provisions to determine whether the application of such provisions to an insurance contract for purposes of qualifying for treatment as a qualified long-term care insurance contract under section 7702B(g)(2) of the Internal Revenue Code of 1986, would improve consumer protections for insured individuals under such contracts.

(2) MEDICAID PARTNERSHIP POLICIES.—

(A) SUBSEQUENT MODEL PROVISIONS.—Not later than 3 months after model provisions described in paragraph (2) or (3) of subsection (c) are adopted by the National Association of Insurance Commissioners, the Secretary of Health and Human Services, in consultation with the Secretary of the Treasury, shall review the model provisions to determine whether the application of such provisions to an insurance contract for purposes of satisfying the requirements for participation in a qualified State long-term care insurance partnership under section 1917(b)(1)(C)(iii) of such Act (42 U.S.C. 1396p(b)(1)(C)(iii)) would improve consumer protections for insured individuals under such contracts.

(B) REVIEW OF OTHER PARTNERSHIP REQUIREMENTS.—The Secretary of Health and Human Services, in consultation with the Secretary of the Treasury, shall review clauses (iii) and (iv) of section 1917(b)(1)(C) for purposes of determining whether the requirements specified in such clauses should be modified to provide improved consumer protections or, as appropriate, to resolve any conflicts with the application of the 2006 model provisions under paragraph (5) of section 1917(b) (as amended by section 302(a)) or with the application of any model provisions that the Secretary determines should apply to an insurance contract as a result of a review required under subparagraph (A).

(b) EXPEDITED RULEMAKING.—

(1) TAX-QUALIFIED POLICIES.—Subject to paragraph (3), if the Secretary of the Treasury determines that any model provisions reviewed under subsection (a)(1) should apply for purposes of an insurance contract qualifying for treatment as a qualified long-term care insurance contract under the Internal Revenue Code of 1986, the Secretary, shall promulgate an interim final rule applying such provisions for such purposes not later than 3 months after making such determination.

(2) MEDICAID PARTNERSHIP POLICIES.—Subject to paragraph (3), if the Secretary of Health and Human Services determines that any model provisions or requirements reviewed under subsection (a)(2) should apply for purposes of an insurance contract satisfying the requirements for participation in a qualified State long-term care insurance partnership under section 1917(b)(1)(C)(iii) of such Act (42 U.S.C. 1396p(b)(1)(C)(iii)), the Secretary, shall promulgate an interim final rule applying such provisions for such purposes not later than 3 months after making such determination.

(3) CONSULTATION REQUIRED.—The Secretary of the Treasury and the Secretary of Health and Human Services, respectively, shall consult with the National Association of Insurance Commissioners and the entities and stakeholders specified in section 101(d) regarding the extent to which it is appropriate to apply the model provisions described in paragraph (1) or (2) (as applicable) to insurance contracts described in such paragraphs through promulgation of an interim final rule. If, after such consultation—

(A) the Secretary of the Treasury determines it would be appropriate to promulgate an interim final rule, the Secretary of the Treasury shall use notice and comment rulemaking to promulgate a rule applying such provisions to insurance contracts described in paragraph (1); and

(B) the Secretary of Health and Human Services determines it would be appropriate to promulgate an interim final rule, the Secretary of Health and Human Services shall use notice and comment rulemaking to promulgate a rule applying such provisions to insurance contracts described in paragraph (2).

(4) RULE OF CONSTRUCTION RELATING TO APPLICATION OF CONGRESSIONAL REVIEW ACT.—Nothing in paragraphs (1), (2), or (3) shall be construed as affecting the application of the sections 801 through 808 of title 5, United States Code (commonly known as the ''Congressional Review Act'') to any interim final rule issued in accordance with such paragraphs.

(5) TECHNICAL AMENDMENT ELIMINATING PRIOR REVIEW STANDARD MADE OBSOLETE.—Section 1917(b)(5) of the Social Security Act (42 U.S.C. 1396p(b)(5)) is amended by striking subparagraph (C).

(c) MODEL PROVISIONS.—In this section, the term ''model provisions'' means—

(1) each provision of the long-term care insurance model regulation, and the long-term care insurance model Act, respectively, promulgated by the National Association of Insurance Commissioners (as adopted as of October 2000 and as of December 2006);

(2) each provision of the model language relating to marketing disclosures and definitions developed under section 102(b)(1); and

(3) each provision of any long-term care insurance model regulation, or the long-term care insurance model Act, respectively, promulgated by the National Association of Insurance Commissioners and adopted after December 2006.

TITLE III—IMPROVED CONSUMER PROTECTIONS FOR MEDICAID PARTNERSHIP POLICIES

SEC. 301. BIENNIAL REPORTS ON IMPACT OF MEDICAID LONG-TERM CARE INSURANCE PARTNERSHIPS.

Section 6021(c) of the Deficit Reduction Act of 2005 (42 U.S.C. 1396p note) is amended to read as follows:

''(c) BIENNIAL REPORTS.—

''(1) IN GENERAL.—Not later than January 1, 2010, and biennially thereafter, the Secretary of Health and Human Services (in this subsection referred to as the 'Secretary') shall issue a report to States and Congress on the long-term care insurance partnerships established in accordance with section 1917(b)(1)(C)(ii) of the Social Security Act (42 U.S.C. 1396p(b)(1)(C)(ii)). Each report shall include (with respect to the period the report addresses) the following information, nationally and on a State-specific basis:

''(A) Analyses of the extent to which such partnerships improve access of individuals to affordable long-term care services and benefits and the impact of such partnerships on Federal and State expenditures on long-term care under the Medicare and Medicaid programs.

''(B) Analyses of the impact of such partnerships on consumer decisionmaking with respect to purchasing, accessing, and retaining coverage under long-term care insurance

policies (as defined in subsection (d)(2)(D)), including a description of the benefits and services offered under such policies, the average premiums for coverage under such policies, the number of policies sold and at what ages, the number of policies retained and for how long, the number of policies for which coverage was exhausted, and the number of insured individuals who were determined eligible for medical assistance under the State Medicaid program.

''(2) DATA.—The reports by issuers of partnership long-term care insurance policies required under section 1917(b)(1)(C)(iii)(VI) of the Social Security Act shall include such data as the Secretary shall specify in order to conduct the analyses required under paragraph (1).

''(3) PUBLIC AVAILABILITY.—The Secretary shall make each report issued under this subsection publicly available through the LTC Insurance Compare website required under subsection (d).

''(4) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as requiring the Secretary to conduct an independent review of each long-term care insurance policy offered under or in connection with such a partnership.

''(5) APPROPRIATION.—Out of any funds in the Treasury not otherwise appropriated, there is appropriated to the Secretary to carry out this subsection, $1,000,000 for the period of fiscal years 2010 through 2012.''.

SEC. 302. ADDITIONAL CONSUMER PROTECTIONS FOR MEDICAID PARTNERSHIPS.

(a) APPLICATION OF 2006 MODEL PROVISIONS.—

(1) UPDATING OF 2000 REQUIREMENTS.—

(A) IN GENERAL.—Section 1917(b)(5)(B)(i) of the Social Security Act (42 U.S.C. 1396p(b)(5)(B)(i)) is amended by striking ''October 2000'' and inserting ''December 2006''.

(B) CONFORMING AMENDMENTS.—

(i) Subclause (XVII) of such section is amended by striking ''section 26'' and inserting ''section 28''.

(ii) Subclause (XVIII) of such section is amended by striking ''section 29'' and inserting ''section 31''.

(iii) Subclause (XIX) of such section is amended by striking ''section 30'' and inserting ''section 32''.

(2) APPLICATION TO GRANDFATHERED PARTNERSHIPS.—Section 1917(b)(1)(C)(iv) of such Act (42 U.S.C. 1396p(b)(1)(C)(iv)) is amended by inserting '', and the State satisfies the requirements of paragraph (5)'' after ''2005''.

(b) APPLICATION OF PRODUCER TRAINING MODEL ACT REQUIREMENTS.—Section 1917(b)(1)(C) of such Act (42 U.S.C. 1396p(b)(1)(C)) is amended—

(1) in clause (iii)(V), by inserting ''and satisfies the producer training requirements specified in section 9 of the model Act specified in paragraph (5)'' after ''coverage of long-term care''; and

(2) in clause (iv), as amended by subsection (a)(2), by inserting ''clause (iii)(V) and'' before ''paragraph (5)''.

(c) APPLICATION OF ADDITIONAL REQUIREMENTS FOR ALL PARTNERSHIPS.—Section 1917(b) of the Social Security Act (42 U.S.C. 1396p(b)) is amended—

(1) in paragraph (1)(C)—

(A) in clause (iii)—

(i) by inserting after subclause (VII) the following new subclause:

''(VIII) The State satisfies the requirements of paragraph (6).''; and

(ii) in the flush sentence at the end, by striking ''paragraph (5)'' and inserting ''paragraphs (5) and (6)''; and

(B) in clause (iv), as amended by subsections (a)(2) and (b)(2), by striking ''paragraph (5)'' and inserting ''paragraphs (5) and (6)''; and

(2) by adding at the end the following new paragraph:

''(6) For purposes of clauses (iii)(VIII) and (iv) of paragraph (1)(C), the requirements of this paragraph are the following:

''(A) The State requires issuers of long-term care insurance policies to—

''(i) use marketing materials approved by the State for purposes of the partnership verbatim in all sales and marketing activities conducted or supported by the issuers in the State with respect to any long-term care insurance policies marketed by the issuer in the State;

''(ii) provide such materials to all agents selling long-term care insurance policies in the State;

''(iii) ensure that agent training and education courses conducted or supported by the issuers incorporate such materials;

''(iv) make such materials available to any consumer upon request, and to make such materials available to all prospective purchasers of a policy offered under a qualified State long-term care insurance partnership before submission of an application for coverage under that policy.

''(B) The State requires issuers of long-term care insurance policies to require agents to use the inflation protection comparison form developed by the National Association of Insurance Commissioners in accordance with section 102(b)(1)(C) of the Confidence in Long-Term Care Insurance Act of 2009 when selling the policies in the State.

''(C) The State requires issuers of long-term care insurance policies sold in the State to comply with the provisions of section 8 of the model Act specified in paragraph (5) relating to contingent nonforfeiture benefits.

''(D) The State enacts legislation, not later than January 1, 2012, that establishes rate stability standards for all issuers of long-term care insurance policies sold in the State that are no less stringent than the premium rate schedule increase standards specified in section 20 of the model regulation specified in paragraph (5).

''(E) The State develops, updates whenever changes are made under the State plan that relate to eligibility for medical assistance for nursing facility services or other long-term care services or the amount, duration, or scope of such assistance, and provides public, readily accessible materials that describe in clear, simple language the terms of such eligibility, the benefits and services provided as such assistance, and rules relating to adjustment or recovery from the estate of an individual who receives such assistance under the State plan. Such materials shall include a clear disclosure that medical assistance is not guaranteed to partnership policyholders who exhaust benefits under a partnership policy, and that Federal changes to the program under this title or State changes to the State plan may affect an individual's eligibility for, or receipt of, such assistance.

''(F) The State—

''(i) through the State Medicaid agency under section 1902(a)(5) and in consultation with the State insurance department, develops written materials explaining how the benefits and rules of long-term care policies offered by issuers participating in the partnership interact with the benefits and rules under the State plan under this title;

''(ii) requires agents to use such materials when selling or otherwise discussing how long-term care policies offered by issuers participating in the partnership work with potential purchasers and to provide the materials to any such purchasers upon request;

''(iii) informs holders of such policies of any changes in eligibility requirements under the State plan under this title and of any changes in estate recovery rules under the State plan as soon as practicable after such changes are made; and

''(iv) agrees to honor the asset protections of any such policy that were provided under the policy when purchased, regardless of whether the State subsequently terminates a partnership program under the State plan.

''(G) The State Medicaid agency under section 1902(a)(5) and the State insurance department enter into a memorandum of understanding to—

''(i) inform consumers about changes in long-term care policies offered by issuers participating in the partnership, changes in the amount, duration, or scope of medical assistance for nursing facility services or other long-term care services offered under the State plan, changes in consumer protections, and any other issues such agency and department determine appropriate; and

''(ii) jointly maintain a nonpublic database of partnership policyholders for purposes of facilitating coordination in eligibility determinations for medical assistance under the State plan and the provision of benefits or other services under such policies and medical assistance provided under the State plan that includes—

''(I) the number of policyholders applying for medical assistance under the State plan; and

''(II) the number of policyholders deemed eligible (and, if applicable, ineligible) for such assistance.

''(H) The State does not apply any limit to the disregard, for purposes of determining the eligibility of a partnership policyholder for medical assistance under the State plan and for purposes of exemption from the estate recovery requirements under the plan, of benefits provided under a partnership policy, including cash benefits provided for long-term care services, and benefits provided under the policy after the effective date of the policyholder's enrollment in the State plan.

''(I) The State enters into agreements with other States that have established qualified State long-term care insurance partnerships under which such States agree to provide reciprocity for policyholders under such partnerships.

''(J) The State provides guaranteed asset protection to all individuals covered under a policy offered under a qualified State long-term care insurance partnership who bought such a policy in the State or in another State with such a partnership and with which the State has a reciprocity agreement at the time of purchase.

''(K) At the option of the State, notwithstanding any limitation that would otherwise be imposed under subsection (f), the State disregards any amount of the equity interest in the home of an individual covered of policy offered under a qualified State long-term care insurance partnership for purposes of determining the individual's eligibility for medical assistance with respect to nursing facility services or other long-term care services.''.

(d) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided in paragraph (2), the amendments made by this section take effect on the date that is 1 year after the date of enactment of this Act.

(2) EXTENSION OF EFFECTIVE DATE FOR STATE LAW AMENDMENT.—In the case of a State plan under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) which the Secretary of Health and Human Services determines requires State legislation in order for the plan to meet the additional requirements imposed by the amendments made by this section, the State plan shall not be regarded as failing to comply with the requirements of such title solely on the basis of its

failure to meet these additional requirements before the first day of the first calendar quarter beginning after the close of the first regular session of the State legislature that begins after the date of enactment of this Act. For purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of the session is considered to be a separate regular session of the State legislature.

SEC. 303. REPORT TO CONGRESS REGARDING NEED FOR MINIMUM ANNUAL COMPOUND INFLATION PROTECTION.

Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall submit a report to Congress that includes the Secretary's recommendation regarding whether legislative or other administrative action should be taken to require all long-term care insurance policies sold after a date determined by the Secretary in connection with a qualified State long-term care insurance partnership under clause (iii) of section 1917(b)(1)(C) of the Social Security Act (42 U.S.C. 1396p(b)(1)(C)) or a long-term care insurance policy offered in connection with a State plan amendment described in clause (iv) of such section, provide, at a minimum, 5 percent annual compound inflation protection, and if so, whether such requirements should be imposed on a basis related to the age of the policyholder at the time of purchase. The Secretary shall include in the report information on the various levels of inflation protection available under such long-term care insurance partnerships and the methodologies used by issuers of such policies to calculate and present various inflation protection options under such policies, including policies with a future purchase option feature.

SUBMITTED RESOLUTIONS

SENATE RESOLUTION 167—A BILL COMMENDING THE PEOPLE WHO HAVE SACRIFICED THEIR PERSONAL FREEDOMS TO BRING ABOUT DEMOCRATIC CHANGE IN THE PEOPLE'S REPUBLIC OF CHINA AND EXPRESSING SYMPATHY FOR THE FAMILIES OF THE PEOPLE WHO WERE KILLED, WOUNDED, OR IMPRISONED, ON THE OCCASION OF THE 20TH ANNIVERSARY OF THE TIANANMEN SQUARE MASSACRE IN BEIJING, CHINA FROM JUNE 3 THROUGH 4, 1989

Mr. INHOFE (for himself, Mr. BROWN, Mr. GRAHAM, Mr. KYL, Mr. MENENDEZ, Mr. VITTER, Mr. LIEBERMAN, Mr. COBURN, and Mr. WEBB) submitted the following resolution; which was referred to the Committee on Foreign Relations:

S. RES. 167

Whereas freedom of expression, assembly, association, and religion are fundamental rights that all people should be able to possess and enjoy;

Whereas, in April 1989, in a demonstration of democratic progress, thousands of students took part in peaceful protests against the communist government of the People's Republic of China in the capital city of Beijing;

Whereas, throughout the month of May 1989, the students, in peaceful demonstrations, drew more people, young and old and from all walks of life, into central Beijing to demand better democracy, basic freedoms of speech and assembly, and an end to corruption;

Whereas, from June 3 through 4, 1989, the Government of China ordered an estimated 300,000 members of the People's Liberation Army to enter Beijing and clear Tiananmen Square (located in central Beijing) by lethal force;

Whereas, by June 7, 1989, the Red Cross of China reported that the People's Liberation Army had killed more than 300 people in Beijing, although foreign journalists who witnessed the events estimate that thousands of people were killed and thousands more wounded;

Whereas more than 20,000 people in China were arrested and detained without trial, due to their suspected involvement in the protests at Tiananmen Square;

Whereas, according to the Department of State, the Government of China has worked to censor information about the massacre at Tiananmen Square by blocking Internet sites and other media outlets, along with other sensitive information that would be damaging to the Government of China;

Whereas the Government of China has continued to oppress the people of China by denying basic human rights, such as freedom of speech and religion, and suppressing minority groups;

Whereas, during the 2008 Olympic Games, the Government of China promised to provide the international media covering the Olympic Games with the same access given the media at all the other Olympic Games, but denied access to certain internet sites and media outlets in attempts to censor free speech;

Whereas the Department of State Human Rights Report for 2008 found that the Government of China had increased already severe cultural and religious suppression of ethnic minorities in Tibetan areas and the Xinjiang Uighur Autonomous Region, increased the persecution of members of Falun Gong, Christians from China, and other religious minorities, increased the detention and harassment of dissidents and journalists, and maintained tight controls on freedom of speech and the Internet;

Whereas the United States Commission on International Religious Freedom in 2009 stated, ''The Chinese government continues to engage in systematic and egregious violations of the freedom of religion or belief, with religious activities tightly controlled and some religious adherents detained, imprisoned, fined, beaten, and harassed.''; and

Whereas the China Aid Association reported that in 2007, there were 693 cases in which Christians from China were detained or arrested and 788 cases in which Christian house church groups were persecuted by the Government of China: Now, therefore, be it

Resolved, That the Senate—

(1) commends the people who have sacrificed their personal freedoms and, in the case of the people who demonstrated at Tiananmen Square in 1989, sacrificed their lives and freedom to—

(A) bring about democratic change in the People's Republic of China; and

(B) gain freedom of expression, assembly, association, and religion for the people of China;

(2) expresses its sympathy for the families of the people who were killed, wounded, or imprisoned due to their involvement in the peaceful protests in Tiananmen Square in Beijing, China from June 3 through 4, 1989;

(3) condemns the ongoing human rights abuses by the Government of China;

(4) calls on the Government of China to—

(A) release all prisoners that are—

(i) still in captivity as a result of their involvement in the events from June 3 through 4, 1989, at Tiananmen Square; and

(ii) imprisoned without cause;

(B) allow freedom of speech and access to information, especially information regarding the events at Tiananmen Square in 1989; and

(C) cease all harassment, intimidation, and imprisonment of—

(i) members of religious and minority groups; and

(ii) people who disagree with policies of the Government of China;

(5) supports efforts by free speech activists in China and elsewhere who are working to overcome censorship (including censorship of the Internet) and the chilling effect of censorship; and

(6) urges the President to support peaceful advocates of free speech around the world.

Mr. INHOFE. Mr. President, I rise today to pay tribute to a true American hero, Army Sergeant Schuyler Patch of Owasso, OK, who died on February 24, 2009 serving our Nation in Kandahar, Afghanistan. Schuyler was assigned to the 2nd Squadron, 106th Cavalry Regiment, 33rd Infantry Brigade Combat Team, in the Illinois National Guard, based out of Kewanee, IL.

Schuyler enlisted in the Oklahoma National Guard in March 2005, and volunteered to deploy in 2006 to Afghanistan. In November 2007, he transferred to the Illinois Army National Guard and volunteered a second time to deploy to Afghanistan in support of Operation Enduring Freedom. He was killed alongside four of his fellow Soldiers, when their vehicle was hit by an IED while on a joint patrol with the Afghan National Security Forces. Schuyler leaves behind his father John Patch of Illinois and mother Colleen Stevens of Owasso, Oklahoma. He also leaves behind a sister, Amber Patch and two brothers, Garrett and Seth Patch.

Schuyler was a selfless and courageous Soldier committed to this country and its freedom. His mother, Colleen, said that he died doing what he loved to do; making a difference in the world. She also expressed his love and care for the Afghan children while he was in Afghanistan. Schuyler's sister, Amber said, ''He loved everything about the Army and he believed in everything he was doing over there.'' His aunt, Julie Morland said, ''We are all very proud of him for even going over the first time and then volunteering to go over. It takes a special person to even join the Guard in the first place. To go there and fight as a volunteer, it takes a special person.''

On Schuyler's online Guest Book, I read through some of the things said about his life and character.

Schuyler's cousin wrote, ''Schuyler was not only brave, he was caring and never afraid to show his love for family and friends. A hello was never complete until he gave those he loved a hug . . . the world will be a sadder place without this fun loving, vibrant, kind, generous young man who always made me smile.''

Another friend wrote, ''He was a great guy and no one that ever knew

him will ever forget him. He is sadly missed and that smile of his will never be forgotten.'' Schuyler's mom Colleen also talked about his incredibly warm smile that will be forever in her mind.

A fellow soldier wrote, ''I was proud to have served with [Patch] in Afghanistan in 2006–2007. He was a good guy and liked to make the best of the situation.''

A friend wrote, ''We will all miss him and we all love him very much. He was the kind of guy who could cheer you up on your worst day and the most outgoing person I'll ever know. Thank you Schuyler for all the great memories we had and thank you so much for serving to protect all of us. I love you.''

Captain Jon Prain, a National Guard chaplain who spoke at his funeral, summed up Schuyler's life well when he said, ''He heard freedom's call. He paid freedom's price, so that we all might enjoy the benefits of freedom . . . He was, and always shall be, an American soldier.''

Schuyler lived a life of love for his family, friends, and country. He will be remembered by many for his contagious smile and warm, affectionate personality. I am honored to pay tribute to this true American hero who volunteered to go into the fight and gave the ultimate sacrifice by giving up his life for our freedom.

AMENDMENTS SUBMITTED AND PROPOSED

SA 1230. Mr. JOHANNS (for himself, Mr. INHOFE, Mr. CHAMBLISS, Mr. ISAKSON, Mr. RISCH, Mr. VITTER, Mr. BARRASSO, Mr. MCCAIN, Mr. COBURN , Mr. MCCONNELL, Mr. BOND, Mr. ROBERTS, Mr. HATCH, Mr. MARTINEZ, Mrs. HUTCHISON, Mr. WICKER, Mr. BUNNING, Mr. KYL, Mr. SESSIONS, Mr. DEMINT, Mr. CORNYN, Mr. THUNE, and Mr. VOINOVICH) submitted an amendment intended to be proposed by him to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table.

SA 1231. Mr. ENZI submitted an amendment intended to be proposed by him to the bill H.R. 1256, supra; which was ordered to lie on the table.

SA 1232. Mr. ENZI submitted an amendment intended to be proposed by him to the bill H.R. 1256, supra; which was ordered to lie on the table.

SA 1233. Mr. MCCAIN submitted an amendment intended to be proposed by him to the bill H.R. 1256, supra; which was ordered to lie on the table.

SA 1234. Mr. DEMINT submitted an amendment intended to be proposed by him to the bill H.R. 1256, supra; which was ordered to lie on the table.

SA 1235. Mr. LAUTENBERG submitted an amendment intended to be proposed by him to the bill H.R. 1256, supra; which was ordered to lie on the table.

SA 1236. Mr. BUNNING submitted an amendment intended to be proposed by him to the bill H.R. 1256, supra; which was ordered to lie on the table.

SA 1237. Mr. BUNNING submitted an amendment intended to be proposed by him to the bill H.R. 1256, supra; which was ordered to lie on the table.

SA 1238. Mr. BUNNING submitted an amendment intended to be proposed by him to the bill H.R. 1256, supra; which was ordered to lie on the table.

SA 1239. Mr. BUNNING submitted an amendment intended to be proposed by him to the bill H.R. 1256, supra; which was ordered to lie on the table.

SA 1240. Mr. ENZI submitted an amendment intended to be proposed by him to the bill H.R. 1256, supra; which was ordered to lie on the table.

SA 1241. Mr. BROWNBACK (for himself, Mr. KYL, and Mr. BOND) submitted an amendment intended to be proposed by him to the bill H.R. 1256, supra; which was ordered to lie on the table.

SA 1242. Mr. BAYH (for himself, Ms. MURKOWSKI, Mr. BURRIS, Mr. LIEBERMAN, Mr. WARNER, Mr. WEBB, and Mr. NELSON of Nebraska) submitted an amendment intended to be proposed by him to the bill H.R. 1256, supra; which was ordered to lie on the table.

SA 1243. Mr. DEMINT (for himself, Mr. KYL, Mr. BUNNING, Mr. MARTINEZ, Mr. JOHANNS, Mr. RISCH, Mr. CRAPO, Mr. MCCONNELL, Mr. BOND, Mr. CORNYN, Mr. CHAMBLISS, Mr. COBURN, Mr. ROBERTS, Mr. INHOFE, Mr. BENNETT, Mr. BURR, and Mr. BROWNBACK) submitted an amendment intended to be proposed by him to the bill H.R. 1256, supra; which was ordered to lie on the table.

SA 1244. Mr. BURR (for himself and Mrs. HAGAN) submitted an amendment intended to be proposed by him to the bill H.R. 1256, supra; which was ordered to lie on the table.

SA 1245. Ms. STABENOW (for herself and Ms. MURKOWSKI) submitted an amendment intended to be proposed by her to the bill H.R. 1256, supra; which was ordered to lie on the table.

SA 1246. Mr. BURR (for himself and Mrs. HAGAN) submitted an amendment intended to be proposed to amendment SA 1247 proposed by Mr. DODD to the bill H.R. 1256, supra.

SA 1247. Mr. DODD proposed an amendment to the bill H.R. 1256, supra.

SA 1248. Mrs. FEINSTEIN (for herself, Mr. BROWNBACK, and Ms. STABENOW) submitted an amendment intended to be proposed by her to the bill H.R. 1256, supra; which was ordered to lie on the table .

SA 1249. Mrs. HAGAN submitted an amendment intended to be proposed by her to the bill H.R. 1256, supra; which was ordered to lie on the table.

SA 1250. Mrs. HAGAN submitted an amendment intended to be proposed by her to the bill H.R. 1256, supra; which was ordered to lie on the table.

SA 1251. Mrs. HAGAN submitted an amendment intended to be proposed by her to the bill H.R. 1256, supra; which was ordered to lie on the table.

SA 1252. Mrs. HAGAN submitted an amendment intended to be proposed by her to the bill H.R. 1256, supra; which was ordered to lie on the table.

SA 1253. Mrs. HAGAN submitted an amendment intended to be proposed by her to the bill H.R. 1256, supra; which was ordered to lie on the table.

SA 1254. Mrs. HAGAN submitted an amendment intended to be proposed by her to the bill H.R. 1256, supra; which was ordered to lie on the table.

SA 1255. Ms. STABENOW (for herself, Mr. BROWNBACK, Ms. MIKULSKI, Mr. VOINOVICH, Mrs. SHAHEEN, Mr. BOND, Mr. BURRIS, Mr. DURBIN, Mr. LEVIN, and Mr. BROWN) submitted an amendment intended to be proposed by her to the bill H.R. 1256, supra; which was ordered to lie on the table.

SA 1256. Mr. SCHUMER (for Mr. LIEBERMAN (for himself, Ms. COLLINS, Mr. AKAKA, and Mr. VOINOVICH)) proposed an amendment to amendment SA 1247 proposed by Mr. DODD to the bill H.R. 1256, supra.

TEXT OF AMENDMENTS

SA 1230. Mr. JOHANNS (for himself, Mr. INHOFE, Mr. CHAMBLISS, Mr. ISAKSON, Mr. RISCH, Mr. VITTER Mr. BARRASSO, Mr. MCCAIN, Mr. COBURN, Mr. MCCONNELL, Mr. BOND, Mr. ROBERTS, Mr. HATCH, Mr. MARTINEZ, Mrs. HUTCHISON, Mr. WICKER, Mr. BUNNING, Mr. KYL, Mr. SESSIONS, Mr. DEMINT, Mr. CORNYN, Mr. THUNE, and Mr. VOINOVICH) submitted an amendment intended to be proposed by him to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. CONGRESSIONAL APPROVAL OF CERTAIN TARP EXPENDITURES.

Notwithstanding any other provision of law, including any provision of the Emergency Economic Stabilization Act of 2008, on and after May 29, 2009, no funds may be disbursed or otherwise obligated under that Act to any entity, if such disbursement would result in the Federal Government acquiring any ownership of the common or preferred stock of the entity receiving such funds, unless the Congress first approves of such disbursement or obligation.

SA 1231. Mr. ENZI submitted an amendment intended to be proposed by him to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

Strike section 2.

SA 1232. Mr. ENZI submitted an amendment intended to be proposed by him to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

In section 919 of the Federal Food Drug, and Cosmetic Act (as added by section 101), add at the end the following:

''(d) ADJUSTMENTS.—

''(1) INFLATION ADJUSTMENT.—With respect to fiscal years beginning with fiscal year

2020, the amount provided for in subsection (b)(1)(K) for a fiscal year shall be adjusted by the Secretary by notice, published in the Federal Register, by the greater of—

''(A) the total percentage change that occurred in the Consumer Price Index for all urban consumers (all items, United States city average), for the 12 month period ending June 30 preceding the fiscal year for which the amount is being adjusted;

''(B) the total percentage change for the previous fiscal year in basic pay under the General Schedule in accordance with section 5332 of title 5, United States Code, as adjusted by any locality-based comparability payment pursuant to section 5304 of such title for Federal employees stationed in the District of Columbia; or

''(C) the average annual change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions, for the first 5 years of the most recent 6-year period ending on September 30 of the year for which such amount is being adjusted.

The adjustment made with respect to each fiscal year under this subsection shall be added on a compounded basis to the sum of all adjustments made for each such fiscal year after fiscal year 2020.

''(2) WORKLOAD ADJUSTMENT.—Beginning with fiscal year 2020, after the amount provided for in subsection (b)(1)(K) is adjusted for a fiscal year in accordance with paragraph (1), the fee revenues shall be further adjusted for such fiscal year to account for changes in the workload of the Secretary in carrying out the responsibilities provided for under this chapter. With respect to such adjustment, the following shall apply:

''(A) The adjustment shall be determined by the Secretary based on a weighted average of the change in the total number of applications under sections 910 and 911 during the previous 12-month period. The Secretary shall publish in the Federal Register the fee revenues and fees resulting from the adjustment and the supporting methodologies.

''(B) Under no circumstances shall the adjustment result in fee revenues for a fiscal year that are less than the fee revenues for fiscal year 2019 (as established under subsection (b)(1)(K)), as adjusted under paragraph (1).''.

SA 1233. Mr. MCCAIN submitted an amendment intended to be proposed by him to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

On page 199, line 10, insert '', except the term shall not include a member of the uniformed services'' before the period.

On page 199, strike lines 15 through 24.

On page 209, line 12, strike all through page 210, line 12.

SA 1234. Mr. DEMINT submitted an amendment intended to be proposed by him to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. POINT OF ORDER TO KEEP HEALTH PLAN AND CHOICE OF DOCTOR AND TO LIMIT GOVERNMENT MANAGED, RATIONED HEALTH CARE.

(a) IN GENERAL.—In the Senate, it shall not be in order, to consider any bill, joint resolution, amendment, motion, or conference report that—

(1) eliminates the ability of Americans to keep their health plan or their choice of doctor (as determined by the Congressional Budget Office); or

(2) decreases the number of Americans enrolled in private health insurance plans, while increasing the number of Americans enrolled in government-managed, rationed health care (as determined by the Congressional Budget Office).

(b) WAIVER.—This section may be waived or suspended only by an affirmative vote of three-fifths of the Members of the Senate, dully chosen and sworn.

(c) APPEALS.—An affirmative vote of three-fifths of the Members of the Senate, duly chosen and sworn, shall be required to sustain an appeal of the ruling of the Chair on a point of order raised under this section.

SA 1235. Mr. LAUTENBERG submitted an amendment intended to be proposed by him to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

At the end of section 907(a)(1) of the Federal Food, Drug, and Cosmetic Act (as added by section 101(b)), add the following:

''(C) CHARACTERIZING FLAVOR.—For purposes of subparagraph (A), the term 'characterizing flavor' means—

''(i) a distinguishable flavor, taste, or aroma imparted by the tobacco product, or any smoke emanating from that product, prior to or during consumption that predominates over the flavor, taste, or aroma of the tobacco; or

''(ii) a distinguishable flavor, taste, or aroma other than tobacco used to advertise or market the tobacco product.

SA 1236. Mr. BUNNING submitted an amendment intended to be proposed by him to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

In section 4, strike subsection (b) and insert the following:

(b) AGRICULTURAL ACTIVITIES.—The provisions of this Act (or an amendment made by this Act) which authorize the Secretary to take action with regards to tobacco products shall not be construed to affect any authority of the Secretary of Agriculture regarding the growing, cultivation, curing or processing of raw tobacco. Nothing in this Act (or amendments) shall be construed to provide the Food and Drug Administration with any authority regarding the growing, cultivation, curing or processing of raw tobacco.

SA 1237. Mr. BUNNING submitted an amendment intended to be proposed by him to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

In section 919 of the Federal Food, Drug, and Cosmetic Act (as added by section 101) add the following:

''(f) TOBACCO GROWER GRANT PROGRAM.—

''(1) IN GENERAL.—The Secretary shall use a portion of the amounts collected under this section to award grants to producers of tobacco leaf, including tobacco growers, tobacco warehouses, and tobacco grower cooperatives, to enable such producers to offset the costs imposed under this chapter.

''(2) APPLICATION.—To be eligible for a grant under paragraph (1), a producer of tobacco leaf shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

''(3) USE OF FUNDS.—A producer of tobacco leaf shall use amounts received under this subsection to pay the additional expenses associated with compliance by such producer with the requirements of this chapter.

''(4) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated, such sums as may be necessary to carry out this subsection.''.

SA 1238. Mr. BUNNING submitted an amendment intended to be proposed by him to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

In section 917 of the Federal Food, Drug, and Cosmetic Act (as added by section 101) strike subsections (a) and (b)(1) and insert the following:

''(a) ESTABLISHMENT.—Not later than 6 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall establish a 14-member advisory committee, to be known as the Tobacco Products Scientific Advisory Committee (in this section referred to as the 'Advisory Committee').

''(b) MEMBERSHIP.—

''(1) IN GENERAL.—

''(A) MEMBERS.—The Secretary shall appoint as members of the Tobacco Products Scientific Advisory Committee individuals who are technically qualified by training and experience in medicine, medical ethics, science, or technology involving the manufacture, evaluation, or use of tobacco products, who are of appropriately diversified

professional backgrounds. The committee shall be composed of—

''(i) 7 individuals who are physicians, dentists, scientists, or health care professionals practicing in the area of oncology, pulmonology, cardiology, toxicology, pharmacology, addiction, or any other relevant specialty;

''(ii) 1 individual who is an officer or employee of a State or local government or of the Federal Government;

''(iii) 1 individual as a representative of the general public;

''(iv) 1 individual as a representative of the interests of the tobacco manufacturing industry;

''(v) 1 individual as a representative of the interests of the small business tobacco manufacturing industry, which position may be filled on a rotating, sequential basis by representatives of different small business tobacco manufacturers based on areas of expertise relevant to the topics being considered by the Advisory Committee; and

''(vi) 3 individuals as representatives of the interests of the tobacco growers, with 1 such individual representing flu tobacco, one such individual representing burley tobacco, and one such individual representing dark tobacco.

''(B) CONFLICTS OF INTEREST.—No members of the committee, other than members appointed pursuant to clauses (iv), (v), and (vi) of subparagraph (A) shall, during the member's tenure on the committee or for the 18-month period prior to becoming such a member, receive any salary, grants, or other payments or support from any business that manufactures, distributes, markets, or sells cigarettes or other tobacco products.''.

SA 1239. Mr. BUNNING submitted an amendment intended to be proposed by him to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. FARMER FEASIBILITY STUDY.

The Secretary of Health and Human Services, acting through the Food and Drug Administration shall conduct a study of the technical, logistical, and economic viability of any standards imposed under the Act (and the amendments made by this Act) on farmers regarding the growing, cultivation, curing, or processing of raw tobacco. Not later than 1 year after the date of enactment of this Act, the Secretary shall submit a report concerning the results of such study to the Committee on Agriculture of the Senate and the Committee on Agriculture of the House of Representatives.

SA 1240. Mr. ENZI submitted an amendment intended to be proposed by him to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

TITLE ____—TOBACCO BUYOUT

SEC. ____01. ESTABLISHMENT OF TOBACCO BUYOUT PROGRAM.

Chapter IX of the Federal Food, Drug, and Cosmetic Act (as added by section 101 and amended by section 301) is further amended by adding at the end the following:

''SEC. 921. ESTABLISHMENT OF TOBACCO BUYOUT PROGRAM.

''(a) IN GENERAL.—The Secretary shall establish a program to require annual reductions in the sale of cigarettes.

''(b) REQUIREMENT.—

''(1) IN GENERAL.—Under the program under subsection (a), each tobacco product manufacturer shall annually certify to the Secretary that—

''(A) with respect to cigarettes made by such manufacturer, the total number of such cigarettes sold during the year for which the certification is submitted is 1 percent less than the total number of such cigarettes sold during the preceding year; or

''(B) such manufacturer has purchased an additional cigarette sales allotment from another manufacturer as provided for in subsection (c).

''(2) INITIAL CERTIFICATION.—With respect to the first year for which a certification is submitted by a tobacco product manufacturer, the 1 percent reduction required under paragraph (1)(A) with respect to the sale of cigarettes shall be determined using the amount of such manufacturer's cigarettes sold in the highest sales year during the preceding 5-year period (as determined by the Secretary).

''(c) ADDITIONAL CIGARETTE SALES ALLOTMENT.—

''(1) IN GENERAL.—A tobacco product manufacturer (referred to in this subsection as the 'contracting manufacturer') to which this section applies may enter into a contract with one or more additional manufacturers (referred to in this subsection as a 'decreased sales manufacturer') to purchase from such manufacturers an additional sales allotment.

''(2) REQUIREMENT.—A contract entered into under paragraph (1) shall—

''(A) require the decreased sales manufacturer to provide for a further reduction in the total number of cigarettes sold during the year involved (beyond that required under subsection (b)(1)) by an amount equal to the additional sales allotment provided for in the contract; and

''(B) permit the contracting manufacturer to increase the total number of cigarettes sold during the year involved by an amount equal to the additional sales allotment provided for in the contract.

''(3) ADDITIONAL SALES ALLOTMENT.—In this subsection, the term 'additional sales allotment' means the number of cigarettes by which the decreased sales manufacturer agrees to further reduce its sales during the year involved.

''(d) ENFORCEMENT.—

''(1) IN GENERAL.—A tobacco product manufacturer that fails to comply with the requirement of subsection (b) for any year shall be subject to a penalty in an amount equal to $2 multiplied by the number of cigarettes by which such manufacturer has failed to comply with such subsection (b). Amounts collected under this paragraph shall be used to carry out paragraph (2).

''(2) TOBACCO USE COUNTER-ADVERTISING.—The Secretary, acting through the Administrator of the Substance Abuse and Mental Health Services Administration, shall carry out a campaign of counter-advertising with respect to tobacco use. The campaign shall consist of the placement of pro-health advertisements regarding tobacco use on television, on radio, in print, on billboards, on movie trailers, on the Internet, and in other media.

''(e) PROCEDURES.—The Secretary shall develop procedures for—

''(1) the submission and verification of certificates under subsection (a);

''(2) the administration and verification of additional cigarette sales allotment contracts under subsection (c); and

''(3) the imposition of penalties under subsection (d).''.

SA 1241. Mr. BROWNBACK (for himself, Mr. KYL, and Mr. BOND) submitted an amendment intended to be proposed by him to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

At the end of the bill, add the following:

DIVISION C—DESIGNATION OF NORTH KOREA AS STATE SPONSOR OF TERRORISM

SEC. 101. FINDINGS.

Congress makes the following findings:

(1) On October 11, 2008, the Department of State removed North Korea from its list of state sponsors of terrorism, on which it had been placed in 1988.

(2) North Korea was removed from that list despite its refusal to account fully for its abduction of foreign citizens, proliferation of nuclear and other dangerous technologies and weapon systems to other state sponsors of terrorism, or its commission of other past acts of terrorism.

(3) On March 17, 2009, American journalists Euna Lee and Laura Ling were abducted near the Chinese-North Korean border by agents of the North Korean government.

(4) The Government of North Korea has announced that these United States citizens will stand trial on June 4, 2009, where they face imprisonment in a North Korean prison camp.

(5) On April 5, 2009, the Government of North Korea tested a long-range ballistic missile in violation of United Nations Security Council Resolutions 1695 and 1718.

(6) After purportedly disabling its Yongbyon nuclear facility in 2008, the Government of North Korea has since announced its re-commissioning.

(7) On April 15, 2009, the Government of North Korea announced it was expelling international inspectors from its Yongbyon nuclear facility and ending its participation in disarmament talks.

(8) On May 25, 2009, the Government of North Korea conducted a second illegal nuclear test, in addition to conducting tests of its ballistic missile systems.

(9) President Barack Obama stated that actions of the Government of North Korea ''are a matter of grave concern to all nations. North Korea's attempts to develop nuclear weapons, as well as its ballistic missile program, constitute a threat to international peace and security. By acting in blatant defiance of the United Nations Security Council, North Korea is directly and recklessly challenging the international community. North Korea's behavior increases tensions and undermines stability in Northeast Asia. Such provocations will only serve to deepen North Korea's isolation. It will not find international acceptance unless it abandons its

pursuit of weapons of mass destruction and their means of delivery.''

SEC. 102. DESIGNATION AS A COUNTRY THAT HAS REPEATEDLY PROVIDED SUPPORT FOR ACTS OF INTERNATIONAL TERRORISM.

(a) DESIGNATION.—The Secretary of State shall designate the Democratic People's Republic of North Korea as a country that has repeatedly provided support for acts of international terrorism for purposes of section 6(j) of the Export Administration Act of 1979 (50 U.S.C. App. 2405(j)), section 40 of the Arms Export Control Act (22 U.S.C. 2780), and section 620A of the Foreign Assistance Act of 1961 (22 U.S.C. 2371).

(b) WAIVER AUTHORITY.—The President may waive the requirements under subsection (a) upon certifying to Congress that the Government of North Korea has—

(1) verifiably dismantled its nuclear weapons programs;

(2) ceased all nuclear and missile proliferation activities;

(3) released United States citizens Euna Lee and Laura Ling;

(4) returned the last remains of United States permanent resident, Reverend Kim Dong-shik;

(5) released, or accounted for, all foreign abductees and prisoners of war; and

(6) released all North Korean prisoners of conscience.

SA 1242. Mr. BAYH (for himself, Ms. MURKOWSKI, Mr. BURRIS, Mr. LIEBERMAN, Mr. WARNER, Mr. WEBB, and Mr. NELSON of Nebraska) submitted an amendment intended to be proposed by him to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

At the end of the bill, add the following:

DIVISION __—NURSE FACULTY LOAN REPAYMENT PROGRAM

SEC. 1. SHORT TITLE.

This division may be cited as the ''Nurses' Higher Education and Loan Repayment Act of 2009''.

SEC. 2. FINDINGS.

The Congress finds the following:

(1) The Health Resources and Services Administration estimates there is currently a shortage of more than 200,000 registered nurses nationwide and projects the shortage will grow to more than 1,000,000 nurses by 2020, 36 percent less than needed to meet demand for nursing care.

(2) The shortage of qualified nursing faculty is the primary factor driving the inability of nursing schools to graduate more registered nurses to meet the Nation's growing workforce demand.

(3) There continues to be strong interest on the part of young Americans to enter the nursing field. The National League for Nursing estimates that 88,000 qualified applications, or 1 out of every 3 submitted to basic registered nurse programs in 2006, were rejected due to lack of capacity.

(4) The American Association of Colleges of Nursing (in this section referred to as the ''AACN'') estimates that 49,948 applicants were turned away specifically from baccalaureate and graduate schools of nursing in 2008 and over 70 percent of the schools responding to the AACN survey reported a lack of nurse faculty as the number 1 reason for turning away qualified applicants. Likewise, nearly 70 percent of the associate's degree registered nurse programs responding to the most recent American Association of Community Colleges Nursing Survey reported a lack of faculty to teach as the number 1 reason for turning away qualified applicants.

(5) Large numbers of faculty members at schools of nursing in the United States are nearing retirement. According to the AACN, the average age of a nurse faculty member is 55 years old and the average age at retirement is 62.

(6) The current nationwide nurse faculty vacancy rate is estimated to be as high as 7.6 percent, including 814 vacant positions at schools of nursing offering baccalaureate and advanced degrees and, in 2006, as many as 880 in associate's degree programs.

(7) Market forces have created disincentives for individuals qualified to become nurse educators from pursing this career. The average annual salary for an associate professor of nursing with a master's degree is nearly 20 percent less than the average salary for a nurse practitioner with a master's degree, according to the 2007 salary survey by the journal ADVANCE for Nurse Practitioners.

(8) The most recent Health Resources and Services Administration survey data indicates that from a total of more than 2,000,000 registered nurses, only 143,113 registered nurses with a bachelor's degree and only 51,318 registered nurses with an associate's degree have continued their education to earn a master's degree in the science of nursing, the minimum credential necessary to teach in all types of registered nurse programs. The majority of these graduates do not become nurse educators.

(9) Current Federal incentive programs to encourage nurses to become educators are inadequate and inaccessible for many interested nurses.

(10) A broad incentive program must be available to willing and qualified nurses that will provide financial support and encourage them to pursue and maintain a career in nursing education.

SEC. 3. NURSE FACULTY LOAN REPAYMENT PROGRAM.

Part E of title VIII of the Public Health Service Act (42 U.S.C. 297a et seq.) is amended by inserting after section 846A the following new section:

''SEC. 846B. NURSE FACULTY LOAN REPAYMENT PROGRAM.

''(a) ESTABLISHMENT.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, may enter into an agreement with eligible individuals for the repayment of education loans, in accordance with this section, to increase the number of qualified nursing faculty.

''(b) AGREEMENTS.—Each agreement entered into under subsection (a) shall require that the eligible individual shall serve as a full-time member of the faculty of an accredited school of nursing for a total period, in the aggregate, of at least 4 years during the 6-year period beginning on the later of—

''(1) the date on which the individual receives a master's or doctorate nursing degree from an accredited school of nursing; or

''(2) the date on which the individual enters into an agreement under subsection (a).

''(c) AGREEMENT PROVISIONS.—Agreements entered into pursuant to subsection (a) shall be entered into on such terms and conditions as the Secretary may determine, except that—

''(1) not more than 300 days after the date on which the 6-year period described under subsection (b) begins, but in no case before the individual starts as a full-time member of the faculty of an accredited school of nursing, the Secretary shall begin making payments, for and on behalf of that individual, on the outstanding principal of, and interest on, any loan the individual obtained to pay for such degree;

''(2) for an individual who has completed a master's degree in nursing—

''(A) payments may not exceed $10,000 per calendar year; and

''(B) total payments may not exceed $40,000; and

''(3) for an individual who has completed a doctorate degree in nursing—

''(A) payments may not exceed $20,000 per calendar year; and

''(B) total payments may not exceed $80,000.

''(d) BREACH OF AGREEMENT.—

''(1) IN GENERAL.—In the case of any agreement made under subsection (a), the individual is liable to the Federal Government for the total amount paid by the Secretary under such agreement, and for interest on such amount at the maximum legal prevailing rate, if the individual fails to meet the agreement terms required under subsection (b).

''(2) WAIVER OR SUSPENSION OF LIABILITY.—In the case of an individual making an agreement for purposes of paragraph (1), the Secretary shall provide for the waiver or suspension of liability under such paragraph if compliance by the individual with the agreement involved is impossible or would involve extreme hardship to the individual or if enforcement of the agreement with respect to the individual would be unconscionable.

''(3) DATE CERTAIN FOR RECOVERY.—Subject to paragraph (2), any amount that the Federal Government is entitled to recover under paragraph (1) shall be paid to the United States not later than the expiration of the 3-year period beginning on the date the United States becomes so entitled.

''(4) AVAILABILITY.—Amounts recovered under paragraph (1) shall be available to the Secretary for making loan repayments under this section and shall remain available for such purpose until expended.

''(e) ELIGIBLE INDIVIDUAL DEFINED.—For purposes of this section, the term 'eligible individual' means an individual who—

''(1) is a United States citizen, national, or lawful permanent resident;

''(2) holds an unencumbered license as a registered nurse; and

''(3) has either already completed a master's or doctorate nursing program at an accredited school of nursing or is currently enrolled on a full-time or part-time basis in such a program.

''(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Secretary such sums as may be necessary for each of fiscal years 2010 through 2014 to carry out this Act. Such sums shall remain available until expended.

''(g) SUNSET.—The provisions of this section shall terminate on December 31, 2020.''.

SA 1243. Mr. DEMINT (for himself, Mr. KYL, Mr. BUNNING, Mr. MARTINEZ, Mr. JOHANNS, Mr. RISCH, Mr. CRAPO, Mr. MCCONNELL, Mr. BOND, Mr. CORNYN, Mr. CHAMBLISS, Mr. COBURN, Mr. ROBERTS, Mr. INHOFE, Mr. BENNETT, Mr. BURR, and Mr. BROWNBACK) submitted an amendment intended to be proposed by him to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5,

United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. STATE-SPONSOR OF TERRORISM.

The Secretary of State shall consider the Government of the Democratic People's Republic of Korea to have repeatedly provided support for acts of international terrorism, and the Democratic People's Republic of Korea shall be subject to the provisions set forth in section 40(d) of the Arms Export Control Act (22 U.S.C. 2780(d)), section 620A(a) of the Foreign Assistance Act of 1961 (22 U.S.C. 2371(a)), and section 6(j) of the Export Administration Act of 1979 (50 App. U.S.C. 2405(j)).

SA 1244. Mr. BURR (for himself and Mrs. HAGAN) submitted an amendment intended to be proposed by him to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Preventing Disease and Death from Tobacco Use Act''.

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

Sec. 1. Short title; table of contents.
Sec. 2. Findings.
Sec. 3. Purpose.
Sec. 4. Scope and effect.
Sec. 5. Severability.
Sec. 6. Effective date.

TITLE I—AUTHORITY OF THE TOBACCO HARM REDUCTION CENTER

Sec. 100. Definitions.
Sec. 101. Center authority over tobacco products.
Sec. 102. Exclusion of other regulatory programs.
Sec. 103. Existing Federal statutes maintained.
Sec. 104. Proceedings in the name of the United States; subpoenas; preemption of State and local law; no private right of action.
Sec. 105. Adulterated tobacco products.
Sec. 106. Misbranded tobacco products.
Sec. 107. Submission of health information to the Administrator.
Sec. 108. Registration and listing.
Sec. 109. General provisions respecting control of tobacco products.
Sec. 110. Smoking article standards.
Sec. 111. Notification and other remedies.
Sec. 112. Records and reports on tobacco products.
Sec. 113. Application for review of certain smoking articles.
Sec. 114. Modified risk tobacco products.
Sec. 115. Judicial review.
Sec. 116. Jurisdiction of and coordination with the Federal Trade Commission.
Sec. 117. Regulation requirement.
Sec. 118. Preservation of State and local authority.
Sec. 119. Tobacco Products Scientific Advisory Committee.
Sec. 120. Drug products used to treat tobacco dependence.

TITLE II—TOBACCO PRODUCTS WARNINGS; CONSTITUENT AND SMOKE CONSTITUENT DISCLOSURE

Sec. 201. Cigarette label and advertising warnings.
Sec. 202. Smokeless tobacco labels and advertising warnings.

TITLE III—PUBLIC DISCLOSURES BY TOBACCO PRODUCTS MANUFACTURERS

Sec. 301. Disclosures on packages of tobacco products.
Sec. 302. Disclosures on packages of smokeless tobacco.
Sec. 303. Public disclosure of ingredients.

TITLE IV—PREVENTION OF ILLICIT TRADE IN TOBACCO PRODUCTS

Sec. 401. Study and report on illicit trade.
Sec. 402. Amendment to section 1926 of the Public Health Service Act.
Sec. 403. Establishment of rankings.

TITLE V—ENFORCEMENT PROVISIONS

Sec. 501. Prohibited acts.
Sec. 502. Injunction proceedings.
Sec. 503. Penalties.
Sec. 504. Seizure.
Sec. 505. Report of minor violations.
Sec. 506. Inspection.
Sec. 507. Effect of compliance.
Sec. 508. Imports.
Sec. 509. Tobacco products for export.

TITLE VI—MISCELLANEOUS PROVISIONS

Sec. 601. Use of payments under the master settlement agreement and individual State settlement agreements.
Sec. 602. Preemption of State Laws Implementing Fire Safety Standard for Cigarettes.
Sec. 603. Inspection by the alcohol and tobacco tax trade bureau of records of certain cigarette and smokeless tobacco sellers.
Sec. 604. Severability.

TITLE VII—TOBACCO GROWER PROTECTION

Sec. 701. Tobacco grower protection.

TITLE VIII—RESTRICTIONS ON YOUTH ACCESS TO TOBACCO PRODUCTS AND EXPOSURE OF YOUTHS TO TOBACCO PRODUCT MARKETING AND ADVERTISING

Sec. 801. Prohibitions on youth targeting.

TITLE IX—USER FEES

Sec. 901. User fees.

SEC. 2. FINDINGS.

The Congress finds the following:

(1) Cigarette smoking is a leading cause of preventable deaths in the United States. Cigarette smoking significantly increases the risk of developing lung cancer, heart disease, chronic bronchitis, emphysema and other serious diseases with adverse health conditions.

(2) The risk for serious diseases is significantly affected by the type of tobacco product and the frequency, duration and manner of use.

(3) No tobacco product has been shown to be safe and without risks. The health risks associated with cigarettes are significantly greater than those associated with the use of smoke-free tobacco and nicotine products.

(4) Nicotine in tobacco products is addictive but is not considered a significant threat to health.

(5) It is the smoke inhaled from burning tobacco which poses the most significant risk of serious diseases.

(6) Quitting cigarette smoking significantly reduces the risk for serious diseases.

(7) Adult tobacco consumers have a right to be fully and accurately informed about the risks of serious diseases, the significant differences in the comparative risks of different tobacco and nicotine-based products, and the benefits of quitting. This information should be based on sound science.

(8) Governments, public health officials, tobacco manufacturers and others share a responsibility to provide adult tobacco consumers with accurate information about the various health risks and comparative risks associated with the use of different tobacco and nicotine products.

(9) Tobacco products should be regulated in a manner that is designed to achieve significant and measurable reductions in the morbidity and mortality associated with tobacco use. Regulations should enhance the information available to adult consumers to permit them to make informed choices, and encourage the development of tobacco and nicotine products with lower risks than cigarettes currently sold in the United States.

(10) The form of regulation should be based on the risks and comparative risks of tobacco and nicotine products and their respective product categories.

(11) The regulation of marketing of tobacco products should be consistent with constitutional protections and enhance an adult consumer's ability to make an informed choice by providing accurate information on the risks and comparative risks of tobacco products.

(12) Reducing the diseases and deaths associated with the use of cigarettes serves public health goals and is in the best interest of consumers and society. Harm reduction should be the critical element of any comprehensive public policy surrounding the health consequences of tobacco use.

(13) Significant reductions in the harm associated with the use of cigarettes can be achieved by providing accurate information regarding the comparative risks of tobacco products to adult tobacco consumers, thereby encouraging smokers to migrate to the use of smoke-free tobacco and nicotine products, and by developing new smoke-free tobacco and nicotine products and other actions.

(14) Governments, public health officials, manufacturers, tobacco producers and consumers should support the development, production, and commercial introduction of tobacco leaf, and tobacco and nicotine-based products that are scientifically shown to reduce the risks associated with the use of existing tobacco products, particularly cigarettes.

(15) Adult tobacco consumers should have access to a range of commercially viable tobacco and nicotine-based products.

(16) There is substantial scientific evidence that selected smokeless tobacco products can satisfy the nicotine addiction of inveterate smokers while eliminating most, if not all, risk of pulmonary and cardiovascular complications of smoking and while reducing the risk of cancer by more than 95 percent.

(17) Transitioning smokers to selected smokeless tobacco products will eliminate environmental tobacco smoke and fire-related hazards.

(18) Current ''abstain, quit, or die'' tobacco control policies in the United States may have reached their maximum possible public health benefit because of the large number of cigarette smokers either unwilling or unable to discontinue their addiction to nicotine.

(19) There is evidence that harm reduction works and can be accomplished in a way that will not increase initiation or impede smoking cessation.

(20) Health-related agencies and organizations, both within the United States and abroad have already gone on record endorsing Harm Reduction as an approach to further reducing tobacco related illness and death.

(21) Current Federal policy requires tobacco product labeling that leaves the incorrect impression that all tobacco product present equal risk.

SEC. 3. PURPOSE.

The purposes of this Act are—

(1) to provide authority to the Tobacco Harm Reduction Center by recognizing it as the primary Federal regulatory authority with respect to tobacco products as provided for in this Act;

(2) to ensure that the Center has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco;

(3) to authorize the Center to set national standards controlling the manufacture of tobacco products and the identity, public disclosure, and amount of ingredients used in such products;

(4) to provide new and flexible enforcement authority to ensure that there is effective oversight of the tobacco industry's efforts to develop, introduce, and promote less harmful tobacco products;

(5) to vest the Center with the authority to regulate the levels of tar, nicotine, and other harmful components of tobacco products;

(6) to ensure that consumers are better informed regarding the relative risks for death and disease between categories of tobacco products;

(7) to continue to allow the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage purchasers;

(8) to impose appropriate regulatory controls on the tobacco industry;

(9) to promote prevention, cessation, and harm reduction policies and regulations to reduce disease risk and the social costs associated with tobacco-related diseases;

(10) to provide authority to the Department of Health and Human Services to regulate tobacco products;

(11) to establish national policies that effectively reduce disease and death associated with cigarette smoking and other tobacco use;

(12) to establish national policies that encourage prevention, cessation, and harm reduction measures regarding the use of tobacco products;

(13) to encourage current cigarette smokers who will not quit to use noncombustible tobacco or nicotine products that have significantly less risk than cigarettes;

(14) to establish national policies that accurately and consistently inform adult tobacco consumers of significant differences in risk between respective tobacco products;

(15) to establish national policies that encourage and assist the development and awareness of noncombustible tobacco and nicotine products;

(16) to coordinate national and State prevention, cessation, and harm reduction programs;

(17) to impose measures to ensure tobacco products are not sold or accessible to underage purchasers; and

(18) to strengthen Federal and State legislation to prevent illicit trade in tobacco products.

SEC. 4. SCOPE AND EFFECT.

(a) INTENDED EFFECT.—Nothing in this Act (or an amendment made by this Act) shall be construed to—

(1) establish a precedent with regard to any other industry, situation, circumstance, or legal action;

(2) affect any action pending in Federal, State, or Tribal court, or any agreement, consent decree, or contract of any kind; or

(3) be applicable to tobacco products or component parts manufactured in the United States for export.

(b) AGRICULTURAL ACTIVITIES.—The provisions of this Act (or an amendment made by this Act) which authorize the Administrator to take certain actions with regard to tobacco and tobacco products shall not be construed to affect any authority of the Secretary of Agriculture under existing law regarding the growing, cultivation, or curing of raw tobacco.

(c) REVENUE ACTIVITIES.—The provisions of this Act (or an amendment made by this Act) which authorize the Administrator to take certain actions with regard to tobacco products shall not be construed to affect any authority of the Secretary of the Treasury under chapter 52 of the Internal Revenue Code of 1986.

SEC. 5. SEVERABILITY.

If any provision of this Act, the amendments made by this Act, or the application of any provision of this Act to any person or circumstance is held to be invalid, the remainder of this Act, the amendments made by this Act, and the application of the provisions of this Act to any other person or circumstance shall not be affected and shall continue to be enforced to the fullest extent possible.

SEC. 6. EFFECTIVE DATE.

Except as otherwise specifically provided, the effective date of this Act shall be the date of its enactment.

TITLE I—AUTHORITY OF THE TOBACCO HARM REDUCTION CENTER

SEC. 100. DEFINITIONS.

In this Act:

(1) The term ''Administrator'' means the chief executive of the Tobacco Regulatory Agency (the Agency responsible for administering and enforcing this Act and regulations promulgated pursuant to this Act).

(2) The term ''adult'' means any individual who has attained the minimum age under applicable State law to be an individual to whom tobacco products may lawfully be sold.

(3) The term ''adult-only facility'' means a facility or restricted area, whether open-air or enclosed, where the operator ensures, or has a reasonable basis to believe, that no youth is present. A facility or restricted area need not be permanently restricted to adults in order to constitute an adult-only facility, if the operator ensures, or has a reasonable basis to believe, that no youth is present during any period of operation as an adult-only facility.

(4) The term ''advertising'' means a communication to the general public by a tobacco product manufacturer, distributor, retailer, or its agents, which identifies a tobacco product by brand name and is intended by such manufacturer, distributor, retailer, or its agents to promote purchases of such tobacco product. Such term shall not include—

(A) any advertising or other communication in any tobacco trade publication or tobacco trade promotional material;

(B) the content of any scientific publication or presentation, or any patent application or other communication to the United States Patent and Trademark Office or any similar office in any other country;

(C) any corporate or financial report or financial communication;

(D) any communication to a lending institution or to securities holders;

(E) any communication not intended for public display or public exposure, except that a direct mailing or direct electronic communication of what otherwise is advertising shall be deemed to be advertising;

(F) any communication in, on, or within a factory, office, plant, warehouse, or other facility related to or associated with the development, manufacture, or storage of tobacco products;

(G) any communication to any governmental agency, body, official, or employee;

(H) any communication to any journalist, editor, Internet blogger, or other author;

(I) any communication in connection with litigation, including arbitration and like proceedings; or

(J) any editorial advertisement that addresses a public issue.

(5) The term ''affiliate'' means a person that directly or indirectly owns or controls, is owned or controlled by, or is under common ownership or control with, another person. The terms ''owns,'' ''is owned'', and ''ownership'' refer to ownership of an equity interest, or the equivalent thereof, of 50 percent or more.

(6) The term ''Agency'' means the Tobacco Regulatory Agency.

(7) The term ''age-verified adult'' means any individual who is an adult and—

(A) who has stated or acknowledged, after being asked, that he or she is an adult and a tobacco product user, and has presented proof of age identifying the individual and verifying that the individual is an adult; or

(B) whose status as an adult has been verified by a commercially available database of such information.

(8) The term ''annual report'' means a tobacco product manufacturer's annual report to the Agency, which provides ingredient information and nicotine yield ratings for each brand style that tobacco product manufacturer manufactures for commercial distribution domestically.

(9) The term ''brand name'' means a brand name of a tobacco product distributed or sold domestically, alone, or in conjunction with any other word, trademark, logo, symbol, motto, selling message, recognizable pattern of colors, or any other indicium of product identification identical or similar to, or identifiable with, those used for any domestic brand of tobacco product. The term shall not include the corporate name of any tobacco product manufacturer that does not, after the effective date of this Act, sell a brand style of tobacco product in the United States that includes such corporate name.

(10) The term ''brand name sponsorship'' means an athletic, musical, artistic, or other social or cultural event, series, or tour, with respect to which payment is made, or other consideration is provided, in exchange for use of a brand name or names—

(A) as part of the name of the event; or

(B) to identify, advertise, or promote such event or an entrant, participant, or team in such event in any other way.

(11) The term ''brand style'' means a tobacco product having a brand name, and distinguished by the selection of the tobacco, ingredients, structural materials, format, configuration, size, package, product descriptor, amount of tobacco, or yield of ''tar'' or nicotine.

(12) The term ''carton'' means a container into which packages of tobacco products are directly placed for distribution or sale, but does not include cases intended for shipping. Such term includes a carton containing 10 packages of cigarettes.

(13) The term ''cartoon'' means any drawing or other depiction of an object, person, animal, creature or any similar caricature that satisfies any of the following criteria:

(A) The use of comically exaggerated features.

(B) The attribution of human characteristics to animals, plants or other objects, or

the similar use of anthropomorphic technique.

(C) The attribution of unnatural or extrahuman abilities, such as imperviousness to pain or injury, X-ray vision, tunneling at very high speeds, or transformation.

The term does not include any drawing or other depiction that, on the effective date of this Act, was in use in the United States in any tobacco product manufacturer's corporate logo or in any tobacco product manufacturer's tobacco product packaging.

(14) The term ''cigar'' has the meaning assigned that term by the Alcohol and Tobacco Tax and Trade Bureau in section 40.11 of title 27, Code of Federal Regulations.

(15) The term ''cigarette'' means—

(A) any roll of tobacco wrapped in paper or in any substance not containing tobacco; or

(B) any roll of tobacco wrapped in any substance containing tobacco which, because of the appearance of the roll of tobacco, the type of tobacco used in the filler, or its package or labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in subparagraph (A).

(16) The term ''competent and reliable scientific evidence'' means evidence based on tests, analyses, research, or studies, conducted and evaluated in an objective manner by individuals qualified to do so, using procedures generally accepted in the relevant scientific disciplines to yield accurate and reliable results.

(17) The term ''distributor'' means any person who furthers the distribution of tobacco products, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the tobacco product to individuals for personal consumption. Common carriers, retailers, and those engaged solely in advertising are not considered distributors for purposes of this Act.

(18) The terms ''domestic'' and ''domestically'' mean within the United States, including activities within the United States involving advertising, marketing, distribution, or sale of tobacco products that are intended for consumption within the United States.

(19) The term ''human image'' means any photograph, drawing, silhouette, statue, model, video, likeness, or depiction of the appearance of a human being, or the appearance of any portion of the body of a human being.

(20) The term ''illicit tobacco product'' means any tobacco product intended for use by consumers in the United States—

(A) as to which not all applicable duties or taxes have been paid in full;

(B) that has been stolen, smuggled, or is otherwise contraband;

(C) that is counterfeit; or

(D) that has or had a label, labeling, or packaging stating, or that stated, that the product is or was for export only, or that it is or was at any time restricted by section 5704 of title 26, United States Code.

(21) The term ''illicit trade'' means any transfer, distribution, or sale in interstate commerce of any illicit tobacco product.

(22) The term ''immediate container'' does not include package liners.

(23) The term ''Indian tribe'' has the meaning assigned that term in section 4(e) of the Indian Self Determination and Education Assistance Act (25 U.S.C. 450b(e)).

(24) The term ''ingredient'' means tobacco and any substance added to tobacco to have an effect in the final tobacco product or when the final tobacco product is used by a consumer.

(25) The term ''International Organization for Standardization (ISO) testing regimen'' means the methods for measuring cigarette smoke yields, as set forth in the most recent version of ISO 3308, entitled ''Routine analytical cigarette-smoking machine—Definition of standard conditions''; ISO 4387, entitled ''Cigarettes—Determination of total and nicotine-free dry particulate matter using a routine analytical smoking machine''; ISO 10315, entitled ''Cigarettes—Determination of nicotine in smoke condensates—Gas-chromatographic method''; ISO 10362–1, entitled ''Cigarettes—Determination of water in smoke condensates—Part 1: Gas-chromatographic method''; and ISO 8454, entitled ''Cigarettes—Determination of carbon monoxide in the vapour phase of cigarette smoke—NDIR method''. A cigarette that does not burn down in accordance with the testing regimen standards may be measured under the same puff regimen using the number of puffs that such a cigarette delivers before it extinguishes, plus an additional three puffs, or with such other modifications as the Administrator may approve.

(26) The term ''interstate commerce'' means all trade, traffic, or other commerce—

(A) within the District of Columbia, or any territory or possession of the United States;

(B) between any point in a State and any point outside thereof;

(C) between points within the same State through any place outside such State; or

(D) over which the United States has jurisdiction.

(27) The term ''label'' means a display of written, printed, or graphic matter upon or applied securely to the immediate container of a tobacco product.

(28) The term ''labeling'' means all labels and other written, printed, or graphic matter (1) upon or applied securely to any tobacco product or any of its containers or wrappers, or (2) accompanying a tobacco product.

(29) The term ''little cigar'' has the meaning assigned that term by the Alcohol and Tobacco Tax and Trade Bureau in section 40.11 of title 27, Code of Federal Regulations.

(30) The term ''loose tobacco'' means any form of tobacco, alone or in combination with any other ingredient or material, that, because of its appearance, form, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco for making or assembling cigarettes, incorporation into pipes, or otherwise used by consumers to make any smoking article.

(31) The term ''manufacture'' means to design, manufacture, fabricate, assemble, process, package, or repackage, label, or relabel, import, or hold or store in a commercial quantity, but does not include—

(A) the growing, curing, de-stemming, or aging of tobacco; or

(B) the holding, storing or transporting of a tobacco product by a common carrier for hire, a public warehouse, a testing laboratory, a distributor, or a retailer.

(32) The term ''nicotine-containing product'' means a product intended for human consumption, other than a tobacco product, that contains added nicotine, whether or not in the form of a salt or solvate, that has been—

(A) synthetically produced, or

(B) obtained from tobacco or other source of nicotine.

(33) The term ''outdoor advertising''—

(A) except as provided in subparagraph (B), means—

(i) billboards;

(ii) signs and placards in arenas, stadiums, shopping malls, and video game arcades (whether any of such are open air or enclosed), but not including any such sign or placard located in an adult-only facility; and

(iii) any other advertisements placed outdoors; and

(B) does not include—

(i) an advertisement on the outside of a tobacco product manufacturing facility; or

(ii) an advertisement that—

(I) is inside a retail establishment that sells tobacco products (other than solely through a vending machine or vending machines);

(II) is placed on the inside surface of a window facing outward; and

(III) is no larger than 14 square feet.

(34) The term ''package'' means a pack, box, carton, pouch, or container of any kind in which a tobacco product or tobacco products are offered for sale, sold, or otherwise distributed to consumers. The term ''package'' does not include an outer container used solely for shipping one or more packages of a tobacco product or tobacco products.

(35) The term ''person'' means any individual, partnership, corporation, committee, association, organization or group of persons, or other legal or business entity.

(36) The term ''proof of age'' means a driver's license or other form of identification that is issued by a governmental authority and includes a photograph and a date of birth of the individual.

(37) The term ''raw tobacco'' means tobacco in a form that is received by a tobacco product manufacturer as an agricultural commodity, whether in a form that is—

(A) natural, stem or leaf;

(B) cured or aged; or (3)

(C) as parts or pieces, but not in a reconstituted form, extracted pulp form, or extract form.

(38) The term ''reduced-exposure claim'' means a statement in advertising or labeling intended for one or more consumers of tobacco products, that a tobacco product provides a reduced exposure of users of that tobacco product to one or more toxicants, as compared to an appropriate reference tobacco product or category of tobacco products. A statement or representation that a tobacco product or the tobacco in a tobacco product contains ''no additives'' or is ''natural'' or that uses a substantially similar term is not a reduced-exposure claim if the advertising or labeling that contains such statement or representation also contains the disclosure required by section 108(h) of this Act.

(39) The term ''reduced-risk claim'' means a statement in advertising or labeling intended for one or more consumers of tobacco products, that a tobacco product provides to users of that product a reduced risk of morbidity or mortality resulting from one or more chronic diseases or serious adverse health conditions associated with tobacco use, as compared to an appropriate reference tobacco product or category of tobacco products, even if it is not stated, represented, or implied that all health risks associated with using that tobacco product have been reduced or eliminated. A statement or representation that a tobacco product or the tobacco in a tobacco product contains ''no additives,'' or is ''natural,'' or that uses a substantially similar term is not a reduced-risk claim if the advertising or labeling that contains such statement or representation also contains the disclosure required by section 108(h).

(40) The term ''retailer'' means any person that—

(A) sells tobacco products to individuals for personal consumption; or

(B) operates a facility where the sale of tobacco products to individuals for personal consumption is permitted.

(41) The term ''sample'' means a tobacco product distributed to members of the public at no cost for the purpose of promoting the

product, but excludes tobacco products distributed—

(A) in conjunction with the sale of other tobacco products;

(B) for market research, medical or scientific study or testing, or teaching;

(C) to persons employed in the trade;

(D) to adult consumers in response to consumer complaints; or

(E) to employees of the manufacturer of the tobacco product.

(42) The term ''small business'' means a tobacco product manufacturer that—

(A) has 150 or fewer employees; and

(B) during the 3-year period prior to the current calendar year, had an average annual gross revenue from tobacco products that did not exceed $40,000,000.

(43) The term ''smokeless tobacco product'' means any form of finely cut, ground, powdered, reconstituted, processed or shaped tobacco, leaf tobacco, or stem tobacco, whether or not combined with any other ingredient, whether or not in extract or extracted form, and whether or not incorporated within any carrier or construct, that is intended to be placed in the oral or nasal cavity, including dry snuff, moist snuff, and chewing tobacco.

(44) The term ''smoking article'' means any tobacco-containing article that is intended, when used by a consumer, to be burned or otherwise to employ heat to produce a vapor, aerosol or smoke that—

(A) incorporates components of tobacco or derived from tobacco; and

(B) is intended to be inhaled by the user.

(45) The term ''State'' means any State of the United States and, except as otherwise specifically provided, includes any Indian tribe or tribal organization, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Island, Kingman Reef, Johnston Atoll, the Northern Marianas, and any other trust territory or possession of the United States.

(46) The term ''tar'' means nicotine-free dry particulate matter as defined in ISO 4387, entitled ''Cigarettes—Determination of total and nicotine-free dry particulate matter using a routine analytical smoking machine''.

(47) The term ''tobacco'' means a tobacco plant or any part of a harvested tobacco plant intended for use in the production of a tobacco product, including leaf, lamina, stem, or stalk, whether in green, cured, or aged form, whether in raw, treated, or processed form, and whether or not combined with other materials, including any by-product, extract, extracted pulp material, or any other material (other than purified nicotine) derived from a tobacco plant or any component thereof, and including strip, filler, stem, powder, and granulated, blended, or reconstituted forms of tobacco.

(48) The term ''tobacco product'' means—

(A) the singular of ''tobacco products'' as defined in section 5702(c) of the Internal Revenue Code of 1986;

(B) any other product that contains tobacco as a principal ingredient and that, because of its appearance, type, or the tobacco used in the product, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a tobacco product as described in subparagraph (A); and

(C) any form of tobacco or any construct incorporating tobacco, intended for human consumption, whether by—

(i) placement in the oral or nasal cavity;

(ii) inhalation of vapor, aerosol, or smoke; or

(iii) any other means.

(49) The term ''tobacco product category'' means a type of tobacco product characterized by its composition, components, and intended use, and includes tobacco products classified as cigarettes, loose tobacco for roll-your-own tobacco products, little cigars, cigars, pipe tobacco, moist snuff, dry snuff, chewing tobacco, and other forms of tobacco products (which are treated in this Act collectively as a single category).

(50) The term ''tobacco product communication'' means any means, medium, or manner for providing information relating to any tobacco product, including face-to-face interaction, mailings by postal service or courier to an individual who is an addressee, and electronic mail to an individual who is an addressee.

(51) The term ''tobacco product manufacturer'' means an entity that directly—

(A) manufactures anywhere a tobacco product that is intended to be distributed commercially in the United States, including a tobacco product intended to be distributed commercially in the United States through an importer;

(B) is the first purchaser for resale in the United States of tobacco products manufactured outside the United States for distribution commercially in the United States; or

(C) is a successor or assign of any of the foregoing.

(52) The term ''toxicant'' means a chemical or physical agent that produces an adverse biological effect.

(53) The term ''transit advertisements'' means advertising on or within private or public vehicles and all advertisements placed at, on, or within any bus stop, taxi stand, transportation waiting area, train station, airport, or any similar location.

(54) The term ''tribal organization'' has the meaning assigned that term in section 4(1) of the Indian Self Determination and Education Assistance Act (25 U.S.C. 450b(1)).

(55) The term ''United States'' means the several States, as defined in this Act.

(56) The term ''vending machine'' means any mechanical, electric, or electronic self-service device that, upon insertion of money, tokens, or any other form of payment, automatically dispenses tobacco products.

(57) The term ''video game arcade'' means an entertainment establishment primarily consisting of video games (other than video games intended primarily for use by adults) or pinball machines.

(58) The term ''youth'' means any individual who in not an adult.

SEC. 101. CENTER AUTHORITY OVER TOBACCO PRODUCTS.

(a) IN GENERAL.—Tobacco products, including modified risk tobacco products for which an order has been issued in accordance with section 117, shall be regulated by the Administrator under this Act.

(b) APPLICABILITY.—This Act shall apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Administrator by regulation deems to be subject to this Act.

(c) CENTER.—The Secretary of Health and Human Services shall establish within the Department of Health and Human Services the Tobacco Harm Reduction Center. The head of the Center shall be an Administrator, who shall assume the statutory authority conferred by this Act, perform the functions that relate to the subject matter of this Act, and have the authority to promulgate regulations for the efficient enforcement of this Act. In promulgating any regulations under such authority, in whole or in part or any regulation that is likely to have an annual effect on the economy of $50,000,000 or more or have a material adverse effect on adult users of tobacco products, tobacco product manufacturers, distributors, or retailers, the Administrator shall—

(1) determine the technological and economic ability of parties that would be required to comply with the regulation to comply with it;

(2) consider experience gained under any relevantly similar regulations at the Federal or State level;

(3) determine the reasonableness of the relationship between the costs of complying with such regulation and the public health benefits to be achieved by such regulation;

(4) determine the reasonable likelihood of measurable and substantial reductions in morbidity and mortality among individual tobacco users;

(5) determine the impact to United States tobacco producers and farm operations;

(6) determine the impact on the availability and use of tobacco products by minors; and

(7) determine the impact on illicit trade of tobacco products.

(d) LIMITATION OF AUTHORITY.—

(1) IN GENERAL.—The provisions of this Act shall not apply to tobacco leaf that is not in the possession of a manufacturer of tobacco products, or to the producers of tobacco leaf, including tobacco growers, tobacco warehouses, and tobacco grower cooperatives, nor shall any employee of the Center have any authority to enter onto a farm owned by a producer of tobacco leaf without the written consent of such producer.

(2) EXCEPTION.—Notwithstanding paragraph (1), if a producer of tobacco leaf is also a tobacco product manufacturer or controlled by a tobacco product manufacturer, the producer shall be subject to this Act in the producer's capacity as a manufacturer. The exception in this subparagraph shall not apply to a producer of tobacco leaf who grows tobacco under a contract with a tobacco product manufacturer and who is not otherwise engaged in the manufacturing process.

(3) RULE OF CONSTRUCTION.—Nothing in this Act shall be construed to grant the Administrator authority to promulgate regulations on any matter that involves the production of tobacco leaf or a producer thereof.

(e) RULEMAKING PROCEDURES.—Each rulemaking under this Act shall be in accordance with chapter 5 of title 5, United States Code.

(f) CONSULTATION PRIOR TO RULEMAKING.—Prior to promulgating rules under this Act, the Administrator shall endeavor to consult with other Federal agencies as appropriate.

SEC. 102. EXCLUSION OF OTHER REGULATORY PROGRAMS.

(a) EXCLUSION OF TOBACCO PRODUCTS AND NICOTINE-CONTAINING PRODUCTS FROM THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.—No tobacco product and no nicotine-containing product shall be regulated as a food, drug, or device in accordance with section 201 (f), (g) or (h) or Chapter IV or V of the Federal Food, Drug, and Cosmetic Act, except that any tobacco product commercially distributed domestically and any nicotine-containing product commercially distributed domestically shall be subject to Chapter V of the Federal Food, Drug, and Cosmetic Act if the manufacturer or a distributor of such product markets it with an explicit claim that the product is intended for use in the cure, mitigation, treatment, or prevention of disease in man or other animals, within the meaning of section 201(g)(1)(C) or section 201(h)(2) of that Act.

(b) LIMITATION ON EFFECT OF THIS ACT.—Nothing in this Act shall be construed to—

(1) establish a precedent with regard to any other industry, situation, circumstance, or legal action; or

(2) affect any action pending in any Federal, State, or Tribal court, or any agreement, consent decree, or contract of any kind.

(c) EXCLUSIONS FROM AUTHORITY OF ADMINISTRATOR.—The authority granted to the Administrator under this Act shall not apply to—

(1) raw tobacco that is not in the possession or control of a tobacco product manufacturer;

(2) raw tobacco that is grown for a tobacco product manufacturer by a grower, and that is in the possession of that grower or of a person that is not a tobacco product manufacturer and is within the scope of subparagraphs (A) through(F) of paragraph (3); or

(3) the activities, materials, facilities, or practices of persons that are not tobacco product manufacturers and that are—

(A) producers of raw tobacco, including tobacco growers;

(B) tobacco warehouses, and other persons that receive raw tobacco from growers;

(C) tobacco grower cooperatives;

(D) persons that cure raw tobacco;

(E) persons that process raw tobacco; and

(F) persons that store raw tobacco for aging.

If a producer of raw tobacco is also a tobacco product manufacturer, an affiliate of a tobacco product manufacturer, or a person producing raw tobacco for a tobacco product manufacturer, then that producer shall be subject to this Act only to the extent of that producer's capacity as a tobacco product manufacturer.

SEC. 103. EXISTING FEDERAL STATUTES MAINTAINED.

Except as amended or repealed by this Act, all Federal statutes in effect as of the effective date of this Act that regulate tobacco, tobacco products, or tobacco product manufacturers shall remain in full force and effect. Such statutes include, without limitation—

(1) the Federal Cigarette Labeling and Advertising Act, sections 1331–1340 of title 15, United States Code, except that section 1335 of title 15, United States Code, is repealed;

(2) the Comprehensive Smokeless Tobacco Health Education Act of 1986, sections 4401–4408 of title 15, United States Code, except that section 4402(f) of title 15, United States Code, is repealed;

(3) section 300x–26 of title 42, United States Code; and

(4) those statutes authorizing regulation of tobacco, tobacco products, or tobacco product manufacturers by the Federal Trade Commission, the Department of Agriculture, the Environmental Protection Agency, the Internal Revenue Service, and the Alcohol and Tobacco Tax and Trade Bureau of the Department of the Treasury.

SEC. 104. PROCEEDINGS IN THE NAME OF THE UNITED STATES; SUBPOENAS; PREEMPTION OF STATE AND LOCAL LAW; NO PRIVATE RIGHT OF ACTION.

In furtherance of this Act:

(1) All proceedings for the enforcement, or to restrain violations, of this Act shall be by and in the name of the United States. Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any proceeding under this section. No State, or political subdivision thereof, may proceed or intervene in any Federal or State court under this Act or under any regulation promulgated under it, or allege any violation thereof except a violation by the Administrator. Nothing in this Act shall be construed to create a right of action by any private person for any violation of any provision of this Act or of any regulation promulgated under it.

(2) With respect to any subject matter addressed by this Act or by any regulation promulgated under it, no requirement or prohibition shall be imposed under State or local law upon any tobacco product manufacturer or distributor.

(3) Paragraph (2) shall not apply to any requirement or prohibition imposed under State or local law before the date of introduction of the bill that was enacted as this Act.

SEC. 105. ADULTERATED TOBACCO PRODUCTS.

A tobacco product shall be deemed to be adulterated—

(1) if it bears or contains any poisonous or deleterious substance other than—

(A) tobacco;

(B) a substance naturally present in tobacco;

(C) a pesticide or fungicide chemical residue in or on tobacco if such pesticide or fungicide chemical is registered by the Environmental Protection Agency for use on tobacco in the United States; or

(D) in the case of imported tobacco, a residue of a pesticide or fungicide chemical that—

(i) is approved for use in the country of origin of the tobacco; and

(ii) has not been banned, and the registration of which has not been canceled, by the Environmental Protection Agency for use on tobacco in the United States) that may render it injurious to health; but, in case the substance is not an added substance, such tobacco product shall not be considered adulterated under this subsection if the quantity of such substance in such tobacco product does not ordinarily render it injurious to health;

(2) if there is significant scientific agreement that, as a result of the tobacco it contains, the tobacco product presents a risk to human health that is materially higher than the risk presented by—

(A) such product on the effective date of this Act; or

(B) if such product was not distributed commercially domestically on that date, by comparable tobacco products of the same style and within the same category that were commercially distributed domestically on that date;

(3) if it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth;

(4) if its package is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health; or

(5) if its ''tar'' yield is in violation of section 111.

SEC. 106. MISBRANDED TOBACCO PRODUCTS.

A tobacco product shall be deemed to be misbranded—

(1) if its labeling is false or misleading in any particular;

(2) if in package form unless it bears a label containing—

(A) an identification of the type of product it is, by the common or usual name of such type of product;

(B) an accurate statement of the quantity of the contents in the package in terms of weight, measure, or numerical count, except that reasonable variations shall be permitted, and exemptions as to small packages shall be established by regulations promulgated by the Administrator;

(C) the name and place of business of the tobacco product manufacturer, packer, or distributor; and

(D) the information required by section 201(c) and (e) or section 202(c) and (e), as applicable;

(3) if any word, statement, or other information required by or under authority of this Act to appear on the label, labeling, or advertising is not prominently placed thereon with such conspicuousness (as compared with other words, statements, or designs on the label, labeling, or advertising, as applicable) and in such terms as to render it reasonably likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(4) if any word, statement, or other information is required by or under this Act to appear on the label, unless such word, statement, or other information also appears on the outside container or wrapper, if any, of the retail package of such tobacco product, or is easily legible through the outside container or wrapper;

(5) if it was manufactured, prepared, or processed in an establishment not duly registered under section 109, if it was not included in a list required by section 109, or if a notice or other information respecting it was not provided as required by section 109;

(6) if its packaging, labeling, or advertising is in violation of this Act or of an applicable regulation promulgated in accordance with this Act;

(7) if it contains tobacco or another ingredient as to which a required disclosure under this Act was not made;

(8) if it is labeled or advertised, or the tobacco contained in it is advertised, as—

(A) containing ''no additives,'' or any substantially similar term, unless the labeling or advertising, as applicable, also contains, clearly and prominently, the following disclosure: ''No additives in our tobacco does NOT mean safer.''; or

(B) being ''natural,'' or any substantially similar term, unless the labeling or advertising, as applicable, also contains, clearly and prominently, the following disclosure: ''Natural does NOT mean safer.'';

(9) if in its labeling or advertising a term descriptive of the tobacco in the tobacco product is used otherwise than in accordance with a sanction or approval granted by a Federal agency;

(10) if with respect to such tobacco product a disclosure required by section 603 was not made;

(11) if with respect to such tobacco product a certification required by section 803 was not submitted or is materially false or misleading; or

(12) if its manufacturer or distributor made with respect to it a claim prohibited by section 115.

SEC. 107. SUBMISSION OF HEALTH INFORMATION TO THE ADMINISTRATOR.

(a) REQUIREMENT.—Each tobacco product manufacturer or importer, or agents thereof, shall submit to the Administrator the following information:

(1) Not later than 18 months after the date of enactment of the Act, a listing of all ingredients, including tobacco, substances, compounds, and additives that are, as of such date, added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand and by quantity in each brand and brand style.

(2) A description of the content, delivery, and form of nicotine in each tobacco product measured in milligrams of nicotine in accordance with regulations promulgated by the Administrator in accordance with section 4(e) of the Federal Cigarette Labeling and Advertising Act.

(3) Beginning 4 years after the date of enactment of this Act, a listing of all constituents, including smoke constituents as applicable, identified by the Administrator as harmful to health in each tobacco product, and as applicable in the smoke of each tobacco product, by brand and by quantity in each brand and subbrand.

(b) DATA SUBMISSION.—At the request of the Administrator, each tobacco product manufacturer or importer of tobacco products, or agents thereof, shall submit the following:

(1) Any or all documents (including underlying scientific information) relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer (or agents thereof) on the health, toxicological, or physiologic effects of tobacco products and their constituents (including smoke constituents), ingredients, components, and additives.

(2) Any or all documents (including underlying scientific information) relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer (or agents thereof) that relate to the issue of whether a significant reduction in risk to health from tobacco products can occur upon the employment of technology available to the manufacturer.

An importer of a tobacco product not manufactured in the United States shall supply the information required of a tobacco product manufacturer under this subsection.

(c) DATA LIST.—

(1) IN GENERAL.—Not later than 4 years after the date of enactment of the Act, and annually thereafter, the Administrator shall publish in a format that is understandable and not misleading to a lay person, and place on public display (in a manner determined by the Administrator) the list established under subsection (d).

(2) CONSUMER RESEARCH.—The Administrator shall conduct periodic consumer research to ensure that the list published under paragraph (1) is not misleading to lay persons. Not later than 5 years after the date of enactment of the Act, the Administrator shall submit to the appropriate committees of Congress a report on the results of such research, together with recommendations on whether such publication should be continued or modified.

(d) DATA COLLECTION.—Not later than 36 months after the date of enactment of this Act, the Administrator shall establish, and periodically revise as appropriate, a list of harmful constituents, including smoke constituents, to health in each tobacco product by brand and by quantity in each brand and subbrand.

SEC. 108. REGISTRATION AND LISTING.

(a) DEFINITIONS.—As used in this section:

(1) The term ''manufacture, preparation, or processing'' shall include repackaging or otherwise changing the container, wrapper, or label of any tobacco product package other than the carton in furtherance of the distribution of the tobacco product from the original place of manufacture to the person that makes final delivery or sale to the ultimate consumer or user, but shall not include the addition of a tax marking or other marking required by law to an already packaged tobacco product.

(2) The term ''name'' shall include in the case of a partnership the name of the general partner and, in the case of a privately held corporation, the name of the chief executive officer of the corporation and the State of incorporation.

(b) ANNUAL REGISTRATION.—Commencing one year after enactment, on or before December 31 of each year, every person that owns or operates any establishment in any State engaged in the manufacture, preparation, or processing of a tobacco product or products for commercial distribution domestically shall register with the Administrator its name, places of business, and all such establishments.

(c) NEW PRODUCERS.—Every person upon first engaging, for commercial distribution domestically, in the manufacture, preparation, or processing of a tobacco product or products in any establishment that it owns or operates in any State shall immediately register with the Administrator its name, places of business, and such establishment.

(d) REGISTRATION OF FOREIGN ESTABLISHMENTS.—

(1) Commencing one year after enactment of this Act, on or before December 31 of each year, the person that, within any foreign country, owns or operates any establishment engaged in the manufacture, preparation, or processing of a tobacco product that is imported or offered for import into the United States shall, through electronic means or other means permitted by the Administrator, register with the Administrator the name and place of business of each such establishment, the name of the United States agent for the establishment, and the name of each importer of such tobacco product in the United States that is known to such person.

(2) Such person also shall provide the information required by subsection (j), including sales made by mail, or through the Internet, or other electronic means.

(3) The Administrator is authorized to enter into cooperative arrangements with officials of foreign countries to ensure that adequate and effective means are available for purposes of determining, from time to time, whether tobacco products manufactured, prepared, or processed by an establishment described in paragraph (1), if imported or offered for import into the United States, shall be refused admission on any of the grounds set forth in section 708.

(e) ADDITIONAL ESTABLISHMENTS.—Every person duly registered in accordance with the foregoing subsections of this section shall immediately register with the Administrator any additional establishment that it owns or operates and in which it begins the manufacture, preparation, or processing of a tobacco product or products for commercial distribution domestically or for import into the United States.

(f) EXCLUSIONS FROM APPLICATION OF THIS SECTION.—The foregoing subsections of this section shall not apply to—

(1) persons that manufacture, prepare, or process tobacco products solely for use in research, teaching, chemical or biological analysis, or export; or

(2) such other classes of persons as the Administrator may by regulation exempt from the application of this section upon a finding that registration by such classes of persons in accordance with this section is not necessary for the protection of the public health.

(g) INSPECTION OF PREMISES.—Every establishment registered with the Administrator pursuant to this section shall be subject to inspection pursuant to section 706; and every such establishment engaged in the manufacture, preparation, or processing of a tobacco product or products shall be so inspected by one or more officers or employees duly designated by the Administrator at least once in the two-year period beginning with the date of registration of such establishment pursuant to this section and at least once in every successive two-year period thereafter, except that inspection of establishments outside the United States may be conducted by other personnel pursuant to a cooperative arrangement under subsection (d)(3).

(h) FILING OF LISTS OF TOBACCO PRODUCTS MANUFACTURED, PREPARED, OR PROCESSED BY REGISTRANTS; STATEMENTS; ACCOMPANYING DISCLOSURES.—

(1) Every person that registers with the Administrator under subsection (b), (c), (d), or (e) shall, at the time of registration under any such subsection, file with the Administrator a list of all brand styles (with each brand style in each list listed by the common or usual name of the tobacco product category to which it belongs and by any proprietary name) that are being manufactured, prepared, or processed by such person for commercial distribution domestically or for import into the United States, and that such person has not included in any list of tobacco products filed by such person with the Administrator under this paragraph or paragraph (2) before such time of registration. Such list shall be prepared in such form and manner as the Administrator may prescribe, and shall be accompanied by the label for each such brand style and a representative sampling of any other labeling and advertising for each;

(2) Each person that registers with the Administrator under this section shall report to the Administrator each August for the preceding six-month period from January through June, and each February for the preceding six-month period form July through December, following information:

(A) A list of each brand style introduced by the registrant for commercial distribution domestically or for import into the United States that has not been included in any list previously filed by such registrant with the Administrator under this subparagraph or paragraph (1). A list under this subparagraph shall list a brand style by the common or usual name of the tobacco product category to which it belongs and by any proprietary name, and shall be accompanied by the other information required by paragraph (1).

(B) If since the date the registrant last made a report under this paragraph (or if such registrant has not previously made a report under this paragraph, since the effective date of this Act) such registrant has discontinued the manufacture, preparation, or processing for commercial distribution domestically or for import into the United States of a brand style included in a list filed by such registrant under subparagraph (A) or paragraph (1), notice of such discontinuance, the date of such discontinuance, and the identity (by the common or usual name of the tobacco product category to which it belongs and by any proprietary name) of such tobacco product.

(C) If, since the date the registrant reported pursuant to subparagraph (B) a notice of discontinuance of a tobacco product, the registrant has resumed the manufacture, preparation, or processing for commercial distribution domestically or for import into the United States of that brand style, notice of such resumption, the date of such resumption, the identity of such brand style (by the common or usual name of the tobacco product category to which it belongs and by any proprietary name), and the other information required by paragraph (1), unless the registrant has previously reported such resumption to the Administrator pursuant to this subparagraph.

(D) Any material change in any information previously submitted pursuant to this paragraph (2) or paragraph (1).

(i) ELECTRONIC REGISTRATION.—Registrations under subsections (b), (c), (d), and (e) (including the submission of updated information) shall be submitted to the Administrator by electronic means, unless the Administrator grants a request for waiver of such requirement because use of electronic means is not reasonable for the person requesting such waiver.

SEC. 109. GENERAL PROVISIONS RESPECTING CONTROL OF TOBACCO PRODUCTS.

(a) IN GENERAL.—Any requirement established by or under section 106, 107, or 113 applicable to a tobacco product shall apply to such tobacco product until the applicability of the requirement to the tobacco product has been changed by action taken under section 111, section 114, section 115, or subsection (d) of this section, and any requirement established by or under section 106, 107, or 113 which is inconsistent with a requirement imposed on such tobacco product under

section 111, section 114, section 115, or subsection (d) of this section shall not apply to such tobacco product.

(b) INFORMATION ON PUBLIC ACCESS AND COMMENT.—Each notice of proposed rulemaking or other notification under section 111, 112, 113, 114, or 115 or under this section, any other notice which is published in the Federal Register with respect to any other action taken under any such section and which states the reasons for such action, and each publication of findings required to be made in connection with rulemaking under any such section shall set forth—

(1) the manner in which interested persons may examine data and other information on which the notice or findings is based; and

(2) the period within which interested persons may present their comments on the notice or findings (including the need therefore) orally or in writing, which period shall be at least 60 days but may not exceed 90 days unless the time is extended by the Administrator by a notice published in the Federal Register stating good cause therefore.

(c) LIMITED CONFIDENTIALITY OF INFORMATION.—Any information reported to or otherwise obtained by the Administrator or the Administrator's representative under section 107, 108, 111, 112, 113, 114, 115, or 504, or under subsection (e) or (f) of this section, which is exempt from disclosure under subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of that section shall be considered confidential and shall not be disclosed, except that the information may be disclosed to other officers or employees concerned with carrying out this Act, or when relevant in any proceeding under this Act.

(d) RESTRICTIONS.—

(1) IN GENERAL.—The Administrator may issue regulations, consistent with this Act, regarding tobacco products if the Administrator determines that such regulation would be appropriate for the protection of the public health. The finding as to whether such regulation would be appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the users of the tobacco product, and taking into account that the standard is reasonably likely to result in measurable and substantial reductions in morbidly and mortality among individual tobacco users.

(2) LABEL STATEMENTS.—The label of a tobacco product shall bear such appropriate statements of the restrictions required by a regulation under subsection (a) as the Administrator may in such regulation prescribe.

(e) GOOD MANUFACTURING PRACTICE REQUIREMENTS.—

(1) METHODS, FACILITIES, AND CONTROLS TO CONFORM.—

(A) IN GENERAL.—In applying manufacturing restrictions to tobacco, the Administrator shall, in accordance with subparagraph (B), prescribe regulations (which may differ based on the type of tobacco product involved) requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation (including a process to assess the performance of a tobacco product), packing, and storage of a tobacco product conform to current good manufacturing practice, or hazard analysis and critical control point methodology, as prescribed in such regulations to assure that the public health is protected and that the tobacco product is in compliance with this Act. Such regulations may provide for the testing of raw tobacco for pesticide chemical residues after a tolerance for such chemical residues has been established.

(B) REQUIREMENTS.—The Administrator shall—

(i) before promulgating any regulation under subparagraph (A), afford the Tobacco Products Scientific Advisory Committee an opportunity to submit recommendations with respect to the regulation proposed to be promulgated;

(ii) before promulgating any regulation under subparagraph (A), afford opportunity for an oral hearing;

(iii) provide the Tobacco Products Scientific Advisory Committee a reasonable time to make its recommendation with respect to proposed regulations under subparagraph (A); and

(iv) in establishing the effective date of a regulation promulgated under this subsection, take into account the differences in the manner in which the different types of tobacco products have historically been produced, the financial resources of the different tobacco product manufacturers, and the state of their existing manufacturing facilities, and shall provide for a reasonable period of time for such manufacturers to conform to good manufacturing practices but no earlier than four years from date of enactment.

(C) ADDITIONAL SPECIAL RULE.—A tobacco product manufactured in or imported into the United States shall not contain foreign-grown flue-cured or burley tobacco that—

(i) was knowingly grown or processed using a pesticide chemical that is not approved under applicable Federal law for use in domestic tobacco farming and processing; or

(ii) in the case of a pesticide chemical that is so approved, was grown or processed using the pesticide chemical in a manner inconsistent with the approved labeling for use of the pesticide chemical in domestic tobacco farming and processing.

(D) EXCLUSION.—Subparagraph (C)(ii) shall not apply to tobacco products manufactured with foreign-grown flue-cured or burley tobacco so long as that foreign grown tobacco was either—

(i) in the inventory of a manufacturer prior to the effective date, or

(ii) planted by the farmer prior to the effective date of this Act and utilized by the manufacturer no later than 3 years after the effective date.

(E) SETTING OF MAXIMUM RESIDUE LIMITS.—The Administrator shall adopt the following pesticide residue standards:

Pesticide residue standards

The maximum concentration of residues of the following pesticides allowed in flue-cured or burley tobacco, expressed as parts by weight of the residue per one million parts by weight of the tobacco (PPM) are:

CHLORDANE.....3.0

DIBROMOCHLOROPROPANE (DBCP).....1.0

DICAMBA (Temporary).... 5.0

ENDRIN....0.1

ETHYLENE DIBROMIDE (EDB)....0.1

FORMOTHION.....0.5

HEXACHLOROBENZENE (HCB)....0.1

METHOXYCHLOR.....0.1

TOXAPHENE.....0.3

2,4-D (Temporary).....5.0

2,4,5-T.....0.1

Sum of ALDRIN and DIELDRIN.....0.1

Sum of CYPERMETHRIN and PERMETHRIN (Temporary).....3.0

Sum of DDT, TDE (DDD), and DDE 0.4

Sum of HEPTACHLOR and HEPTACHLOR EPOXIDE.....0.1

(F) MAXIMUM RESIDUE LIMITS.—The Administrator shall adopt regulations within one year of the effective date of this Act to establish maximum residue limits for pesticides identified under subparagraph (E) but not included in the table of such subparagraph to account for the fact that weather and agronomic conditions will cause pesticides identified in subparagraph (E) to be detected in foreign-grown tobacco even where the farmer has not knowingly added such pesticide.

(2) EXEMPTIONS; VARIANCES.—

(A) PETITION.—Any person subject to any requirement prescribed under paragraph (1) may petition the Administrator for a permanent or temporary exemption or variance from such requirement. Such a petition shall be submitted to the Administrator in such form and manner as the Administrator shall prescribe and shall—

(i) in the case of a petition for an exemption from a requirement, set forth the basis for the petitioner's determination that compliance with the requirement is not required to assure that the tobacco product will be in compliance with this Act;

(ii) in the case of a petition for a variance from a requirement, set forth the methods proposed to be used in, and the facilities and controls proposed to be used for, the manufacture, packing, and storage of the tobacco product in lieu of the methods, facilities, and controls prescribed by the requirement; and

(iii) contain such other information as the Administrator shall prescribe.

(B) REFERRAL TO THE TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE.—The Administrator may refer to the Tobacco Products Scientific Advisory Committee any petition submitted under subparagraph (A). The Tobacco Products Scientific Advisory Committee shall report its recommendations to the Administrator with respect to a petition referred to it within 60 days after the date of the petition's referral. Within 60 days after—

(i) the date the petition was submitted to the Administrator under subparagraph (A); or

(ii) the day after the petition was referred to the Tobacco Products Scientific Advisory Committee,

whichever occurs later, the Administrator shall by order either deny the petition or approve it.

(C) APPROVAL.—The Administrator may approve—

(i) a petition for an exemption for a tobacco product from a requirement if the Administrator determines that compliance with such requirement is not required to assure that the tobacco product will be in compliance with this Act; and

(ii) a petition for a variance for a tobacco product from a requirement if the Administrator determines that the methods to be used in, and the facilities and controls to be used for, the manufacture, packing, and storage of the tobacco product in lieu of the methods, facilities, and controls prescribed by the requirement are sufficient to assure that the tobacco product will be in compliance with this Act.

(D) CONDITIONS.—An order of the Administrator approving a petition for a variance shall prescribe such conditions respecting the methods used in, and the facilities and controls used for, the manufacture, packing, and storage of the tobacco product to be granted the variance under the petition as may be necessary to assure that the tobacco product will be in compliance with this Act.

(E) HEARING.—After the issuance of an order under subparagraph (B) respecting a petition, the petitioner shall have an opportunity for an informal hearing on such order.

(3) COMPLIANCE.—Compliance with requirements under this subsection shall not be required before the end of the 3-year period following the date of enactment of this Act.

(f) RESEARCH AND DEVELOPMENT.—The Administrator may enter into contracts for research, testing, and demonstrations respecting tobacco products and may obtain tobacco products for research, testing, and demonstration purposes.

SEC. 110. SMOKING ARTICLE STANDARDS.

(a) IN GENERAL.—

(1) RESTRICTIONS ON DESCRIPTORS USED IN MARKETING OF CIGARETTES.—

(A) IN GENERAL.—Except as provided in subparagraph (B), no person shall use, with respect to any cigarette brand style commercially distributed domestically, on the portion of the package of such cigarette brand style that customarily is visible to consumers before purchase, or in advertising of such cigarette brand style any of the following as a descriptor of any cigarette brand style—

(i) the name of any candy or fruit;

(ii) the word ''candy,'' ''citrus,'' ''cream,'' ''fruit,'' ''sugar,'' ''sweet,'' ''tangy,'' or ''tart,''; or

(iii) any extension or variation of any of the words ''candy,'' ''citrus,'' ''cream,'' ''fruit,'' ''sugar,'' ''sweet,'' ''tangy,'' or ''tart,'' including but not limited to ''creamy,'' or ''fruity.''

(B) LIMITATION.—Subparagraph (A) shall not apply to the use of the following words or to any extension or variation of any of them: ''clove'' and ''menthol''.

(C) SCENTED MATERIALS.—No person shall use, in the advertising or labeling of any cigarette commercially distributed domestically, any scented materials, except in an adult-only facility.

(D) DEFINITIONS.—In this section:

(i) The term ''candy'' means a confection made from sugar or sugar substitute, including any confection identified generically or by brand, and shall include the words ''cacao,'' ''chocolate,'' ''cinnamon,'' ''cocoa,'' ''honey,'' ''licorice,'' ''maple,'' ''mocha,'' and ''vanilla.''

(ii) The term ''fruit'' means any fruit identified by generic name, type, or variety, including but not limited to ''apple,'' ''banana,'' ''cherry,'' and ''orange.'' The term ''fruit'' does not include words that identify seeds, nuts or peppers, or types or varieties thereof or words that are extensions or variations of such words.

(2) SMOKING ARTICLE STANDARDS.—

(A) IN GENERAL.—The Administrator may adopt smoking article standards in addition to those in paragraph (1) if the Administrator finds that a smoking article standard is appropriate for the protection of the public health.

(B) DETERMINATIONS.—

(i) CONSIDERATIONS.—In making a finding described in subparagraph (A), the Administrator shall consider scientific evidence concerning—

(I) the risks and benefits to the users of smoking articles of the proposed standard; and

(II) that the standard is reasonably likely to result in measurable and substantial reductions in morbidity and mortality among individual tobacco users.

(ii) ADDITIONAL CONSIDERATIONS.—In the event that the Administrator makes a determination, set forth in a proposed smoking article standard in a proposed rule, that it is appropriate for the protection of public health to require the reduction or elimination of an additive, constituent (including a smoke constituent), or other component of a smoking article because the Administrator has found that the additive, constituent, or other component is harmful, any party objecting to the proposed standard on the ground that the proposed standard will not reduce or eliminate the risk of illness or injury may provide for the Administrator's consideration scientific evidence that demonstrates that the proposed standard will not reduce or eliminate the risk of illness or injury.

(3) CONTENT OF SMOKING ARTICLE STANDARDS.—A smoking article standard established under this section for a smoking article—

(A) may include provisions that are appropriate for the protection of the public health, including provisions, where appropriate—

(i) for ''tar'' and nicotine yields of the product;

(ii) for the reduction of other constituents, including smoke constituents, or harmful components of the product; or

(iii) relating to any other requirement under subparagraph (B); and

(B) may, where appropriate for the protection of the public health, include—

(i) provisions respecting the construction, components, ingredients, additives, constituents, including smoke constituents, and properties of the smoking article;

(ii) provisions for the testing (on a sample basis or, if necessary, on an individual basis) of the smoking article;

(iii) provisions for the measurement of the smoking article characteristics of the smoking article; and

(iv) provisions requiring that the results of each or of certain of the tests of the smoking article required to be made under clause (ii) show that the smoking article is in conformity with the portions of the standard for which the test or tests were required.

(4) PERIODIC REEVALUATION OF SMOKING ARTICLE STANDARDS.—The Administrator may provide for periodic evaluation of smoking article standards established under this section to determine whether such standards should be changed to reflect new medical, scientific, or other technological data.

(5) CIGARETTE ''TAR'' LIMITS.—

(A) NO INCREASE IN ''TAR'' YIELDS.—No cigarette manufacturer shall distribute for sale domestically a brand style of cigarettes that generates a ''tar'' yield greater than the ''tar'' yield of that brand style of cigarettes on the date of introduction of this Act, as determined by the ISO smoking regimen and its associated tolerances. The ''tar'' tolerances for cigarettes with ISO ''tar'' yields in the range of 1 to 20 milligrams per cigarette, based on variations arising from sampling procedure, test method, and sampled product, itself, are the greater of plus or minus—

(i) 15 percent; or

(ii) 1 milligram per cigarette.

(B) LIMIT ON NEW CIGARETTES.—After the effective date of this Act, no cigarette manufacturer shall manufacture for commercial distribution domestically a brand style of cigarettes that both—

(i) was not in commercial distribution domestically on the effective date of this Act, and

(ii) generates a ''tar'' yield of greater than 20 milligrams per cigarette as determined by the ISO smoking regimen and its associated tolerances.

(C) LIMIT ON ALL CIGARETTES.—After December 31, 2010, no cigarette manufacturer shall manufacture for commercial distribution domestically a brand style of cigarettes that generates a ''tar'' yield greater than 20 milligrams per cigarette as determined by the ISO smoking regimen and its associated tolerances.

(D) REVIEW BY ADMINISTRATOR.—After the effective date of this Act, the Administrator shall evaluate the available scientific evidence addressing the potential relationship between historical ''tar'' yield values and risk of harm to smokers. If upon a review of that evidence, and after consultation with technical experts of the Tobacco Harm Reduction Center and the Centers for Disease Control and Prevention and notice and an opportunity for public comment, the Administrator determines, that a reduction in ''tar'' yield may reasonably be expected to provide a meaningful reduction of the risk or risks of harm to smokers, the Administrator shall issue an order that—

(i) provides that no cigarette manufacturer shall manufacture for commercial distribution domestically a cigarette that generates a ''tar'' yield that exceeds 14 milligrams as determined by the ISO smoking regimen and its associated tolerances; and

(ii) provides a reasonable time for manufacturers to come into compliance with such prohibition.

(6) INVOLVEMENT OF OTHER AGENCIES; INFORMED PERSONS.—In carrying out duties under this section, the Administrator shall endeavor to—

(A) use personnel, facilities, and other technical support available in other Federal agencies;

(B) consult with other Federal agencies concerned with standard setting and other nationally or internationally recognized standard-setting entities; and

(C) invite appropriate participation, through joint or other conferences, workshops, or other means, by informed persons representative of scientific, professional, industry, agricultural, or consumer organizations who in the Administrator's judgment can make a significant contribution.

(b) CONSIDERATIONS BY ADMINISTRATOR.—

(1) TECHNICAL ACHIEVABILITY.—The Administrator shall consider information submitted in connection with a proposed standard regarding the technical achievability of compliance with such standard.

(2) OTHER CONSIDERATIONS.—The Administrator shall consider all other information submitted in connection with a proposed standard, such as the creation of a significant demand for contraband or other tobacco products that do not meet the requirements of this Act and the significance of such demand.

(c) PROPOSED STANDARDS.—

(1) IN GENERAL.—The Administrator shall publish in the Federal Register a notice of proposed rulemaking for the establishment, amendment, or revocation of any smoking article standard.

(2) REQUIREMENTS OF NOTICE.—A notice of proposed rulemaking for the establishment or amendment of a smoking article standard shall—

(A) set forth a finding with supporting justification that the smoking article standard is appropriate for the protection of the public health;

(B) invite interested persons to submit a draft or proposed smoking article standard for consideration by the Administrator;

(C) invite interested persons to submit comments on structuring the standard so that it does not advantage foreign-grown tobacco over domestically grown tobacco; and

(D) invite the Secretary of Agriculture to provide any information or analysis which the Secretary of Agriculture believes is relevant to the proposed smoking article standard.

(3) FINDING.—A notice of proposed rulemaking for the revocation of a smoking article standard shall set forth a finding with supporting justification that the smoking article standard is no longer appropriate for the protection of the public health.

(4) COMMENT.—The Administrator shall provide for a comment period of not less than 90 days.

(d) PROMULGATION.—

(1) IN GENERAL.—After the expiration of the period for comment on a notice of proposed rulemaking published under subsection (c) respecting a standard and after consideration of comments submitted under subsections (b) and (c) and any report from the Tobacco Products Scientific Advisory Committee, if the Administrator determines that the standard would be appropriate for the

protection of the public health, the Administrator shall—

(A) promulgate a regulation establishing a smoking article standard and publish in the Federal Register findings on the matters referred to in subsection (c); or

(B) publish a notice terminating the proceeding for the development of the standard together with the reasons for such termination.

(2) EFFECTIVE DATE.—A regulation establishing a smoking article standard shall set forth the date or dates upon which the standard shall take effect, but no such regulation may take effect before 1 year after the date of its publication unless the Administrator determines that an earlier effective date is necessary for the protection of the public health. Such date or dates shall be established so as to minimize, consistent with the public health, economic loss to, and disruption or dislocation of, domestic and international trade. In establishing such effective date or dates, the Administrator shall consider information submitted in connection with a proposed product standard by interested parties, including manufacturers and tobacco growers, regarding the technical achievability of compliance with the standard, and including information concerning the existence of patents that make it impossible to comply in the timeframe envisioned in the proposed standard.

(3) LIMITATION ON POWER GRANTED.—Because of the importance of a decision of the Administrator to issue a regulation—

(A) banning cigarettes, smokeless smoking articles, little cigars, cigars other than little cigars, pipe tobacco, or roll-your-own smoking articles;

(B) requiring the reduction of ''tar'' or nicotine yields of a smoking article to zero;

(C) prohibiting the sale of any smoking article in face-to-face transactions by a specific category of retail outlets;

(D) establishing a minimum age of sale of smoking articles to any person older than 18 years of age; or

(E) requiring that the sale or distribution of a smoking article be limited to the written or oral authorization of a practitioner licensed by law to prescribe medical products,

the Administrator is prohibited from taking such actions under this Act.

(4) MATCHBOOKS.—For purposes of any regulations issued by the Administrator under this Act, matchbooks of conventional size containing not more than 20 paper matches, and which are customarily given away for free with the purchase of smoking articles, shall be considered as adult-written publications which shall be permitted to contain advertising.

(5) AMENDMENT; REVOCATION.—

(A) AUTHORITY.—The Administrator, upon the Administrator's own initiative or upon petition of an interested person, may by a regulation, promulgated in accordance with the requirements of subsection (c) and paragraph (2), amend or revoke a smoking article standard.

(B) EFFECTIVE DATE.—The Administrator may declare a proposed amendment of a smoking article standard to be effective on and after its publication in the Federal Register and until the effective date of any final action taken on such amendment if the Administrator determines that making it so effective is in the public interest.

(6) REFERRAL TO ADVISORY COMMITTEE.—

(A) IN GENERAL.—The Administrator shall refer a proposed regulation for the establishment, amendment, or revocation of a smoking article standard to the Tobacco Products Scientific Advisory Committee for a report and recommendation with respect to any matter involved in the proposed regulation which requires the exercise of scientific judgment.

(B) INITIATION OF REFERRAL.—The Administrator shall make a referral under this paragraph—

(i) on the Administrator's own initiative; or

(ii) upon the request of an interested person that—

(I) demonstrates good cause for the referral; and

(II) is made before the expiration of the period for submission of comments on the proposed regulation.

(C) PROVISION OF DATA.—If a proposed regulation is referred under this paragraph to the Tobacco Products Scientific Advisory Committee, the Administrator shall provide the Advisory Committee with the data and information on which such proposed regulation is based.

(D) REPORT AND RECOMMENDATION.—The Tobacco Products Scientific Advisory Committee shall, within 90 days after the referral of a proposed regulation under this paragraph and after independent study of the data and information furnished to it by the Administrator and other data and information before it, submit to the Administrator a report and recommendation respecting such regulation, together with all underlying data and information and a statement of the reason or basis for the recommendation.

(E) PUBLIC AVAILABILITY.—The Administrator shall make a copy of each report and recommendation under subparagraph (D) publicly available.

SEC. 111. NOTIFICATION AND OTHER REMEDIES.

(a) NOTIFICATION.—If the Administrator determines that—

(1) a tobacco product which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm materially above the risk for death and disease of tobacco products currently in interstate commerce, to the public health; and

(2) notification under this subsection is necessary to eliminate the unreasonable risk of such harm and no more practicable means is available under the provisions of this Act (other than this section) to eliminate such risk,

the Administrator may issue such order as may be necessary to assure that adequate notification is provided in an appropriate form, by the persons and means best suited under the circumstances involved, to all persons who should properly receive such notification in order to eliminate such risk. The Administrator may order notification by any appropriate means, including public service announcements. Before issuing an order under this subsection, the Administrator shall consult with the persons who are to give notice under the order.

(b) NO EXEMPTION FROM OTHER LIABILITY.—Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided under such order shall be taken into account.

(c) RECALL AUTHORITY.—

(1) IN GENERAL.—If the Administrator finds that there is a reasonable probability that a tobacco product contains a manufacturing or other defect not ordinarily contained in tobacco products on the market that would cause serious, acute adverse health consequences or death, the Administrator shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the tobacco product) to immediately cease distribution of such tobacco product. The order shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order and on whether the order should be amended to require a recall of such tobacco product. If, after providing an opportunity for such a hearing, the Administrator determines that inadequate grounds exist to support the actions required by the order, the Administrator shall vacate the order.

(2) AMENDMENT OF ORDER TO REQUIRE RECALL.—

(A) IN GENERAL.—If, after providing an opportunity for an informal hearing under paragraph (1), the Administrator determines that the order should be amended to include a recall of the tobacco product with respect to which the order was issued, the Administrator shall, except as provided in subparagraph (B), amend the order to require a recall. The Administrator shall specify a timetable in which the tobacco product recall will occur and shall require periodic reports to the Administrator describing the progress of the recall.

(B) NOTICE.—An amended order under subparagraph (A)—

(i) shall not include recall of a tobacco product from individuals; and

(ii) shall provide for notice to persons subject to the risks associated with the use of such tobacco product.

In providing the notice required by clause (ii), the Administrator may use the assistance of retailers and other persons who distributed such tobacco product. If a significant number of such persons cannot be identified, the Administrator shall notify such persons under section 705(b).

(3) REMEDY NOT EXCLUSIVE.—The remedy provided by this subsection shall be in addition to remedies provided by subsection (a).

SEC. 112. RECORDS AND REPORTS ON TOBACCO PRODUCTS.

Every person who is a tobacco product manufacturer or importer of a tobacco product shall establish and maintain such records, make such reports, and provide such information, as the Administrator may by regulation reasonably require to assure that such tobacco product is not adulterated or misbranded.

SEC. 113. APPLICATION FOR REVIEW OF CERTAIN SMOKING ARTICLES.

(a) IN GENERAL.—

(1) NEW SMOKING ARTICLE DEFINED.—For purposes of this section the term ''new smoking article'' means—

(A) any smoking article that was not commercially marketed in the United States as of the date of enactment of this Act; and

(B) any smoking article that incorporates a significant modification (including changes in design, component, part, or constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or other additive or ingredient) of a smoking article where the modified product was commercially marketed in the United States after the date of enactment of this Act.

(2) PREMARKET REVIEW REQUIRED.—

(A) NEW PRODUCTS.—An order under subsection (c)(1)(A) for a new smoking article is required unless the product—

(i) is substantially equivalent to a smoking article commercially marketed in the United States as of date of enactment of this Act; and

(ii) is in compliance with the requirements of this Act.

(B) CONSUMER TESTING.—This section shall not apply to smoking articles that are provided to adult tobacco consumers for purposes of consumer testing. For purposes of

this section, the term ''consumer testing'' means an assessment of smoking articles that is conducted by or under the control and direction of a manufacturer for the purpose of evaluating consumer acceptance of such smoking articles, utilizing only the quantity of cigarettes that is reasonably necessary for such assessment

(3) SUBSTANTIALLY EQUIVALENT DEFINED.—

(A) IN GENERAL.—In this section, the term ''substantially equivalent'' or ''substantial equivalence'' means, with respect to the smoking article being compared to the predicate smoking article, that the Administrator by order has found that the smoking article—

(i) has the same general characteristics as the predicate smoking article; or

(ii) has different characteristics and the information submitted contains information, including clinical data if deemed necessary by the Administrator, that demonstrates that it is not appropriate to regulate the product under this section because the product does not raise different questions of public health for the consumer of the product.

(B) CHARACTERISTICS.—In subparagraph (A), the term ''characteristics'' means the materials, ingredients, design, composition, heating source, or other features of a smoking article.

(C) LIMITATION.—A smoking article may not be found to be substantially equivalent to a predicate smoking article that has been removed from the market at the initiative of the Administrator or that has been determined by a judicial order to be misbranded or adulterated.

(4) HEALTH INFORMATION.—As part of a submission respecting a smoking article, the person required to file a premarket notification shall provide an adequate summary of any health information related to the smoking article or state that such information will be made available upon request by any person.

(b) APPLICATION.—

(1) CONTENTS.—An application under this section shall contain—

(A) full reports of all information, published or known to, or which should reasonably be known to, the applicant, concerning investigations which have been made to show the health risks of such smoking article and whether such smoking article presents less risk than other smoking articles;

(B) a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such smoking article;

(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such smoking article;

(D) an identifying reference to any smoking article standard under section 111 which would be applicable to any aspect of such smoking article, and either adequate information to show that such aspect of such smoking article fully meets such smoking article standard or adequate information to justify any deviation from such standard;

(E) such samples of such smoking article and of components thereof as the Administrator may reasonably require;

(F) specimens of the labeling proposed to be used for such smoking article; and

(G) such other information relevant to the subject matter of the application as the Administrator may require.

(2) REFERRAL TO TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE.—Upon receipt of an application meeting the requirements set forth in paragraph (1), the Administrator—

(A) may, on the Administrator's own initiative; or

(B) may, upon the request of an applicant, refer such application to the Tobacco Products Scientific Advisory Committee for reference and for submission (within such period as the Administrator may establish) of a report and recommendation respecting the application, together with all underlying data and the reasons or basis for the recommendation.

(c) ACTION ON APPLICATION.—

(1) DEADLINE.—As promptly as possible, but in no event later than 90 days after the receipt of an application under subsection (b), the Administrator, after considering the report and recommendation submitted under subsection (b)(2), shall—

(A) issue an order that the new product may be introduced or delivered for introduction into interstate commerce if the Administrator finds that none of the grounds specified in paragraph (2) of this subsection applies; or

(B) issue an order that the new product may not be introduced or delivered for introduction into interstate commerce if the Administrator finds (and sets forth the basis for such finding as part of or accompanying such denial) that 1 or more grounds for denial specified in paragraph (2) of this subsection apply.

(2) DENIAL OF APPLICATION.—The Administrator shall deny an application submitted under subsection (b) if, upon the basis of the information submitted to the Administrator as part of the application and any other information before the Administrator with respect to such smoking article, the Administrator finds that—

(A) there is a lack of a showing that permitting such smoking article to be marketed would be appropriate for the protection of the public health;

(B) the methods used in, or the facilities or controls used for, the manufacture, processing, or packing of such smoking article do not conform to the requirements of section 110(e);

(C) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; or

(D) such smoking article is not shown to conform to a smoking article standard in effect under section 111, and there is a lack of adequate information to justify the deviation from such standard.

(3) DENIAL INFORMATION.—Any denial of an application shall, insofar as the Administrator determines to be practicable, be accompanied by a statement informing the applicant of the measures required to remove such application from deniable form (which measures may include further research by the applicant in accordance with 1 or more protocols prescribed by the Administrator).

(4) BASIS FOR FINDING.—For purposes of this section, the finding as to whether the commercial introduction of a smoking article for which an application has been submitted is appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the users of the smoking article, and taking into account whether such commercial introduction is reasonably likely to increase the morbidly and mortality among individual tobacco users.

(d) WITHDRAWAL AND TEMPORARY SUSPENSION.—

(1) IN GENERAL.—The Administrator shall, upon obtaining, where appropriate, advice on scientific matters from the Tobacco Products Scientific Advisory Committee, and after due notice and opportunity for informal hearing for a smoking article for which an order was issued under subsection (c)(1)(A), issue an order withdrawing the order if the Administrator finds—

(A) that the continued marketing of such smoking article no longer is appropriate for the protection of the public health;

(B) that the application contained or was accompanied by an untrue statement of a material fact;

(C) that the applicant—

(i) has failed to establish a system for maintaining records, or has repeatedly or deliberately failed to maintain records or to make reports, required by an applicable regulation under section 113; or

(ii) has refused to permit access to, or copying or verification of, such records as required by section 110; or

(D) on the basis of new information before the Administrator with respect to such smoking article, evaluated together with the evidence before the Administrator when the application was reviewed, that the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or installation of such smoking article do not conform with the requirements of section 110(e) and were not brought into conformity with such requirements within a reasonable time after receipt of written notice from the Administrator of nonconformity;

(E) on the basis of new information before the Administrator, evaluated together with the evidence before the Administrator when the application was reviewed, that the labeling of such smoking article, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Administrator of such fact; or

(F) on the basis of new information before the Administrator, evaluated together with the evidence before the Administrator when such order was issued, that such smoking article is not shown to conform in all respects to a smoking article standard which is in effect under section 111, compliance with which was a condition to the issuance of an order relating to the application, and that there is a lack of adequate information to justify the deviation from such standard.

(2) APPEAL.—The holder of an application subject to an order issued under paragraph (1) withdrawing an order issued pursuant to subsection (c)(1)(A) may, by petition filed on or before the 30th day after the date upon which such holder receives notice of such withdrawal, obtain review thereof in accordance with section 116.

(3) TEMPORARY SUSPENSION.—If, after providing an opportunity for an informal hearing, the Administrator determines there is reasonable probability that the continuation of distribution of a smoking article under an order would cause serious, adverse health consequences or death, that is greater than ordinarily caused by smoking articles on the market, the Administrator shall by order temporarily suspend the authority of the manufacturer to market the product. If the Administrator issues such an order, the Administrator shall proceed expeditiously under paragraph (1) to withdraw such application.

(e) SERVICE OF ORDER.—An order issued by the Administrator under this section shall be served—

(1) in person by any officer or employee of the department designated by the Administrator; or

(2) by mailing the order by registered mail or certified mail addressed to the applicant at the applicant's last known address in the records of the Administrator.

(f) RECORDS.—

(1) ADDITIONAL INFORMATION.—In the case of any smoking article for which an order issued pursuant to subsection (c)(1)(A) for an

application filed under subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Administrator, as the Administrator may by regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Administrator to determine, or facilitate a determination of, whether there is or may be grounds for withdrawing or temporarily suspending such order.

(2) ACCESS TO RECORDS.—Each person required under this section to maintain records, and each person in charge of custody thereof, shall, upon request of an officer or employee designated by the Administrator, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

(g) INVESTIGATIONAL SMOKING ARTICLE EXEMPTION FOR INVESTIGATIONAL USE.—The Administrator may exempt smoking articles intended for investigational use from the provisions of this Act under such conditions as the Administrator may by regulation prescribe.

SEC. 114. MODIFIED RISK TOBACCO PRODUCTS.

(a) IN GENERAL.—No person may introduce or deliver for introduction into interstate commerce any modified risk tobacco product unless an order issued pursuant to subsection (g) is effective with respect to such product.

(b) DEFINITIONS.—In this section:

(1) MODIFIED RISK TOBACCO PRODUCT.—The term ''modified risk tobacco product'' means any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products.

(2) SOLD OR DISTRIBUTED.—

(A) IN GENERAL.—With respect to a tobacco product, the term ''sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products'' means a tobacco product—

(i) the label, labeling, or advertising of which represents explicitly or implicitly that—

(I) the tobacco product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products;

(II) the tobacco product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance; or

(III) the tobacco product or its smoke does not contain or is free of a substance;

(ii) the label, labeling, or advertising of which uses the descriptors ''light'', ''mild'', ''low'', ''medium'', ''ultra light'', ''low tar'' or ''ultra low tar''; or

(iii) the tobacco product manufacturer of which has taken any action directed to consumers through the media or otherwise, other than by means of the tobacco product's label, labeling, or advertising, after the date of enactment of the Act, respecting the product that would be reasonably expected to result in consumers believing that the tobacco product or its smoke may present a lower risk of disease or is less harmful than one or more commercially marketed tobacco products, or presents a reduced exposure to, or does not contain or is free of, a substance or substances.

(B) LIMITATION.—No tobacco product shall be considered to be ''sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products'', except as described in subparagraph (A).

(C) SMOKELESS TOBACCO PRODUCT.—No smokeless tobacco product shall be considered to be ''sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products''.

(3) EFFECTIVE DATE.—The provisions of paragraph (2)(A)(ii) shall take effect 12 months after the date of enactment of the Act.

(c) TOBACCO DEPENDENCE PRODUCTS.—A product that is intended to be used for the treatment of tobacco dependence, including smoking cessation, is not a modified risk tobacco product under this section if it has been approved as a drug or device by the Center and is subject to the requirements of chapter V.

(d) FILING.—Any person may file with the Administrator an application for a modified risk tobacco product. Such application shall include—

(1) a description of the proposed product and any proposed advertising and labeling;

(2) the conditions for using the product;

(3) the formulation of the product;

(4) sample product labels and labeling;

(5) all documents (including underlying scientific information) relating to research findings conducted, supported, or possessed by the tobacco product manufacturer relating to the effect of the product on tobacco-related diseases and health-related conditions, including information both favorable and unfavorable to the ability of the product to reduce risk or exposure and relating to human health;

(6) data and information on how consumers actually use the tobacco product; and

(7) such other information as the Administrator may require.

(e) PUBLIC AVAILABILITY.—The Administrator shall make the application described in subsection (d) publicly available (except matters in the application which are trade secrets or otherwise confidential, commercial information) and shall request comments by interested persons on the information contained in the application and on the label, labeling, and advertising accompanying such application.

(f) ADVISORY COMMITTEE.—

(1) IN GENERAL.—The Administrator shall refer to the Tobacco Products Scientific Advisory Committee any application submitted under this section.

(2) RECOMMENDATIONS.—Not later than 60 days after the date an application is referred to the Tobacco Products Scientific Advisory Committee under paragraph (1), the Advisory Committee shall report its recommendations on the application to the Administrator.

(g) MARKETING.—

(1) MODIFIED RISK PRODUCTS.—Except as provided in paragraph (2), the Administrator shall, with respect to an application submitted under this section, issue an order that a modified risk product may be commercially marketed only if the Administrator determines that the applicant has demonstrated that such product, as it is actually used by consumers, will—

(A) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and

(B) is reasonably likely to result in measurable and substantial reductions in morbidity and mortality among individual tobacco users.

(2) SPECIAL RULE FOR CERTAIN PRODUCTS.—

(A) IN GENERAL.—The Administrator may issue an order that a tobacco product may be introduced or delivered for introduction into interstate commerce, pursuant to an application under this section, with respect to a tobacco product that may not be commercially marketed under paragraph (1) if the Secretary makes the findings required under this paragraph and determines that the applicant has demonstrated that—

(i) such order would be appropriate to promote the public health;

(ii) any aspect of the label, labeling, and advertising for such product that would cause the tobacco product to be a modified risk tobacco product under subsection (b) is limited to an explicit or implicit representation that such tobacco product or its smoke does not contain or is free of a substance or contains a reduced level of a substance, or presents a reduced exposure to a substance in tobacco smoke;

(iii) scientific evidence is not available and, using the best available scientific methods, cannot be made available without conducting long-term epidemiological studies for an application to meet the standards set forth in paragraph (1); and

(iv) the scientific evidence that is available without conducting long-term epidemiological studies demonstrates that a measurable and substantial reduction in morbidity or mortality among individual tobacco users is reasonably likely in subsequent studies.

(B) ADDITIONAL FINDINGS REQUIRED.—To issue an order under subparagraph (A) the Administrator must also find that the applicant has demonstrated that—

(i) the magnitude of the overall reductions in exposure to the substance or substances which are the subject of the application is substantial, such substance or substances are harmful, and the product as actually used exposes consumers to the specified reduced level of the substance or substances;

(ii) the product as actually used by consumers will not expose them to higher levels of other harmful substances compared to the similar types of tobacco products then on the market unless such increases are minimal and the reasonably likely overall impact of use of the product remains a substantial and measurable reduction in overall morbidity and mortality among individual tobacco users;

(iii) testing of actual consumer perception shows that, as the applicant proposes to label and market the product, consumers will not be misled into believing that the product—

(I) is or has been demonstrated to be significantly less harmful; or

(II) presents or has been demonstrated to present significant less of a risk of disease than other commercially marketed tobacco products; and

(iv) issuance of an order with respect to the application is expected to benefit the health of users of tobacco products.

(3) BASIS.—The determinations under paragraphs (1) and (2) shall be based on—

(A) the scientific evidence submitted by the applicant; and

(B) scientific evidence and other information that is made available to the Administrator.

(h) ADDITIONAL CONDITIONS FOR MARKETING.—

(1) MODIFIED RISK PRODUCTS.—The Administrator shall require for the marketing of a product under this section that any advertising or labeling concerning modified risk products enable the public to comprehend the information concerning modified risk and to understand the relative significance of such information in the context of total health and in relation to all of the diseases and health-related conditions associated with the use of tobacco products.

(2) COMPARATIVE CLAIMS.—

(A) IN GENERAL.—The Administrator may require for the marketing of a product under this subsection that a claim comparing a tobacco product to other commercially marketed tobacco products shall compare the tobacco product to a commercially marketed tobacco product that is representative of that type of tobacco product on the market (for example the average value of the top 3

brands of an established regular tobacco product).

(B) QUANTITATIVE COMPARISONS.—The Administrator may also require, for purposes of subparagraph (A), that the percent (or fraction) of change and identity of the reference tobacco product and a quantitative comparison of the amount of the substance claimed to be reduced shall be stated in immediate proximity to the most prominent claim.

(i) POSTMARKET SURVEILLANCE AND STUDIES.—

(1) IN GENERAL.—The Administrator shall require, with respect to a product for which an applicant obtained an order under subsection (g)(1), that the applicant conduct postmarket surveillance and studies for such a tobacco product to determine the impact of the order issuance on consumer perception, behavior, and health, to enable the Administrator to review the accuracy of the determinations upon which the order was based, and to provide information that the Administrator determines is otherwise necessary regarding the use or health risks involving the tobacco product. The results of postmarket surveillance and studies shall be submitted to the Administrator on an annual basis.

(2) SURVEILLANCE PROTOCOL.—Each applicant required to conduct a surveillance of a tobacco product under paragraph (1) shall, within 30 days after receiving notice that the applicant is required to conduct such surveillance, submit, for the approval of the Administrator, a protocol for the required surveillance. The Administrator, within 30 days of the receipt of such protocol, shall determine if the principal investigator proposed to be used in the surveillance has sufficient qualifications and experience to conduct such surveillance and if such protocol will result in collection of the data or other information designated by the Administrator as necessary to protect the public health.

(j) WITHDRAWAL OF AUTHORIZATION.—The Administrator, after an opportunity for an informal hearing, shall withdraw an order under subsection (g) if the Administrator determines that—

(1) the applicant, based on new information, can no longer make the demonstrations required under subsection (g), or the Administrator can no longer make the determinations required under subsection (g);

(2) the application failed to include material information or included any untrue statement of material fact;

(3) any explicit or implicit representation that the product reduces risk or exposure is no longer valid, including if—

(A) a tobacco product standard is established pursuant to section 111;

(B) an action is taken that affects the risks presented by other commercially marketed tobacco products that were compared to the product that is the subject of the application; or

(C) any postmarket surveillance or studies reveal that the order is no longer consistent with the protection of the public health;

(4) the applicant failed to conduct or submit the postmarket surveillance and studies required under subsection (g)(2)(C)(ii) or subsection (i); or

(5) the applicant failed to meet a condition imposed under subsection (h).

(k) CHAPTER IV OR V.—A product for which the Administrator has issued an order pursuant to subsection (g) shall not be subject to chapter IV or V of the Federal Food, Drug, and Cosmetic Act.

(l) IMPLEMENTING REGULATIONS OR GUIDANCE.—

(1) SCIENTIFIC EVIDENCE.—Not later than 2 years after the date of enactment of the Act, the Administrator shall issue regulations or guidance (or any combination thereof) on the scientific evidence required for assessment and ongoing review of modified risk tobacco products. Such regulations or guidance shall—

(A) to the extent that adequate scientific evidence exists, establish minimum standards for scientific studies needed prior to issuing an order under subsection (g) to show a reasonable likelihood that a substantial reduction in morbidity or mortality among individual tobacco users occurs for products described in subsection (g)(1) or is reasonably likely for products described in subsection (g)(2);

(B) include validated biomarkers, intermediate clinical endpoints, and other feasible outcome measures, as appropriate;

(C) establish minimum standards for postmarket studies, that shall include regular and long-term assessments of health outcomes and mortality, intermediate clinical endpoints, consumer perception of harm reduction, and the impact on quitting behavior and new use of tobacco products, as appropriate;

(D) establish minimum standards for required postmarket surveillance, including ongoing assessments of consumer perception; and

(E) establish a reasonable timetable for the Administrator to review an application under this section.

(2) CONSULTATION.—The regulations or guidance issued under paragraph (1) may be developed in consultation with the Institute of Medicine, and with the input of other appropriate scientific and medical experts, on the design and conduct of such studies and surveillance.

(3) REVISION.—The regulations or guidance under paragraph (1) shall be revised on a regular basis as new scientific information becomes available.

(4) NEW TOBACCO PRODUCTS.—Not later than 2 years after the date of enactment of the Act, the Administrator shall issue a regulation or guidance that permits the filing of a single application for any tobacco product that is a new tobacco product under section 114 and which the applicant seeks to commercially market under this section.

SEC. 115. JUDICIAL REVIEW.

(a) RIGHT TO REVIEW.—

(1) IN GENERAL.—Not later than 60 days after—

(A) the promulgation of a regulation under section 111 establishing, amending, or revoking a tobacco product standard; or

(B) a denial of an application under section 114(c),

any person adversely affected by such regulation or denial may file a petition for judicial review of such regulation or denial with the United States Court of Appeals for the District of Columbia or for the circuit in which such person resides or has their principal place of business.

(2) REQUIREMENTS.—

(A) COPY OF PETITION.—A copy of the petition filed under paragraph (1) shall be transmitted by the clerk of the court involved to the Administrator.

(B) RECORD OF PROCEEDINGS.—On receipt of a petition under subparagraph (A), the Administrator shall file in the court in which such petition was filed—

(i) the record of the proceedings on which the regulation or order was based; and

(ii) a statement of the reasons for the issuance of such a regulation or order.

(C) DEFINITION OF RECORD.—In this section, the term ''record'' means—

(i) all notices and other matter published in the Federal Register with respect to the regulation or order reviewed;

(ii) all information submitted to the Administrator with respect to such regulation or order;

(iii) proceedings of any panel or advisory committee with respect to such regulation or order;

(iv) any hearing held with respect to such regulation or order; and

(v) any other information identified by the Administrator, in the administrative proceeding held with respect to such regulation or order, as being relevant to such regulation or order.

(b) STANDARD OF REVIEW.—Upon the filing of the petition under subsection (a) for judicial review of a regulation or order, the court shall have jurisdiction to review the regulation or order in accordance with chapter 7 of title 5, United States Code, and to grant appropriate relief, including interim relief, as provided for in such chapter. A regulation or denial described in subsection (a) shall be reviewed in accordance with section 706(2)(A) of title 5, United States Code.

(c) FINALITY OF JUDGMENT.—The judgment of the court affirming or setting aside, in whole or in part, any regulation or order shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of title 28, United States Code.

(d) OTHER REMEDIES.—The remedies provided for in this section shall be in addition to, and not in lieu of, any other remedies provided by law.

(e) REGULATIONS AND ORDERS MUST RECITE BASIS IN RECORD.—To facilitate judicial review, a regulation or order issued under section 110, 111, 112, 113, 114, or 119 shall contain a statement of the reasons for the issuance of such regulation or order in the record of the proceedings held in connection with its issuance.

SEC. 116. JURISDICTION OF AND COORDINATION WITH THE FEDERAL TRADE COMMISSION.

Except where expressly provided in this Act, nothing in this Act shall be construed as limiting or diminishing the authority of the Federal Trade Commission to enforce the laws under its jurisdiction with respect to the advertising, sale, or distribution of tobacco products.

SEC. 117. REGULATION REQUIREMENT.

(a) TESTING, REPORTING, AND DISCLOSURE.—Not later than 36 months after the date of enactment of the Act, the Administrator shall promulgate regulations under this Act that meet the requirements of subsection (b).

(b) CONTENTS OF RULES.—The regulations promulgated under subsection (a)—

(1) shall require annual testing and reporting of tobacco product constituents, ingredients, and additives, including smoke constituents, by brand style that the Administrator determines should be tested to protect the public health, provided that, for purposes of the testing requirements of this paragraph, tobacco products manufactured and sold by a single tobacco product manufacturer that are identical in all respects except the labels, packaging design, logo, trade dress, trademark, brand name, or any combination thereof, shall be considered as a single brand style; and

(2) may require that tobacco product manufacturers, packagers, or importers make disclosures relating to the results of the testing of tar and nicotine through labels or advertising.

(c) AUTHORITY.—The Administrator shall have the authority under this Act to conduct or to require the testing, reporting, or disclosure of tobacco product constituents, including smoke constituents.

(d) JOINT LABORATORY TESTING SERVICES.—The Administrator shall allow any 2 or more tobacco product manufacturers to join together to purchase laboratory testing services required by this section on a group basis

in order to ensure that such manufacturers receive access to, and fair pricing of, such testing services.

(e) EXTENSIONS FOR LIMITED LABORATORY CAPACITY.—

(1) IN GENERAL.—The regulations promulgated under subsection (a) shall provide that a tobacco product manufacturer shall not be considered to be in violation of this section before the applicable deadline, if—

(A) the tobacco products of such manufacturer are in compliance with all other requirements of this Act; and

(B) the conditions described in paragraph (2) are met.

(2) CONDITIONS.—Notwithstanding the requirements of this section, the Administrator may delay the date by which a tobacco product manufacturer must be in compliance with the testing and reporting required by this section until such time as the testing is reported if, not later than 90 days before the deadline for reporting in accordance with this section, a tobacco product manufacturer provides evidence to the Administrator demonstrating that—

(A) the manufacturer has submitted the required products for testing to a laboratory and has done so sufficiently in advance of the deadline to create a reasonable expectation of completion by the deadline;

(B) the products currently are awaiting testing by the laboratory; and

(C) neither that laboratory nor any other laboratory is able to complete testing by the deadline at customary, nonexpedited testing fees.

(3) EXTENSION.—The Administrator, taking into account the laboratory testing capacity that is available to tobacco product manufacturers, shall review and verify the evidence submitted by a tobacco product manufacturer in accordance with paragraph (2). If the Administrator finds that the conditions described in such paragraph are met, the Administrator shall notify the tobacco product manufacturer that the manufacturer shall not be considered to be in violation of the testing and reporting requirements of this section until the testing is reported or until 1 year after the reporting deadline has passed, whichever occurs sooner. If, however, the Administrator has not made a finding before the reporting deadline, the manufacturer shall not be considered to be in violation of such requirements until the Administrator finds that the conditions described in paragraph (2) have not been met, or until 1 year after the reporting deadline, whichever occurs sooner.

(4) ADDITIONAL EXTENSION.—In addition to the time that may be provided under paragraph (3), the Administrator may provide further extensions of time, in increments of no more than 1 year, for required testing and reporting to occur if the Administrator determines, based on evidence properly and timely submitted by a tobacco product manufacturer in accordance with paragraph (2), that a lack of available laboratory capacity prevents the manufacturer from completing the required testing during the period described in paragraph (3).

(f) RULE OF CONSTRUCTION.—Nothing in subsection (d) or (e) shall be construed to authorize the extension of any deadline, or to otherwise affect any timeframe, under any provision of this Act other than this section.

SEC. 118. PRESERVATION OF STATE AND LOCAL AUTHORITY.

(a) IN GENERAL.—

(1) PRESERVATION.—Except as provided in paragraph (2)(A), nothing in this Act, or rules promulgated under this Act, shall be construed to limit the authority of a Federal agency (including the Armed Forces), a State or political subdivision of a State, or the government of an Indian tribe to enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products that is in addition to requirements established under this Act, including a law, rule, regulation, or other measure relating to or prohibiting the sale, distribution, possession, or use of tobacco products by individuals of any age, information reporting to the State. No provision of this Act shall limit or otherwise affect any State, Tribal, or local taxation of tobacco products.

(2) PREEMPTION OF CERTAIN STATE AND LOCAL REQUIREMENTS.—

(A) IN GENERAL.—No State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this Act relating to tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products.

(B) EXCEPTION.—Subparagraph (A) does not apply to requirements relating to the sale, distribution, possession, information reporting to the State, use of, tobacco product by individuals of any age. Information disclosed to a State under subparagraph (A) that is exempt from disclosure under section 552(b)(4) of title 5, United States Code, shall be treated as a trade secret and confidential information by the State.

(b) RULE OF CONSTRUCTION REGARDING PRODUCT LIABILITY.—No provision of this Act relating to a tobacco product shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.

SEC. 119. TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE.

(a) ESTABLISHMENT.—Not later than 6 months after the date of enactment of this Act, the Administrator shall establish a 16-member advisory committee, to be known as the Tobacco Products Scientific Advisory Committee (in this section referred to as the ''Advisory Committee'').

(b) MEMBERSHIP.—

(1) IN GENERAL.—

(A) MEMBERS.—The Administrator shall appoint as members of the Tobacco Harm Reduction Advisory Committee individuals who are technically qualified by training and experience in medicine, medical ethics, science, or technology involving the manufacture, evaluation, or use of tobacco products, who are of appropriately diversified professional backgrounds. The committee shall be composed of—

(i) 6 individuals who are physicians, dentists, scientists, or health care professionals practicing in the area of oncology, pulmonology, cardiology, toxicology, pharmacology, addiction, or any other relevant specialty;

(ii) 2 individuals who are an officer or employee of a State or local government or of the Federal Government;

(iii) 2 representatives of the general public;

(iv) 2 representatives of the interests of the tobacco manufacturing industry;

(v) 1 representative of the interests of the small business tobacco manufacturing industry, which position may be filled on a rotating, sequential basis by representatives of different small business tobacco manufacturers based on areas of expertise relevant to the topics being considered by the Advisory Committee;

(vi) 1 individual as a representative of the interests of the tobacco growers; and

(vii) 1 individual who is an expert in illicit trade of tobacco products.

(B) CONFLICTS OF INTEREST.—No members of the committee, other than members appointed pursuant to clauses (iv), (v), and (vi) of subparagraph (A) shall, during the member's tenure on the committee or for the 18-month period prior to becoming such a member, receive any salary, grants, or other payments or support from any business that manufactures, distributes, markets, or sells cigarettes or other tobacco products or government agency with any form of jurisdiction over tobacco products.

(2) LIMITATION.—The Administrator may not appoint to the Advisory Committee any individual who is in the regular full-time employ of the Tobacco Harm Reduction Center or any agency responsible for the enforcement of this Act. The Administrator may appoint Federal officials as ex officio members.

(3) CHAIRPERSON.—The Administrator shall designate 1 of the members appointed under clauses (i), (ii), and (iii) of paragraph (1)(A) to serve as chairperson.

(c) DUTIES.—The Tobacco Products Scientific Advisory Committee shall provide advice, information, and recommendations to the Administrator—

(1) as provided in this Act;

(2) on the implementation of prevention, cessation, and harm reduction policies;

(3) on implementation of policies and programs to fully inform consumers of the respective risks of tobacco products; and

(4) on its review of other safety, dependence, or health issues relating to tobacco products as requested by the Administrator.

(d) COMPENSATION; SUPPORT; FACA.—

(1) COMPENSATION AND TRAVEL.—Members of the Advisory Committee who are not officers or employees of the United States, while attending conferences or meetings of the committee or otherwise engaged in its business, shall be entitled to receive compensation at rates to be fixed by the Administrator, which may not exceed the daily equivalent of the rate in effect under the Senior Executive Schedule under section 5382 of title 5, United States Code, for each day (including travel time) they are so engaged; and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5, United States Code, for persons in the Government service employed intermittently.

(2) ADMINISTRATIVE SUPPORT.—The Administrator shall furnish the Advisory Committee clerical and other assistance.

(3) NONAPPLICATION OF FACA.—Section 14 of the Federal Advisory Committee Act does not apply to the Advisory Committee.

(e) PROCEEDINGS OF ADVISORY PANELS AND COMMITTEES.—The Advisory Committee shall make and maintain a transcript of any proceeding of the panel or committee. Each such panel and committee shall delete from any transcript made under this subsection information which is exempt from disclosure under section 552(b) of title 5, United States Code.

SEC. 120. DRUG PRODUCTS USED TO TREAT TOBACCO DEPENDENCE.

(a) REPORT ON INNOVATIVE PRODUCTS.—

(1) IN GENERAL.—Not later than 3 years after the date of enactment of this Act, the Administrator, after consultation with recognized scientific, medical, and public health experts (including both Federal agencies and nongovernmental entities, the Institute of Medicine of the National Academy of Sciences, and the Society for Research on Nicotine and Tobacco), shall submit to the Congress a report that examines how best to promote, and encourage the development and use by current tobacco users of innovative

tobacco and nicotine products and treatments (including nicotine-based and non-nicotine-based products and treatments) to better achieve, in a manner that best protects and promotes the public health—

(A) total abstinence from tobacco use;

(B) reductions in consumption of tobacco; and

(C) reductions in the harm associated with continued tobacco use by moving current users to noncombustible tobacco products.

(2) RECOMMENDATIONS.—The report under paragraph (1) shall include the recommendations of the Administrator on how the Tobacco Harm and Reduction Center should coordinate and facilitate the exchange of information on such innovative products and treatments among relevant offices and centers within the Center and within the National Institutes of Health, the Centers for Disease Control and Prevention, and other relevant Federal and State agencies.

TITLE II—TOBACCO PRODUCTS WARNINGS; CONSTITUENT AND SMOKE CONSTITUENT DISCLOSURE

SEC. 201. CIGARETTE LABEL AND ADVERTISING WARNINGS.

(a) AMENDMENT.—Section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) is amended to read as follows:

"SEC. 4. LABELING.

''(a) LABEL REQUIREMENTS.—

''(1) IN GENERAL.—It shall be unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any cigarettes the package of which fails to bear, in accordance with the requirements of this section, one of the following labels:

''WARNING: Cigarettes are addictive.

''WARNING: Tobacco smoke can harm your children.

''WARNING: Cigarettes cause fatal lung disease.

''WARNING: Cigarettes cause cancer.

''WARNING: Cigarettes cause strokes and heart disease.

''WARNING: Smoking during pregnancy can harm your baby.

''WARNING: Smoking can kill you.

''WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.

''WARNING: Quitting smoking now greatly reduces serious risks to your health.

''(2) PLACEMENT; TYPOGRAPHY; ETC.—Each label statement required by paragraph (1) shall be located in the lower portion of the front panel of the package, directly on the package underneath the cellophane or other clear wrapping. Each label statement shall comprise at least the bottom 25 percent of the front panel of the package. The word 'WARNING' shall appear in capital letters and all text shall be in conspicuous and legible 17-point type, unless the text of the label statement would occupy more than 70 percent of such area, in which case the text may be in a smaller conspicuous and legible type size, provided that at least 60 percent of such area is occupied by required text. The text shall be black on a white background, or white on a black background, in a manner that contrasts, by typography, layout, or color, with all other printed material on the package, in an alternating fashion under the plan submitted under subsection (c).

''(3) DOES NOT APPLY TO FOREIGN DISTRIBUTION.—The provisions of this subsection do not apply to a tobacco product manufacturer or distributor of cigarettes which does not manufacture, package, or import cigarettes for sale or distribution within the United States.

''(4) APPLICABILITY TO RETAILERS.—A retailer of cigarettes shall not be in violation of this subsection for packaging that—

''(A) contains a warning label;

''(B) is supplied to the retailer by a license- or permit-holding smoking article manufacturer, importer, or distributor; and

''(C) is not altered by the retailer in a way that is material to the requirements of this subsection.

''(b) ADVERTISING REQUIREMENTS.—

''(1) IN GENERAL.—It shall be unlawful for any tobacco product manufacturer, importer, distributor, or retailer of cigarettes to advertise or cause to be advertised within the United States any cigarette unless its advertising bears, in accordance with the requirements of this section, one of the labels specified in subsection (a).

''(2) TYPOGRAPHY, ETC.—Each label statement required by subsection (a) in cigarette advertising shall comply with the standards set forth in this paragraph. For press and poster advertisements, each such statement and (where applicable) any required statement relating to tar, nicotine, or other constituent (including a smoke constituent) yield shall comprise at least 20 percent of the area of the advertisement and shall appear in a conspicuous and prominent format and location at the bottom of each advertisement within the trim area. The word 'WARNING' shall appear in capital letters, and each label statement shall appear in conspicuous and legible type. The text of the label statement shall be black if the background is white and white if the background is black, under the plan submitted under subsection (c). The label statements shall be enclosed by a rectangular border that is the same color as the letters of the statements and that is the width of the first downstroke of the capital 'W' of the word 'WARNING' in the label statements. The text of such label statements shall be in a typeface pro rata to the following requirements: 45-point type for a whole-page broadsheet newspaper advertisement; 39-point type for a half-page broadsheet newspaper advertisement; 39-point type for a whole-page tabloid newspaper advertisement; 27-point type for a half-page tabloid newspaper advertisement; 31.5-point type for a double page spread magazine or whole-page magazine advertisement; 22.5-point type for a 28 centimeter by 3 column advertisement; and 15-point type for a 20 centimeter by 2 column advertisement. The label statements shall be in English, except that—

''(A) in the case of an advertisement that appears in a newspaper, magazine, periodical, or other publication that is not in English, the statements shall appear in the predominant language of the publication; and

''(B) in the case of any other advertisement that is not in English, the statements shall appear in the same language as that principally used in the advertisement.

''(3) MATCHBOOKS.—Notwithstanding paragraph (2), for matchbooks (defined as containing not more than 20 matches) customarily given away with the purchase of smokeless tobacco products, each label statement required by subsection (a) may be printed on the inside cover of the matchbook.

''(c) MARKETING REQUIREMENTS.—

''(1) RANDOM DISPLAY.—The label statements specified in subsection (a)(1) shall be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the smokeless tobacco product manufacturer, importer, distributor, or retailer and approved by the Secretary.

''(2) ROTATION.—The label statements specified in subsection (a)(1) shall be rotated quarterly in alternating sequence in advertisements for each brand of cigarettes in accordance with a plan submitted by the smokeless tobacco product manufacturer, importer, distributor, or retailer to, and approved by, the Secretary.

''(3) REVIEW.—The Secretary shall review each plan submitted under paragraph (2) and approve it if the plan—

''(A) will provide for the equal distribution and display on packaging and the rotation required in advertising under this subsection; and

''(B) assures that all of the labels required under this section will be displayed by the smokeless tobacco product manufacturer, importer, distributor, or retailer at the same time.

''(4) APPLICABILITY TO RETAILERS.—This subsection and subsection (b) apply to a retailer only if that retailer is responsible for or directs the label statements required under this section except that this paragraph shall not relieve a retailer of liability if the retailer displays, in a location open to the public, an advertisement that does not contain a warning label or has been altered by the retailer in a way that is material to the requirements of this subsection and subsection (b).''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect 24 months after the date of enactment of this Act. Such effective date shall be with respect to the date of manufacture, provided that, in any case, beginning 30 days after such effective date, a manufacturer shall not introduce into the domestic commerce of the United States any product, irrespective of the date of manufacture, that is not in conformance with section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333), as amended by subsection (a).

SEC. 202. SMOKELESS TOBACCO LABELS AND ADVERTISING WARNINGS.

(a) AMENDMENT.—Section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4402) is amended to read as follows:

"SEC. 3. SMOKELESS TOBACCO WARNING.

''(a) GENERAL RULE.—

''(1) It shall be unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any smokeless tobacco product unless the product package bears, in accordance with the requirements of this Act, one of the following labels:

''WARNING: This product can cause mouth cancer.

''WARNING: This product can cause gum disease and tooth loss.

''WARNING: This product has significantly lower risks for diseases associated with cigarettes.

''WARNING: Smokeless tobacco is addictive.

''(2) The label statements required by paragraph (1) shall be introduced by each smokeless tobacco product manufacturer, packager, importer, distributor, or retailer of smokeless tobacco products concurrently into the distribution chain of such products.

''(3) The provisions of this subsection do not apply to a smokeless tobacco product manufacturer or distributor of any smokeless tobacco product that does not manufacture, package, or import smokeless tobacco products for sale or distribution within the United States.

''(4) A retailer of smokeless tobacco products shall not be in violation of this subsection for packaging that—

''(A) contains a warning label;

''(B) is supplied to the retailer by a license- or permit-holding smokeless tobacco product manufacturer, importer, or distributor; and

''(C) is not altered by the retailer in a way that is material to the requirements of this subsection.

''(b) REQUIRED LABELS.—

''(1) It shall be unlawful for any smokeless tobacco product manufacturer, packager, importer, distributor, or retailer of smokeless tobacco products to advertise or cause to be advertised within the United States any smokeless tobacco product unless its advertising bears, in accordance with the requirements of this section, one of the labels specified in subsection (a).

''(2)(A) Each label statement required by subsection (a) in smokeless tobacco advertising shall comply with the standards set forth in this paragraph.

''(B) For press and poster advertisements, each such statement and (where applicable) any required statement relating to nicotine, or other constituent yield shall comprise at least 20 percent of the area of the advertisement.

''(C) The word 'WARNING' shall appear in capital letters, and each label statement shall appear in conspicuous and legible type.

''(D) The text of the label statement shall be black on a white background, or white on a black background, in an alternating fashion under the plan submitted under paragraph (3).

''(E) The label statements shall be enclosed by a rectangular border that is the same color as the letters of the statements and that is the width of the first downstroke of the capital 'W' of the word 'WARNING' in the label statements.

''(F) The text of such label statements shall be in a typeface pro rata to the following requirements: 45-point type for a whole-page broadsheet newspaper advertisement; 39-point type for a half-page broadsheet newspaper advertisement; 39-point type for a whole-page tabloid newspaper advertisement; 27-point type for a half-page tabloid newspaper advertisement; 31.5-point type for a double page spread magazine or whole-page magazine advertisement; 22.5-point type for a 28 centimeter by 3 column advertisement; and 15-point type for a 20 centimeter by 2 column advertisement.

''(G) The label statements shall be in English, except that—

''(i) in the case of an advertisement that appears in a newspaper, magazine, periodical, or other publication that is not in English, the statements shall appear in the predominant language of the publication; and

''(ii) in the case of any other advertisement that is not in English, the statements shall appear in the same language as that principally used in the advertisement.

''(3)(A) The label statements specified in subsection (a)(1) shall be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the smokeless tobacco product manufacturer, importer, distributor, or retailer and approved by the Secretary.

''(B) The label statements specified in subsection (a)(1) shall be rotated quarterly in alternating sequence in advertisements for each brand of smokeless tobacco product in accordance with a plan submitted by the smokeless tobacco product manufacturer, importer, distributor, or retailer to, and approved by, the Secretary.

''(C) The Secretary shall review each plan submitted under subparagraphs (A) and (B) and approve it if the plan—

''(i) will provide for the equal distribution and display on packaging and the rotation required in advertising under this subsection; and

''(ii) assures that all of the labels required under this section will be displayed by the smokeless tobacco product manufacturer, importer, distributor, or retailer at the same time.

''(D) This paragraph applies to a retailer only if that retailer is responsible for or directs the label statements under this section, unless the retailer displays, in a location open to the public, an advertisement that does not contain a warning label or has been altered by the retailer in a way that is material to the requirements of this subsection.

''(c) TELEVISION AND RADIO ADVERTISING.—It is unlawful to advertise smokeless tobacco on any medium of electronic communications subject to the jurisdiction of the Federal Communications Commission.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect 24 months after the date of enactment of this Act. Such effective date shall be with respect to the date of manufacture, provided that, in any case, beginning 30 days after such effective date, a manufacturer shall not introduce into the domestic commerce of the United States any product, irrespective of the date of manufacture, that is not in conformance with section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4402), as amended by subsection (a).

TITLE III—PUBIC DISCLOSURES BY TOBACCO PRODUCTS MANUFACTURERS

SEC. 301. DISCLOSURES ON PACKAGES OF TOBACCO PRODUCTS.

(a) BACK FACE FOR REQUIRED DISCLOSURES.—For purposes of this section—

(1) the principal face of a package of a tobacco product is the face that has the largest surface area or, for faces with identical surface areas, any of the faces that have the largest surface area; a package shall not be characterized as having more than 2 principal faces;

(2) the front face shall be the principal face of the package;

(3) if the front and back faces are of different sizes in terms of area, then the larger face shall be the front face;

(4) the back face shall be the principal face of a package that is opposite the front face of the package;

(5) the bottom 50 percent of the back face of the package shall be allocated for required package disclosures in accordance with this section; and

(6) if a package of a tobacco product is cylindrical, a contiguous area constituting 30 percent of the total surface area of the cylinder shall be deemed the back face.

(b) REQUIRED INFORMATION ON BACK FACE.—Not later than 24 months after the effective date of this Act, the bottom 50 percent of the back face of a package of a tobacco product shall be available solely for disclosures required by or under this Act, the Federal Cigarette Labeling and Advertising Act, sections 1331–1340 of title 15, United States Code, and any other Federal statute. Such disclosures shall include—

(1) the printed name and address of the manufacturer, packer, or distributor, and any other identification associated with the manufacturer, packer, or distributor or with the tobacco product that the Administrator may require;

(2) a list of ingredients as required by subsection (e); and

(3) the appropriate tax registration number.

(c) PACKAGE DISCLOSURE OF INGREDIENTS.—Not later than 24 months after the effective date of this Act, the package of a tobacco product shall bear a list of the common or usual names of the ingredients present in the tobacco product in an amount greater than 0.1 percent of the total dry weight of the tobacco (including all ingredients), that shall comply with the following:

(1) Such listing of ingredients shall appear under, or be conspicuously accompanied by, the heading ''Tobacco and principal tobacco ingredients''.

(2) Tobacco may be listed as ''tobacco,'' and shall be the first listed ingredient.

(3) After tobacco, the ingredients shall be listed in descending order of predominance, by weight.

(4) Spices and natural and artificial flavors may be listed, respectively, as ''spices'' and ''natural and artificial flavors'' without naming each.

(5) Preservatives may be listed as ''preservatives'' without naming each.

(6) The disclosure of any ingredient in accordance with this section may, at the option of the tobacco product manufacturer, designate the functionality or purpose of that ingredient.

(7) The package say state ''Not for sale to minors''.

(8) In the case of a package of cigarettes, the package shall state that smokeless tobacco has significantly lower risks for disease and death than cigarettes.

SEC. 302. DISCLOSURES ON PACKAGES OF SMOKELESS TOBACCO.

(a) BACK FACE FOR REQUIRED DISCLOSURES.—For purposes of this section—

(1) the principal face of a package of smokeless tobacco is the face that has the largest surface area or, for faces with identical surface areas, any of the faces that have the largest surface area; a package shall not be characterized as having more than two principal faces;

(2) the front or top face shall be the principal face of the package;

(3) if the front or top and back or bottom faces are of different sizes in terms of area, then the larger face shall be the front or top face;

(4) the back or bottom face of the package shall be the principal face of a package that is opposite the front or top face of the package;

(5) beginning 24 months after the effective date of this Act, 50 percent of the back or bottom face of the package shall be allocated for required package disclosures in accordance with this section; and

(6) if the package is cylindrical, a contiguous area constituting 30 percent of the total surface area of the cylinder shall be deemed the back face.

(b) REQUIRED INFORMATION ON BACK OR BOTTOM FACE.—50 percent of the back or bottom face of a package of smokeless tobacco shall be available solely for disclosures required by or under this Act, the Comprehensive Smokeless Tobacco Health Education Act of 1986, sections 4401–4408 of title 15, United States Code, and any other Federal statute. Such disclosures shall include a list of ingredients as required by subsection (e).

(c) PACKAGE DISCLOSURE OF INGREDIENTS.—Commencing 24 months after the effective date of this Act, a package of smokeless tobacco shall bear a list of the common or usual names of the ingredients present in the smokeless tobacco in an amount greater than 0.1 percent of the total dry weight of the tobacco (including all ingredients).

(1) Such listing of ingredients shall appears under, or be conspicuously accompanied by, the heading ''Tobacco and principal tobacco ingredients''.

(2) Tobacco may be listed as ''tobacco,'' and shall be the first listed ingredient.

(3) After tobacco, the ingredients shall be listed in descending order of predominance, by weight.

(4) Spices and natural and artificial flavors may be listed, respectively, as ''spices'' and

''natural and artificial flavors'' without naming each.

(5) Preservatives may be listed as ''preservatives'' without naming each.

(6) The disclosure of any ingredient in accordance with this section may, at the option of the tobacco product manufacturer, designate the functionality or purpose of that ingredient.

(7) Not for sale to minors.

SEC. 303. PUBLIC DISCLOSURE OF INGREDIENTS.

(a) REGULATIONS.—Not later than 24 months after the effective date of this Act, the Administrator shall, by regulation, establish standards under which each tobacco product manufacturer shall disclose publicly, and update at least annually—

(1) a list of the ingredients it uses in each brand style it manufactures for commercial distribution domestically, as provided in subsection (b); and

(2) a composite list of all the ingredients it uses in any of the brand styles it manufactures for commercial distribution domestically, as provided in subsection (c).

(b) INGREDIENTS TO BE DISCLOSED AS TO EACH BRAND STYLE.—

(1) IN GENERAL.—With respect to the public disclosure required by subsection (a)(1), as to each brand style, the tobacco product manufacture shall disclose the common or usual name of each ingredient present in the brand style in an amount greater than 0.1 percent of the total dry weight of the tobacco (including all ingredients).

(2) REQUIREMENTS.—Disclosure under paragraph (1) shall comply with the following:

(A) Tobacco may be listed as ''tobacco,'' and shall be the first listed ingredient.

(B) After tobacco, the ingredients shall be listed in descending order of predominance, by weight.

(C) Spices and natural and artificial flavors may be listed, respectively, as ''spices'' and ''natural and artificial flavors'' without naming each.

(D) Preservatives may be listed as ''preservatives'' without naming each.

(E) The disclosure of any ingredient in accordance with this section may, at the option of the tobacco product manufacturer, designate the functionality or purpose of that ingredient.

(c) AGGREGATE DISCLOSURE OF INGREDIENTS.—

(1) IN GENERAL.—The public disclosure required of a tobacco product manufacturer by subsection (a)(2) shall consist of a single list of all ingredients used in any brand style a tobacco product manufacturer manufactures for commercial distribution domestically, without regard to the quantity used, and including, separately, each spice, each natural or artificial flavoring, and each preservative.

(2) LISTING.—The ingredients shall be listed by their respective common or usual names in descending order of predominance by the total weight used annually by the tobacco product manufacturer in manufacturing tobacco products for commercial distribution domestically.

(d) NO REQUIRED DISCLOSURE OF QUANTITIES.—The Administrator shall not require any public disclosure of quantitative information about any ingredient in a tobacco product.

(e) DISCLOSURE ON WEBSITE.—The public disclosures required by subsection (a) of this section may be by posting on an Internet-accessible website, or other location electronically accessible to the public, which is identified on all packages of a tobacco product manufacturer's tobacco products.

(f) TIMING OF INITIAL REQUIRED DISCLOSURES.—No disclosure pursuant to this section shall be required to commence until the regulations under subsection (a) have been in effect for not less than 1 year.

TITLE IV—PREVENTION OF ILLICIT TRADE IN TOBACCO PRODUCTS

SEC. 401. STUDY AND REPORT ON ILLICIT TRADE.

(a) The Administrator shall, after consultation with other relevant agencies including Customs and Tobacco Tax Bureau, conduct a study of trade in tobacco products that involves passage of tobacco products either between the States or from or to any other country across any border of the United States to—

(1) collect data on such trade in tobacco products, including illicit trade involving tobacco products, and make recommendations on the monitoring and enforcement of such trade;

(2) collect data on any advertising intended to be broadcast, transmitted, or distributed from or to the United States from or to another country and make recommendations on how to prevent or eliminate, and what technologies could help facilitate the elimination of, such advertising; and

(3) collect data on such trade in tobacco products by person that is not—

(A) a participating manufacturer (as that term is defined in section II(jj) of the Master Settlement Agreement of November 23, 1998, between certain of the States and certain tobacco product manufacturers); or

(B) an affiliate or subsidiary of a participating manufacturer.

(b) Not later than 18 months after the effective date of this Act, the Administrator shall submit to the Secretary, and committees of relevant jurisdiction in Congress, a report the recommendations of the study conducted under subsection (a).

SEC. 402. AMENDMENT TO SECTION 1926 OF THE PUBLIC HEALTH SERVICE ACT.

Section 1926 of the Public Health Service Act (42 U.S.C. § 300x–26) is amended by adding at the end thereof the following:

''(e)(1) Subject to paragraphs (2) and (3), for the first fiscal year after enactment and each subsequent fiscal year, the Secretary shall reduce, as provided in subsection (h), the amount of any grant under section 300x–21 of this title for any State that does not have in effect a statute with substantially the following provisions:

''SEC. 1. DISTRIBUTION TO MINORS.

''(a) No person shall distribute a tobacco product to an individual under 18 years of age or a different minimum age established under State law. A person who violates this subsection is liable for a civil money penalty of not less than $25 nor more than $125 for each violation of this subsection;

''(b) The employer of an employee who has violated subsection (a) twice while in the employ of such employer is liable for a civil money penalty of $125 for each subsequent violation by such employee.

''(c) It shall be a defense to a charge brought under subsection (a) that—

''(1) the defendant—

''(A) relied upon proof of age that appeared on its face to be valid in accordance with the Federal Tobacco Act of 2007;

''(B) had complied with the requirements of section 5 and, if applicable, section 7; or

''(C) relied upon a commercially available electronic age verification service to confirm that the person was an age-verified adult; or

''(2) the individual to whom the tobacco product was distributed was at the time of the distribution used in violation of subsection 8(b).

''SEC. 2. PURCHASE, RECEIPT, OR POSSESSION BY MINORS PROHIBITED.

''(a) An individual under 18 years of age or a different minimum age established under State law shall not purchase or attempt to purchase, receive or attempt to receive, possess or attempt to possess, a tobacco product. An individual who violates this subsection is liable for a civil money penalty of not less than $25 nor more than $125 for each such violation, and shall be required to perform not less than four hours nor more than ten hours of community service. Upon the second or each subsequent violation of this subsection, such individual shall be required to perform not less than eight hours nor more than twenty hours of community service.

''(b) A law enforcement agency, upon determining that an individual under 18 years of age or a different minimum age established under State law allegedly purchased, received, possessed, or attempted to purchase, receive, or possess, a tobacco product in violation of subsection (a) shall notify the individual's parent or parents, custodian, or guardian as to the nature of the alleged violation if the name and address of a parent or parents, guardian, or custodian is reasonably ascertainable by the law enforcement agency. The notice required by this subsection shall be made not later than 48 hours after the individual who allegedly violated subsection (a) is cited by such agency for the violation. The notice may be made by any means reasonably calculated to give prompt actual notice, including notice in person, by telephone, or by first-class mail.

''(c) Subsection (a) does not prohibit an individual under 18 years of age or a different minimum age established under State law from possessing a tobacco product during regular working hours and in the course of such individual's employment if the tobacco product is not possessed for such individual's consumption.

''SEC. 3. OUT-OF-PACKAGE DISTRIBUTION.

''It shall be unlawful for any person to distribute cigarettes or a smokeless tobacco product other than in an unopened package that complies in full with section 108 of the Federal Tobacco Act of 2007. A person who distributes a cigarette or a smokeless tobacco product in violation of this section is liable for a civil money penalty of not less than $25 nor more than $125 for each such violation.

''SEC. 4. SIGNAGE.

''It shall be unlawful for any person who sells tobacco products over-the-counter to fail to post conspicuously on the premises where such person sells tobacco products over-the-counter a sign communicating that—

''(1) the sale of tobacco products to individuals under 18 years of age or a different minimum age established under State law is prohibited by law;

''(2) the purchase of tobacco products by individuals under 18 years of age or a different minimum age established under State law is prohibited by law; and

''(3) proof of age may be demanded before tobacco products are sold.

A person who fails to post a sign that complies fully with this section is liable for a civil money penalty of not less than $25 nor more than $125.

''SEC. 5. NOTIFICATION OF EMPLOYEES.

''(a) Within 180 days of the effective date of the Preventing Disease and Death from Tobacco Use Act, every person engaged in the business of selling tobacco products at retail shall implement a program to notify each employee employed by that person who sells tobacco products at retail that—

''(1) the sale or other distribution of tobacco products to any individual under 18 years of age or a different minimum age established under State law, and the purchase, receipt, or possession of tobacco products in a place open to the public by any individual under 18 years of age or a different minimum age established under State law, is prohibited; and

''(2) out-of-package distribution of cigarettes and smokeless tobacco products is prohibited.

Any employer failing to provide the required notice to any employee shall be liable for a civil money penalty of not less than $25 nor more than $125 for each such violation.

''(b) It shall be a defense to a charge that an employer violated subsection (a) of this section that the employee acknowledged receipt, either in writing or by electronic means, prior to the alleged violation, of a statement in substantially the following form:

''I understand that State law prohibits the distribution of tobacco products to individuals under 18 years of age or a different minimum age established under State law and out-of-package distribution of cigarettes and smokeless tobacco products, and permits a defense based on evidence that a prospective purchaser's proof of age was reasonably relied upon and appeared on its face to be valid. I understand that if I sell, give, or voluntarily provide a tobacco product to an individual under 18 years of age or a different minimum age established under State law, I may be found responsible for a civil money penalty of not less than $25 nor more than $125 for each violation. I promise to comply with this law.'''''

''(c) If an employer is charged with a violation of subsection (a) and the employer uses as a defense to such charge the defense provided by subsection (b), the employer shall be deemed to be liable for such violation if such employer pays the penalty imposed on the employee involved in such violation or in any way reimburses the employee for such penalty.

''SEC. 6. SELF-SERVICE DISPLAYS.

''(a) It shall be unlawful for any person who sells tobacco products over-the-counter at retail to maintain packages of such products in any location accessible to customers that is not under the control of a cashier or other employee during regular business hours. This subsection does not apply to any adult-only facility.

''(b) Any person who violates subsection (a) is liable for a civil money penalty of not less than $25 nor more than $125 for each such violation, except that no person shall be responsible for more than one violation per day at any one retail store.

''SEC. 7. DISTRIBUTION BY MAIL OR COURIER.

''(a) It shall be unlawful to distribute or sell tobacco products directly to consumers by mail or courier, unless the person receiving purchase requests for tobacco products takes reasonable action to prevent delivery to individuals who are not adults by—

''(1) requiring that addressees of the tobacco products be age-verified adults;

''(2) making good faith efforts to verify that such addressees have attained the minimum age for purchase of tobacco products established by the respective States wherein the addresses of the addressees are located; and

''(3) addressing the tobacco products delivered by mail or courier to a physical addresses and not to post office boxes.

''(b) Any person who violates subsection (a) is liable for a civil money penalty of not less than $25 nor more than $125 for each such violation.

''SEC. 8. RANDOM UNANNOUNCED INSPECTIONS; REPORTING; AND COMPLIANCE.

''(a) The State Police, or a local law enforcement authority duly designated by the State Police, shall enforce this Act in a manner that can reasonably be expected to reduce the extent to which tobacco products are distributed to individuals under 18 years of age or a different minimum age established under State law and shall conduct random, unannounced inspections in accordance with the procedures set forth in this Act and in regulations issued under section 1926 of the Federal Public Health Service Act (42 U.S.C. § 300x–26).

''(b) The State may engage an individual under 18 years of age or a different minimum age established under State law to test compliance with this Act, except that such an individual may be used to test compliance with this Act only if the testing is conducted under the following conditions:

''(1) Prior to use of any individual under 18 years of age or a different minimum age established under State law in a random, unannounced inspection, written consent shall be obtained from a parent, custodian, or guardian of such individual;

''(2) An individual under 18 years of age or a different minimum age established under State law shall act solely under the supervision and direction of the State Police or a local law enforcement authority duly designated by the State Police during a random, unannounced inspection;

''(3) An individual under 18 years of age or a different minimum age established under State law used in random, unannounced inspections shall not be used in any such inspection at a store in which such individual is a regular customer; and

''(4) If an individual under 18 years of age or a different minimum age established under State law participating in random, unannounced inspections is questioned during such an inspection about such individual's age, such individual shall state his or her actual age and shall present a true and correct proof of age if requested at any time during the inspection to present it.

''(c) Any person who uses any individual under 18 years of age or a different minimum age established under State law, other than as permitted by subsection (b), to test compliance with this Act, is liable for a civil money penalty of not less than $25 nor more than $125 for each such violation.

''(d) Civil money penalties collected for violations of this Act and fees collected under section 9 shall be used only to defray the costs of administration and enforcement of this Act.

''SEC. 9. LICENSURE.

''(a) Each person engaged in the over-the-counter distribution at retail of tobacco products shall hold a license issued under this section. A separate license shall be required for each place of business where tobacco products are distributed at retail. A license issued under this section is not assignable and is valid only for the person in whose name it is issued and for the place of business designated in the license.

''(b) The annual license fee is $25 for each place of business where tobacco products are distributed at retail.

''(c) Every application for a license, including renewal of a license, under this section shall be made upon a form provided by the appropriate State agency or department, and shall set forth the name under which the applicant transacts or intends to transact business, the location of the place of business for which the license is to be issued, the street address to which all notices relevant to the license are to be sent (in this Act referred to as ''notice address''), and any other identifying information that the appropriate State agency or department may require.

''(d) The appropriate State agency or department shall issue or renew a license or deny an application for a license or the renewal of a license within 30 days of receiving a properly completed application and the license fee. The appropriate State agency or department shall provide notice to an applicant of action on an application denying the issuance of a license or refusing to renew a license.

''(e) Every license issued by the appropriate State agency or department pursuant to this section shall be valid for 1 year from the date of issuance and shall be renewed upon application except as otherwise provided in this Act.

''(f) Upon notification of a change of address for a place of business for which a license has been issued, a license shall be reissued for the new address without the filing of a new application.

''(g) The appropriate State agency or department shall notify every person in the State who is engaged in the distribution at retail of tobacco products of the license requirements of this section and of the date by which such person should have obtained a license.

''(h)(1) Except as provided in paragraph (2), any person who engages in the distribution at retail of tobacco products without a license required by this section is liable for a civil money penalty in an amount equal to (i) two times the applicable license fee, and (ii) $50 for each day that such distribution continues without a license.

''(2) Any person who engages in the distribution at retail of tobacco products after a license issued under this section has been suspended or revoked is liable for a civil money penalty of $100 per day for each day on which such distribution continues after the date such person received notice of such suspension or revocation.

''(i) No person shall engage in the distribution at retail of tobacco products on or after 180 days after the date of enactment this Act unless such person is authorized to do so by a license issued pursuant to this section or is an employee or agent of a person that has been issued such a license.

''SEC. 10. SUSPENSION, REVOCATION, DENIAL, AND NONRENEWAL OF LICENSES.

''(a) Upon a finding that a licensee has been determined by a court of competent jurisdiction to have violated this Act during the license term, the State shall notify the licensee in writing, served personally or by registered mail at the notice address, that any subsequent violation of this Act at the same place of business may result in an administrative action to suspend the license for a period determined by the specify the appropriate State agency or department.

''(b) Upon finding that a further violation by this Act has occurred involving the same place of business for which the license was issued and the licensee has been served notice once under subsection (a), the appropriate State agency or department may initiate an administrative action to suspend the license for a period to be determined by the appropriate State agency or department but not to exceed six months. If an administrative action to suspend a license is initiated, the appropriate State agency or department shall immediately notify the licensee in writing at the notice address of the initiation of the action and the reasons therefor and permit the licensee an opportunity, at least 30 days after written notice is served personally or by registered mail upon the licensee, to show why suspension of the license would be unwarranted or unjust.

''(c) The appropriate State agency or department may initiate an administrative action to revoke a license that previously has been suspended under subsection (b) if, after the suspension and during the one-year period for which the license was issued, the licensee committed a further violation of this Act, at the same place of business for which the license was issued. If an administrative action to revoke a license is initiated, the appropriate State agency or department shall immediately notify the licensee in

writing at the notice address of the initiation of the action and the reasons therefor and permit the licensee an opportunity, at least 30 days after written notice is served personally or by registered mail upon the licensee, to show why revocation of the license would be unwarranted or unjust.

''(d) A person whose license has been suspended or revoked with respect to a place of business pursuant to this section shall pay a fee of $50 for the renewal or reissuance of the license at that same place of business, in addition to any applicable annual license fees.

''(e) Revocation of a license under subsection (c) with respect to a place of business shall not be grounds to deny an application by any person for a new license with respect to such place of business for more than 12 months subsequent to the date of such revocation. Revocation or suspension of a license with respect to a particular place of business shall not be grounds to deny an application for a new license, to refuse to renew a license, or to revoke or suspend an existing license at any other place of business.

''(f) A licensee may seek judicial review of an action of the appropriate State agency or department suspending, revoking, denying, or refusing to renew a license under this section by filing a complaint in a court of competent jurisdiction. Any such complaint shall be filed within 30 days after the date on which notice of the action is received by the licensee. The court shall review the evidence de novo.

''(g) The State shall not report any action suspending, revoking, denying, or refusing to renew a license under this section to the Federal Secretary of Health and Human Services, unless the opportunity for judicial review of the action pursuant to subsection (f), if any, has been exhausted or the time for seeking such judicial review has expired.

''SEC. 11. NO PRIVATE RIGHT OF ACTION.

''Nothing in this Act shall be construed to create a right of action by any private person for any violation of any provision of this Act.

''SEC. 12. JURISDICTION AND VENUE.

''Any action alleging a violation of this Act may be brought only in a court of general jurisdiction in the city or county where the violation is alleged to have occurred.

''SEC. 13. REPORT.

''The appropriate State agency or department shall prepare for submission annually to the Federal Secretary of Health and Human Services the report required by section 1926 of the Federal Public Health Service Act (42 U.S.C. 300x–26).'''.

''(2) In the case of a State whose legislature does not convene a regular session in fiscal year 2007, and in the case of a State whose legislature does not convene a regular session in fiscal year 2008, the requirement described in subsection (e)(1) as a condition of a receipt of a grant under section 300x–21 of this title shall apply only for fiscal year 2009 and subsequent fiscal years.

''(3) Subsection (e)(1) shall not affect any State or local law that (A) was in effect on the date of introduction of the Federal Tobacco Act of 2007, and (B) covers the same subject matter as the law described in subsection (e)(1). Any State law that meets the conditions of this paragraph shall also be deemed to meet the requirement described in subsection (e)(1) as a condition of a receipt of a grant under section 300x–21 of this title, if such State law is at least as stringent as the law described in subsection (e)(1).

''(f)(1) For the first applicable fiscal year and for each subsequent fiscal year, a funding agreement for a grant under section 300x–21 of this title is a funding agreement under which the State involved will enforce the law described in subsection (e)(1) of this section in a manner that can reasonably be expected to reduce the extent to which tobacco products are available to individuals under the age of 18 or a different minimum age established under State law for the purchase of tobacco products.

''(2) For the first applicable fiscal year and for each subsequent fiscal year, a funding agreement for a grant under section 300x–21 of this title is a funding agreement under which the State involved will—

''(A) conduct random, unannounced inspections to ensure compliance with the law described in subsection (e)(1); and

''(B) annually submit to the Secretary a report describing—

''(i) the activities carried out by the State to enforce such law during the fiscal year preceding the fiscal year for which the State is seeking the grant;

''(ii) the extent of success the State has achieved in reducing the availability of tobacco products to individuals under 18 years of age or a different minimum age established under State law, including the results of the inspections conducted under subparagraph (A); and

''(iii) the strategies to be utilized by the State for enforcing such law during the fiscal year for which the grant is sought.

''(g) The law specified in subsection (e)(1) may be administered and enforced by a State using—

''(1) any amounts made available to the State through a grant under section 300x–21 of this title;

''(2) any amounts made available to the State under section 300w of this title;

''(3) any fees collected for licenses issued pursuant to the law described in subsection (e)(1);

''(4) any fines or penalties assessed for violations of the law specified in subsection (e)(1); or

''(5) any other funding source that the legislature of the State may prescribe by statute.

''(h) Before making a grant under section 300x–21 of this title to a State for the first applicable fiscal year or any subsequent fiscal year, the Secretary shall make a determination of whether the State has maintained compliance with subsections (e) and (f) of this section. If, after notice to the State and an opportunity for a hearing, the Secretary determines that the State is not in compliance with such subsections, the Secretary shall reduce the amount of the allotment under section 300x–21 of this title for the State for the fiscal year involved by an amount equal to—

''(1) In the case of the first applicable fiscal year, 10 percent of the amount determined under section 300x–33 for the State for the fiscal year;

''(2) In the case of the first fiscal year following such applicable fiscal year, 20 percent of the amount determined under section 300x–33 for the State for the fiscal year;

''(3) In the case of the second such fiscal year, 30 percent of the amount determined under section 300x–33 for the State for the fiscal year; and

''(4) In the case of the third such fiscal year or any subsequent fiscal year, 40 percent of the amount determined under section 300x–33 for the State for the fiscal year.

The Secretary shall not have authority or discretion to grant to any State a waiver of the terms and requirements of this subsection or subsection (e) or (f).

''(i) For the purposes of subsections (e) through (h) of this section the term 'first applicable fiscal year' means—

''(1) fiscal year 2009, in the case of any State described in subsection (e)(2) of this section; and

''(2) fiscal year 2008, in the case of any other State.

''(j) For purposes of subsections (e) through (h) of this section, references to section 300x–21 shall include any successor grant programs.''

''(k) As required by paragraph (1), and subject to paragraph (4), an Indian tribe shall satisfy the requirements of subsection (e)(1) of this section by enacting a law or ordinance with substantially the same provisions as the law described in subsection (e)(1).

''(1) An Indian tribe shall comply with subsection (e)(1) of this section within 180 days after the Administrator finds, in accordance with this paragraph, that—

''(A) the Indian tribe has a governing body carrying out substantial governmental powers and duties;

''(B) the functions to be exercised by the Indian tribe under this Act pertain to activities on trust land within the jurisdiction of the tribe; and

''(C) the Indian tribe is reasonably expected to be capable of carrying out the functions required under this section.

Within 2 years of the date of enactment of the Federal Tobacco Act of 2007, as to each Indian tribe in the United States, the Administrator shall make the findings contemplated by this paragraph or determine that such findings cannot be made, in accordance with the procedures specified in paragraph (4).

''(2) As to Indian tribes subject to subsection (e)(1) of this section, the Administrator shall promulgate regulations that—

''(A) provide whether and to what extent, if any, the law described in subsection (e)(1) may be modified as adopted by Indian tribes; and

''(B) ensure, to the extent possible, that each Indian tribe's retailer licensing program under subsection (e)(1) is no less stringent than the program of the State or States in which the Indian tribe is located.

''(3) If with respect to any Indian tribe the Administrator determines that compliance with the requirements of subsection (e)(1) is inappropriate or administratively infeasible, the Administrator shall specify other means for the Indian tribe to achieve the purposes of the law described in subsection (e)(1) with respect to persons who engage in the distribution at retail of tobacco products on tribal lands.

''(4) The findings and regulations promulgated under paragraphs (1) and (2) shall be promulgated in conformance with section 553 of title 5, United States Code, and shall comply with the following provisions:

''(A) In making findings as provided in paragraph (1), and in drafting and promulgating regulations as provided in paragraph (2) (including drafting and promulgating any revised regulations), the Administrator shall confer with, and allow for active participation by, representatives and members of Indian tribes, and tribal organizations.

''(B) In carrying out rulemaking processes under this subsection, the Administrator shall follow the guidance of subchapter III of chapter 5 of title 5, United States Code, commonly known as the 'Negotiated Rulemaking Act of 1990.'

''(C) The tribal participants in the negotiation process referred to in subparagraph (B) shall be nominated by and shall represent the groups described in this subsection and shall include tribal representatives from all geographic regions.

''(D) The negotiations conducted under this paragraph (4) shall be conducted in a timely manner.

''(E) If the Administrator determines that an extension of the deadlines under subsection (k)(1) of this section is appropriate,

the Secretary may submit proposed legislation to Congress for the extension of such deadlines.

''(5) This subsection shall not affect any law or ordinance that (A) was in effect on tribal lands on the date of introduction of the Preventing Disease and Death from Tobacco Use Act, and (B) covers the same subject matter as the law described in subsection (e)(1). Any law or ordinance that meets the conditions of this paragraph shall also be deemed to meet the requirement described in subsection (k)(1), if such law or ordinance is at least as stringent as the law described in subsection (e)(1).

''(6) For purposes of this subsection—

''(A) 'Administrator' means the Administrator of the Tobacco Harm Reduction Center.

''(B) 'Indian tribe' has the meaning assigned that term in section 4(e) of the Indian Self Determination and Education Assistance Act, section 450b(e) of title 25, United States Code.

''(C) 'Tribal lands' means all lands within the exterior boundaries of any Indian reservation, all lands the title to which is held by the United States in trust for an Indian tribe, or lands the title to which is held by an Indian tribe subject to a restriction by the United States against alienation, and all dependent Indian communities.

''(D) 'tribal organization' has the meaning assigned that term in section 4(l) of the Indian Self Determination and Education Assistance Act, section 450b(l) of title 25, United States Code.''.

SEC. 403. ESTABLISHMENT OF RANKINGS.

(a) STANDARDS AND PROCEDURES FOR RANKINGS.—Within 24 months after the effective date of this Act, the Administrator shall, by regulation, after consultation with an Advisory Committee established for such purpose, establish the standards and procedures for promulgating rankings, comprehensible to consumers of tobacco products, of the following categories of tobacco products and also nicotine-containing products on the basis of the relative risks of serious or chronic tobacco-related diseases and adverse health conditions those categories of tobacco products and also nicotine-containing products respectively present—

(1) cigarettes;

(2) loose tobacco for roll-your-own tobacco products;

(3) little cigars;

(4) cigars;

(5) pipe tobacco;

(6) moist snuff;

(7) dry snuff;

(8) chewing tobacco;

(9) other forms of tobacco products, including pelletized tobacco and compressed tobacco, treated collectively as a single category; and

(10) other nicotine-containing products, treated collectively as a single category.

The Administrator shall not have authority or discretion to establish a relative-risk ranking of any category or subcategory of tobacco products or any category or subcategory of nicotine-containing products other than the ten categories specified in this subsection.

(b) CONSIDERATIONS IN PROMULGATING REGULATIONS.—In promulgating regulations under this section, the Administrator—

(1) shall take into account relevant epidemiologic studies and other relevant competent and reliable scientific evidence; and

(2) in assessing the risks of serious or chronic tobacco-related diseases and adverse health conditions presented by a particular category, shall consider the range of tobacco products or nicotine-containing products within the category, and shall give appropriate weight to the market shares of the respective products in the category.

(c) PROMULGATION OF RANKINGS OF CATEGORIES.—Once the initial regulations required by subsection (a) are in effect, the Administrator shall promptly, by order, after notice and an opportunity for comment, promulgate to the general public rankings of the categories of tobacco products and nicotine-containing products in accordance with those regulations. The Administrator shall promulgate the initial rankings of those categories of tobacco products and nicotine-containing products to the general public not later than January 1, 2010. Thereafter, on an annual basis, the Administrator shall, by order, promulgate to the general public updated rankings that are (1) in accordance with those regulations, and (2) reflect the scientific evidence available at the time of promulgation. The Administrator shall open and maintain an ongoing public docket for receipt of data and other information submitted by any person with respect to such annual promulgation of rankings.

TITLE V—ENFORCEMENT PROVISIONS

SEC. 501. PROHIBITED ACTS.

The following acts and the causing thereof are hereby prohibited—

(1) the introduction or delivery for introduction into interstate commerce of any tobacco product that is adulterated or misbranded;

(2) the adulteration or misbranding of any tobacco product in interstate commerce;

(3) the receipt in interstate commerce of any tobacco product that is known to be adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise;

(4) the failure to establish or maintain any record, or make any report or other submission, or to provide any notice required by or under this Act; or the refusal to permit access to, verification of, or copying of any record as required by this Act;

(5) the refusal to permit entry or inspection as authorized by this Act;

(6) the making to the Administrator of a statement, report, certification or other submission required by this Act, with knowledge that such statement, report, certification, or other submission is false in a material aspect;

(7) the manufacturing, shipping, receiving, storing, selling, distributing, possession, or use of any tobacco product with knowledge that it is an illicit tobacco product;

(8) the forging, simulating without proper permission, falsely representing, or without proper authority using any brand name;

(9) the using by any person to his or her own advantage, or revealing, other than to the Administrator or officers or employees of the Agency, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of this Act concerning any item which as a trade secret is entitled to protection; except that the foregoing does not authorize the withholding of information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee;

(10) the alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a tobacco product, if such act is done while such tobacco product is held for sale (whether or not the first sale) after shipment in interstate commerce, and results in such tobacco product being adulterated or misbranded;

(11) the importation of any tobacco product that is adulterated, misbranded, or otherwise not in compliance with this Act; and

(12) the commission of any act prohibited by section 201 of this Act.

SEC. 502. INJUNCTION PROCEEDINGS.

(a) The district courts of the United States shall have jurisdiction, for cause shown, to restrain violations of this Act, except for violations of section 701(k).

(b) In case of an alleged violation of an injunction or restraining order issued under this section, which also constitutes a violation of this Act, trial shall be by the court, or upon demand of the defendant, by a jury.

SEC. 503. PENALTIES.

(a) CRIMINAL PENALTIES.—Any person who willfully violates a provision of section 501 of this Act shall be imprisoned for not more than one year or fined not more than $25,000, or both.

(b) CIVIL PENALTIES FOR VIOLATION OF SECTION 803.—

(1) Any person who knowingly distributes or sells, other than through retail sale or retail offer for sale, any cigarette brand style in violation of section 803(a)—

(A) for a first offense shall be liable for a civil penalty not to exceed $10,000 for each distribution or sale, or

(B) for a second offense shall be liable for a civil penalty not to exceed $25,000 for each distribution or sale,

except that the penalty imposed against any person with respect to violations during any 30-day period shall not exceed $100,000.

(2) Any retailer who knowingly distributes, sells or offers for sale any cigarette brand style in violation of section 803(a) shall—

(A) for a first offense for each sale or offer for sale of cigarettes, if the total number of packages of cigarettes sold or offered for sale—

(i) does not exceed 50 packages of cigarettes, be liable for a civil penalty not to exceed $500 for each sale or offer for sale, and

(ii) exceeds 50 packages of cigarettes, be liable for a civil penalty not to exceed $1,000 for each sale or offer for sale;

(B) for each subsequent offense for each sale or offer for sale of cigarettes, if the total number of cigarettes sold or offered for sale—

(i) does not exceed 50 packages of cigarettes, be liable for a civil penalty not to exceed $2,000 for each sale or offer for sale, and

(ii) exceeds 50 packages of cigarettes, be liable for a civil penalty not to exceed $5,000 for each sale or offer for sale;

except that the penalty imposed against any person during any 30-day period shall not exceed $25,000.

SEC. 504. SEIZURE.

(a) ARTICLES SUBJECT TO SEIZURE.—

(1) Any tobacco product that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of this Act, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the tobacco product is found. No libel for condemnation shall be instituted under this Act for any alleged misbranding if there is pending in any court a libel for condemnation proceeding under this Act based upon the same alleged misbranding, and not more than one such proceeding shall be instituted if no such proceeding is so pending, except that such limitations shall not apply—

(A) when such misbranding has been the basis of a prior judgment in favor of the United States, in a criminal, injunction, or libel for condemnation proceeding under this Act, or

(B) when the Administrator has probable cause to believe from facts found, without hearing, by the Administrator or any officer or employee of the Agency that the misbranded tobacco product is dangerous to health beyond the inherent danger to health posed by tobacco, or that the labeling of the misbranded tobacco product is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer. In any case where the number of libel for condemnation proceedings is limited as above provided, the proceeding pending or instituted shall, on application of the claimant, seasonably made, be removed for trial to any district agreed upon by stipulation between the parties, or, in case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, to which the case shall be removed for trial.

(2) The following shall be liable to be proceeded against at any time on libel of information and condemned in any district court of the United States within the jurisdiction of which they are found—

(A) any tobacco product that is an illicit tobacco product;

(B) any container of an illicit tobacco product;

(C) any equipment or thing used in making an illicit tobacco product; and

(D) any adulterated or misbranded tobacco product.

(3)(A) Except as provided in subparagraph (B), no libel for condemnation may be instituted under paragraph (1) or (2) against any tobacco product which—

(i) is misbranded under this Act because of its advertising, and

(ii) is being held for sale to the ultimate consumer in an establishment other than an establishment owned or operated by a manufacturer, packer, or distributor of the tobacco product.

(B) A libel for condemnation may be instituted under paragraph (1) or (2) against a tobacco product described in subparagraph (A) if the tobacco product's advertising which resulted in the tobacco product being misbranded was disseminated in the establishment in which the tobacco product is being held for sale to the ultimate consumer—

(i) such advertising was disseminated by, or under the direction of, the owner or operator of such establishment, or

(ii) all or part of the cost of such advertising was paid by such owner or operator.

(b) PROCEDURES.—The tobacco product, equipment, or other thing proceeded against shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty; except that on demand of either party any issue of fact joined in any such case shall be tried by jury. When libel for condemnation proceedings under this section, involving the same claimant and the same issues of adulteration or misbranding, are pending in two or more jurisdictions, such pending proceedings, upon application of the claimant seasonably made to the court of one such jurisdiction, shall be consolidated for trial by order of such court, and tried in (1) any district selected by the claimant where one of such proceedings is pending; or (2) a district agreed upon by stipulation between the parties. If no order for consolidation is so made within a reasonable time, the claimant may apply to the court of one such jurisdiction and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, in which all such pending proceedings shall be consolidated for trial and tried. Such order of consolidation shall not apply so as to require the removal of any case the date for trial of which has been fixed. The court granting such order shall give prompt notification thereof to the other courts having jurisdiction of the cases covered thereby.

(c) SAMPLES AND ANALYSES.—The court at any time after seizure up to a reasonable time before trial shall by order allow any party to a condemnation proceeding, the party's attorney or agent, to obtain a representative sample of the article seized and a true copy of the analysis, if any, on which the proceeding is based and the identifying marks or numbers, if any, of the packages from which the samples analyzed were obtained.

(d) DISPOSITION OF CONDEMNED TOBACCO PRODUCTS.—(1) Any tobacco product condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, direct; and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States; but such tobacco product shall not be sold under such decree contrary to the provisions of this Act or the laws of the jurisdiction in which sold. After entry of the decree and upon the payment of the costs of such proceedings and the execution of a good and sufficient bond conditioned that such article shall not be sold or disposed of contrary to the provisions of this Act or the laws of any State in which sold, the court may by order direct that such tobacco product be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this Act, under the supervision of an officer or employee duly designated by the Administrator; and the expenses of such supervision shall be paid by the person obtaining release of the tobacco product under bond. If the tobacco product was imported into the United States and the person seeking its release establishes (A) that the adulteration, misbranding, or violation did not occur after the tobacco product was imported, and (B) that the person seeking the release of the tobacco product had no cause for believing that it was adulterated, misbranded, or in violation before it was released from customs custody, the court may permit the tobacco product to be delivered to the owner for exportation under section 709 in lieu of destruction upon a showing by the owner that there is a reasonable certainty that the tobacco product will not be re-imported into the United States.

(2) The provisions of paragraph (1) of this subsection shall, to the extent deemed appropriate by the court, apply to any equipment or other thing which is not otherwise within the scope of such paragraph and which is referred to in paragraph (2) of subsection (a).

(3) Whenever in any proceeding under this section, involving paragraph (2) of subsection (a), the condemnation of any equipment or thing (other than a tobacco product) is decreed, the court shall allow the claim of any claimant, to the extent of such claimant's interest, for remission or mitigation of such forfeiture if such claimant proves to the satisfaction of the court (A) that such claimant has not caused the equipment or thing to be within one of the categories referred to in such paragraph (2) and has no interest in any tobacco product referred to therein, (B) that such claimant has an interest in such equipment or other thing as owner or lienor or otherwise, acquired by such claimant in good faith, and (C) that such claimant at no time had any knowledge or reason to believe that such equipment or other thing was being or would be used in, or to facilitate, the violation of laws of the United States relating to any illicit tobacco product.

(e) COSTS AND FEES.—When a decree of condemnation is entered against the tobacco product or other article, court costs and fees, and storage and other proper expenses shall be awarded against the person, if any, intervening as claimant of the tobacco product or other article.

(f) REMOVAL FOR TRIAL.—In the case of removal for trial of any case as provided by subsection (a) or (b)—

(1) The clerk of the court from which removal is made shall promptly transmit to the court in which the case is to be tried all records in the case necessary in order that such court may exercise jurisdiction.

(2) The court to which such case was removed shall have the powers and be subject to the duties, for purposes of such case, which the court from which removal was made would have had, or to which such court would have been subject, if such case had not been removed.

(g) ADMINISTRATIVE DETENTION OF TOBACCO PRODUCTS.—

(1) DETENTION AUTHORITY.—

(A) IN GENERAL.—An officer or qualified employee of the Agency may order the detention, in accordance with this subsection, of any tobacco product that is found during an inspection, examination, or investigation under this Act conducted by such officer or qualified employee, if the officer or qualified employee has credible evidence or information indicating that such article presents a threat of serious adverse health consequences beyond those normally inherent in the use of tobacco products.

(B) ADMINISTRATOR'S APPROVAL.—A tobacco product or component thereof may be ordered detained under subparagraph (A) if, but only if, the Administrator or an official designated by the Administrator approves the order. An official may not be so designated unless the official is an officer with supervisory responsibility for the inspection, examination, or investigation that led to the order.

(2) PERIOD OF DETENTION.—A tobacco product may be detained under paragraph (1) for a reasonable period, not to exceed 20 days, unless a greater period, not to exceed 30 days, is necessary, to institute an action under subsection (a) or section 702.

(3) SECURITY OF DETAINED TOBACCO PRODUCT.—An order under paragraph (1) may require that the tobacco product to be detained be labeled or marked as detained, and shall require that the tobacco product be maintained in or removed to a secure facility, as appropriate. A tobacco product subject to such an order shall not be transferred by any person from the place at which the tobacco product is ordered detained, or from the place to which the tobacco product is so removed, as the case may be, until released by the Administrator or until the expiration of the detention period applicable under such order, whichever occurs first. This subsection may not be construed as authorizing the delivery of the tobacco product pursuant to the execution of a bond while the tobacco product is subject to the order, and section 709 does not authorize the delivery of the tobacco product pursuant to the execution of a bond while the article is subject to the order.

(4) APPEAL OF DETENTION ORDER.—

(A) IN GENERAL.—With respect to a tobacco product ordered detained under paragraph (1), any person who would be entitled to be a

claimant of such tobacco product if the tobacco product were seized under subsection (a) may appeal the order to the Administrator. Within five days after such an appeal is filed, the Administrator, after providing opportunity for an informal hearing, shall confirm or terminate the order involved, and such confirmation by the Administrator shall be considered a final agency action for purposes of section 702 of title 5, United States Code. If during such five-day period the Administrator fails to provide such an opportunity, or to confirm or terminate such order, the order is deemed to be terminated.

(B) EFFECT OF INSTITUTING COURT ACTION.—The process under subparagraph (A) for the appeal of an order under paragraph (1) terminates if the Administrator institutes an action under subsection (a) or section 702 regarding the tobacco product involved.

SEC. 505. REPORT OF MINOR VIOLATIONS.

Nothing in this Act shall be construed as requiring the Administrator to report for prosecution, or for institution of libel or injunction proceedings, minor violations of this Act whenever the Administrator believes that the public interest will be adequately served by a suitable written notice or warning.

SEC. 506. INSPECTION.

(a) AUTHORITY TO INSPECT.—The Administrator shall have the power to inspect the premises of a tobacco product manufacturer for purposes of determining compliance with this Act, or the regulations promulgated under it. Officers of the Agency designated by the Administrator, upon presenting appropriate credentials and a written notice to the person in charge of the premises, are authorized to enter, at reasonable times, without a search warrant, any factory, warehouse, or other establishment in which tobacco products are manufactured, processed, packaged, or held for domestic distribution. Any such inspection shall be conducted within reasonable limits and in a reasonable manner, and shall be limited to examining only those things, including but not limited to records, relevant to determining whether violations of this Act, or regulations under it, have occurred. No inspection authorized by this section shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act), or research data. A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.

(b) REPORT OF OBSERVATIONS.—Before leaving the premises, the officer of the Agency who has supervised or conducted the inspection shall give to the person in charge of the premises a report in writing setting forth any conditions or practices that appear to manifest a violation of this Act, or the regulations under it.

(c) SAMPLES.—If the officer has obtained any sample in the course of inspection, prior to leaving the premises that officer shall give to the person in charge of the premises a receipt describing the samples obtained. As to each sample obtained, the officer shall furnish promptly to the person in charge of the premises a copy of the sample and of any analysis made upon the sample.

SEC. 507. EFFECT OF COMPLIANCE.

Compliance with the provisions of this Act and the regulations promulgated under it shall constitute a complete defense to any civil action, including but not limited to any products liability action, that seeks to recover damages, whether compensatory or punitive, based upon an alleged defect in the labeling or advertising of any tobacco product distributed for sale domestically.

SEC. 508. IMPORTS.

(a) IMPORTS; LIST OF REGISTERED FOREIGN ESTABLISHMENTS; SAMPLES FROM UNREGISTERED FOREIGN ESTABLISHMENTS; EXAMINATION AND REFUSAL OF ADMISSION.—The Secretary of Homeland Security shall deliver to the Administrator, upon request by the Administrator, samples of tobacco products that are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may appear before the Administrator and have the right to introduce testimony. The Administrator shall furnish to the Secretary of Homeland Security a list of establishments registered pursuant to subsection (d) of section 109 of this Act, and shall request that, if any tobacco products manufactured, prepared, or processed in an establishment not so registered are imported or offered for import into the United States, samples of such tobacco products be delivered to the Administrator, with notice of such delivery to the owner or consignee, who may appear before the Administrator and have the right to introduce testimony. If it appears from the examination of such samples or otherwise that (1) such tobacco product is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or (2) such tobacco product is adulterated, misbranded, or otherwise in violation of this Act, then such tobacco product shall be refused admission, except as provided in subsection (b) of this section. The Secretary of Homeland Security shall cause the destruction of any such tobacco product refused admission unless such tobacco product is exported, under regulations prescribed by the Secretary of Homeland Security, within ninety days of the date of notice of such refusal or within such additional time as may be permitted pursuant to such regulations.

(b) DISPOSITION OF REFUSED TOBACCO PRODUCTS.—Pending decision as to the admission of a tobacco product being imported or offered for import, the Secretary of Homeland Security may authorize delivery of such tobacco product to the owner or consignee upon the execution by such consignee of a good and sufficient bond providing for the payment of such liquidated damages in the event of default as may be required pursuant to regulations of the Secretary of Homeland Security. If it appears to the Administrator that a tobacco product included within the provisions of clause (3) of subsection (a) of this section can, by relabeling or other action, be brought into compliance with this Act or rendered other than a tobacco product, final determination as to admission of such tobacco product may be deferred and, upon filing of timely written application by the owner or consignee and the execution by such consignee of a bond as provided in the preceding provisions of this subsection, the Administrator may, in accordance with regulations, authorize the applicant to perform such relabeling or other action specified in such authorization (including destruction or export of rejected tobacco products or portions thereof, as may be specified in the Administrator's authorization). All such relabeling or other action pursuant to such authorization shall in accordance with regulations be under the supervision of an officer or employee of the Agency designated by the Administrator, or an officer or employee of the Department of Homeland Security designated by the Secretary of Homeland Security.

(c) CHARGES CONCERNING REFUSED TOBACCO PRODUCTS.—All expenses (including travel, per diem or subsistence, and salaries of officers or employees of the United States) in connection with the destruction provided for in subsection (a) of this section and the supervision of the relabeling or other action authorized under the provisions of subsection (b) of this section, the amount of such expenses to be determined in accordance with regulations, and all expenses in connection with the storage, cartage, or labor with respect to any tobacco product refused admission under subsection (a) of this section, shall be paid by the owner or consignee and, in default of such payment, shall constitute a lien against any future importations made by such owner or consignee.

SEC. 509. TOBACCO PRODUCTS FOR EXPORT.

(a) EXEMPTION FOR TOBACCO PRODUCTS EXPORTED.—Except as provided in subsection (b), a tobacco product intended for export shall be exempt from this Act if—

(1) it is not in conflict with the laws of the country to which it is intended fore export, as shown by either (A) a document issued by the government of that country or (B) a document provided by a person knowledgeable with respect to the relevant laws of that country and qualified by training and experience to opine on whether the tobacco product is or is not in conflict with such laws;

(2) it is labeled on the outside of the shipping package that it is intended for export; and

(3) the particular units of tobacco product intended for export have not been sold or offered for sale in domestic commerce.

(b) PRODUCTS FOR U.S. ARMED FORCES OVERSEAS.—A tobacco product intended for export shall not be exempt from this Act if it is intended for sale or distribution to members or units of the Armed Forces of the United States located outside of the United States.

(c) This Act shall not apply to a person that manufactures and/or distributes tobacco products solely for export under subsection (a), except to the extent such tobacco products are subject to subsection (b).

TITLE VI—MISCELLANEOUS PROVISIONS

SEC. 601. USE OF PAYMENTS UNDER THE MASTER SETTLEMENT AGREEMENT AND INDIVIDUAL STATE SETTLEMENT AGREEMENTS.

(a) REDUCTION OF GRANT AMOUNTS.—(1) For fiscal year 2010 and each subsequent fiscal year, the Secretary shall reduce, as provided in subsection (b), the amount of any grant under section 1921 of the Public Health Service Act (42 U.S.C. § 300x–21) for any State that spends on tobacco control programs from the funds received by such State pursuant to the Master Settlement Agreement, the Florida Settlement Agreement, the Minnesota Settlement Agreement, the Mississippi Memorandum of Understanding, or the Texas Settlement Agreement, as applicable, less than 20 percent of the amounts received by that State from settlement payments.

(2) In the case of a State whose legislature does not convene a regular session in fiscal year 2009 or 2010, and in the case of a State whose legislature does not convene a regular session in fiscal year 2010, the requirement described in subsection (a)(1) as a condition of receipt of a grant under section 1921 of the Public Health Service Act shall apply only for fiscal year 2009 and subsequent fiscal years.

(b) DETERMINATION OF STATE SPENDING.—Before making a grant under section 1921 of the Public Health Service Act, section 300x–21 of title 42, United States Code, to a State for the first applicable fiscal year or any subsequent fiscal year, the Secretary shall make a determination of whether, during the immediately preceding fiscal year, the State has spent on tobacco control programs, from

the funds received by such State pursuant to the Master Settlement Agreement, the Florida Settlement Agreement, the Minnesota Settlement Agreement, the Mississippi Memorandum of Understanding, or the Texas Settlement Agreement, as applicable, at least the amount referenced in (a)(1). If, after notice to the State and an opportunity for a hearing, the Secretary determines that the State has spent less than such amount, the Secretary shall reduce the amount of the allotment under section 300x–21 of title 42, United States Code, for the State for the fiscal year involved by an amount equal to—

(1) in the case of the first applicable fiscal year, 10 percent of the amount determined under section 300x–33 of title 42, United States Code, for the State for the fiscal year;

(2) in the case of the first fiscal year following such applicable fiscal year, 20 percent of the amount determined under section 300x–33 of title 42, United States Code, for the State for the fiscal year;

(3) in the case of the second such fiscal year, 30 percent of the amount determined under section 300x–33 of title 42, United States Code, for the State for the fiscal year; and

(4) in the case of the third such fiscal year or any subsequent fiscal year, 40 percent of the amount determined under section 300x–33 of title 42, United States Code, for the State for the fiscal year.

The Secretary shall not have authority or discretion to grant to any State a waiver of the terms and requirements of this subsection or subsection (a).

(c) DEFINITIONS.—For the purposes of this section—

(1) The term ''first applicable fiscal year'' means—

(A) fiscal year 2011, in the case of any State described in subsection (a)(2) of this section; and

(B) fiscal year 2010, in the case of any other State.

(2) The term ''Florida Settlement Agreement'' means the Settlement Agreement, together with the exhibits thereto, entered into on August 25, 1997, between the State of Florida and signatory tobacco product manufacturers, as specified therein.

(3) The term ''Master Settlement Agreement'' means the Master Settlement Agreement, together with the exhibits thereto, entered into on November 23, 1998, between the signatory States and signatory tobacco product manufacturers, as specified therein.

(4) The term ''Minnesota Settlement Agreement'' means the Settlement Agreement, together with the exhibits thereto, entered into on May 8, 1998, between the State of Minnesota and signatory tobacco product manufacturers, as specified therein.

(5) The term ''Mississippi Memorandum of Understanding'' means the Memorandum of Understanding, together with the exhibits thereto and Settlement Agreement contemplated therein, entered into on July 2, 1997, between the State of Mississippi and signatory tobacco product manufacturers, as specified therein.

(6) The term ''Secretary'' means the Secretary of Health and Human Services.

(7) The term ''Texas Settlement Agreement'' means the Settlement Agreement, together with the exhibits thereto, entered into on January 16, 1998, between the State of Texas and signatory tobacco product manufacturers, as specified therein.

SEC. 602. PREEMPTION OF STATE LAWS IMPLEMENTING FIRE SAFETY STANDARD FOR CIGARETTES.

(a) IN GENERAL.—With respect to fire safety standards for cigarettes, no State or political subdivision shall—

(1) require testing of cigarettes that would be in addition to, or different from, the testing prescribed in subsection (b); or

(2) require a performance standard that is in addition to, or different from, the performance standard set forth in subsection (b).

(b) TEST METHOD AND PERFORMANCE STANDARD.—

(1) To the extent a State or political subdivision enacts or has enacted legislation or a regulation setting a fire safety standard for cigarettes, the test method employed shall be—

(A) the American Society of Testing and Materials (''ASTM'') standard E2187–4, entitled ''Standard Test Method for Measuring the Ignition Strength of Cigarettes'';

(B) for each cigarette on 10 layers of filter paper;

(C) so that a replicate test of 40 cigarettes for each brand style of cigarettes comprises a complete test trial for that brand style; and

(D) in a laboratory that has been accredited in accordance with ISO/IEC 17205 of the International Organization for Standardization (''ISO'') and that has an implemented quality control and quality assurance program that includes a procedure capable of determining the repeatability of the testing results to a repeatability value that is no greater than 0.19.

(2) To the extent a State or political subdivision enacts or has enacted legislation or a regulation setting a fire safety standard for cigarettes, the performance standard employed shall be that no more than 25 percent of the cigarettes of that brand style tested in a complete test in accordance with paragraph (1) exhibit full-length burns

(c) EXCEPTION TO SUBSECTION (b).—In the event that a manufacturer of a cigarette that a State or political subdivision or its respective delegated agency determines cannot be tested in accordance with the test method prescribed in subsection (b)(1)(A), the manufacturer shall propose a test method and performance standard for the cigarette to the State or political subdivision. Upon approval of the proposed test method and a determination by the State or political division that the performance standard proposed by the manufacturer is equivalent to the performance standard prescribed in subsection (b)(2), the manufacturer may employ such test method and performance standard to certify such cigarette pursuant to this subsection notwithstanding subsection (b).

SEC. 603. INSPECTION BY THE ALCOHOL AND TOBACCO TAX TRADE BUREAU OF RECORDS OF CERTAIN CIGARETTE AND SMOKELESS TOBACCO SELLERS.

(a) IN GENERAL.—Any officer of the Bureau of the Alcohol and Tobacco Tax Trade Bureau may, during normal business hours, enter the premises of any person described in subsection (b) for the purposes of inspecting—

(1) any records or information required to be maintained by such person under the provisions of law referred to in subsection (d); or

(2) any cigarettes or smokeless tobacco kept or stored by such person at such premises.

(b) COVERED PERSONS.—Subsection (a) applies to any person who engages in a delivery sale, and who ships, sells, distributes, or receives any quantity in excess of 10,000 cigarettes, or any quantity in excess of 500 single-unit consumer-sized cans or packages of smokeless tobacco, within a single month.

(c) RELIEF.—

(1) IN GENERAL.—The district courts of the United States shall have the authority in a civil action under this subsection to compel inspections authorized by subsection (a).

(2) VIOLATIONS.—Whoever violates subsection (a) or an order issued pursuant to paragraph (1) shall be subject to a civil penalty in an amount not to exceed $10,000 for each violation.

(d) COVERED PROVISIONS OF LAW.—The provisions of law referred to in this subsection are—

(1) the Act of October 19, 1949 (15 U.S.C. 375; commonly referred to as the ''Jenkins Act'');

(2) chapter 114 of title 18, United States Code; and

(3) this Act.

(e) DELIVERY SALE DEFINED.—In this section, the term ''delivery sale'' has the meaning given that term in 2343(e) of title 18, United States Code, as amended by this Act.

SEC. 604. SEVERABILITY.

If any provision of this Act, the amendments made by this Act, or the application of any provision of this Act to any person or circumstance is held to be invalid, the remainder of this Act, the amendments made by this Act, and the application of the provisions of this Act to any other person or circumstance shall not be affected, and shall continue to be enforced to the fullest extent possible.

TITLE VII—TOBACCO GROWER PROTECTION

SEC. 701. TOBACCO GROWER PROTECTION.

No provision in this Act shall allow the Administrator or any other person to require changes to traditional farming practices, including standard cultivation practices, curing processes, seed composition, tobacco type, fertilization, soil, record keeping, or any other requirement affecting farming practices.

TITLE VIII—RESTRICTIONS ON YOUTH ACCESS TO TOBACCO PRODUCTS AND EXPOSURE OF YOUTHS TO TOBACCO PRODUCT MARKETING AND ADVERTISING

SEC. 801. PROHIBITIONS ON YOUTH TARGETING.

Effective beginning on the date that is 18 months after the effective date of this Act, no person shall engage in any of the following activities or practices in the advertising, promotion, or marketing of any tobacco product:

(1) The use, or causing the use, of any cartoon in the advertising, promoting, packaging, or labeling of any tobacco product.

(2) The use, or causing the use, of any human image in the advertising, promoting, packaging, or labeling of any tobacco product, except for the following:

(A) The use, or continued use, in advertising, promoting, marketing, packaging, or labeling of any human image appearing on a tobacco product package before December 31, 2009.

(B) The use, or continued use, of a human image in the advertising, promoting, or marketing of a tobacco product, if conducted solely in an adult-only facility or facilities.

(C) The use, or continued use, of a human image in a tobacco product communication means directed solely to persons that the tobacco product manufacturer has a good-faith belief are age-verified adults.

(3) The advertising of tobacco products in any magazine or newspaper intended for distribution to the general public.

(4) The engaging in any brand name sponsorship in the United States, other than a brand name sponsorship occurring solely in an adult-only facility or facilities.

(5) The engaging in any brand name sponsorship of any event in the United States in which any paid participants or contestants are youths.

(6) The sponsoring of any athletic event between opposing teams in any football, basketball, baseball, soccer, or hockey league.

(7)(A) The securing of a right, by agreement, to name any stadium or arena located within the United States with a brand name; or

(B) otherwise causing a stadium or arena located within the United States to be named with a brand name.

(8) The securing of a right by agreement pursuant to which payment is made or other consideration is provided to use a brand name in association with any football, basketball, baseball, soccer, or hockey league, or any team involved in any such league.

(9) The use of, or causing the use of, by agreement requiring the payment of money or other consideration, a brand name with any nationally recognized or nationally established trade name or brand designation of any non-tobacco item or service, or any nationally recognized or nationally established sports team, entertainment group or individual celebrity for purposes of advertising, except for an agreement between or among persons that enter into such agreement for the sole purpose of avoiding infringement claims.

(10) The license, express authorization, or otherwise causing of any person to use or advertise within the United States any brand name in a manner that—

(A) does not pertain to a tobacco product; or

(B) causes that person to use the brand name to advertise, promote, package or label, distribute, or sell any product or service that is not a tobacco product.

(11) The marketing, distribution, offering, selling, licensing, or authorizing of, or the causing to be marketed, distributed, offered, sold, licensed, or authorized, any apparel or other merchandise (other than a tobacco product) bearing a brand name, except—

(A) apparel or other merchandise that is used by individuals representing a tobacco product manufacturer within an adult-only facility and that is not distributed, by sale or otherwise, to any member of the general public;

(B) apparel or merchandise provided to an adult employee of a tobacco product manufacturer for use by such employee;

(C) items or materials used to hold or display tobacco products at retail;

(D) items or materials the sole function of which is to advertise tobacco products;

(E) written or electronic publications;

(F) coupons or other items used by adults solely in connection with the purchase of tobacco products;

(G) that the composition, structure, form, or appearance of any tobacco product, package, label, or labeling shall not be affected by the prohibitions of this paragraph; and

(H) that no person shall be required to retrieve, collect or otherwise recover any item or material that was marketed, distributed, offered, sold, licensed, or caused to be marketed, distributed, offered, sold, or licensed by such person.

(12) The distribution, or causing the distribution, of any free sample domestically, except in an adult-only facility or facilities to individuals who are age-verified adults.

(13) The making of, or causing to be made, any payment or the payment of, or causing to be paid, any other consideration to any other person to use, display, make reference to, or use as a prop in any performance medium (for the purposes of this paragraph, the terms ''performance medium'' and ''performance media'' mean any motion picture, television show, theatrical production or other live performance, live or recorded performance of music, commercial film or video, or video game), any tobacco product, tobacco product package, advertisement for a tobacco product, or any other item bearing a brand name; except for the following:

(A) Performance media for which the audience or viewers are within one or more adult-only facilities, if such performance media are not audible or visible to persons outside such adult-only facility or facilities.

(B) Performance media not intended to be heard or viewed by the general public.

(A) Instructional performance media that concern tobacco products and their use, and that are intended to be heard or viewed only by, or provided only to, age-verified adults.

(A) Performance media used in tobacco product communications to age-verified adults.

(14) Engaging in outdoor advertising or transit advertisements of tobacco products within the United States, except for the following:

(A) Advertising that is within an adult-only facility.

(B) The use of outdoor advertising for purposes of identification of an adult-only facility, to the extent that such outdoor advertising is placed at the site, premises, or location of the adult-only facility.

(C) The use of outdoor advertising in identifying a brand name sponsorship at an adult-only facility, if such outdoor advertising—

(i) is placed at the site, premises, or location of the adult-only facility where such brand name sponsorship will occur no more than 30 days before the start of the initial sponsored event; and

(ii) is removed within 10 days after the end of the last sponsored event.

(15) The distribution or sale domestically of any package or other container of cigarettes containing fewer than 20 cigarettes.

(16) The advertising of tobacco products on any broadcast, cable, or satellite transmission to a television or radio receiver, or other medium of electronic communication subject to the jurisdiction of the Federal Communications Commission, except electronic communications—

(A) contained on log-in or home pages containing no tobacco product advertising other than brand name identification;

(B) in an adult-only facility or facilities; or

(C) through the Internet or other individual user-accessible electronic communication means, including websites accessible using the Internet, if the advertiser takes reasonable action to restrict access to individuals who are adults by—

(i) requiring individuals accessing such electronic communications to be age-verified adults, and

(ii) making good faith efforts to verify that such individuals are adults.

(18) The distribution or sale of tobacco products directly to consumers by mail or courier, unless the person receiving purchase requests for tobacco products takes reasonable action to prevent delivery to individuals who are not adults by—

(A) requiring that the addressees of the tobacco products be age-verified adults;

(B) making good faith efforts to verify that such addressees are adults; and

(C) addressing the tobacco products delivered by mail, courier or common carrier to a physical address and not a post office box.

(19) The providing of any gift of a non-tobacco product, except matches, in connection with the purchase of a tobacco product.

(20) The engaging in the sponsorship or promotion, or causing the sponsorship or promotion, of any consumer sweepstakes, contest, drawing, or similar activity resulting in the award of a prize in connection with advertising.

(21) The offering, promoting, conducting, or authorizing, or causing to be offered, promoted, conducted, or authorized, any consumer sweepstakes, drawing, contest, or other activity resulting in the award of a prize, based on redemption of a proof-of-purchase, coupon, or other item awarded as a result of the purchase or use of a tobacco product.

(22) The making of, or causing to be made, any payment or the payment of, or causing to be paid, any other consideration, to any other person with regard to the display or placement of any cigarettes, or any advertising for cigarettes, in any retail establishment that is not an adult-only facility.

TITLE IX—USER FEES

SEC. 901. USER FEES.

(a) ASSESSMENT OF USER FEES.—The Administrator shall assess an annual user fee for each fiscal year beginning in fiscal year 2010, in an amount calculated in accordance with this section, upon each tobacco product manufacturer (including each importer) that is subject to this Act.

(b) USE OF FEE.—The Administrator shall utilize an amount equal to the amount of user fees collected under this section in each fiscal year to pay for the costs of the activities of the Tobacco Regulatory Agency related to the regulation of tobacco products under this Act.

(c) AMOUNT OF FEE.—

(1) IN GENERAL.—Except as provided in paragraph (2), the total amount of user fees assessed for each fiscal year pursuant to this section shall be sufficient, and shall not exceed the amount necessary, to pay for the costs of the activities described in subsection (b) for that fiscal year.

(2) TOTAL.—The total assessment under this section—

(A) for fiscal year 2010 shall be $100,000,000; and

(B) for each subsequent fiscal year, shall not exceed the limit on the assessment imposed during the previous fiscal year, as adjusted by the Administrator (after notice, published in the Federal Register) to reflect the greater of—

(i) the total percentage change that occurred in the Consumer Price Index for all urban consumers (all items; United States city average) for the 12-month period ending on June 30 preceding the fiscal year for which fees are being established; or

(ii) the total percentage change for the previous fiscal year in basic pay under the General Schedule in accordance with section 5332 of title 5, United States Code, as adjusted by any locality-based comparability payment pursuant to section 5304 of such title for Federal employees stationed in the District of Columbia.

(3) NOTIFICATION.—The Administrator shall notify each tobacco product manufacturer subject to this section of the amount of the annual assessment imposed on such tobacco product manufacturer under subsection (d). Such notifications shall occur not later than the July 31 prior to the beginning of the fiscal year for which such assessment is made, and payments of all assessments shall be made not later than 60 days after each such notification. Such notification shall contain a complete list of the assessments imposed on tobacco product manufacturers for that fiscal year.

(d) LIABILITY OF TOBACCO PRODUCT MANUFACTURERS FOR USER FEES.—

(1) IN GENERAL.—The user fee to be paid by each tobacco product manufacturer shall be determined in each fiscal year by multiplying—

(A) such tobacco product manufacturer's market share of tobacco products, as determined under regulations issued pursuant to subsection (e); by

(B) the total user fee assessment for such fiscal year, as determined under subsection (c).

(2) LIMITATION.—Except as provided in paragraph (3), no tobacco product manufacturer shall be required to pay a percentage of a total annual user fee for all tobacco product manufacturers that exceeds the market share of such manufacturer.

(3) FAILURE TO PAY.—If—

(A) a tobacco product manufacturer fails to pay its user fee share in full by the due date;

(B) the Administrator, after diligent inquiry, concludes that such manufacturer is unlikely to pay its user fee share in full by the time such payment will be needed by the Administrator; and

(C) the Administrator and the Department of Justice make diligent efforts to obtain payment in full from such tobacco product manufacturer;

the Administrator may re-allocate the unpaid amount owed by that tobacco product manufacturer to the other tobacco product manufacturers on the basis of their respective market shares. If the Administrator takes such action, the Administrator shall set a reasonable time, not less than 60 days from the date of the notice of the amount due, for payment of that amount. If and to the extent that the Administrator ultimately receives from that tobacco product manufacturer or any successor to such tobacco product manufacturer any payment in respect of the previously unpaid obligation, the Administrator shall credit such payment to the tobacco product manufacturers that paid portions of the re-allocated amount, in proportion to their respective payments of such amount.

(e) REGULATIONS.—Not later than 12 months after the date of enactment of this Act, the Administrator shall, by regulation, establish a system for determining the market shares of tobacco products for each tobacco product manufacturer subject to this section. In promulgating regulations under this subsection, the Administrator shall—

(1) take into account the differences between categories and subcategories of tobacco products in terms of sales, manner of unit packaging, and any other factors relevant to the calculation of market share for a tobacco product manufacturer;

(2) take into account that different tobacco product manufacturers rely to varying degrees on the sales of different categories and subcategories of tobacco products; and

(3) provide that the market share of tobacco products for each tobacco product manufacturer shall be recalculated on an annual basis.

SA 1245. Ms. STABENOW (for herself and Ms. MURKOWSKI) submitted an amendment intended to be proposed by her to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. __. REPORTING OF DATA IN APPLICATIONS FOR DRUGS, BIOLOGICAL PRODUCTS, AND DEVICES.

(a) DRUGS.—

(1) NEW DRUG APPLICATIONS.—Section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) is amended—

(A) in paragraph (1), in the second sentence—

(i) by striking ''drug, and (G)'' and inserting ''drug; (G)''; and

(ii) by inserting before the period the following: ''; and (H) the information required under paragraph (7)''; and

(B) by adding at the end the following:

''(7)(A) With respect to clinical data in an application under this subsection, the Secretary may deny such an application if the application fails to meet the requirements of sections 314.50(d)(5)(v) and 314.50(d)(5)(vi)(a) of title 21, Code of Federal Regulations.

''(B) The Secretary shall modify the sections referred to in subparagraph (A) to require that an application under this subsection include any clinical data possessed by the applicant that relates to the safety or effectiveness of the drug involved by gender, age, and racial subgroup.

''(C) Promptly after approving an application under this subsection, the Secretary shall, through an Internet site of the Department of Health and Human Services, make available to the public the information submitted to the Secretary pursuant to subparagraphs (A) and (B), subject to sections 301(j) and 520(h)(1) of this Act, subsection (b)(4) of section 552 of title 5, United States Code (commonly referred to as the 'Freedom of Information Act'), and other provisions of law that relate to trade secrets or confidential commercial information.

''(D) The Secretary shall develop guidance for staff of the Food and Drug Administration to ensure that applications under this subsection are adequately reviewed to determine whether the applications include the information required pursuant to subparagraphs (A) and (B).''.

(2) INVESTIGATIONAL NEW DRUG APPLICATIONS.—Section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) is amended—

(A) in paragraph (2), by striking ''Subject to paragraph (3),'' and inserting ''Subject to paragraphs (3) and (5),'' ; and

(B) by adding at the end the following:

''(5)(A) The Secretary may place a clinical hold (as described in paragraph (3)) on an investigation if the sponsor of the investigation fails to meet the requirements of section 312.33(a) of title 21, Code of Federal Regulations.

''(B) The Secretary shall modify the section referred to in subparagraph (A) to require that reports under such section include any clinical data possessed by the sponsor of the investigation that relates to the safety or effectiveness of the drug involved by gender, age, and racial subgroup.''.

(b) BIOLOGICAL PRODUCT LICENSE APPLICATIONS.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended by adding at the end the following:

''(k) The provisions of section 505(b)(7) of the Federal Food, Drug, and Cosmetic Act (relating to clinical data submission) apply with respect to an application under subsection (a) of this section to the same extent and in the same manner as such provisions apply with respect to an application under section 505(b) of such Act.''.

(c) DEVICES.—

(1) PREMARKET APPROVAL.—Section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e) is amended—

(A) in subsection (c)(1)—

(i) in subparagraph (G)—

(I) by moving the margin 2 ems to the left; and

(II) by striking ''and'' after the semicolon at the end;

(ii) by redesignating subparagraph (H) as subparagraph (I); and

(iii) by inserting after subparagraph (G) the following subparagraph:

''(H) the information required under subsection (d)(7); and''; and

(B) in subsection (d), by adding at the end the following paragraph:

''(7) To the extent consistent with the regulation of devices, the provisions of section 505(b)(7) (relating to clinical data submission) apply with respect to an application for premarket approval of a device under subsection (c) of this section to the same extent and in the same manner as such provisions apply with respect to an application for premarket approval of a drug under section 505(b).''.

(2) INVESTIGATIONAL DEVICES.—Section 520(g)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g)(2)) is amended by adding at the end the following subparagraph:

''(D) To the extent consistent with the regulation of devices, the provisions of section 505(i)(5) (relating to individual study information) apply with respect to an application for an exemption pursuant to subparagraph (A) of this paragraph to the same extent and in the same manner as such provisions apply with respect to an application for an exemption under section 505(i).''.

(d) RULES OF CONSTRUCTION.—This Act and the amendments made by this Act may not be construed—

(1) as establishing new requirements under the Federal Food, Drug, and Cosmetic Act relating to the design of clinical investigations that were not otherwise in effect on the day before the date of the enactment of this Act; or

(2) as having any effect on the authority of the Secretary of Health and Human Services to enforce regulations under the Federal Food, Drug, and Cosmetic Act that are not expressly referenced in this Act or the amendments made by this Act.

(e) APPLICATION.—This section and the amendments made by this section apply only with respect to applications received under section 505 or 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360e) or section 351 of the Public Health Service Act (42 U.S.C. 262) on or after the date of the enactment of this Act.

SA 1246. Mr. BURR (for himself and Mrs. HAGAN) submitted an amendment intended to be proposed to amendment SA 1247 proposed by Mr. DODD to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Preventing Disease and Death from Tobacco Use Act''.

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

Sec. 1. Short title; table of contents.
Sec. 2. Findings.
Sec. 3. Purpose.
Sec. 4. Scope and effect.
Sec. 5. Severability.
Sec. 6. Effective date.

TITLE I—AUTHORITY OF THE TOBACCO HARM REDUCTION CENTER

Sec. 100. Definitions.
Sec. 101. Center authority over tobacco products.
Sec. 102. Exclusion of other regulatory programs.

Sec. 103. Existing Federal statutes maintained.
Sec. 104. Proceedings in the name of the United States; subpoenas; preemption of State and local law; no private right of action.
Sec. 105. Adulterated tobacco products.
Sec. 106. Misbranded tobacco products.
Sec. 107. Submission of health information to the Administrator.
Sec. 108. Registration and listing.
Sec. 109. General provisions respecting control of tobacco products.
Sec. 110. Smoking article standards.
Sec. 111. Notification and other remedies.
Sec. 112. Records and reports on tobacco products.
Sec. 113. Application for review of certain smoking articles.
Sec. 114. Reduced risk tobacco products.
Sec. 115. Judicial review.
Sec. 116. Jurisdiction of and coordination with the Federal Trade Commission.
Sec. 117. Regulation requirement.
Sec. 118. Preservation of State and local authority.
Sec. 119. Tobacco Products Scientific Advisory Committee.
Sec. 120. Drug products used to treat tobacco dependence.

TITLE II—TOBACCO PRODUCTS WARNINGS; CONSTITUENT AND SMOKE CONSTITUENT DISCLOSURE

Sec. 201. Cigarette label and advertising warnings.
Sec. 202. Smokeless tobacco labels and advertising warnings.

TITLE III—PUBLIC DISCLOSURES BY TOBACCO PRODUCTS MANUFACTURERS

Sec. 301. Disclosures on packages of tobacco products.
Sec. 302. Disclosures on packages of smokeless tobacco.
Sec. 303. Public disclosure of ingredients.

TITLE IV—PREVENTION OF ILLICIT TRADE IN TOBACCO PRODUCTS

Sec. 401. Study and report on illicit trade.
Sec. 402. Amendment to section 1926 of the Public Health Service Act.
Sec. 403. Establishment of rankings.

TITLE V—ENFORCEMENT PROVISIONS

Sec. 501. Prohibited acts.
Sec. 502. Injunction proceedings.
Sec. 503. Penalties.
Sec. 504. Seizure.
Sec. 505. Report of minor violations.
Sec. 506. Inspection.
Sec. 507. Effect of compliance.
Sec. 508. Imports.
Sec. 509. Tobacco products for export.

TITLE VI—MISCELLANEOUS PROVISIONS

Sec. 601. Use of payments under the master settlement agreement and individual State settlement agreements.
Sec. 602. Inspection by the alcohol and tobacco tax trade bureau of records of certain cigarette and smokeless tobacco sellers.
Sec. 603. Severability.

TITLE VII—TOBACCO GROWER PROTECTION

Sec. 701. Tobacco grower protection.

TITLE VIII—RESTRICTIONS ON YOUTH ACCESS TO TOBACCO PRODUCTS AND EXPOSURE OF YOUTHS TO TOBACCO PRODUCT MARKETING AND ADVERTISING

Sec. 801. Prohibitions on youth targeting.

TITLE IX—MISCELLANEOUS PROVISIONS

Sec. 901. User fees.

SEC. 2. FINDINGS.

The Congress finds the following:

(1) Cigarette smoking is a leading cause of preventable deaths in the United States. Cigarette smoking significantly increases the risk of developing lung cancer, heart disease, chronic bronchitis, emphysema and other serious diseases with adverse health conditions.

(2) The risk for serious diseases is significantly affected by the type of tobacco product and the frequency, duration and manner of use.

(3) No tobacco product has been shown to be safe and without risks. The health risks associated with cigarettes are significantly greater than those associated with the use of smoke-free tobacco and nicotine products.

(4) Nicotine in tobacco products is addictive but is not considered a significant threat to health.

(5) It is the smoke inhaled from burning tobacco which poses the most significant risk of serious diseases.

(6) Quitting cigarette smoking significantly reduces the risk for serious diseases.

(7) Adult tobacco consumers have a right to be fully and accurately informed about the risks of serious diseases, the significant differences in the comparative risks of different tobacco and nicotine-based products, and the benefits of quitting. This information should be based on sound science.

(8) Governments, public health officials, tobacco manufacturers and others share a responsibility to provide adult tobacco consumers with accurate information about the various health risks and comparative risks associated with the use of different tobacco and nicotine products.

(9) Tobacco products should be regulated in a manner that is designed to achieve significant and measurable reductions in the morbidity and mortality associated with tobacco use. Regulations should enhance the information available to adult consumers to permit them to make informed choices, and encourage the development of tobacco and nicotine products with lower risks than cigarettes currently sold in the United States.

(10) The form of regulation should be based on the risks and comparative risks of tobacco and nicotine products and their respective product categories.

(11) The regulation of marketing of tobacco products should be consistent with constitutional protections and enhance an adult consumer's ability to make an informed choice by providing accurate information on the risks and comparative risks of tobacco products.

(12) Reducing the diseases and deaths associated with the use of cigarettes serves public health goals and is in the best interest of consumers and society. Harm reduction should be the critical element of any comprehensive public policy surrounding the health consequences of tobacco use.

(13) Significant reductions in the harm associated with the use of cigarettes can be achieved by providing accurate information regarding the comparative risks of tobacco products to adult tobacco consumers, thereby encouraging smokers to migrate to the use of smoke-free tobacco and nicotine products, and by developing new smoke-free tobacco and nicotine products and other actions.

(14) Governments, public health officials, manufacturers, tobacco producers and consumers should support the development, production, and commercial introduction of tobacco leaf, and tobacco and nicotine-based products that are scientifically shown to reduce the risks associated with the use of existing tobacco products, particularly cigarettes.

(15) Adult tobacco consumers should have access to a range of commercially viable tobacco and nicotine-based products.

(16) There is substantial scientific evidence that selected smokeless tobacco products can satisfy the nicotine addiction of inveterate smokers while eliminating most, if not all, risk of pulmonary and cardiovascular complications of smoking and while reducing the risk of cancer by more than 95 percent.

(17) Transitioning smokers to selected smokeless tobacco products will eliminate environmental tobacco smoke and fire-related hazards.

(18) Current ''abstain, quit, or die'' tobacco control policies in the United States may have reached their maximum possible public health benefit because of the large number of cigarette smokers either unwilling or unable to discontinue their addiction to nicotine.

(19) There is evidence that harm reduction works and can be accomplished in a way that will not increase initiation or impede smoking cessation.

(20) Health-related agencies and organizations, both within the United States and abroad have already gone on record endorsing Harm Reduction as an approach to further reducing tobacco related illness and death.

(21) Current Federal policy requires tobacco product labeling that leaves the incorrect impression that all tobacco product present equal risk.

SEC. 3. PURPOSE.

The purposes of this Act are—

(1) to provide authority to the Tobacco Harm Reduction Center by recognizing it as the primary Federal regulatory authority with respect to tobacco products as provided for in this Act;

(2) to ensure that the Center has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco;

(3) to authorize the Center to set national standards controlling the manufacture of tobacco products and the identity, public disclosure, and amount of ingredients used in such products;

(4) to provide new and flexible enforcement authority to ensure that there is effective oversight of the tobacco industry's efforts to develop, introduce, and promote less harmful tobacco products;

(5) to vest the Center with the authority to regulate the levels of tar, nicotine, and other harmful components of tobacco products;

(6) to ensure that consumers are better informed regarding the relative risks for death and disease between categories of tobacco products;

(7) to continue to allow the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage purchasers;

(8) to impose appropriate regulatory controls on the tobacco industry;

(9) to promote prevention, cessation, and harm reduction policies and regulations to reduce disease risk and the social costs associated with tobacco-related diseases;

(10) to provide authority to the Department of Health and Human Services to regulate tobacco products;

(11) to establish national policies that effectively reduce disease and death associated with cigarette smoking and other tobacco use;

(12) to establish national policies that encourage prevention, cessation, and harm reduction measures regarding the use of tobacco products;

(13) to encourage current cigarette smokers who will not quit to use noncombustible tobacco or nicotine products that have significantly less risk than cigarettes;

(14) to establish national policies that accurately and consistently inform adult tobacco consumers of significant differences in risk between respective tobacco products;

(15) to establish national policies that encourage and assist the development and awareness of noncombustible tobacco and nicotine products;

(16) to coordinate national and State prevention, cessation, and harm reduction programs;

(17) to impose measures to ensure tobacco products are not sold or accessible to underage purchasers; and

(18) to strengthen Federal and State legislation to prevent illicit trade in tobacco products.

SEC. 4. SCOPE AND EFFECT.

(a) INTENDED EFFECT.—Nothing in this Act (or an amendment made by this Act) shall be construed to—

(1) establish a precedent with regard to any other industry, situation, circumstance, or legal action;

(2) affect any action pending in Federal, State, or Tribal court, or any agreement, consent decree, or contract of any kind; or

(3) be applicable to tobacco products or component parts manufactured in the United States for export.

(b) AGRICULTURAL ACTIVITIES.—The provisions of this Act (or an amendment made by this Act) which authorize the Administrator to take certain actions with regard to tobacco and tobacco products shall not be construed to affect any authority of the Secretary of Agriculture under existing law regarding the growing, cultivation, or curing of raw tobacco.

(c) REVENUE ACTIVITIES.—The provisions of this Act (or an amendment made by this Act) which authorize the Administrator to take certain actions with regard to tobacco products shall not be construed to affect any authority of the Secretary of the Treasury under chapter 52 of the Internal Revenue Code of 1986.

SEC. 5. SEVERABILITY.

If any provision of this Act, the amendments made by this Act, or the application of any provision of this Act to any person or circumstance is held to be invalid, the remainder of this Act, the amendments made by this Act, and the application of the provisions of this Act to any other person or circumstance shall not be affected and shall continue to be enforced to the fullest extent possible.

SEC. 6. EFFECTIVE DATE.

Except as otherwise specifically provided, the effective date of this Act shall be the date of its enactment.

TITLE I—AUTHORITY OF THE TOBACCO HARM REDUCTION CENTER

SEC. 100. DEFINITIONS.

In this Act:

(1) The term ''Administrator'' means the chief executive of the Tobacco Regulatory Agency (the Agency responsible for administering and enforcing this Act and regulations promulgated pursuant to this Act).

(2) The term ''adult'' means any individual who has attained the minimum age under applicable State law to be an individual to whom tobacco products may lawfully be sold.

(3) The term ''adult-only facility'' means a facility or restricted area, whether open-air or enclosed, where the operator ensures, or has a reasonable basis to believe, that no youth is present. A facility or restricted area need not be permanently restricted to adults in order to constitute an adult-only facility, if the operator ensures, or has a reasonable basis to believe, that no youth is present during any period of operation as an adult-only facility.

(4) The term ''advertising'' means a communication to the general public by a tobacco product manufacturer, distributor, retailer, or its agents, which identifies a tobacco product by brand name and is intended by such manufacturer, distributor, retailer, or its agents to promote purchases of such tobacco product. Such term shall not include—

(A) any advertising or other communication in any tobacco trade publication or tobacco trade promotional material;

(B) the content of any scientific publication or presentation, or any patent application or other communication to the United States Patent and Trademark Office or any similar office in any other country;

(C) any corporate or financial report or financial communication;

(D) any communication to a lending institution or to securities holders;

(E) any communication not intended for public display or public exposure, except that a direct mailing or direct electronic communication of what otherwise is advertising shall be deemed to be advertising;

(F) any communication in, on, or within a factory, office, plant, warehouse, or other facility related to or associated with the development, manufacture, or storage of tobacco products;

(G) any communication to any governmental agency, body, official, or employee;

(H) any communication to any journalist, editor, Internet blogger, or other author;

(I) any communication in connection with litigation, including arbitration and like proceedings; or

(J) any editorial advertisement that addresses a public issue.

(5) The term ''affiliate'' means a person that directly or indirectly owns or controls, is owned or controlled by, or is under common ownership or control with, another person. The terms ''owns,'' ''is owned'', and ''ownership'' refer to ownership of an equity interest, or the equivalent thereof, of 50 percent or more.

(6) The term ''Agency'' means the Tobacco Regulatory Agency.

(7) The term ''age-verified adult'' means any individual who is an adult and—

(A) who has stated or acknowledged, after being asked, that he or she is an adult and a tobacco product user, and has presented proof of age identifying the individual and verifying that the individual is an adult; or

(B) whose status as an adult has been verified by a commercially available database of such information.

(8) The term ''annual report'' means a tobacco product manufacturer's annual report to the Agency, which provides ingredient information and nicotine yield ratings for each brand style that tobacco product manufacturer manufactures for commercial distribution domestically.

(9) The term ''brand name'' means a brand name of a tobacco product distributed or sold domestically, alone, or in conjunction with any other word, trademark, logo, symbol, motto, selling message, recognizable pattern of colors, or any other indicium of product identification identical or similar to, or identifiable with, those used for any domestic brand of tobacco product. The term shall not include the corporate name of any tobacco product manufacturer that does not, after the effective date of this Act, sell a brand style of tobacco product in the United States that includes such corporate name.

(10) The term ''brand name sponsorship'' means an athletic, musical, artistic, or other social or cultural event, series, or tour, with respect to which payment is made, or other consideration is provided, in exchange for use of a brand name or names—

(A) as part of the name of the event; or

(B) to identify, advertise, or promote such event or an entrant, participant, or team in such event in any other way.

(11) The term ''brand style'' means a tobacco product having a brand name, and distinguished by the selection of the tobacco, ingredients, structural materials, format, configuration, size, package, product descriptor, amount of tobacco, or yield of ''tar'' or nicotine.

(12) The term ''carton'' means a container into which packages of tobacco products are directly placed for distribution or sale, but does not include cases intended for shipping. Such term includes a carton containing 10 packages of cigarettes.

(13) The term ''cartoon'' means any drawing or other depiction of an object, person, animal, creature or any similar caricature that satisfies any of the following criteria:

(A) The use of comically exaggerated features.

(B) The attribution of human characteristics to animals, plants or other objects, or the similar use of anthropomorphic technique.

(C) The attribution of unnatural or extrahuman abilities, such as imperviousness to pain or injury, X-ray vision, tunneling at very high speeds, or transformation.

The term does not include any drawing or other depiction that, on the effective date of this Act, was in use in the United States in any tobacco product manufacturer's corporate logo or in any tobacco product manufacturer's tobacco product packaging.

(14) The term ''cigar'' has the meaning assigned that term by the Alcohol and Tobacco Tax and Trade Bureau in section 40.11 of title 27, Code of Federal Regulations.

(15) The term ''cigarette'' means—

(A) any roll of tobacco wrapped in paper or in any substance not containing tobacco; or

(B) any roll of tobacco wrapped in any substance containing tobacco which, because of the appearance of the roll of tobacco, the type of tobacco used in the filler, or its package or labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in subparagraph (A).

(16) The term ''competent and reliable scientific evidence'' means evidence based on tests, analyses, research, or studies, conducted and evaluated in an objective manner by individuals qualified to do so, using procedures generally accepted in the relevant scientific disciplines to yield accurate and reliable results.

(17) The term ''distributor'' means any person who furthers the distribution of tobacco products, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the tobacco product to individuals for personal consumption. Common carriers, retailers, and those engaged solely in advertising are not considered distributors for purposes of this Act.

(18) The terms ''domestic'' and ''domestically'' mean within the United States, including activities within the United States involving advertising, marketing, distribution, or sale of tobacco products that are intended for consumption within the United States.

(19) The term ''human image'' means any photograph, drawing, silhouette, statue, model, video, likeness, or depiction of the appearance of a human being, or the appearance of any portion of the body of a human being.

(20) The term ''illicit tobacco product'' means any tobacco product intended for use by consumers in the United States—

(A) as to which not all applicable duties or taxes have been paid in full;

(B) that has been stolen, smuggled, or is otherwise contraband;

(C) that is counterfeit; or

(D) that has or had a label, labeling, or packaging stating, or that stated, that the product is or was for export only, or that it is or was at any time restricted by section 5704 of title 26, United States Code.

(21) The term ''illicit trade'' means any transfer, distribution, or sale in interstate commerce of any illicit tobacco product.

(22) The term ''immediate container'' does not include package liners.

(23) The term ''Indian tribe'' has the meaning assigned that term in section 4(e) of the Indian Self Determination and Education Assistance Act (25 U.S.C. 450b(e)).

(24) The term ''ingredient'' means tobacco and any substance added to tobacco to have an effect in the final tobacco product or when the final tobacco product is used by a consumer.

(25) The term ''International Organization for Standardization (ISO) testing regimen'' means the methods for measuring cigarette smoke yields, as set forth in the most recent version of ISO 3308, entitled ''Routine analytical cigarette-smoking machine—Definition of standard conditions''; ISO 4387, entitled ''Cigarettes—Determination of total and nicotine-free dry particulate matter using a routine analytical smoking machine''; ISO 10315, entitled ''Cigarettes—Determination of nicotine in smoke condensates—Gas-chromatographic method''; ISO 10362–1, entitled ''Cigarettes—Determination of water in smoke condensates—Part 1: Gas-chromatographic method''; and ISO 8454, entitled ''Cigarettes—Determination of carbon monoxide in the vapour phase of cigarette smoke—NDIR method''. A cigarette that does not burn down in accordance with the testing regimen standards may be measured under the same puff regimen using the number of puffs that such a cigarette delivers before it extinguishes, plus an additional three puffs, or with such other modifications as the Administrator may approve.

(26) The term ''interstate commerce'' means all trade, traffic, or other commerce—

(A) within the District of Columbia, or any territory or possession of the United States;

(B) between any point in a State and any point outside thereof;

(C) between points within the same State through any place outside such State; or

(D) over which the United States has jurisdiction.

(27) The term ''label'' means a display of written, printed, or graphic matter upon or applied securely to the immediate container of a tobacco product.

(28) The term ''labeling'' means all labels and other written, printed, or graphic matter (1) upon or applied securely to any tobacco product or any of its containers or wrappers, or (2) accompanying a tobacco product.

(29) The term ''little cigar'' has the meaning assigned that term by the Alcohol and Tobacco Tax and Trade Bureau in section 40.11 of title 27, Code of Federal Regulations.

(30) The term ''loose tobacco'' means any form of tobacco, alone or in combination with any other ingredient or material, that, because of its appearance, form, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco for making or assembling cigarettes, incorporation into pipes, or otherwise used by consumers to make any smoking article.

(31) The term ''manufacture'' means to design, manufacture, fabricate, assemble, process, package, or repackage, label, or relabel, import, or hold or store in a commercial quantity, but does not include—

(A) the growing, curing, de-stemming, or aging of tobacco; or

(B) the holding, storing or transporting of a tobacco product by a common carrier for hire, a public warehouse, a testing laboratory, a distributor, or a retailer.

(32) The term ''nicotine-containing product'' means a product intended for human consumption, other than a tobacco product, that contains added nicotine, produced and intended to be absorbed from the skin, mouth, or nose, or inhaled as a vapor or aerosol.

(33) The term ''outdoor advertising''—

(A) except as provided in subparagraph (B), means—

(i) billboards;

(ii) signs and placards in arenas, stadiums, shopping malls, and video game arcades (whether any of such are open air or enclosed), but not including any such sign or placard located in an adult-only facility; and

(iii) any other advertisements placed outdoors; and

(B) does not include—

(i) an advertisement on the outside of a tobacco product manufacturing facility; or

(ii) an advertisement that—

(I) is inside a retail establishment that sells tobacco products (other than solely through a vending machine or vending machines);

(II) is placed on the inside surface of a window facing outward; and

(III) is no larger than 14 square feet.

(34) The term ''package'' means a pack, box, carton, pouch, or container of any kind in which a tobacco product or tobacco products are offered for sale, sold, or otherwise distributed to consumers. The term ''package'' does not include an outer container used solely for shipping one or more packages of a tobacco product or tobacco products.

(35) The term ''person'' means any individual, partnership, corporation, committee, association, organization or group of persons, or other legal or business entity.

(36) The term ''proof of age'' means a driver's license or other form of identification that is issued by a governmental authority and includes a photograph and a date of birth of the individual.

(37) The term ''raw tobacco'' means tobacco in a form that is received by a tobacco product manufacturer as an agricultural commodity, whether in a form that is—

(A) natural, stem or leaf;

(B) cured or aged; or (3)

(C) as parts or pieces, but not in a reconstituted form, extracted pulp form, or extract form.

(38) The term ''reduced-exposure claim'' means a statement in advertising or labeling that a tobacco product provides a reduced exposure to one or more toxicants, as compared to an appropriate reference tobacco product within the same category of tobacco products. Such a statement must include the wording ''reduction in risk has not been demonstrated for this reduction in exposure''. A statement or representation that a tobacco product or the tobacco in a tobacco product contains ''no additives'' or is ''natural'' or that uses a substantially similar term is not a reduced-exposure claim if the advertising or labeling that contains such statement or representation also contains the disclosure required by section 108(h) of this Act.

(39) The term ''reduced-risk claim'' means a statement in advertising or labeling that a tobacco product provides a reduced risk of illness and death compared to cigarettes. A statement or representation that a tobacco product or the tobacco in a tobacco product contains ''no additives,'' or is ''natural,'' or that uses a substantially similar term is not a reduced-risk claim if the advertising or labeling that contains such statement or representation also contains the disclosure required by section 108(h).

(40) The term ''retailer'' means any person that—

(A) sells tobacco products to individuals for personal consumption; or

(B) operates a facility where the sale of tobacco products to individuals for personal consumption is permitted.

(41) The term ''sample'' means a tobacco product distributed to members of the public at no cost for the purpose of promoting the product, but excludes tobacco products distributed—

(A) in conjunction with the sale of other tobacco products;

(B) for market research, medical or scientific study or testing, or teaching;

(C) to persons employed in the trade;

(D) to adult consumers in response to consumer complaints; or

(E) to employees of the manufacturer of the tobacco product.

(42) The term ''small business'' means a tobacco product manufacturer that—

(A) has 150 or fewer employees; and

(B) during the 3-year period prior to the current calendar year, had an average annual gross revenue from tobacco products that did not exceed $40,000,000.

(43) The term ''smokeless tobacco product'' means any form of finely cut, ground, powdered, reconstituted, processed or shaped tobacco, leaf tobacco, or stem tobacco, whether or not combined with any other ingredient, whether or not in extract or extracted form, and whether or not incorporated within any carrier or construct, that is intended to be placed in the oral or nasal cavity, including dry snuff, moist snuff, and chewing tobacco.

(44) The term ''smoking article'' means any tobacco-containing article that is intended, when used by a consumer, to be burned or otherwise to employ heat to produce a vapor, aerosol or smoke that—

(A) incorporates components of tobacco or derived from tobacco; and

(B) is intended to be inhaled by the user.

(45) The term ''State'' means any State of the United States and, except as otherwise specifically provided, includes any Indian tribe or tribal organization, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Island, Kingman Reef, Johnston Atoll, the Northern Marianas, and any other trust territory or possession of the United States.

(46) The term ''tar'' means nicotine-free dry particulate matter as defined in ISO 4387, entitled ''Cigarettes—Determination of total and nicotine-free dry particulate matter using a routine analytical smoking machine''.

(47) The term ''tobacco'' means a tobacco plant or any part of a harvested tobacco plant intended for use in the production of a tobacco product, including leaf, lamina, stem, or stalk, whether in green, cured, or aged form, whether in raw, treated, or processed form, and whether or not combined with other materials, including any by-product, extract, extracted pulp material, or any other material (other than purified nicotine) derived from a tobacco plant or any component thereof, and including strip, filler, stem, powder, and granulated, blended, or reconstituted forms of tobacco.

(48) The term ''tobacco product'' means—

(A) the singular of ''tobacco products'' as defined in section 5702(c) of the Internal Revenue Code of 1986;

(B) any other product that contains tobacco as a principal ingredient and that, because of its appearance, type, or the tobacco

used in the product, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a tobacco product as described in subparagraph (A); and

(C) any form of tobacco or any construct incorporating tobacco, intended for human consumption, whether by—

(i) placement in the oral or nasal cavity;

(ii) inhalation of vapor, aerosol, or smoke; or

(iii) any other means.

(49) The term ''tobacco product category'' means a type of tobacco product characterized by its composition, components, and intended use, and includes tobacco products classified as cigarettes, loose tobacco for roll-your-own tobacco products, little cigars, cigars, pipe tobacco, moist snuff, dry snuff, chewing tobacco, and other forms of tobacco products (which are treated in this Act collectively as a single category).

(50) The term ''tobacco product communication'' means any means, medium, or manner for providing information relating to any tobacco product, including face-to-face interaction, mailings by postal service or courier to an individual who is an addressee, and electronic mail to an individual who is an addressee.

(51) The term ''tobacco product manufacturer'' means an entity that directly—

(A) manufactures anywhere a tobacco product that is intended to be distributed commercially in the United States, including a tobacco product intended to be distributed commercially in the United States through an importer;

(B) is the first purchaser for resale in the United States of tobacco products manufactured outside the United States for distribution commercially in the United States; or

(C) is a successor or assign of any of the foregoing.

(52) The term ''toxicant'' means a chemical or physical agent that produces an adverse biological effect.

(53) The term ''transit advertisements'' means advertising on or within private or public vehicles and all advertisements placed at, on, or within any bus stop, taxi stand, transportation waiting area, train station, airport, or any similar location.

(54) The term ''tribal organization'' has the meaning assigned that term in section 4(1) of the Indian Self Determination and Education Assistance Act (25 U.S.C. 450b(1)).

(55) The term ''United States'' means the several States, as defined in this Act.

(56) The term ''vending machine'' means any mechanical, electric, or electronic self-service device that, upon insertion of money, tokens, or any other form of payment, automatically dispenses tobacco products.

(57) The term ''video game arcade'' means an entertainment establishment primarily consisting of video games (other than video games intended primarily for use by adults) or pinball machines.

(58) The term ''youth'' means any individual who in not an adult.

SEC. 101. CENTER AUTHORITY OVER TOBACCO PRODUCTS.

(a) IN GENERAL.—Tobacco products, including reduced risk tobacco products for which an order has been issued in accordance with section 117, shall be regulated by the Administrator under this Act.

(b) APPLICABILITY.—This Act shall apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Administrator by regulation deems to be subject to this Act.

(c) CENTER.—The Secretary of Health and Human Services shall establish within the Department of Health and Human Services the Tobacco Harm Reduction Center. The head of the Center shall be an Administrator, who shall assume the statutory authority conferred by this Act, perform the functions that relate to the subject matter of this Act, to conduct postmarket surveillance, research, and public education activities and have the authority to promulgate regulations for the efficient enforcement of this Act. In promulgating any regulations under such authority, in whole or in part or any regulation that is likely to have an annual effect on the economy of $50,000,000 or more or have a material adverse effect on adult users of tobacco products, tobacco product manufacturers, distributors, or retailers, the Administrator shall—

(1) determine the technological and economic ability of parties that would be required to comply with the regulation to comply with it;

(2) consider experience gained under any relevantly similar regulations at the Federal or State level;

(3) determine the reasonableness of the relationship between the costs of complying with such regulation and the public health benefits to be achieved by such regulation;

(4) determine the reasonable likelihood of measurable and substantial reductions in morbidity and mortality among individual tobacco users;

(5) determine the impact to United States tobacco producers and farm operations;

(6) determine the impact on the availability and use of tobacco products by minors; and

(7) determine the impact on illicit trade of tobacco products.

(d) LIMITATION OF AUTHORITY.—

(1) IN GENERAL.—The provisions of this Act shall not apply to tobacco leaf that is not in the possession of a manufacturer of tobacco products, or to the producers of tobacco leaf, including tobacco growers, tobacco warehouses, and tobacco grower cooperatives, nor shall any employee of the Center have any authority to enter onto a farm owned by a producer of tobacco leaf without the written consent of such producer.

(2) EXCEPTION.—Notwithstanding paragraph (1), if a producer of tobacco leaf is also a tobacco product manufacturer or controlled by a tobacco product manufacturer, the producer shall be subject to this Act in the producer's capacity as a manufacturer. The exception in this subparagraph shall not apply to a producer of tobacco leaf who grows tobacco under a contract with a tobacco product manufacturer and who is not otherwise engaged in the manufacturing process.

(3) RULE OF CONSTRUCTION.—Nothing in this Act shall be construed to grant the Administrator authority to promulgate regulations on any matter that involves the production of tobacco leaf or a producer thereof.

(e) RULEMAKING PROCEDURES.—Each rulemaking under this Act shall be in accordance with chapter 5 of title 5, United States Code.

(f) CONSULTATION PRIOR TO RULEMAKING.—Prior to promulgating rules under this Act, the Administrator shall endeavor to consult with other Federal agencies as appropriate.

SEC. 102. EXCLUSION OF OTHER REGULATORY PROGRAMS.

(a) EXCLUSION OF TOBACCO PRODUCTS AND NICOTINE-CONTAINING PRODUCTS FROM THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.—No tobacco product and no nicotine-containing product shall be regulated as a food, drug, or device in accordance with section 201 (f), (g) or (h) or Chapter IV or V of the Federal Food, Drug, and Cosmetic Act, except that any tobacco product commercially distributed domestically and any nicotine-containing product commercially distributed domestically shall be subject to Chapter V of the Federal Food, Drug, and Cosmetic Act if the manufacturer or a distributor of such product markets it with an explicit claim that the product is intended for use in the cure, mitigation, treatment, or prevention of disease in man or other animals, within the meaning of section 201(g)(1)(C) or section 201(h)(2) of that Act.

(b) LIMITATION ON EFFECT OF THIS ACT.—Nothing in this Act shall be construed to—

(1) establish a precedent with regard to any other industry, situation, circumstance, or legal action; or

(2) affect any action pending in any Federal, State, or Tribal court, or any agreement, consent decree, or contract of any kind.

(c) EXCLUSIONS FROM AUTHORITY OF ADMINISTRATOR.—The authority granted to the Administrator under this Act shall not apply to—

(1) raw tobacco that is not in the possession or control of a tobacco product manufacturer;

(2) raw tobacco that is grown for a tobacco product manufacturer by a grower, and that is in the possession of that grower or of a person that is not a tobacco product manufacturer and is within the scope of subparagraphs (A) through(F) of paragraph (3); or

(3) the activities, materials, facilities, or practices of persons that are not tobacco product manufacturers and that are—

(A) producers of raw tobacco, including tobacco growers;

(B) tobacco warehouses, and other persons that receive raw tobacco from growers;

(C) tobacco grower cooperatives;

(D) persons that cure raw tobacco;

(E) persons that process raw tobacco; and

(F) persons that store raw tobacco for aging.

If a producer of raw tobacco is also a tobacco product manufacturer, an affiliate of a tobacco product manufacturer, or a person producing raw tobacco for a tobacco product manufacturer, then that producer shall be subject to this Act only to the extent of that producer's capacity as a tobacco product manufacturer.

SEC. 103. EXISTING FEDERAL STATUTES MAINTAINED.

Except as amended or repealed by this Act, all Federal statutes in effect as of the effective date of this Act that regulate tobacco, tobacco products, or tobacco product manufacturers shall remain in full force and effect. Such statutes include, without limitation—

(1) the Federal Cigarette Labeling and Advertising Act, sections 1331–1340 of title 15, United States Code, except that section 1335 of title 15, United States Code, is repealed;

(2) the Comprehensive Smokeless Tobacco Health Education Act of 1986, sections 4401–4408 of title 15, United States Code, except that section 4402(f) of title 15, United States Code, is repealed;

(3) section 300x–26 of title 42, United States Code; and

(4) those statutes authorizing regulation of tobacco, tobacco products, or tobacco product manufacturers by the Federal Trade Commission, the Department of Agriculture, the Environmental Protection Agency, the Internal Revenue Service, and the Alcohol and Tobacco Tax and Trade Bureau of the Department of the Treasury.

SEC. 104. PROCEEDINGS IN THE NAME OF THE UNITED STATES; SUBPOENAS; PREEMPTION OF STATE AND LOCAL LAW; NO PRIVATE RIGHT OF ACTION.

In furtherance of this Act:

(1) All proceedings for the enforcement, or to restrain violations, of this Act shall be by and in the name of the United States. Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any

proceeding under this section. No State, or political subdivision thereof, may proceed or intervene in any Federal or State court under this Act or under any regulation promulgated under it, or allege any violation thereof except a violation by the Administrator. Nothing in this Act shall be construed to create a right of action by any private person for any violation of any provision of this Act or of any regulation promulgated under it.

(2) With respect to any subject matter addressed by this Act or by any regulation promulgated under it, no requirement or prohibition shall be imposed under State or local law upon any tobacco product manufacturer or distributor.

(3) Paragraph (2) shall not apply to any requirement or prohibition imposed under State or local law before the date of introduction of the bill that was enacted as this Act.

SEC. 105. ADULTERATED TOBACCO PRODUCTS.

A tobacco product shall be deemed to be adulterated—

(1) if it bears or contains any poisonous or deleterious substance other than—

(A) tobacco;

(B) a substance naturally present in tobacco;

(C) a pesticide or fungicide chemical residue in or on tobacco if such pesticide or fungicide chemical is registered by the Environmental Protection Agency for use on tobacco in the United States; or

(D) in the case of imported tobacco, a residue of a pesticide or fungicide chemical that—

(i) is approved for use in the country of origin of the tobacco; and

(ii) has not been banned, and the registration of which has not been canceled, by the Environmental Protection Agency for use on tobacco in the United States) that may render it injurious to health; but, in case the substance is not an added substance, such tobacco product shall not be considered adulterated under this subsection if the quantity of such substance in such tobacco product does not ordinarily render it injurious to health;

(2) if there is significant scientific agreement that, as a result of the tobacco it contains, the tobacco product presents a risk to human health that is materially higher than the risk presented by—

(A) such product on the effective date of this Act; or

(B) if such product was not distributed commercially domestically on that date, by comparable tobacco products of the same style and within the same category that were commercially distributed domestically on that date;

(3) if it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth;

(4) if its package is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health; or

(5) if its ''tar'' yield is in violation of section 111.

SEC. 106. MISBRANDED TOBACCO PRODUCTS.

A tobacco product shall be deemed to be misbranded—

(1) if its labeling is false or misleading in any particular;

(2) if in package form unless it bears a label containing—

(A) an identification of the type of product it is, by the common or usual name of such type of product;

(B) an accurate statement of the quantity of the contents in the package in terms of weight, measure, or numerical count, except that reasonable variations shall be permitted, and exemptions as to small packages shall be established by regulations promulgated by the Administrator;

(C) the name and place of business of the tobacco product manufacturer, packer, or distributor; and

(D) the information required by section 201(c) and (e) or section 202(c) and (e), as applicable;

(3) if any word, statement, or other information required by or under authority of this Act to appear on the label, labeling, or advertising is not prominently placed thereon with such conspicuousness (as compared with other words, statements, or designs on the label, labeling, or advertising, as applicable) and in such terms as to render it reasonably likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(4) if any word, statement, or other information is required by or under this Act to appear on the label, unless such word, statement, or other information also appears on the outside container or wrapper, if any, of the retail package of such tobacco product, or is easily legible through the outside container or wrapper;

(5) if it was manufactured, prepared, or processed in an establishment not duly registered under section 109, if it was not included in a list required by section 109, or if a notice or other information respecting it was not provided as required by section 109;

(6) if its packaging, labeling, or advertising is in violation of this Act or of an applicable regulation promulgated in accordance with this Act;

(7) if it contains tobacco or another ingredient as to which a required disclosure under this Act was not made;

(8) if it is labeled or advertised, or the tobacco contained in it is advertised, as—

(A) containing ''no additives,'' or any substantially similar term, unless the labeling or advertising, as applicable, also contains, clearly and prominently, the following disclosure: ''No additives in our tobacco does NOT mean safer.''; or

(B) being ''natural,'' or any substantially similar term, unless the labeling or advertising, as applicable, also contains, clearly and prominently, the following disclosure: ''Natural does NOT mean safer.'';

(9) if in its labeling or advertising a term descriptive of the tobacco in the tobacco product is used otherwise than in accordance with a sanction or approval granted by a Federal agency;

(10) if with respect to such tobacco product a disclosure required by section 603 was not made;

(11) if with respect to such tobacco product a certification required by section 803 was not submitted or is materially false or misleading; or

(12) if its manufacturer or distributor made with respect to it a claim prohibited by section 115.

SEC. 107. SUBMISSION OF HEALTH INFORMATION TO THE ADMINISTRATOR.

(a) REQUIREMENT.—Each tobacco product manufacturer or importer, or agents thereof, shall submit to the Administrator the following information:

(1) Not later than 18 months after the date of enactment of the Act, a listing of all ingredients, including tobacco, substances, compounds, and additives that are, as of such date, added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand and by quantity in each brand and brand style.

(2) A description of the content, delivery, and form of nicotine in each tobacco product measured in milligrams of nicotine in accordance with regulations promulgated by the Administrator in accordance with section 4(e) of the Federal Cigarette Labeling and Advertising Act.

(3) Beginning 4 years after the date of enactment of this Act, a listing of all constituents, including smoke constituents as applicable, identified by the Administrator as harmful to health in each tobacco product, and as applicable in the smoke of each tobacco product, by brand and by quantity in each brand and subbrand.

(b) DATA SUBMISSION.—At the request of the Administrator, each tobacco product manufacturer or importer of tobacco products, or agents thereof, shall submit the following:

(1) Any or all documents (including underlying scientific information) relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer (or agents thereof) on the health, toxicological, or physiologic effects of tobacco products and their constituents (including smoke constituents), ingredients, components, and additives.

(2) Any or all documents (including underlying scientific information) relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer (or agents thereof) that relate to the issue of whether a significant reduction in risk to health from tobacco products can occur upon the employment of technology available to the manufacturer.

An importer of a tobacco product not manufactured in the United States shall supply the information required of a tobacco product manufacturer under this subsection.

(c) DATA LIST.—

(1) IN GENERAL.—Not later than 4 years after the date of enactment of the Act, and annually thereafter, the Administrator shall publish in a format that is understandable and not misleading to a lay person, and place on public display (in a manner determined by the Administrator) the list established under subsection (d).

(2) CONSUMER RESEARCH.—The Administrator shall conduct periodic consumer research to ensure that the list published under paragraph (1) is not misleading to lay persons. Not later than 5 years after the date of enactment of the Act, the Administrator shall submit to the appropriate committees of Congress a report on the results of such research, together with recommendations on whether such publication should be continued or modified.

(d) DATA COLLECTION.—Not later than 36 months after the date of enactment of this Act, the Administrator shall establish, and periodically revise as appropriate, a list of harmful constituents, including smoke constituents, to health in each tobacco product by brand and by quantity in each brand and subbrand.

SEC. 108. REGISTRATION AND LISTING.

(a) DEFINITIONS.—As used in this section:

(1) The term ''manufacture, preparation, or processing'' shall include repackaging or otherwise changing the container, wrapper, or label of any tobacco product package other than the carton in furtherance of the distribution of the tobacco product from the original place of manufacture to the person that makes final delivery or sale to the ultimate consumer or user, but shall not include the addition of a tax marking or other marking required by law to an already packaged tobacco product.

(2) The term ''name'' shall include in the case of a partnership the name of the general partner and, in the case of a privately held corporation, the name of the chief executive officer of the corporation and the State of incorporation.

(b) ANNUAL REGISTRATION.—Commencing one year after enactment, on or before December 31 of each year, every person that

owns or operates any establishment in any State engaged in the manufacture, preparation, or processing of a tobacco product or products for commercial distribution domestically shall register with the Administrator its name, places of business, and all such establishments.

(c) NEW PRODUCERS.—Every person upon first engaging, for commercial distribution domestically, in the manufacture, preparation, or processing of a tobacco product or products in any establishment that it owns or operates in any State shall immediately register with the Administrator its name, places of business, and such establishment.

(d) REGISTRATION OF FOREIGN ESTABLISHMENTS.—

(1) Commencing one year after enactment of this Act, on or before December 31 of each year, the person that, within any foreign country, owns or operates any establishment engaged in the manufacture, preparation, or processing of a tobacco product that is imported or offered for import into the United States shall, through electronic means or other means permitted by the Administrator, register with the Administrator the name and place of business of each such establishment, the name of the United States agent for the establishment, and the name of each importer of such tobacco product in the United States that is known to such person.

(2) Such person also shall provide the information required by subsection (j), including sales made by mail, or through the Internet, or other electronic means.

(3) The Administrator is authorized to enter into cooperative arrangements with officials of foreign countries to ensure that adequate and effective means are available for purposes of determining, from time to time, whether tobacco products manufactured, prepared, or processed by an establishment described in paragraph (1), if imported or offered for import into the United States, shall be refused admission on any of the grounds set forth in section 708.

(e) ADDITIONAL ESTABLISHMENTS.—Every person duly registered in accordance with the foregoing subsections of this section shall immediately register with the Administrator any additional establishment that it owns or operates and in which it begins the manufacture, preparation, or processing of a tobacco product or products for commercial distribution domestically or for import into the United States.

(f) EXCLUSIONS FROM APPLICATION OF THIS SECTION.—The foregoing subsections of this section shall not apply to—

(1) persons that manufacture, prepare, or process tobacco products solely for use in research, teaching, chemical or biological analysis, or export; or

(2) such other classes of persons as the Administrator may by regulation exempt from the application of this section upon a finding that registration by such classes of persons in accordance with this section is not necessary for the protection of the public health.

(g) INSPECTION OF PREMISES.—Every establishment registered with the Administrator pursuant to this section shall be subject to inspection pursuant to section 706; and every such establishment engaged in the manufacture, preparation, or processing of a tobacco product or products shall be so inspected by one or more officers or employees duly designated by the Administrator at least once in the two-year period beginning with the date of registration of such establishment pursuant to this section and at least once in every successive two-year period thereafter, except that inspection of establishments outside the United States may be conducted by other personnel pursuant to a cooperative arrangement under subsection (d)(3).

(h) FILING OF LISTS OF TOBACCO PRODUCTS MANUFACTURED, PREPARED, OR PROCESSED BY REGISTRANTS; STATEMENTS; ACCOMPANYING DISCLOSURES.—

(1) Every person that registers with the Administrator under subsection (b), (c), (d), or (e) shall, at the time of registration under any such subsection, file with the Administrator a list of all brand styles (with each brand style in each list listed by the common or usual name of the tobacco product category to which it belongs and by any proprietary name) that are being manufactured, prepared, or processed by such person for commercial distribution domestically or for import into the United States, and that such person has not included in any list of tobacco products filed by such person with the Administrator under this paragraph or paragraph (2) before such time of registration. Such list shall be prepared in such form and manner as the Administrator may prescribe, and shall be accompanied by the label for each such brand style and a representative sampling of any other labeling and advertising for each;

(2) Each person that registers with the Administrator under this section shall report to the Administrator each August for the preceding six-month period from January through June, and each February for the preceding six-month period form July through December, following information:

(A) A list of each brand style introduced by the registrant for commercial distribution domestically or for import into the United States that has not been included in any list previously filed by such registrant with the Administrator under this subparagraph or paragraph (1). A list under this subparagraph shall list a brand style by the common or usual name of the tobacco product category to which it belongs and by any proprietary name, and shall be accompanied by the other information required by paragraph (1).

(B) If since the date the registrant last made a report under this paragraph (or if such registrant has not previously made a report under this paragraph, since the effective date of this Act) such registrant has discontinued the manufacture, preparation, or processing for commercial distribution domestically or for import into the United States of a brand style included in a list filed by such registrant under subparagraph (A) or paragraph (1), notice of such discontinuance, the date of such discontinuance, and the identity (by the common or usual name of the tobacco product category to which it belongs and by any proprietary name) of such tobacco product.

(C) If, since the date the registrant reported pursuant to subparagraph (B) a notice of discontinuance of a tobacco product, the registrant has resumed the manufacture, preparation, or processing for commercial distribution domestically or for import into the United States of that brand style, notice of such resumption, the date of such resumption, the identity of such brand style (by the common or usual name of the tobacco product category to which it belongs and by any proprietary name), and the other information required by paragraph (1), unless the registrant has previously reported such resumption to the Administrator pursuant to this subparagraph.

(D) Any material change in any information previously submitted pursuant to this paragraph (2) or paragraph (1).

(i) ELECTRONIC REGISTRATION.—Registrations under subsections (b), (c), (d), and (e) (including the submission of updated information) shall be submitted to the Administrator by electronic means, unless the Administrator grants a request for waiver of such requirement because use of electronic means is not reasonable for the person requesting such waiver.

SEC. 109. GENERAL PROVISIONS RESPECTING CONTROL OF TOBACCO PRODUCTS.

(a) IN GENERAL.—Any requirement established by or under section 106, 107, or 113 applicable to a tobacco product shall apply to such tobacco product until the applicability of the requirement to the tobacco product has been changed by action taken under section 111, section 114, section 115, or subsection (d) of this section, and any requirement established by or under section 106, 107, or 113 which is inconsistent with a requirement imposed on such tobacco product under section 111, section 114, section 115, or subsection (d) of this section shall not apply to such tobacco product.

(b) INFORMATION ON PUBLIC ACCESS AND COMMENT.—Each notice of proposed rulemaking or other notification under section 111, 112, 113, 114, or 115 or under this section, any other notice which is published in the Federal Register with respect to any other action taken under any such section and which states the reasons for such action, and each publication of findings required to be made in connection with rulemaking under any such section shall set forth—

(1) the manner in which interested persons may examine data and other information on which the notice or findings is based; and

(2) the period within which interested persons may present their comments on the notice or findings (including the need therefore) orally or in writing, which period shall be at least 60 days but may not exceed 90 days unless the time is extended by the Administrator by a notice published in the Federal Register stating good cause therefore.

(c) LIMITED CONFIDENTIALITY OF INFORMATION.—Any information reported to or otherwise obtained by the Administrator or the Administrator's representative under section 107, 108, 111, 112, 113, 114, 115, or 504, or under subsection (e) or (f) of this section, which is exempt from disclosure under subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of that section shall be considered confidential and shall not be disclosed, except that the information may be disclosed to other officers or employees concerned with carrying out this Act, or when relevant in any proceeding under this Act.

(d) RESTRICTIONS.—

(1) IN GENERAL.—The Administrator may issue regulations, consistent with this Act, regarding tobacco products if the Administrator determines that such regulation would be appropriate for the protection of the public health. The finding as to whether such regulation would be appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the users of the tobacco product, and taking into account that the standard is reasonably likely to result in measurable and substantial reductions in morbidly and mortality among individual tobacco users.

(2) LABEL STATEMENTS.—The label of a tobacco product shall bear such appropriate statements of the restrictions required by a regulation under subsection (a) as the Administrator may in such regulation prescribe.

(e) GOOD MANUFACTURING PRACTICE REQUIREMENTS.—

(1) METHODS, FACILITIES, AND CONTROLS TO CONFORM.—

(A) IN GENERAL.—In applying manufacturing restrictions to tobacco, the Administrator shall, in accordance with subparagraph (B), prescribe regulations (which may differ based on the type of tobacco product involved) requiring that the methods used in, and the facilities and controls used for, the

manufacture, preproduction design validation (including a process to assess the performance of a tobacco product), packing, and storage of a tobacco product conform to current good manufacturing practice, or hazard analysis and critical control point methodology, as prescribed in such regulations to assure that the public health is protected and that the tobacco product is in compliance with this Act. Such regulations may provide for the testing of raw tobacco for pesticide chemical residues after a tolerance for such chemical residues has been established.

(B) REQUIREMENTS.—The Administrator shall—

(i) before promulgating any regulation under subparagraph (A), afford the Tobacco Products Scientific Advisory Committee an opportunity to submit recommendations with respect to the regulation proposed to be promulgated;

(ii) before promulgating any regulation under subparagraph (A), afford opportunity for an oral hearing;

(iii) provide the Tobacco Products Scientific Advisory Committee a reasonable time to make its recommendation with respect to proposed regulations under subparagraph (A); and

(iv) in establishing the effective date of a regulation promulgated under this subsection, take into account the differences in the manner in which the different types of tobacco products have historically been produced, the financial resources of the different tobacco product manufacturers, and the state of their existing manufacturing facilities, and shall provide for a reasonable period of time for such manufacturers to conform to good manufacturing practices but no earlier than four years from date of enactment.

(C) ADDITIONAL SPECIAL RULE.—A tobacco product manufactured in or imported into the United States shall not contain foreign-grown flue-cured or burley tobacco that—

(i) was knowingly grown or processed using a pesticide chemical that is not approved under applicable Federal law for use in domestic tobacco farming and processing; or

(ii) in the case of a pesticide chemical that is so approved, was grown or processed using the pesticide chemical in a manner inconsistent with the approved labeling for use of the pesticide chemical in domestic tobacco farming and processing.

(D) EXCLUSION.—Subparagraph (C)(ii) shall not apply to tobacco products manufactured with foreign-grown flue-cured or burley tobacco so long as that foreign grown tobacco was either—

(i) in the inventory of a manufacturer prior to the effective date, or

(ii) planted by the farmer prior to the effective date of this Act and utilized by the manufacturer no later than 3 years after the effective date.

(E) SETTING OF MAXIMUM RESIDUE LIMITS.—The Administrator shall adopt the following pesticide residue standards:

Pesticide residue standards

The maximum concentration of residues of the following pesticides allowed in flue-cured or burley tobacco, expressed as parts by weight of the residue per one million parts by weight of the tobacco (PPM) are:

CHLORDANE.....3.0
DIBROMOCHLOROPROPANE (DBCP).....1.0
DICAMBA (Temporary).... 5.0
ENDRIN....0.1
ETHYLENE DIBROMIDE (EDB)....0.1
FORMOTHION.....0.5
HEXACHLOROBENZENE (HCB)....0.1
METHOXYCHLOR.....0.1
TOXAPHENE.....0.3
2,4-D (Temporary).....5.0
2,4,5-T.....0.1
Sum of ALDRIN and DIELDRIN.....0.1
Sum of CYPERMETHRIN and PERMETHRIN (Temporary).....3.0
Sum of DDT, TDE (DDD), and DDE 0.4
Sum of HEPTACHLOR and HEPTACHLOR EPOXIDE.....0.1

(F) MAXIMUM RESIDUE LIMITS.—The Administrator shall adopt regulations within one year of the effective date of this Act to establish maximum residue limits for pesticides identified under subparagraph (E) but not included in the table of such subparagraph to account for the fact that weather and agronomic conditions will cause pesticides identified in subparagraph (E) to be detected in foreign-grown tobacco even where the farmer has not knowingly added such pesticide.

(2) EXEMPTIONS; VARIANCES.—

(A) PETITION.—Any person subject to any requirement prescribed under paragraph (1) may petition the Administrator for a permanent or temporary exemption or variance from such requirement. Such a petition shall be submitted to the Administrator in such form and manner as the Administrator shall prescribe and shall—

(i) in the case of a petition for an exemption from a requirement, set forth the basis for the petitioner's determination that compliance with the requirement is not required to assure that the tobacco product will be in compliance with this Act;

(ii) in the case of a petition for a variance from a requirement, set forth the methods proposed to be used in, and the facilities and controls proposed to be used for, the manufacture, packing, and storage of the tobacco product in lieu of the methods, facilities, and controls prescribed by the requirement; and

(iii) contain such other information as the Administrator shall prescribe.

(B) REFERRAL TO THE TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE.—The Administrator may refer to the Tobacco Products Scientific Advisory Committee any petition submitted under subparagraph (A). The Tobacco Products Scientific Advisory Committee shall report its recommendations to the Administrator with respect to a petition referred to it within 60 days after the date of the petition's referral. Within 60 days after—

(i) the date the petition was submitted to the Administrator under subparagraph (A); or

(ii) the day after the petition was referred to the Tobacco Products Scientific Advisory Committee,

whichever occurs later, the Administrator shall by order either deny the petition or approve it.

(C) APPROVAL.—The Administrator may approve—

(i) a petition for an exemption for a tobacco product from a requirement if the Administrator determines that compliance with such requirement is not required to assure that the tobacco product will be in compliance with this Act; and

(ii) a petition for a variance for a tobacco product from a requirement if the Administrator determines that the methods to be used in, and the facilities and controls to be used for, the manufacture, packing, and storage of the tobacco product in lieu of the methods, facilities, and controls prescribed by the requirement are sufficient to assure that the tobacco product will be in compliance with this Act.

(D) CONDITIONS.—An order of the Administrator approving a petition for a variance shall prescribe such conditions respecting the methods used in, and the facilities and controls used for, the manufacture, packing, and storage of the tobacco product to be granted the variance under the petition as may be necessary to assure that the tobacco product will be in compliance with this Act.

(E) HEARING.—After the issuance of an order under subparagraph (B) respecting a petition, the petitioner shall have an opportunity for an informal hearing on such order.

(3) COMPLIANCE.—Compliance with requirements under this subsection shall not be required before the end of the 3-year period following the date of enactment of this Act.

(f) RESEARCH AND DEVELOPMENT.—The Administrator may enter into contracts for research, testing, and demonstrations respecting tobacco products and may obtain tobacco products for research, testing, and demonstration purposes.

SEC. 110. SMOKING ARTICLE STANDARDS.

(a) IN GENERAL.—

(1) RESTRICTIONS ON DESCRIPTORS USED IN MARKETING OF CIGARETTES.—

(A) IN GENERAL.—Except as provided in subparagraph (B), no person shall use, with respect to any cigarette brand style commercially distributed domestically, on the portion of the package of such cigarette brand style that customarily is visible to consumers before purchase, or in advertising of such cigarette brand style any of the following as a descriptor of any cigarette brand style—

(i) the name of any candy or fruit;

(ii) the word ''candy,'' ''citrus,'' ''cream,'' ''fruit,'' ''sugar,'' ''sweet,'' ''tangy,'' or ''tart,''; or

(iii) any extension or variation of any of the words ''candy,'' ''citrus,'' ''cream,'' ''fruit,'' ''sugar,'' ''sweet,'' ''tangy,'' or ''tart,'' including but not limited to ''creamy,'' or ''fruity.''

(B) LIMITATION.—Subparagraph (A) shall not apply to the use of the following words or to any extension or variation of any of them: ''clove'' and ''menthol''.

(C) SCENTED MATERIALS.—No person shall use, in the advertising or labeling of any cigarette commercially distributed domestically, any scented materials, except in an adult-only facility.

(D) DEFINITIONS.—In this section:

(i) The term ''candy'' means a confection made from sugar or sugar substitute, including any confection identified generically or by brand, and shall include the words ''cacao,'' ''chocolate,'' ''cinnamon,'' ''cocoa,'' ''honey,'' ''licorice,'' ''maple,'' ''mocha,'' and ''vanilla.''

(ii) The term ''fruit'' means any fruit identified by generic name, type, or variety, including but not limited to ''apple,'' ''banana,'' ''cherry,'' and ''orange.'' The term ''fruit'' does not include words that identify seeds, nuts or peppers, or types or varieties thereof or words that are extensions or variations of such words.

(2) SMOKING ARTICLE STANDARDS.—

(A) IN GENERAL.—The Administrator may adopt smoking article standards in addition to those in paragraph (1) if the Administrator finds that a smoking article standard is appropriate for the protection of the public health.

(B) DETERMINATIONS.—

(i) CONSIDERATIONS.—In making a finding described in subparagraph (A), the Administrator shall consider scientific evidence concerning—

(I) the risks and benefits to the users of smoking articles of the proposed standard; and

(II) that the standard is reasonably likely to result in measurable and substantial reductions in morbidity and mortality among individual tobacco users.

(ii) ADDITIONAL CONSIDERATIONS.—In the event that the Administrator makes a determination, set forth in a proposed smoking article standard in a proposed rule, that it is

appropriate for the protection of public health to require the reduction or elimination of an additive, constituent (including a smoke constituent), or other component of a smoking article because the Administrator has found that the additive, constituent, or other component is harmful, any party objecting to the proposed standard on the ground that the proposed standard will not reduce or eliminate the risk of illness or injury may provide for the Administrator's consideration scientific evidence that demonstrates that the proposed standard will not reduce or eliminate the risk of illness or injury.

(3) CONTENT OF SMOKING ARTICLE STANDARDS.—A smoking article standard established under this section for a smoking article—

(A) may include provisions that are appropriate for the protection of the public health, including provisions, where appropriate—

(i) for ''tar'' and nicotine yields of the product;

(ii) for the reduction of other constituents, including smoke constituents, or harmful components of the product; or

(iii) relating to any other requirement under subparagraph (B); and

(B) may, where appropriate for the protection of the public health, include—

(i) provisions respecting the construction, components, ingredients, additives, constituents, including smoke constituents, and properties of the smoking article;

(ii) provisions for the testing (on a sample basis or, if necessary, on an individual basis) of the smoking article;

(iii) provisions for the measurement of the smoking article characteristics of the smoking article; and

(iv) provisions requiring that the results of each or of certain of the tests of the smoking article required to be made under clause (ii) show that the smoking article is in conformity with the portions of the standard for which the test or tests were required.

(4) PERIODIC REEVALUATION OF SMOKING ARTICLE STANDARDS.—The Administrator may provide for periodic evaluation of smoking article standards established under this section to determine whether such standards should be changed to reflect new medical, scientific, or other technological data.

(5) CIGARETTE ''TAR'' LIMITS.—

(A) NO INCREASE IN ''TAR'' YIELDS.—No cigarette manufacturer shall distribute for sale domestically a brand style of cigarettes that generates a ''tar'' yield greater than the ''tar'' yield of that brand style of cigarettes on the date of introduction of this Act, as determined by the ISO smoking regimen and its associated tolerances. The ''tar'' tolerances for cigarettes with ISO ''tar'' yields in the range of 1 to 20 milligrams per cigarette, based on variations arising from sampling procedure, test method, and sampled product, itself, are the greater of plus or minus—

(i) 15 percent; or

(ii) 1 milligram per cigarette.

(B) LIMIT ON NEW CIGARETTES.—After the effective date of this Act, no cigarette manufacturer shall manufacture for commercial distribution domestically a brand style of cigarettes that both—

(i) was not in commercial distribution domestically on the effective date of this Act, and

(ii) generates a ''tar'' yield of greater than 20 milligrams per cigarette as determined by the ISO smoking regimen and its associated tolerances.

(C) LIMIT ON ALL CIGARETTES.—After December 31, 2010, no cigarette manufacturer shall manufacture for commercial distribution domestically a brand style of cigarettes that generates a ''tar'' yield greater than 20 milligrams per cigarette as determined by the ISO smoking regimen and its associated tolerances.

(D) REVIEW BY ADMINISTRATOR.—After the effective date of this Act, the Administrator shall evaluate the available scientific evidence addressing the potential relationship between historical ''tar'' yield values and risk of harm to smokers. If upon a review of that evidence, and after consultation with technical experts of the Tobacco Harm Reduction Center and the Centers for Disease Control and Prevention and notice and an opportunity for public comment, the Administrator determines, that a reduction in ''tar'' yield may reasonably be expected to provide a meaningful reduction of the risk or risks of harm to smokers, the Administrator shall issue an order that—

(i) provides that no cigarette manufacturer shall manufacture for commercial distribution domestically a cigarette that generates a ''tar'' yield that exceeds 14 milligrams as determined by the ISO smoking regimen and its associated tolerances; and

(ii) provides a reasonable time for manufacturers to come into compliance with such prohibition.

(6) INVOLVEMENT OF OTHER AGENCIES; INFORMED PERSONS.—In carrying out duties under this section, the Administrator shall endeavor to—

(A) use personnel, facilities, and other technical support available in other Federal agencies;

(B) consult with other Federal agencies concerned with standard setting and other nationally or internationally recognized standard-setting entities; and

(C) invite appropriate participation, through joint or other conferences, workshops, or other means, by informed persons representative of scientific, professional, industry, agricultural, or consumer organizations who in the Administrator's judgment can make a significant contribution.

(b) CONSIDERATIONS BY ADMINISTRATOR.—

(1) TECHNICAL ACHIEVABILITY.—The Administrator shall consider information submitted in connection with a proposed standard regarding the technical achievability of compliance with such standard.

(2) OTHER CONSIDERATIONS.—The Administrator shall consider all other information submitted in connection with a proposed standard, such as the creation of a significant demand for contraband or other tobacco products that do not meet the requirements of this Act and the significance of such demand.

(c) PROPOSED STANDARDS.—

(1) IN GENERAL.—The Administrator shall publish in the Federal Register a notice of proposed rulemaking for the establishment, amendment, or revocation of any smoking article standard.

(2) REQUIREMENTS OF NOTICE.—A notice of proposed rulemaking for the establishment or amendment of a smoking article standard shall—

(A) set forth a finding with supporting justification that the smoking article standard is appropriate for the protection of the public health;

(B) invite interested persons to submit a draft or proposed smoking article standard for consideration by the Administrator;

(C) invite interested persons to submit comments on structuring the standard so that it does not advantage foreign-grown tobacco over domestically grown tobacco; and

(D) invite the Secretary of Agriculture to provide any information or analysis which the Secretary of Agriculture believes is relevant to the proposed smoking article standard.

(3) FINDING.—A notice of proposed rulemaking for the revocation of a smoking article standard shall set forth a finding with supporting justification that the smoking article standard is no longer appropriate for the protection of the public health.

(4) COMMENT.—The Administrator shall provide for a comment period of not less than 90 days.

(d) PROMULGATION.—

(1) IN GENERAL.—After the expiration of the period for comment on a notice of proposed rulemaking published under subsection (c) respecting a standard and after consideration of comments submitted under subsections (b) and (c) and any report from the Tobacco Products Scientific Advisory Committee, if the Administrator determines that the standard would be appropriate for the protection of the public health, the Administrator shall—

(A) promulgate a regulation establishing a smoking article standard and publish in the Federal Register findings on the matters referred to in subsection (c); or

(B) publish a notice terminating the proceeding for the development of the standard together with the reasons for such termination.

(2) EFFECTIVE DATE.—A regulation establishing a smoking article standard shall set forth the date or dates upon which the standard shall take effect, but no such regulation may take effect before 1 year after the date of its publication unless the Administrator determines that an earlier effective date is necessary for the protection of the public health. Such date or dates shall be established so as to minimize, consistent with the public health, economic loss to, and disruption or dislocation of, domestic and international trade. In establishing such effective date or dates, the Administrator shall consider information submitted in connection with a proposed product standard by interested parties, including manufacturers and tobacco growers, regarding the technical achievability of compliance with the standard, and including information concerning the existence of patents that make it impossible to comply in the timeframe envisioned in the proposed standard.

(3) LIMITATION ON POWER GRANTED.—Because of the importance of a decision of the Administrator to issue a regulation—

(A) banning cigarettes, smokeless smoking articles, little cigars, cigars other than little cigars, pipe tobacco, or roll-your-own smoking articles;

(B) requiring the reduction of ''tar'' or nicotine yields of a smoking article to zero;

(C) prohibiting the sale of any smoking article in face-to-face transactions by a specific category of retail outlets;

(D) establishing a minimum age of sale of smoking articles to any person older than 18 years of age; or

(E) requiring that the sale or distribution of a smoking article be limited to the written or oral authorization of a practitioner licensed by law to prescribe medical products, the Administrator is prohibited from taking such actions under this Act.

(4) MATCHBOOKS.—For purposes of any regulations issued by the Administrator under this Act, matchbooks of conventional size containing not more than 20 paper matches, and which are customarily given away for free with the purchase of smoking articles, shall be considered as adult-written publications which shall be permitted to contain advertising.

(5) AMENDMENT; REVOCATION.—

(A) AUTHORITY.—The Administrator, upon the Administrator's own initiative or upon petition of an interested person, may by a regulation, promulgated in accordance with the requirements of subsection (c) and paragraph (2), amend or revoke a smoking article standard.

(B) EFFECTIVE DATE.—The Administrator may declare a proposed amendment of a smoking article standard to be effective on and after its publication in the Federal Register and until the effective date of any final action taken on such amendment if the Administrator determines that making it so effective is in the public interest.

(6) REFERRAL TO ADVISORY COMMITTEE.—

(A) IN GENERAL.—The Administrator shall refer a proposed regulation for the establishment, amendment, or revocation of a smoking article standard to the Tobacco Products Scientific Advisory Committee for a report and recommendation with respect to any matter involved in the proposed regulation which requires the exercise of scientific judgment.

(B) INITIATION OF REFERRAL.—The Administrator shall make a referral under this paragraph—

(i) on the Administrator's own initiative; or

(ii) upon the request of an interested person that—

(I) demonstrates good cause for the referral; and

(II) is made before the expiration of the period for submission of comments on the proposed regulation.

(C) PROVISION OF DATA.—If a proposed regulation is referred under this paragraph to the Tobacco Products Scientific Advisory Committee, the Administrator shall provide the Advisory Committee with the data and information on which such proposed regulation is based.

(D) REPORT AND RECOMMENDATION.—The Tobacco Products Scientific Advisory Committee shall, within 90 days after the referral of a proposed regulation under this paragraph and after independent study of the data and information furnished to it by the Administrator and other data and information before it, submit to the Administrator a report and recommendation respecting such regulation, together with all underlying data and information and a statement of the reason or basis for the recommendation.

(E) PUBLIC AVAILABILITY.—The Administrator shall make a copy of each report and recommendation under subparagraph (D) publicly available.

SEC. 111. NOTIFICATION AND OTHER REMEDIES.

(a) NOTIFICATION.—If the Administrator determines that—

(1) a tobacco product which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm materially above the risk for death and disease of tobacco products currently in interstate commerce, to the public health; and

(2) notification under this subsection is necessary to eliminate the unreasonable risk of such harm and no more practicable means is available under the provisions of this Act (other than this section) to eliminate such risk,

the Administrator may issue such order as may be necessary to assure that adequate notification is provided in an appropriate form, by the persons and means best suited under the circumstances involved, to all persons who should properly receive such notification in order to eliminate such risk. The Administrator may order notification by any appropriate means, including public service announcements. Before issuing an order under this subsection, the Administrator shall consult with the persons who are to give notice under the order.

(b) NO EXEMPTION FROM OTHER LIABILITY.—Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided under such order shall be taken into account.

(c) RECALL AUTHORITY.—

(1) IN GENERAL.—If the Administrator finds that there is a reasonable probability that a tobacco product contains a manufacturing or other defect not ordinarily contained in tobacco products on the market that would cause serious, acute adverse health consequences or death, the Administrator shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the tobacco product) to immediately cease distribution of such tobacco product. The order shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order and on whether the order should be amended to require a recall of such tobacco product. If, after providing an opportunity for such a hearing, the Administrator determines that inadequate grounds exist to support the actions required by the order, the Administrator shall vacate the order.

(2) AMENDMENT OF ORDER TO REQUIRE RECALL.—

(A) IN GENERAL.—If, after providing an opportunity for an informal hearing under paragraph (1), the Administrator determines that the order should be amended to include a recall of the tobacco product with respect to which the order was issued, the Administrator shall, except as provided in subparagraph (B), amend the order to require a recall. The Administrator shall specify a timetable in which the tobacco product recall will occur and shall require periodic reports to the Administrator describing the progress of the recall.

(B) NOTICE.—An amended order under subparagraph (A)—

(i) shall not include recall of a tobacco product from individuals; and

(ii) shall provide for notice to persons subject to the risks associated with the use of such tobacco product.

In providing the notice required by clause (ii), the Administrator may use the assistance of retailers and other persons who distributed such tobacco product. If a significant number of such persons cannot be identified, the Administrator shall notify such persons under section 705(b).

(3) REMEDY NOT EXCLUSIVE.—The remedy provided by this subsection shall be in addition to remedies provided by subsection (a).

SEC. 112. RECORDS AND REPORTS ON TOBACCO PRODUCTS.

Every person who is a tobacco product manufacturer or importer of a tobacco product shall establish and maintain such records, make such reports, and provide such information, as the Administrator may by regulation reasonably require to assure that such tobacco product is not adulterated or misbranded.

SEC. 113. APPLICATION FOR REVIEW OF CERTAIN SMOKING ARTICLES.

(a) IN GENERAL.—

(1) NEW SMOKING ARTICLE DEFINED.—For purposes of this section the term ''new smoking article'' means—

(A) any smoking article that was not commercially marketed in the United States as of the date of enactment of this Act; and

(B) any smoking article that incorporates a significant modification (including changes in design, component, part, or constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or other additive or ingredient) of a smoking article where the reduced product was commercially marketed in the United States after the date of enactment of this Act.

(2) PREMARKET REVIEW REQUIRED.—

(A) NEW PRODUCTS.—An order under subsection (c)(1)(A) for a new smoking article is required unless the product—

(i) is substantially equivalent to a smoking article commercially marketed in the United States as of date of enactment of this Act; and

(ii) is in compliance with the requirements of this Act.

(B) CONSUMER TESTING.—This section shall not apply to smoking articles that are provided to adult tobacco consumers for purposes of consumer testing. For purposes of this section, the term ''consumer testing'' means an assessment of smoking articles that is conducted by or under the control and direction of a manufacturer for the purpose of evaluating consumer acceptance of such smoking articles, utilizing only the quantity of cigarettes that is reasonably necessary for such assessment

(3) SUBSTANTIALLY EQUIVALENT DEFINED.—

(A) IN GENERAL.—In this section, the term ''substantially equivalent'' or ''substantial equivalence'' means, with respect to the smoking article being compared to the predicate smoking article, that the Administrator by order has found that the smoking article—

(i) has the same general characteristics as the predicate smoking article; or

(ii) has different characteristics and the information submitted contains information, including clinical data if deemed necessary by the Administrator, that demonstrates that it is not appropriate to regulate the product under this section because the product does not raise different questions of public health for the consumer of the product.

(B) CHARACTERISTICS.—In subparagraph (A), the term ''characteristics'' means the materials, ingredients, design, composition, heating source, or other features of a smoking article.

(C) LIMITATION.—A smoking article may not be found to be substantially equivalent to a predicate smoking article that has been removed from the market at the initiative of the Administrator or that has been determined by a judicial order to be misbranded or adulterated.

(4) HEALTH INFORMATION.—As part of a submission respecting a smoking article, the person required to file a premarket notification shall provide an adequate summary of any health information related to the smoking article or state that such information will be made available upon request by any person.

(b) APPLICATION.—

(1) CONTENTS.—An application under this section shall contain—

(A) full reports of all information, published or known to, or which should reasonably be known to, the applicant, concerning investigations which have been made to show the health risks of such smoking article and whether such smoking article presents less risk than other smoking articles;

(B) a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such smoking article;

(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such smoking article;

(D) an identifying reference to any smoking article standard under section 111 which would be applicable to any aspect of such smoking article, and either adequate information to show that such aspect of such smoking article fully meets such smoking

article standard or adequate information to justify any deviation from such standard;

(E) such samples of such smoking article and of components thereof as the Administrator may reasonably require;

(F) specimens of the labeling proposed to be used for such smoking article; and

(G) such other information relevant to the subject matter of the application as the Administrator may require.

(2) REFERRAL TO TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE.—Upon receipt of an application meeting the requirements set forth in paragraph (1), the Administrator—

(A) may, on the Administrator's own initiative; or

(B) may, upon the request of an applicant, refer such application to the Tobacco Products Scientific Advisory Committee for reference and for submission (within such period as the Administrator may establish) of a report and recommendation respecting the application, together with all underlying data and the reasons or basis for the recommendation.

(c) ACTION ON APPLICATION.—

(1) DEADLINE.—As promptly as possible, but in no event later than 90 days after the receipt of an application under subsection (b), the Administrator, after considering the report and recommendation submitted under subsection (b)(2), shall—

(A) issue an order that the new product may be introduced or delivered for introduction into interstate commerce if the Administrator finds that none of the grounds specified in paragraph (2) of this subsection applies; or

(B) issue an order that the new product may not be introduced or delivered for introduction into interstate commerce if the Administrator finds (and sets forth the basis for such finding as part of or accompanying such denial) that 1 or more grounds for denial specified in paragraph (2) of this subsection apply.

(2) DENIAL OF APPLICATION.—The Administrator shall deny an application submitted under subsection (b) if, upon the basis of the information submitted to the Administrator as part of the application and any other information before the Administrator with respect to such smoking article, the Administrator finds that—

(A) there is a lack of a showing that permitting such smoking article to be marketed would be appropriate for the protection of the public health;

(B) the methods used in, or the facilities or controls used for, the manufacture, processing, or packing of such smoking article do not conform to the requirements of section 110(e);

(C) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; or

(D) such smoking article is not shown to conform to a smoking article standard in effect under section 111, and there is a lack of adequate information to justify the deviation from such standard.

(3) DENIAL INFORMATION.—Any denial of an application shall, insofar as the Administrator determines to be practicable, be accompanied by a statement informing the applicant of the measures required to remove such application from deniable form (which measures may include further research by the applicant in accordance with 1 or more protocols prescribed by the Administrator).

(4) BASIS FOR FINDING.—For purposes of this section, the finding as to whether the commercial introduction of a smoking article for which an application has been submitted is appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the users of the smoking article, and taking into account whether such commercial introduction is reasonably likely to increase the morbidly and mortality among individual tobacco users.

(d) WITHDRAWAL AND TEMPORARY SUSPENSION.—

(1) IN GENERAL.—The Administrator shall, upon obtaining, where appropriate, advice on scientific matters from the Tobacco Products Scientific Advisory Committee, and after due notice and opportunity for informal hearing for a smoking article for which an order was issued under subsection (c)(1)(A), issue an order withdrawing the order if the Administrator finds—

(A) that the continued marketing of such smoking article no longer is appropriate for the protection of the public health;

(B) that the application contained or was accompanied by an untrue statement of a material fact;

(C) that the applicant—

(i) has failed to establish a system for maintaining records, or has repeatedly or deliberately failed to maintain records or to make reports, required by an applicable regulation under section 113; or

(ii) has refused to permit access to, or copying or verification of, such records as required by section 110; or

(D) on the basis of new information before the Administrator with respect to such smoking article, evaluated together with the evidence before the Administrator when the application was reviewed, that the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or installation of such smoking article do not conform with the requirements of section 110(e) and were not brought into conformity with such requirements within a reasonable time after receipt of written notice from the Administrator of nonconformity;

(E) on the basis of new information before the Administrator, evaluated together with the evidence before the Administrator when the application was reviewed, that the labeling of such smoking article, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Administrator of such fact; or

(F) on the basis of new information before the Administrator, evaluated together with the evidence before the Administrator when such order was issued, that such smoking article is not shown to conform in all respects to a smoking article standard which is in effect under section 111, compliance with which was a condition to the issuance of an order relating to the application, and that there is a lack of adequate information to justify the deviation from such standard.

(2) APPEAL.—The holder of an application subject to an order issued under paragraph (1) withdrawing an order issued pursuant to subsection (c)(1)(A) may, by petition filed on or before the 30th day after the date upon which such holder receives notice of such withdrawal, obtain review thereof in accordance with section 116.

(3) TEMPORARY SUSPENSION.—If, after providing an opportunity for an informal hearing, the Administrator determines there is reasonable probability that the continuation of distribution of a smoking article under an order would cause serious, adverse health consequences or death, that is greater than ordinarily caused by smoking articles on the market, the Administrator shall by order temporarily suspend the authority of the manufacturer to market the product. If the Administrator issues such an order, the Administrator shall proceed expeditiously under paragraph (1) to withdraw such application.

(e) SERVICE OF ORDER.—An order issued by the Administrator under this section shall be served—

(1) in person by any officer or employee of the department designated by the Administrator; or

(2) by mailing the order by registered mail or certified mail addressed to the applicant at the applicant's last known address in the records of the Administrator.

(f) RECORDS.—

(1) ADDITIONAL INFORMATION.—In the case of any smoking article for which an order issued pursuant to subsection (c)(1)(A) for an application filed under subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Administrator, as the Administrator may by regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Administrator to determine, or facilitate a determination of, whether there is or may be grounds for withdrawing or temporarily suspending such order.

(2) ACCESS TO RECORDS.—Each person required under this section to maintain records, and each person in charge of custody thereof, shall, upon request of an officer or employee designated by the Administrator, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

(g) INVESTIGATIONAL SMOKING ARTICLE EXEMPTION FOR INVESTIGATIONAL USE.—The Administrator may exempt smoking articles intended for investigational use from the provisions of this Act under such conditions as the Administrator may by regulation prescribe.

SEC. 114. REDUCED RISK TOBACCO PRODUCTS.

(a) IN GENERAL.—No person may introduce or deliver for introduction into interstate commerce any reduced risk tobacco product unless an order issued pursuant to subsection (g) is effective with respect to such product.

(b) DEFINITIONS.—In this section:

(1) REDUCED RISK TOBACCO PRODUCT.—The term ''reduced risk tobacco product'' means any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products.

(2) SOLD OR DISTRIBUTED.—

(A) IN GENERAL.—With respect to a tobacco product, the term ''sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products'' means a tobacco product—

(i) the label, labeling, or advertising of which represents explicitly or implicitly that—

(I) the tobacco product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products;

(II) the tobacco product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance; or

(III) the tobacco product or its smoke does not contain or is free of a substance;

(ii) the label, labeling, or advertising of which uses the descriptors ''light'', ''mild'', ''low'', ''medium'', ''ultra light'', ''low tar'' or ''ultra low tar''; or

(iii) the tobacco product manufacturer of which has taken any action directed to consumers through the media or otherwise, other than by means of the tobacco product's label, labeling, or advertising, after the date of enactment of the Act, respecting the product that would be reasonably expected to result in consumers believing that the tobacco product or its smoke may present a lower

risk of disease or is less harmful than one or more commercially marketed tobacco products, or presents a reduced exposure to, or does not contain or is free of, a substance or substances.

(B) LIMITATION.—No tobacco product shall be considered to be ''sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products'', except as described in subparagraph (A).

(C) SMOKELESS TOBACCO PRODUCT.—No smokeless tobacco product shall be considered to be ''sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products''.

(3) EFFECTIVE DATE.—The provisions of paragraph (2)(A)(ii) shall take effect 12 months after the date of enactment of the Act.

(c) TOBACCO DEPENDENCE PRODUCTS.—A product that is intended to be used for the treatment of tobacco dependence, including smoking cessation, is not a reduced risk tobacco product under this section if it has been approved as a drug or device by the Center and is subject to the requirements of chapter V.

(d) FILING.—Any person may file with the Administrator an application for a reduced risk tobacco product. Such application shall include—

(1) a description of the proposed product and any proposed advertising and labeling;

(2) the conditions for using the product;

(3) the formulation of the product;

(4) sample product labels and labeling;

(5) all documents (including underlying scientific information) relating to research findings conducted, supported, or possessed by the tobacco product manufacturer relating to the effect of the product on tobacco-related diseases and health-related conditions, including information both favorable and unfavorable to the ability of the product to reduce risk or exposure and relating to human health;

(6) data and information on how consumers actually use the tobacco product; and

(7) such other information as the Administrator may require.

(e) PUBLIC AVAILABILITY.—The Administrator shall make the application described in subsection (d) publicly available (except matters in the application which are trade secrets or otherwise confidential, commercial information) and shall request comments by interested persons on the information contained in the application and on the label, labeling, and advertising accompanying such application.

(f) ADVISORY COMMITTEE.—

(1) IN GENERAL.—The Administrator shall refer to the Tobacco Products Scientific Advisory Committee any application submitted under this section.

(2) RECOMMENDATIONS.—Not later than 60 days after the date an application is referred to the Tobacco Products Scientific Advisory Committee under paragraph (1), the Advisory Committee shall report its recommendations on the application to the Administrator.

(g) MARKETING.—

(1) REDUCED RISK PRODUCTS.—Except as provided in paragraph (2), the Administrator shall, with respect to an application submitted under this section, issue an order that a reduced risk product may be commercially marketed only if the Administrator determines that the applicant has demonstrated that such product, as it is actually used by consumers, will—

(A) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and

(B) is reasonably likely to result in measurable and substantial reductions in morbidity and mortality among individual tobacco users.

(2) SPECIAL RULE FOR CERTAIN PRODUCTS.—The Administrator may issue an order that a tobacco product may be introduced or delivered for introduction into interstate commerce, pursuant to an application under this section, with respect to a tobacco product that may not be commercially marketed under paragraph (1) if the Secretary makes the findings required under this paragraph and determines that the applicant has demonstrated that—

(A) such order would be appropriate to promote the public health; and

(B) the scientific evidence that is available without conducting long-term epidemiological studies demonstrates that a measurable and substantial reduction in morbidity or mortality among individual tobacco users is reasonably likely in subsequent studies.

(3) BASIS.—The determinations under paragraphs (1) and (2) shall be based on—

(A) the scientific evidence submitted by the applicant; and

(B) scientific evidence and other information that is made available to the Administrator.

(h) ADDITIONAL CONDITIONS FOR MARKETING.—

(1) REDUCED RISK PRODUCTS.—The Administrator shall require for the marketing of a product under this section that any advertising or labeling concerning reduced risk products enable the public to comprehend the information concerning reduced risk and to understand the relative significance of such information in the context of total health and in relation to all of the diseases and health-related conditions associated with the use of cigarettes and other tobacco products.

(2) COMPARATIVE CLAIMS.—The Administrator may require for the marketing of a product under this subsection that a claim comparing a tobacco product to other commercially marketed tobacco products shall compare the tobacco product to the known risk of cigarettes.

(i) POSTMARKET SURVEILLANCE AND STUDIES.—Under the guidance of the Scientific Advisory Committee, the Tobacco Harm Reduction Center shall engage in postmarket surveillance studies and other research as needed to ascertain the health impact of each of the major classes of tobacco and other nicotine containing products in the United States, ascertain the possible presence of unusual levels of harm from specific tobacco products, and determine the steps that should be taken to further reduce illness, death and other social harms from tobacco products.

(j) WITHDRAWAL OF AUTHORIZATION.—The Administrator, after an opportunity for an informal hearing, shall withdraw an order under subsection (g) if the Administrator determines that—

(1) the applicant, based on new information, can no longer make the demonstrations required under subsection (g), or the Administrator can no longer make the determinations required under subsection (g);

(2) the application failed to include material information or included any untrue statement of material fact;

(3) any explicit or implicit representation that the product reduces risk or exposure is no longer valid, including if—

(A) a tobacco product standard is established pursuant to section 111;

(B) an action is taken that affects the risks presented by other commercially marketed tobacco products that were compared to the product that is the subject of the application; or

(C) any postmarket surveillance or studies reveal that the order is no longer consistent with the protection of the public health;

(4) the applicant failed to conduct or submit the postmarket surveillance and studies required under subsection (g)(2)(C)(ii) or subsection (i); or

(5) the applicant failed to meet a condition imposed under subsection (h).

(k) CHAPTER IV OR V.—A product for which the Administrator has issued an order pursuant to subsection (g) shall not be subject to chapter IV or V of the Federal Food, Drug, and Cosmetic Act.

(l) IMPLEMENTING REGULATIONS OR GUIDANCE.—

(1) SCIENTIFIC EVIDENCE.—Not later than 2 years after the date of enactment of the Act, the Administrator shall issue regulations or guidance (or any combination thereof) on the scientific evidence required for assessment and ongoing review of reduced risk tobacco products. Such regulations or guidance shall—

(A) to the extent that adequate scientific evidence exists, establish minimum standards for scientific studies needed prior to issuing an order under subsection (g) to show a reasonable likelihood that a substantial reduction in morbidity or mortality among individual tobacco users occurs for products described in subsection (g)(1) or is reasonably likely for products described in subsection (g)(2);

(B) include validated biomarkers, intermediate clinical endpoints, and other feasible outcome measures, as appropriate;

(C) establish minimum standards for postmarket studies, that shall include regular and long-term assessments of health outcomes and mortality, intermediate clinical endpoints, consumer perception of harm reduction, and the impact on quitting behavior and new use of tobacco products, as appropriate;

(D) establish minimum standards for required postmarket surveillance, including ongoing assessments of consumer perception; and

(E) establish a reasonable timetable for the Administrator to review an application under this section.

(2) CONSULTATION.—The regulations or guidance issued under paragraph (1) may be developed in consultation with the Institute of Medicine, and with the input of other appropriate scientific and medical experts, on the design and conduct of such studies and surveillance.

(3) REVISION.—The regulations or guidance under paragraph (1) shall be revised on a regular basis as new scientific information becomes available.

(4) NEW TOBACCO PRODUCTS.—Not later than 2 years after the date of enactment of the Act, the Administrator shall issue a regulation or guidance that permits the filing of a single application for any tobacco product that is a new tobacco product under section 114 and which the applicant seeks to commercially market under this section.

SEC. 115. JUDICIAL REVIEW.

(a) RIGHT TO REVIEW.—

(1) IN GENERAL.—Not later than 60 days after—

(A) the promulgation of a regulation under section 111 establishing, amending, or revoking a tobacco product standard; or

(B) a denial of an application under section 114(c),

any person adversely affected by such regulation or denial may file a petition for judicial review of such regulation or denial with the United States Court of Appeals for the District of Columbia or for the circuit in which such person resides or has their principal place of business.

(2) REQUIREMENTS.—

(A) COPY OF PETITION.—A copy of the petition filed under paragraph (1) shall be transmitted by the clerk of the court involved to the Administrator.

(B) RECORD OF PROCEEDINGS.—On receipt of a petition under subparagraph (A), the Administrator shall file in the court in which such petition was filed—

(i) the record of the proceedings on which the regulation or order was based; and

(ii) a statement of the reasons for the issuance of such a regulation or order.

(C) DEFINITION OF RECORD.—In this section, the term ''record'' means—

(i) all notices and other matter published in the Federal Register with respect to the regulation or order reviewed;

(ii) all information submitted to the Administrator with respect to such regulation or order;

(iii) proceedings of any panel or advisory committee with respect to such regulation or order;

(iv) any hearing held with respect to such regulation or order; and

(v) any other information identified by the Administrator, in the administrative proceeding held with respect to such regulation or order, as being relevant to such regulation or order.

(b) STANDARD OF REVIEW.—Upon the filing of the petition under subsection (a) for judicial review of a regulation or order, the court shall have jurisdiction to review the regulation or order in accordance with chapter 7 of title 5, United States Code, and to grant appropriate relief, including interim relief, as provided for in such chapter. A regulation or denial described in subsection (a) shall be reviewed in accordance with section 706(2)(A) of title 5, United States Code.

(c) FINALITY OF JUDGMENT.—The judgment of the court affirming or setting aside, in whole or in part, any regulation or order shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of title 28, United States Code.

(d) OTHER REMEDIES.—The remedies provided for in this section shall be in addition to, and not in lieu of, any other remedies provided by law.

(e) REGULATIONS AND ORDERS MUST RECITE BASIS IN RECORD.—To facilitate judicial review, a regulation or order issued under section 110, 111, 112, 113, 114, or 119 shall contain a statement of the reasons for the issuance of such regulation or order in the record of the proceedings held in connection with its issuance.

SEC. 116. JURISDICTION OF AND COORDINATION WITH THE FEDERAL TRADE COMMISSION.

Except where expressly provided in this Act, nothing in this Act shall be construed as limiting or diminishing the authority of the Federal Trade Commission to enforce the laws under its jurisdiction with respect to the advertising, sale, or distribution of tobacco products.

SEC. 117. REGULATION REQUIREMENT.

(a) TESTING, REPORTING, AND DISCLOSURE.—Not later than 36 months after the date of enactment of the Act, the Administrator shall promulgate regulations under this Act that meet the requirements of subsection (b).

(b) CONTENTS OF RULES.—The regulations promulgated under subsection (a)—

(1) shall require annual testing and reporting of tobacco product constituents, ingredients, and additives, including smoke constituents, by brand style that the Administrator determines should be tested to protect the public health, provided that, for purposes of the testing requirements of this paragraph, tobacco products manufactured and sold by a single tobacco product manufacturer that are identical in all respects except the labels, packaging design, logo, trade dress, trademark, brand name, or any combination thereof, shall be considered as a single brand style; and

(2) may require that tobacco product manufacturers, packagers, or importers make disclosures relating to the results of the testing of tar and nicotine through labels or advertising.

(c) AUTHORITY.—The Administrator shall have the authority under this Act to conduct or to require the testing, reporting, or disclosure of tobacco product constituents, including smoke constituents.

(d) JOINT LABORATORY TESTING SERVICES.—The Administrator shall allow any 2 or more tobacco product manufacturers to join together to purchase laboratory testing services required by this section on a group basis in order to ensure that such manufacturers receive access to, and fair pricing of, such testing services.

(e) EXTENSIONS FOR LIMITED LABORATORY CAPACITY.—

(1) IN GENERAL.—The regulations promulgated under subsection (a) shall provide that a tobacco product manufacturer shall not be considered to be in violation of this section before the applicable deadline, if—

(A) the tobacco products of such manufacturer are in compliance with all other requirements of this Act; and

(B) the conditions described in paragraph (2) are met.

(2) CONDITIONS.—Notwithstanding the requirements of this section, the Administrator may delay the date by which a tobacco product manufacturer must be in compliance with the testing and reporting required by this section until such time as the testing is reported if, not later than 90 days before the deadline for reporting in accordance with this section, a tobacco product manufacturer provides evidence to the Administrator demonstrating that—

(A) the manufacturer has submitted the required products for testing to a laboratory and has done so sufficiently in advance of the deadline to create a reasonable expectation of completion by the deadline;

(B) the products currently are awaiting testing by the laboratory; and

(C) neither that laboratory nor any other laboratory is able to complete testing by the deadline at customary, nonexpedited testing fees.

(3) EXTENSION.—The Administrator, taking into account the laboratory testing capacity that is available to tobacco product manufacturers, shall review and verify the evidence submitted by a tobacco product manufacturer in accordance with paragraph (2). If the Administrator finds that the conditions described in such paragraph are met, the Administrator shall notify the tobacco product manufacturer that the manufacturer shall not be considered to be in violation of the testing and reporting requirements of this section until the testing is reported or until 1 year after the reporting deadline has passed, whichever occurs sooner. If, however, the Administrator has not made a finding before the reporting deadline, the manufacturer shall not be considered to be in violation of such requirements until the Administrator finds that the conditions described in paragraph (2) have not been met, or until 1 year after the reporting deadline, whichever occurs sooner.

(4) ADDITIONAL EXTENSION.—In addition to the time that may be provided under paragraph (3), the Administrator may provide further extensions of time, in increments of no more than 1 year, for required testing and reporting to occur if the Administrator determines, based on evidence properly and timely submitted by a tobacco product manufacturer in accordance with paragraph (2), that a lack of available laboratory capacity prevents the manufacturer from completing the required testing during the period described in paragraph (3).

(f) RULE OF CONSTRUCTION.—Nothing in subsection (d) or (e) shall be construed to authorize the extension of any deadline, or to otherwise affect any timeframe, under any provision of this Act other than this section.

SEC. 118. PRESERVATION OF STATE AND LOCAL AUTHORITY.

(a) IN GENERAL.—

(1) PRESERVATION.—Except as provided in paragraph (2)(A), nothing in this Act, or rules promulgated under this Act, shall be construed to limit the authority of a Federal agency (including the Armed Forces), a State or political subdivision of a State, or the government of an Indian tribe to enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products that is in addition to requirements established under this Act, including a law, rule, regulation, or other measure relating to or prohibiting the sale, distribution, possession, or use of tobacco products by individuals of any age, information reporting to the State. No provision of this Act shall limit or otherwise affect any State, Tribal, or local taxation of tobacco products.

(2) PREEMPTION OF CERTAIN STATE AND LOCAL REQUIREMENTS.—

(A) IN GENERAL.—No State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this Act relating to tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or reduced risk tobacco products.

(B) EXCEPTION.—Subparagraph (A) does not apply to requirements relating to the sale, distribution, possession, information reporting to the State, use of, tobacco product by individuals of any age. Information disclosed to a State under subparagraph (A) that is exempt from disclosure under section 552(b)(4) of title 5, United States Code, shall be treated as a trade secret and confidential information by the State.

(b) RULE OF CONSTRUCTION REGARDING PRODUCT LIABILITY.—No provision of this Act relating to a tobacco product shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.

SEC. 119. TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE.

(a) ESTABLISHMENT.—Not later than 6 months after the date of enactment of this Act, the Administrator shall establish a 19-member advisory committee, to be known as the Tobacco Products Scientific Advisory Committee (in this section referred to as the ''Advisory Committee'').

(b) MEMBERSHIP.—

(1) IN GENERAL.—

(A) MEMBERS.—The Administrator shall appoint as members of the Tobacco Harm Reduction Advisory Committee individuals who are technically qualified by training and experience in medicine, public health, medical ethics or other science or technology involving the means by which cigarettes and other tobacco products cause illness, death and other societal harms, and the steps that can be taken by government and the private sector to most rapidly and substantially reduce said illness, death and other societal harms. The committee shall be composed of—

(i) 10 individuals who are physicians, dentists, other scientists or other public health or healthcare professionals;

(ii) 4 individuals representing the general public;

(iii) 2 representatives of the interests of the tobacco manufacturing industry;

(iv) 1 representative of the interests of the small business tobacco manufacturing industry, which position may be filled on a rotating, sequential basis by representatives of different small business tobacco manufacturers based on areas of expertise relevant to the topics being considered by the Advisory Committee;

(v) 1 individual as a representative of the interests of the tobacco growers; and

(vi) 1 individual who is an expert in illicit trade of tobacco products.

(B) CONFLICTS OF INTEREST.—No members of the committee, other than members appointed pursuant to clauses (iv), (v), and (vi) of subparagraph (A) shall, during the member's tenure on the committee or for the 18-month period prior to becoming such a member, receive any salary, grants, or other payments or support from any business that manufactures, distributes, markets, or sells cigarettes or other tobacco products or government agency with any form of jurisdiction over tobacco products.

(2) LIMITATION.—The Administrator may not appoint to the Advisory Committee any individual who is in the regular full-time employ of the Tobacco Harm Reduction Center or any agency responsible for the enforcement of this Act. The Administrator may appoint Federal officials as ex officio members.

(3) CHAIRPERSON.—The Administrator shall designate 1 of the members appointed under clauses (i), (ii), and (iii) of paragraph (1)(A) to serve as chairperson.

(c) DUTIES.—The Tobacco Products Scientific Advisory Committee shall provide advice, information, and recommendations to the Administrator—

(1) as provided in this Act;

(2) on the implementation of prevention, cessation, and harm reduction policies;

(3) on implementation of policies and programs to fully inform consumers of the respective risks of tobacco products; and

(4) on its review of other safety, dependence, or health issues relating to tobacco products as requested by the Administrator.

(d) COMPENSATION; SUPPORT; FACA.—

(1) COMPENSATION AND TRAVEL.—Members of the Advisory Committee who are not officers or employees of the United States, while attending conferences or meetings of the committee or otherwise engaged in its business, shall be entitled to receive compensation at rates to be fixed by the Administrator, which may not exceed the daily equivalent of the rate in effect under the Senior Executive Schedule under section 5382 of title 5, United States Code, for each day (including travel time) they are so engaged; and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5, United States Code, for persons in the Government service employed intermittently.

(2) ADMINISTRATIVE SUPPORT.—The Administrator shall furnish the Advisory Committee clerical and other assistance.

(3) NONAPPLICATION OF FACA.—Section 14 of the Federal Advisory Committee Act does not apply to the Advisory Committee.

(e) PROCEEDINGS OF ADVISORY PANELS AND COMMITTEES.—The Advisory Committee shall make and maintain a transcript of any proceeding of the panel or committee. Each such panel and committee shall delete from any transcript made under this subsection information which is exempt from disclosure under section 552(b) of title 5, United States Code.

SEC. 120. DRUG PRODUCTS USED TO TREAT TOBACCO DEPENDENCE.

(a) REPORT ON INNOVATIVE PRODUCTS.—

(1) IN GENERAL.—Not later than 3 years after the date of enactment of this Act, the Administrator, after consultation with recognized scientific, medical, and public health experts (including both Federal agencies and nongovernmental entities, the Institute of Medicine of the National Academy of Sciences, and the Society for Research on Nicotine and Tobacco), shall submit to the Congress a report that examines how best to promote, and encourage the development and use by current tobacco users of innovative tobacco and nicotine products and treatments (including nicotine-based and non-nicotine-based products and treatments) to better achieve, in a manner that best protects and promotes the public health—

(A) total abstinence from tobacco use;

(B) reductions in consumption of tobacco; and

(C) reductions in the harm associated with continued tobacco use by moving current users to noncombustible tobacco products.

(2) RECOMMENDATIONS.—The report under paragraph (1) shall include the recommendations of the Administrator on how the Tobacco Harm and Reduction Center should coordinate and facilitate the exchange of information on such innovative products and treatments among relevant offices and centers within the Center and within the National Institutes of Health, the Centers for Disease Control and Prevention, and other relevant Federal and State agencies.

TITLE II—TOBACCO PRODUCTS WARNINGS; CONSTITUENT AND SMOKE CONSTITUENT DISCLOSURE

SEC. 201. CIGARETTE LABEL AND ADVERTISING WARNINGS.

(a) AMENDMENT.—Section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) is amended to read as follows:

"SEC. 4. LABELING.

''(a) LABEL REQUIREMENTS.—

''(1) IN GENERAL.—It shall be unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any cigarettes the package of which fails to bear, in accordance with the requirements of this section, one of the following labels:

''WARNING: Cigarettes are addictive.

''WARNING: Tobacco smoke can harm your children.

''WARNING: Cigarettes cause fatal lung disease.

''WARNING: Cigarettes cause cancer.

''WARNING: Cigarettes cause strokes and heart disease.

''WARNING: Smoking during pregnancy can harm your baby.

''WARNING: Smoking can kill you.

''WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.

''WARNING: Quitting smoking now greatly reduces serious risks to your health.

''(2) PLACEMENT; TYPOGRAPHY; ETC.—Each label statement required by paragraph (1) shall be located in the lower portion of the front panel of the package, directly on the package underneath the cellophane or other clear wrapping. Each label statement shall comprise at least the bottom 25 percent of the front panel of the package. The word 'WARNING' shall appear in capital letters and all text shall be in conspicuous and legible 17-point type, unless the text of the label statement would occupy more than 70 percent of such area, in which case the text may be in a smaller conspicuous and legible type size, provided that at least 60 percent of such area is occupied by required text. The text shall be black on a white background, or white on a black background, in a manner that contrasts, by typography, layout, or color, with all other printed material on the package, in an alternating fashion under the plan submitted under subsection (c). The Secretary shall by regulation adjust the format and type size of the warnings required under this Act to include color graphics depicting the negative health consequences of smoking on the bottom portion of the front and rear panels.

''(3) DOES NOT APPLY TO FOREIGN DISTRIBUTION.—The provisions of this subsection do not apply to a tobacco product manufacturer or distributor of cigarettes which does not manufacture, package, or import cigarettes for sale or distribution within the United States.

''(4) APPLICABILITY TO RETAILERS.—A retailer of cigarettes shall not be in violation of this subsection for packaging that—

''(A) contains a warning label;

''(B) is supplied to the retailer by a license- or permit-holding smoking article manufacturer, importer, or distributor; and

''(C) is not altered by the retailer in a way that is material to the requirements of this subsection.

''(b) ADVERTISING REQUIREMENTS.—

''(1) IN GENERAL.—It shall be unlawful for any tobacco product manufacturer, importer, distributor, or retailer of cigarettes to advertise or cause to be advertised within the United States any cigarette unless its advertising bears, in accordance with the requirements of this section, one of the labels specified in subsection (a).

''(2) TYPOGRAPHY, ETC.—Each label statement required by subsection (a) in cigarette advertising shall comply with the standards set forth in this paragraph. For press and poster advertisements, each such statement and (where applicable) any required statement relating to tar, nicotine, or other constituent (including a smoke constituent) yield shall comprise at least 20 percent of the area of the advertisement and shall appear in a conspicuous and prominent format and location at the bottom of each advertisement within the trim area. The word 'WARNING' shall appear in capital letters, and each label statement shall appear in conspicuous and legible type. The text of the label statement shall be black if the background is white and white if the background is black, under the plan submitted under subsection (c). The label statements shall be enclosed by a rectangular border that is the same color as the letters of the statements and that is the width of the first downstroke of the capital 'W' of the word 'WARNING' in the label statements. The text of such label statements shall be in a typeface pro rata to the following requirements: 45-point type for a whole-page broadsheet newspaper advertisement; 39-point type for a half-page broadsheet newspaper advertisement; 39-point type for a whole-page tabloid newspaper advertisement; 27-point type for a half-page tabloid newspaper advertisement; 31.5-point type for a double page spread magazine or whole-page magazine advertisement; 22.5-point type for a 28 centimeter by 3 column advertisement; and 15-point type for a 20 centimeter by 2 column advertisement. The label statements shall be in English, except that—

''(A) in the case of an advertisement that appears in a newspaper, magazine, periodical, or other publication that is not in English, the statements shall appear in the predominant language of the publication; and

''(B) in the case of any other advertisement that is not in English, the statements shall

appear in the same language as that principally used in the advertisement.

''(3) MATCHBOOKS.—Notwithstanding paragraph (2), for matchbooks (defined as containing not more than 20 matches) customarily given away with the purchase of smokeless tobacco products, each label statement required by subsection (a) may be printed on the inside cover of the matchbook.

''(c) MARKETING REQUIREMENTS.—

''(1) RANDOM DISPLAY.—The label statements specified in subsection (a)(1) shall be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the smokeless tobacco product manufacturer, importer, distributor, or retailer and approved by the Secretary.

''(2) ROTATION.—The label statements specified in subsection (a)(1) shall be rotated quarterly in alternating sequence in advertisements for each brand of cigarettes in accordance with a plan submitted by the smokeless tobacco product manufacturer, importer, distributor, or retailer to, and approved by, the Secretary.

''(3) REVIEW.—The Secretary shall review each plan submitted under paragraph (2) and approve it if the plan—

''(A) will provide for the equal distribution and display on packaging and the rotation required in advertising under this subsection; and

''(B) assures that all of the labels required under this section will be displayed by the smokeless tobacco product manufacturer, importer, distributor, or retailer at the same time.

''(4) APPLICABILITY TO RETAILERS.—This subsection and subsection (b) apply to a retailer only if that retailer is responsible for or directs the label statements required under this section except that this paragraph shall not relieve a retailer of liability if the retailer displays, in a location open to the public, an advertisement that does not contain a warning label or has been altered by the retailer in a way that is material to the requirements of this subsection and subsection (b).''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect 24 months after the date of enactment of this Act. Such effective date shall be with respect to the date of manufacture, provided that, in any case, beginning 30 days after such effective date, a manufacturer shall not introduce into the domestic commerce of the United States any product, irrespective of the date of manufacture, that is not in conformance with section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333), as amended by subsection (a).

SEC. 202. SMOKELESS TOBACCO LABELS AND ADVERTISING WARNINGS.

(a) AMENDMENT.—Section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4402) is amended to read as follows:

''SEC. 3. SMOKELESS TOBACCO WARNING.

''(a) GENERAL RULE.—

''(1) It shall be unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any smokeless tobacco product unless the product package bears, in accordance with the requirements of this Act, the following labels:

''WARNING: Smokeless tobacco is addictive.

''(2) Rotating warnings for all smokeless products shall consist of 'lower risk than cigarettes' and 'addictive' and the Secretary shall have the discretion to add warnings relating to mouth cancer, gum disease, and tooth loss to those smokeless products that have a demonstrated risk of such hazards.

''(3) The two main rotating warnings should be extended to the 'nicotine containing products.'

''(4) The label statements required by paragraph (1) shall be introduced by each smokeless tobacco product manufacturer, packager, importer, distributor, or retailer of smokeless tobacco products concurrently into the distribution chain of such products.

''(5) The provisions of this subsection do not apply to a smokeless tobacco product manufacturer or distributor of any smokeless tobacco product that does not manufacture, package, or import smokeless tobacco products for sale or distribution within the United States.

''(6) A retailer of smokeless tobacco products shall not be in violation of this subsection for packaging that—

''(A) contains a warning label;

''(B) is supplied to the retailer by a license- or permit-holding smokeless tobacco product manufacturer, importer, or distributor; and

''(C) is not altered by the retailer in a way that is material to the requirements of this subsection.

''(b) REQUIRED LABELS.—

''(1) It shall be unlawful for any smokeless tobacco product manufacturer, packager, importer, distributor, or retailer of smokeless tobacco products to advertise or cause to be advertised within the United States any smokeless tobacco product unless its advertising bears, in accordance with the requirements of this section, one of the labels specified in subsection (a).

''(2)(A) Each label statement required by subsection (a) in smokeless tobacco advertising shall comply with the standards set forth in this paragraph.

''(B) For press and poster advertisements, each such statement and (where applicable) any required statement relating to nicotine, or other constituent yield shall comprise at least 20 percent of the area of the advertisement.

''(C) The word 'WARNING' shall appear in capital letters, and each label statement shall appear in conspicuous and legible type.

''(D) The text of the label statement shall be black on a white background, or white on a black background, in an alternating fashion under the plan submitted under paragraph (3).

''(E) The label statements shall be enclosed by a rectangular border that is the same color as the letters of the statements and that is the width of the first downstroke of the capital 'W' of the word 'WARNING' in the label statements.

''(F) The text of such label statements shall be in a typeface pro rata to the following requirements: 45-point type for a whole-page broadsheet newspaper advertisement; 39-point type for a half-page broadsheet newspaper advertisement; 39-point type for a whole-page tabloid newspaper advertisement; 27-point type for a half-page tabloid newspaper advertisement; 31.5-point type for a double page spread magazine or whole-page magazine advertisement; 22.5-point type for a 28 centimeter by 3 column advertisement; and 15-point type for a 20 centimeter by 2 column advertisement.

''(G) The label statements shall be in English, except that—

''(i) in the case of an advertisement that appears in a newspaper, magazine, periodical, or other publication that is not in English, the statements shall appear in the predominant language of the publication; and

''(ii) in the case of any other advertisement that is not in English, the statements shall appear in the same language as that principally used in the advertisement.

''(3)(A) The label statements specified in subsection (a)(1) shall be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the smokeless tobacco product manufacturer, importer, distributor, or retailer and approved by the Secretary.

''(B) The label statements specified in subsection (a)(1) shall be rotated quarterly in alternating sequence in advertisements for each brand of smokeless tobacco product in accordance with a plan submitted by the smokeless tobacco product manufacturer, importer, distributor, or retailer to, and approved by, the Secretary.

''(C) The Secretary shall review each plan submitted under subparagraphs (A) and (B) and approve it if the plan—

''(i) will provide for the equal distribution and display on packaging and the rotation required in advertising under this subsection; and

''(ii) assures that all of the labels required under this section will be displayed by the smokeless tobacco product manufacturer, importer, distributor, or retailer at the same time.

''(D) This paragraph applies to a retailer only if that retailer is responsible for or directs the label statements under this section, unless the retailer displays, in a location open to the public, an advertisement that does not contain a warning label or has been altered by the retailer in a way that is material to the requirements of this subsection.

''(c) TELEVISION AND RADIO ADVERTISING.—It is unlawful to advertise smokeless tobacco on any medium of electronic communications subject to the jurisdiction of the Federal Communications Commission.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect 24 months after the date of enactment of this Act. Such effective date shall be with respect to the date of manufacture, provided that, in any case, beginning 30 days after such effective date, a manufacturer shall not introduce into the domestic commerce of the United States any product, irrespective of the date of manufacture, that is not in conformance with section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4402), as amended by subsection (a).

TITLE III—PUBIC DISCLOSURES BY TOBACCO PRODUCTS MANUFACTURERS

SEC. 301. DISCLOSURES ON PACKAGES OF TOBACCO PRODUCTS.

(a) BACK FACE FOR REQUIRED DISCLOSURES.—For purposes of this section—

(1) the principal face of a package of a tobacco product is the face that has the largest surface area or, for faces with identical surface areas, any of the faces that have the largest surface area; a package shall not be characterized as having more than 2 principal faces;

(2) the front face shall be the principal face of the package;

(3) if the front and back faces are of different sizes in terms of area, then the larger face shall be the front face;

(4) the back face shall be the principal face of a package that is opposite the front face of the package;

(5) the bottom 50 percent of the back face of the package shall be allocated for required package disclosures in accordance with this section; and

(6) if a package of a tobacco product is cylindrical, a contiguous area constituting 30 percent of the total surface area of the cylinder shall be deemed the back face.

(b) REQUIRED INFORMATION ON BACK FACE.—Not later than 24 months after the effective date of this Act, the bottom 50 percent of the back face of a package of a tobacco product shall be available solely for disclosures required by or under this Act, the Federal Cigarette Labeling and Advertising Act, sections 1331–1340 of title 15, United States Code, and any other Federal statute. Such disclosures shall include—

(1) the printed name and address of the manufacturer, packer, or distributor, and any other identification associated with the manufacturer, packer, or distributor or with the tobacco product that the Administrator may require;

(2) a list of ingredients as required by subsection (e); and

(3) the appropriate tax registration number.

(c) PACKAGE DISCLOSURE OF INGREDIENTS.—Not later than 24 months after the effective date of this Act, the package of a tobacco product shall bear a list of the common or usual names of the ingredients present in the tobacco product in an amount greater than 0.1 percent of the total dry weight of the tobacco (including all ingredients), that shall comply with the following:

(1) Such listing of ingredients shall appear under, or be conspicuously accompanied by, the heading ''Tobacco and principal tobacco ingredients''.

(2) Tobacco may be listed as ''tobacco,'' and shall be the first listed ingredient.

(3) After tobacco, the ingredients shall be listed in descending order of predominance, by weight.

(4) Spices and natural and artificial flavors may be listed, respectively, as ''spices'' and ''natural and artificial flavors'' without naming each.

(5) Preservatives may be listed as ''preservatives'' without naming each.

(6) The disclosure of any ingredient in accordance with this section may, at the option of the tobacco product manufacturer, designate the functionality or purpose of that ingredient.

(7) The package say state ''Not for sale to minors''.

(8) In the case of a package of cigarettes, the package shall state that smokeless tobacco has significantly lower risks for disease and death than cigarettes.

SEC. 302. DISCLOSURES ON PACKAGES OF SMOKELESS TOBACCO.

(a) BACK FACE FOR REQUIRED DISCLOSURES.—For purposes of this section—

(1) the principal face of a package of smokeless tobacco is the face that has the largest surface area or, for faces with identical surface areas, any of the faces that have the largest surface area; a package shall not be characterized as having more than two principal faces;

(2) the front or top face shall be the principal face of the package;

(3) if the front or top and back or bottom faces are of different sizes in terms of area, then the larger face shall be the front or top face;

(4) the back or bottom face of the package shall be the principal face of a package that is opposite the front or top face of the package;

(5) beginning 24 months after the effective date of this Act, 50 percent of the back or bottom face of the package shall be allocated for required package disclosures in accordance with this section; and

(6) if the package is cylindrical, a contiguous area constituting 30 percent of the total surface area of the cylinder shall be deemed the back face.

(b) REQUIRED INFORMATION ON BACK OR BOTTOM FACE.—50 percent of the back or bottom face of a package of smokeless tobacco shall be available solely for disclosures required by or under this Act, the Comprehensive Smokeless Tobacco Health Education Act of 1986, sections 4401–4408 of title 15, United States Code, and any other Federal statute. Such disclosures shall include a list of ingredients as required by subsection (e).

(c) PACKAGE DISCLOSURE OF INGREDIENTS.—Commencing 24 months after the effective date of this Act, a package of smokeless tobacco shall bear a list of the common or usual names of the ingredients present in the smokeless tobacco in an amount greater than 0.1 percent of the total dry weight of the tobacco (including all ingredients).

(1) Such listing of ingredients shall appears under, or be conspicuously accompanied by, the heading ''Tobacco and principal tobacco ingredients''.

(2) Tobacco may be listed as ''tobacco,'' and shall be the first listed ingredient.

(3) After tobacco, the ingredients shall be listed in descending order of predominance, by weight.

(4) Spices and natural and artificial flavors may be listed, respectively, as ''spices'' and ''natural and artificial flavors'' without naming each.

(5) Preservatives may be listed as ''preservatives'' without naming each.

(6) The disclosure of any ingredient in accordance with this section may, at the option of the tobacco product manufacturer, designate the functionality or purpose of that ingredient.

(7) Not for sale to minors.

SEC. 303. PUBLIC DISCLOSURE OF INGREDIENTS.

(a) REGULATIONS.—Not later than 24 months after the effective date of this Act, the Administrator shall, by regulation, establish standards under which each tobacco product manufacturer shall disclose publicly, and update at least annually—

(1) a list of the ingredients it uses in each brand style it manufactures for commercial distribution domestically, as provided in subsection (b); and

(2) a composite list of all the ingredients it uses in any of the brand styles it manufactures for commercial distribution domestically, as provided in subsection (c).

(b) INGREDIENTS TO BE DISCLOSED AS TO EACH BRAND STYLE.—

(1) IN GENERAL.—With respect to the public disclosure required by subsection (a)(1), as to each brand style, the tobacco product manufacture shall disclose the common or usual name of each ingredient present in the brand style in an amount greater than 0.1 percent of the total dry weight of the tobacco (including all ingredients).

(2) REQUIREMENTS.—Disclosure under paragraph (1) shall comply with the following:

(A) Tobacco may be listed as ''tobacco,'' and shall be the first listed ingredient.

(B) After tobacco, the ingredients shall be listed in descending order of predominance, by weight.

(C) Spices and natural and artificial flavors may be listed, respectively, as ''spices'' and ''natural and artificial flavors'' without naming each.

(D) Preservatives may be listed as ''preservatives'' without naming each.

(E) The disclosure of any ingredient in accordance with this section may, at the option of the tobacco product manufacturer, designate the functionality or purpose of that ingredient.

(c) AGGREGATE DISCLOSURE OF INGREDIENTS.—

(1) IN GENERAL.—The public disclosure required of a tobacco product manufacturer by subsection (a)(2) shall consist of a single list of all ingredients used in any brand style a tobacco product manufacturer manufactures for commercial distribution domestically, without regard to the quantity used, and including, separately, each spice, each natural or artificial flavoring, and each preservative.

(2) LISTING.—The ingredients shall be listed by their respective common or usual names in descending order of predominance by the total weight used annually by the tobacco product manufacturer in manufacturing tobacco products for commercial distribution domestically.

(d) NO REQUIRED DISCLOSURE OF QUANTITIES.—The Administrator shall not require any public disclosure of quantitative information about any ingredient in a tobacco product.

(e) DISCLOSURE ON WEBSITE.—The public disclosures required by subsection (a) of this section may be by posting on an Internet-accessible website, or other location electronically accessible to the public, which is identified on all packages of a tobacco product manufacturer's tobacco products.

(f) TIMING OF INITIAL REQUIRED DISCLOSURES.—No disclosure pursuant to this section shall be required to commence until the regulations under subsection (a) have been in effect for not less than 1 year.

TITLE IV—PREVENTION OF ILLICIT TRADE IN TOBACCO PRODUCTS

SEC. 401. STUDY AND REPORT ON ILLICIT TRADE.

(a) The Administrator shall, after consultation with other relevant agencies including Customs and Tobacco Tax Bureau, conduct a study of trade in tobacco products that involves passage of tobacco products either between the States or from or to any other country across any border of the United States to—

(1) collect data on such trade in tobacco products, including illicit trade involving tobacco products, and make recommendations on the monitoring and enforcement of such trade;

(2) collect data on any advertising intended to be broadcast, transmitted, or distributed from or to the United States from or to another country and make recommendations on how to prevent or eliminate, and what technologies could help facilitate the elimination of, such advertising; and

(3) collect data on such trade in tobacco products by person that is not—

(A) a participating manufacturer (as that term is defined in section II(jj) of the Master Settlement Agreement of November 23, 1998, between certain of the States and certain tobacco product manufacturers); or

(B) an affiliate or subsidiary of a participating manufacturer.

(b) Not later than 18 months after the effective date of this Act, the Administrator shall submit to the Secretary, and committees of relevant jurisdiction in Congress, a report the recommendations of the study conducted under subsection (a).

SEC. 402. AMENDMENT TO SECTION 1926 OF THE PUBLIC HEALTH SERVICE ACT.

Section 1926 of the Public Health Service Act (42 U.S.C. § 300x–26) is amended by adding at the end thereof the following:

''(e)(1) Subject to paragraphs (2) and (3), for the first fiscal year after enactment and each subsequent fiscal year, the Secretary shall reduce, as provided in subsection (h), the amount of any grant under section 300x–21 of this title for any State that does not have in effect a statute with substantially the following provisions:

''''SEC. 1. DISTRIBUTION TO MINORS.

'''(a) No person shall distribute a tobacco product to an individual under 18 years of age or a different minimum age established under State law. A person who violates this subsection is liable for a civil money penalty of not less than $25 nor more than $125 for each violation of this subsection;

'''(b) The employer of an employee who has violated subsection (a) twice while in the

employ of such employer is liable for a civil money penalty of $125 for each subsequent violation by such employee.

''(c) It shall be a defense to a charge brought under subsection (a) that—

''(1) the defendant—

''(A) relied upon proof of age that appeared on its face to be valid in accordance with the Preventing Disease and Death from Tobacco Use Act;

''(B) had complied with the requirements of section 5 and, if applicable, section 7; or

''(C) relied upon a commercially available electronic age verification service to confirm that the person was an age-verified adult; or

''(2) the individual to whom the tobacco product was distributed was at the time of the distribution used in violation of subsection 7(b).

''SEC. 2. OUT-OF-PACKAGE DISTRIBUTION.

''It shall be unlawful for any person to distribute cigarettes or a smokeless tobacco product other than in an unopened package that complies in full with section 108 of the Preventing Disease and Death from Tobacco Use Act. A person who distributes a cigarette or a smokeless tobacco product in violation of this section is liable for a civil money penalty of not less than $25 nor more than $125 for each such violation.

''SEC. 3. SIGNAGE.

''It shall be unlawful for any person who sells tobacco products over-the-counter to fail to post conspicuously on the premises where such person sells tobacco products over-the-counter a sign communicating that—

''(1) the sale of tobacco products to individuals under 18 years of age or a different minimum age established under State law is prohibited by law;

''(2) the purchase of tobacco products by individuals under 18 years of age or a different minimum age established under State law is prohibited by law; and

''(3) proof of age may be demanded before tobacco products are sold.

A person who fails to post a sign that complies fully with this section is liable for a civil money penalty of not less than $25 nor more than $125.

''SEC. 4. NOTIFICATION OF EMPLOYEES.

''(a) Within 180 days of the effective date of the Preventing Disease and Death from Tobacco Use Act, every person engaged in the business of selling tobacco products at retail shall implement a program to notify each employee employed by that person who sells tobacco products at retail that—

''(1) the sale or other distribution of tobacco products to any individual under 18 years of age or a different minimum age established under State law, and the purchase, receipt, or possession of tobacco products in a place open to the public by any individual under 18 years of age or a different minimum age established under State law, is prohibited; and

''(2) out-of-package distribution of cigarettes and smokeless tobacco products is prohibited.

Any employer failing to provide the required notice to any employee shall be liable for a civil money penalty of not less than $25 nor more than $125 for each such violation.

''(b) It shall be a defense to a charge that an employer violated subsection (a) of this section that the employee acknowledged receipt, either in writing or by electronic means, prior to the alleged violation, of a statement in substantially the following form:

''I understand that State law prohibits the distribution of tobacco products to individuals under 18 years of age or a different minimum age established under State law and out-of-package distribution of cigarettes and smokeless tobacco products, and permits a defense based on evidence that a prospective purchaser's proof of age was reasonably relied upon and appeared on its face to be valid. I understand that if I sell, give, or voluntarily provide a tobacco product to an individual under 18 years of age or a different minimum age established under State law, I may be found responsible for a civil money penalty of not less than $25 nor more than $125 for each violation. I promise to comply with this law.'' ''

''(c) If an employer is charged with a violation of subsection (a) and the employer uses as a defense to such charge the defense provided by subsection (b), the employer shall be deemed to be liable for such violation if such employer pays the penalty imposed on the employee involved in such violation or in any way reimburses the employee for such penalty.

''SEC. 5. SELF-SERVICE DISPLAYS.

''(a) It shall be unlawful for any person who sells tobacco products over-the-counter at retail to maintain packages of such products in any location accessible to customers that is not under the control of a cashier or other employee during regular business hours. This subsection does not apply to any adult-only facility.

''(b) Any person who violates subsection (a) is liable for a civil money penalty of not less than $25 nor more than $125 for each such violation, except that no person shall be responsible for more than one violation per day at any one retail store.

''SEC. 6. DISTRIBUTION BY MAIL OR COURIER.

''(a) It shall be unlawful to distribute or sell tobacco products directly to consumers by mail or courier, unless the person receiving purchase requests for tobacco products takes reasonable action to prevent delivery to individuals who are not adults by—

''(1) requiring that addressees of the tobacco products be age-verified adults;

''(2) making good faith efforts to verify that such addressees have attained the minimum age for purchase of tobacco products established by the respective States wherein the addresses of the addressees are located; and

''(3) addressing the tobacco products delivered by mail or courier to a physical addresses and not to post office boxes.

''(b) Any person who violates subsection (a) is liable for a civil money penalty of not less than $25 nor more than $125 for each such violation.

''SEC. 7. RANDOM UNANNOUNCED INSPECTIONS; REPORTING; AND COMPLIANCE.

''(a) The State Police, or a local law enforcement authority duly designated by the State Police, or a public health authority shall enforce this Act in a manner that can reasonably be expected to reduce the extent to which tobacco products are distributed to individuals under 18 years of age or a different minimum age established under State law and shall conduct random, unannounced inspections in accordance with the procedures set forth in this Act and in regulations issued under section 1926 of the Federal Public Health Service Act (42 U.S.C. § 300x–26).

''(b) The State may engage an individual under 18 years of age or a different minimum age established under State law to test compliance with this Act, except that such an individual may be used to test compliance with this Act only if the testing is conducted under the following conditions:

''(1) Prior to use of any individual under 18 years of age or a different minimum age established under State law in a random, unannounced inspection, written consent shall be obtained from a parent, custodian, or guardian of such individual;

''(2) An individual under 18 years of age or a different minimum age established under State law shall act solely under the supervision and direction of the State Police or a local law enforcement authority, or public health authority duly designated by the State Police during a random, unannounced inspection;

''(3) An individual under 18 years of age or a different minimum age established under State law used in random, unannounced inspections shall not be used in any such inspection at a store in which such individual is a regular customer; and

''(4) If an individual under 18 years of age or a different minimum age established under State law participating in random, unannounced inspections is questioned during such an inspection about such individual's age, such individual shall state his or her actual age and shall present a true and correct proof of age if requested at any time during the inspection to present it.

''(c) Any person who uses any individual under 18 years of age or a different minimum age established under State law, other than as permitted by subsection (b), to test compliance with this Act, is liable for a civil money penalty of not less than $25 nor more than $125 for each such violation.

''(d) Civil money penalties collected for violations of this Act and fees collected under section 9 shall be used only to defray the costs of administration and enforcement of this Act.

''SEC. 8. LICENSURE.

''(a) Each person engaged in the over-the-counter distribution at retail of tobacco products shall hold a license issued under this section. A separate license shall be required for each place of business where tobacco products are distributed at retail. A license issued under this section is not assignable and is valid only for the person in whose name it is issued and for the place of business designated in the license.

''(b) The annual license fee is $25 for each place of business where tobacco products are distributed at retail.

''(c) Every application for a license, including renewal of a license, under this section shall be made upon a form provided by the appropriate State agency or department, and shall set forth the name under which the applicant transacts or intends to transact business, the location of the place of business for which the license is to be issued, the street address to which all notices relevant to the license are to be sent (in this Act referred to as ''notice address''), and any other identifying information that the appropriate State agency or department may require.

''(d) The appropriate State agency or department shall issue or renew a license or deny an application for a license or the renewal of a license within 30 days of receiving a properly completed application and the license fee. The appropriate State agency or department shall provide notice to an applicant of action on an application denying the issuance of a license or refusing to renew a license.

''(e) Every license issued by the appropriate State agency or department pursuant to this section shall be valid for 1 year from the date of issuance and shall be renewed upon application except as otherwise provided in this Act.

''(f) Upon notification of a change of address for a place of business for which a license has been issued, a license shall be reissued for the new address without the filing of a new application.

''(g) The appropriate State agency or department shall notify every person in the State who is engaged in the distribution at retail of tobacco products of the license requirements of this section and of the date by

which such person should have obtained a license.

''(h)(1) Except as provided in paragraph (2), any person who engages in the distribution at retail of tobacco products without a license required by this section is liable for a civil money penalty in an amount equal to (i) two times the applicable license fee, and (ii) $50 for each day that such distribution continues without a license.

''(2) Any person who engages in the distribution at retail of tobacco products after a license issued under this section has been suspended or revoked is liable for a civil money penalty of $100 per day for each day on which such distribution continues after the date such person received notice of such suspension or revocation.

''(i) No person shall engage in the distribution at retail of tobacco products on or after 180 days after the date of enactment this Act unless such person is authorized to do so by a license issued pursuant to this section or is an employee or agent of a person that has been issued such a license.

''SEC. 9. SUSPENSION, REVOCATION, DENIAL, AND NONRENEWAL OF LICENSES.

''(a) Upon a finding that a licensee has been determined by a court of competent jurisdiction to have violated this Act during the license term, the State shall notify the licensee in writing, served personally or by registered mail at the notice address, that any subsequent violation of this Act at the same place of business may result in an administrative action to suspend the license for a period determined by the specify the appropriate State agency or department.

''(b) Upon finding that a further violation by this Act has occurred involving the same place of business for which the license was issued and the licensee has been served notice once under subsection (a), the appropriate State agency or department may initiate an administrative action to suspend the license for a period to be determined by the appropriate State agency or department but not to exceed six months. If an administrative action to suspend a license is initiated, the appropriate State agency or department shall immediately notify the licensee in writing at the notice address of the initiation of the action and the reasons therefor and permit the licensee an opportunity, at least 30 days after written notice is served personally or by registered mail upon the licensee, to show why suspension of the license would be unwarranted or unjust.

''(c) The appropriate State agency or department may initiate an administrative action to revoke a license that previously has been suspended under subsection (b) if, after the suspension and during the one-year period for which the license was issued, the licensee committed a further violation of this Act, at the same place of business for which the license was issued. If an administrative action to revoke a license is initiated, the appropriate State agency or department shall immediately notify the licensee in writing at the notice address of the initiation of the action and the reasons therefor and permit the licensee an opportunity, at least 30 days after written notice is served personally or by registered mail upon the licensee, to show why revocation of the license would be unwarranted or unjust.

''(d) A person whose license has been suspended or revoked with respect to a place of business pursuant to this section shall pay a fee of $50 for the renewal or reissuance of the license at that same place of business, in addition to any applicable annual license fees.

''(e) Revocation of a license under subsection (c) with respect to a place of business shall not be grounds to deny an application by any person for a new license with respect to such place of business for more than 12 months subsequent to the date of such revocation. Revocation or suspension of a license with respect to a particular place of business shall not be grounds to deny an application for a new license, to refuse to renew a license, or to revoke or suspend an existing license at any other place of business.

''(f) A licensee may seek judicial review of an action of the appropriate State agency or department suspending, revoking, denying, or refusing to renew a license under this section by filing a complaint in a court of competent jurisdiction. Any such complaint shall be filed within 30 days after the date on which notice of the action is received by the licensee. The court shall review the evidence de novo.

''(g) The State shall not report any action suspending, revoking, denying, or refusing to renew a license under this section to the Federal Secretary of Health and Human Services, unless the opportunity for judicial review of the action pursuant to subsection (f), if any, has been exhausted or the time for seeking such judicial review has expired.

''SEC. 10. NO PRIVATE RIGHT OF ACTION.

''Nothing in this Act shall be construed to create a right of action by any private person for any violation of any provision of this Act.

''SEC. 11. JURISDICTION AND VENUE.

''Any action alleging a violation of this Act may be brought only in a court of general jurisdiction in the city or county where the violation is alleged to have occurred.

''SEC. 12. REPORT.

''The appropriate State agency or department shall prepare for submission annually to the Federal Secretary of Health and Human Services the report required by section 1926 of the Federal Public Health Service Act (42 U.S.C. 300x–26).'''.

''(2) In the case of a State whose legislature does not convene a regular session in fiscal year 2007, and in the case of a State whose legislature does not convene a regular session in fiscal year 2008, the requirement described in subsection (e)(1) as a condition of a receipt of a grant under section 300x–21 of this title shall apply only for fiscal year 2009 and subsequent fiscal years.

''(3) Subsection (e)(1) shall not affect any State or local law that (A) was in effect on the date of introduction of the Federal Tobacco Act of 2007, and (B) covers the same subject matter as the law described in subsection (e)(1). Any State law that meets the conditions of this paragraph shall also be deemed to meet the requirement described in subsection (e)(1) as a condition of a receipt of a grant under section 300x–21 of this title, if such State law is at least as stringent as the law described in subsection (e)(1).

''(f)(1) For the first applicable fiscal year and for each subsequent fiscal year, a funding agreement for a grant under section 300x–21 of this title is a funding agreement under which the State involved will enforce the law described in subsection (e)(1) of this section in a manner that can reasonably be expected to reduce the extent to which tobacco products are available to individuals under the age of 18 or a different minimum age established under State law for the purchase of tobacco products.

''(2) For the first applicable fiscal year and for each subsequent fiscal year, a funding agreement for a grant under section 300x–21 of this title is a funding agreement under which the State involved will—

''(A) conduct random, unannounced inspections to ensure compliance with the law described in subsection (e)(1); and

''(B) annually submit to the Secretary a report describing—

''(i) the activities carried out by the State to enforce such law during the fiscal year preceding the fiscal year for which the State is seeking the grant;

''(ii) the extent of success the State has achieved in reducing the availability of tobacco products to individuals under 18 years of age or a different minimum age established under State law, including the results of the inspections conducted under subparagraph (A); and

''(iii) the strategies to be utilized by the State for enforcing such law during the fiscal year for which the grant is sought.

''(g) The law specified in subsection (e)(1) may be administered and enforced by a State using—

''(1) any amounts made available to the State through a grant under section 300x–21 of this title;

''(2) any amounts made available to the State under section 300w of this title;

''(3) any fees collected for licenses issued pursuant to the law described in subsection (e)(1);

''(4) any fines or penalties assessed for violations of the law specified in subsection (e)(1); or

''(5) any other funding source that the legislature of the State may prescribe by statute.

''(h) Before making a grant under section 300x–21 of this title to a State for the first applicable fiscal year or any subsequent fiscal year, the Secretary shall make a determination of whether the State has maintained compliance with subsections (e) and (f) of this section. If, after notice to the State and an opportunity for a hearing, the Secretary determines that the State is not in compliance with such subsections, the Secretary shall reduce the amount of the allotment under section 300x–21 of this title for the State for the fiscal year involved by an amount equal to—

''(1) In the case of the first applicable fiscal year, 10 percent of the amount determined under section 300x–33 for the State for the fiscal year;

''(2) In the case of the first fiscal year following such applicable fiscal year, 20 percent of the amount determined under section 300x–33 for the State for the fiscal year;

''(3) In the case of the second such fiscal year, 30 percent of the amount determined under section 300x–33 for the State for the fiscal year; and

''(4) In the case of the third such fiscal year or any subsequent fiscal year, 40 percent of the amount determined under section 300x–33 for the State for the fiscal year.

The Secretary shall not have authority or discretion to grant to any State a waiver of the terms and requirements of this subsection or subsection (e) or (f).

''(i) For the purposes of subsections (e) through (h) of this section the term 'first applicable fiscal year' means—

''(1) fiscal year 2009, in the case of any State described in subsection (e)(2) of this section; and

''(2) fiscal year 2008, in the case of any other State.

''(j) For purposes of subsections (e) through (h) of this section, references to section 300x–21 shall include any successor grant programs.''

''(k) As required by paragraph (1), and subject to paragraph (4), an Indian tribe shall satisfy the requirements of subsection (e)(1) of this section by enacting a law or ordinance with substantially the same provisions as the law described in subsection (e)(1).

''(1) An Indian tribe shall comply with subsection (e)(1) of this section within 180 days after the Administrator finds, in accordance with this paragraph, that—

''(A) the Indian tribe has a governing body carrying out substantial governmental powers and duties;

''(B) the functions to be exercised by the Indian tribe under this Act pertain to activities on trust land within the jurisdiction of the tribe; and

''(C) the Indian tribe is reasonably expected to be capable of carrying out the functions required under this section.

Within 2 years of the date of enactment of the Federal Tobacco Act of 2007, as to each Indian tribe in the United States, the Administrator shall make the findings contemplated by this paragraph or determine that such findings cannot be made, in accordance with the procedures specified in paragraph (4).

''(2) As to Indian tribes subject to subsection (e)(1) of this section, the Administrator shall promulgate regulations that—

''(A) provide whether and to what extent, if any, the law described in subsection (e)(1) may be modified as adopted by Indian tribes; and

''(B) ensure, to the extent possible, that each Indian tribe's retailer licensing program under subsection (e)(1) is no less stringent than the program of the State or States in which the Indian tribe is located.

''(3) If with respect to any Indian tribe the Administrator determines that compliance with the requirements of subsection (e)(1) is inappropriate or administratively infeasible, the Administrator shall specify other means for the Indian tribe to achieve the purposes of the law described in subsection (e)(1) with respect to persons who engage in the distribution at retail of tobacco products on tribal lands.

''(4) The findings and regulations promulgated under paragraphs (1) and (2) shall be promulgated in conformance with section 553 of title 5, United States Code, and shall comply with the following provisions:

''(A) In making findings as provided in paragraph (1), and in drafting and promulgating regulations as provided in paragraph (2) (including drafting and promulgating any revised regulations), the Administrator shall confer with, and allow for active participation by, representatives and members of Indian tribes, and tribal organizations.

''(B) In carrying out rulemaking processes under this subsection, the Administrator shall follow the guidance of subchapter III of chapter 5 of title 5, United States Code, commonly known as the 'Negotiated Rulemaking Act of 1990.'

''(C) The tribal participants in the negotiation process referred to in subparagraph (B) shall be nominated by and shall represent the groups described in this subsection and shall include tribal representatives from all geographic regions.

''(D) The negotiations conducted under this paragraph (4) shall be conducted in a timely manner.

''(E) If the Administrator determines that an extension of the deadlines under subsection (k)(1) of this section is appropriate, the Secretary may submit proposed legislation to Congress for the extension of such deadlines.

''(5) This subsection shall not affect any law or ordinance that (A) was in effect on tribal lands on the date of introduction of the Preventing Disease and Death from Tobacco Use Act, and (B) covers the same subject matter as the law described in subsection (e)(1). Any law or ordinance that meets the conditions of this paragraph shall also be deemed to meet the requirement described in subsection (k)(1), if such law or ordinance is at least as stringent as the law described in subsection (e)(1).

''(6) For purposes of this subsection—

''(A) 'Administrator' means the Administrator of the Tobacco Harm Reduction Center.

''(B) 'Indian tribe' has the meaning assigned that term in section 4(e) of the Indian Self Determination and Education Assistance Act, section 450b(e) of title 25, United States Code.

''(C) 'Tribal lands' means all lands within the exterior boundaries of any Indian reservation, all lands the title to which is held by the United States in trust for an Indian tribe, or lands the title to which is held by an Indian tribe subject to a restriction by the United States against alienation, and all dependent Indian communities.

''(D) 'tribal organization' has the meaning assigned that term in section 4(l) of the Indian Self Determination and Education Assistance Act, section 450b(l) of title 25, United States Code.''.

SEC. 403. ESTABLISHMENT OF RANKINGS.

(a) STANDARDS AND PROCEDURES FOR RANKINGS.—Within 24 months after the effective date of this Act, the Administrator shall, by regulation, after consultation with an Advisory Committee established for such purpose, establish the standards and procedures for promulgating rankings, comprehensible to consumers of tobacco products, of the following categories of tobacco products and also nicotine-containing products on the basis of the relative risks of serious or chronic tobacco-related diseases and adverse health conditions those categories of tobacco products and also nicotine-containing products respectively present—

(1) smoking articles, including—

(A) cigarettes;

(B) cigars;

(C) little cigars;

(D) loose tobacco for roll-your own tobacco products;

(E) loose tobacco for pipes, hookas, and other pipe-like devices; and

(F) other smoking articles;

(2) smokeless products, including—

(A) chewing tobacco;

(B) dry snuff;

(C) snus (a type of moist snuff);

(D) other forms of moist snuff; and

(E) dissolvable tobacco products (such as sticks, orbs, or lozenges); and

(3) nicotine containing non-tobacco or tobacco extract products, including—

(A) nicotine gum;

(B) nicotine patches;

(C) electronic cigarettes; and

(D) other forms of such products.

The Administrator shall not have authority or discretion to establish a relative-risk ranking of any category or subcategory of tobacco products or any category or subcategory of nicotine-containing products other than the ten categories specified in this subsection.

(b) CONSIDERATIONS IN PROMULGATING REGULATIONS.—In promulgating regulations under this section, the Administrator—

(1) shall take into account relevant epidemiologic studies and other relevant competent and reliable scientific evidence; and

(2) in assessing the risks of serious or chronic tobacco-related diseases and adverse health conditions presented by a particular category, shall consider the range of tobacco products or nicotine-containing products within the category, and shall give appropriate weight to the market shares of the respective products in the category.

(c) PROMULGATION OF RANKINGS OF CATEGORIES.—Once the initial regulations required by subsection (a) are in effect, the Administrator shall promptly, by order, after notice and an opportunity for comment, promulgate to the general public rankings of the categories of tobacco products and nicotine-containing products in accordance with those regulations. The Administrator shall promulgate the initial rankings of those categories of tobacco products and nicotine-containing products to the general public not later than January 1, 2010. Thereafter, on an annual basis, the Administrator shall, by order, promulgate to the general public updated rankings that are (1) in accordance with those regulations, and (2) reflect the scientific evidence available at the time of promulgation. The Administrator shall open and maintain an ongoing public docket for receipt of data and other information submitted by any person with respect to such annual promulgation of rankings.

TITLE V—ENFORCEMENT PROVISIONS

SEC. 501. PROHIBITED ACTS.

The following acts and the causing thereof are hereby prohibited—

(1) the introduction or delivery for introduction into interstate commerce of any tobacco product that is adulterated or misbranded;

(2) the adulteration or misbranding of any tobacco product in interstate commerce;

(3) the receipt in interstate commerce of any tobacco product that is known to be adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise;

(4) the failure to establish or maintain any record, or make any report or other submission, or to provide any notice required by or under this Act; or the refusal to permit access to, verification of, or copying of any record as required by this Act;

(5) the refusal to permit entry or inspection as authorized by this Act;

(6) the making to the Administrator of a statement, report, certification or other submission required by this Act, with knowledge that such statement, report, certification, or other submission is false in a material aspect;

(7) the manufacturing, shipping, receiving, storing, selling, distributing, possession, or use of any tobacco product with knowledge that it is an illicit tobacco product;

(8) the forging, simulating without proper permission, falsely representing, or without proper authority using any brand name;

(9) the using by any person to his or her own advantage, or revealing, other than to the Administrator or officers or employees of the Agency, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of this Act concerning any item which as a trade secret is entitled to protection; except that the foregoing does not authorize the withholding of information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee;

(10) the alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a tobacco product, if such act is done while such tobacco product is held for sale (whether or not the first sale) after shipment in interstate commerce, and results in such tobacco product being adulterated or misbranded;

(11) the importation of any tobacco product that is adulterated, misbranded, or otherwise not in compliance with this Act; and

(12) the commission of any act prohibited by section 201 of this Act.

SEC. 502. INJUNCTION PROCEEDINGS.

(a) The district courts of the United States shall have jurisdiction, for cause shown, to restrain violations of this Act, except for violations of section 701(k).

(b) In case of an alleged violation of an injunction or restraining order issued under this section, which also constitutes a violation of this Act, trial shall be by the court, or upon demand of the defendant, by a jury.

SEC. 503. PENALTIES.

(a) CRIMINAL PENALTIES.—Any person who willfully violates a provision of section 501 of this Act shall be imprisoned for not more than one year or fined not more than $25,000, or both.

(b) CIVIL PENALTIES FOR VIOLATION OF SECTION 803.—

(1) Any person who knowingly distributes or sells, other than through retail sale or retail offer for sale, any cigarette brand style in violation of section 803(a)—

(A) for a first offense shall be liable for a civil penalty not to exceed $10,000 for each distribution or sale, or

(B) for a second offense shall be liable for a civil penalty not to exceed $25,000 for each distribution or sale,

except that the penalty imposed against any person with respect to violations during any 30-day period shall not exceed $100,000.

(2) Any retailer who knowingly distributes, sells or offers for sale any cigarette brand style in violation of section 803(a) shall—

(A) for a first offense for each sale or offer for sale of cigarettes, if the total number of packages of cigarettes sold or offered for sale—

(i) does not exceed 50 packages of cigarettes, be liable for a civil penalty not to exceed $500 for each sale or offer for sale, and

(ii) exceeds 50 packages of cigarettes, be liable for a civil penalty not to exceed $1,000 for each sale or offer for sale;

(B) for each subsequent offense for each sale or offer for sale of cigarettes, if the total number of cigarettes sold or offered for sale—

(i) does not exceed 50 packages of cigarettes, be liable for a civil penalty not to exceed $2,000 for each sale or offer for sale, and

(ii) exceeds 50 packages of cigarettes, be liable for a civil penalty not to exceed $5,000 for each sale or offer for sale;

except that the penalty imposed against any person during any 30-day period shall not exceed $25,000.

SEC. 504. SEIZURE.

(a) ARTICLES SUBJECT TO SEIZURE.—

(1) Any tobacco product that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of this Act, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the tobacco product is found. No libel for condemnation shall be instituted under this Act for any alleged misbranding if there is pending in any court a libel for condemnation proceeding under this Act based upon the same alleged misbranding, and not more than one such proceeding shall be instituted if no such proceeding is so pending, except that such limitations shall not apply—

(A) when such misbranding has been the basis of a prior judgment in favor of the United States, in a criminal, injunction, or libel for condemnation proceeding under this Act, or

(B) when the Administrator has probable cause to believe from facts found, without hearing, by the Administrator or any officer or employee of the Agency that the misbranded tobacco product is dangerous to health beyond the inherent danger to health posed by tobacco, or that the labeling of the misbranded tobacco product is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer. In any case where the number of libel for condemnation proceedings is limited as above provided, the proceeding pending or instituted shall, on application of the claimant, seasonably made, be removed for trial to any district agreed upon by stipulation between the parties, or, in case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, to which the case shall be removed for trial.

(2) The following shall be liable to be proceeded against at any time on libel of information and condemned in any district court of the United States within the jurisdiction of which they are found—

(A) any tobacco product that is an illicit tobacco product;

(B) any container of an illicit tobacco product;

(C) any equipment or thing used in making an illicit tobacco product; and

(D) any adulterated or misbranded tobacco product.

(3)(A) Except as provided in subparagraph (B), no libel for condemnation may be instituted under paragraph (1) or (2) against any tobacco product which—

(i) is misbranded under this Act because of its advertising, and

(ii) is being held for sale to the ultimate consumer in an establishment other than an establishment owned or operated by a manufacturer, packer, or distributor of the tobacco product.

(B) A libel for condemnation may be instituted under paragraph (1) or (2) against a tobacco product described in subparagraph (A) if the tobacco product's advertising which resulted in the tobacco product being misbranded was disseminated in the establishment in which the tobacco product is being held for sale to the ultimate consumer—

(i) such advertising was disseminated by, or under the direction of, the owner or operator of such establishment, or

(ii) all or part of the cost of such advertising was paid by such owner or operator.

(b) PROCEDURES.—The tobacco product, equipment, or other thing proceeded against shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty; except that on demand of either party any issue of fact joined in any such case shall be tried by jury. When libel for condemnation proceedings under this section, involving the same claimant and the same issues of adulteration or misbranding, are pending in two or more jurisdictions, such pending proceedings, upon application of the claimant seasonably made to the court of one such jurisdiction, shall be consolidated for trial by order of such court, and tried in (1) any district selected by the claimant where one of such proceedings is pending; or (2) a district agreed upon by stipulation between the parties. If no order for consolidation is so made within a reasonable time, the claimant may apply to the court of one such jurisdiction and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, in which all such pending proceedings shall be consolidated for trial and tried. Such order of consolidation shall not apply so as to require the removal of any case the date for trial of which has been fixed. The court granting such order shall give prompt notification thereof to the other courts having jurisdiction of the cases covered thereby.

(c) SAMPLES AND ANALYSES.—The court at any time after seizure up to a reasonable time before trial shall by order allow any party to a condemnation proceeding, the party's attorney or agent, to obtain a representative sample of the article seized and a true copy of the analysis, if any, on which the proceeding is based and the identifying marks or numbers, if any, of the packages from which the samples analyzed were obtained.

(d) DISPOSITION OF CONDEMNED TOBACCO PRODUCTS.—(1) Any tobacco product condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, direct; and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States; but such tobacco product shall not be sold under such decree contrary to the provisions of this Act or the laws of the jurisdiction in which sold. After entry of the decree and upon the payment of the costs of such proceedings and the execution of a good and sufficient bond conditioned that such article shall not be sold or disposed of contrary to the provisions of this Act or the laws of any State in which sold, the court may by order direct that such tobacco product be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this Act, under the supervision of an officer or employee duly designated by the Administrator; and the expenses of such supervision shall be paid by the person obtaining release of the tobacco product under bond. If the tobacco product was imported into the United States and the person seeking its release establishes (A) that the adulteration, misbranding, or violation did not occur after the tobacco product was imported, and (B) that the person seeking the release of the tobacco product had no cause for believing that it was adulterated, misbranded, or in violation before it was released from customs custody, the court may permit the tobacco product to be delivered to the owner for exportation under section 709 in lieu of destruction upon a showing by the owner that there is a reasonable certainty that the tobacco product will not be re-imported into the United States.

(2) The provisions of paragraph (1) of this subsection shall, to the extent deemed appropriate by the court, apply to any equipment or other thing which is not otherwise within the scope of such paragraph and which is referred to in paragraph (2) of subsection (a).

(3) Whenever in any proceeding under this section, involving paragraph (2) of subsection (a), the condemnation of any equipment or thing (other than a tobacco product) is decreed, the court shall allow the claim of any claimant, to the extent of such claimant's interest, for remission or mitigation of such forfeiture if such claimant proves to the satisfaction of the court (A) that such claimant has not caused the equipment or thing to be within one of the categories referred to in such paragraph (2) and has no interest in any tobacco product referred to therein, (B) that such claimant has an interest in such equipment or other thing as owner or lienor or otherwise, acquired by such claimant in good faith, and (C) that such claimant at no time had any knowledge or reason to believe that such equipment or other thing was being or would be used in, or to facilitate, the violation of laws of the United States relating to any illicit tobacco product.

(e) COSTS AND FEES.—When a decree of condemnation is entered against the tobacco product or other article, court costs and fees, and storage and other proper expenses shall

be awarded against the person, if any, intervening as claimant of the tobacco product or other article.

(f) REMOVAL FOR TRIAL.—In the case of removal for trial of any case as provided by subsection (a) or (b)—

(1) The clerk of the court from which removal is made shall promptly transmit to the court in which the case is to be tried all records in the case necessary in order that such court may exercise jurisdiction.

(2) The court to which such case was removed shall have the powers and be subject to the duties, for purposes of such case, which the court from which removal was made would have had, or to which such court would have been subject, if such case had not been removed.

(g) ADMINISTRATIVE DETENTION OF TOBACCO PRODUCTS.—

(1) DETENTION AUTHORITY.—

(A) IN GENERAL.—An officer or qualified employee of the Agency may order the detention, in accordance with this subsection, of any tobacco product that is found during an inspection, examination, or investigation under this Act conducted by such officer or qualified employee, if the officer or qualified employee has credible evidence or information indicating that such article presents a threat of serious adverse health consequences beyond those normally inherent in the use of tobacco products.

(B) ADMINISTRATOR'S APPROVAL.—A tobacco product or component thereof may be ordered detained under subparagraph (A) if, but only if, the Administrator or an official designated by the Administrator approves the order. An official may not be so designated unless the official is an officer with supervisory responsibility for the inspection, examination, or investigation that led to the order.

(2) PERIOD OF DETENTION.—A tobacco product may be detained under paragraph (1) for a reasonable period, not to exceed 20 days, unless a greater period, not to exceed 30 days, is necessary, to institute an action under subsection (a) or section 702.

(3) SECURITY OF DETAINED TOBACCO PRODUCT.—An order under paragraph (1) may require that the tobacco product to be detained be labeled or marked as detained, and shall require that the tobacco product be maintained in or removed to a secure facility, as appropriate. A tobacco product subject to such an order shall not be transferred by any person from the place at which the tobacco product is ordered detained, or from the place to which the tobacco product is so removed, as the case may be, until released by the Administrator or until the expiration of the detention period applicable under such order, whichever occurs first. This subsection may not be construed as authorizing the delivery of the tobacco product pursuant to the execution of a bond while the tobacco product is subject to the order, and section 709 does not authorize the delivery of the tobacco product pursuant to the execution of a bond while the article is subject to the order.

(4) APPEAL OF DETENTION ORDER.—

(A) IN GENERAL.—With respect to a tobacco product ordered detained under paragraph (1), any person who would be entitled to be a claimant of such tobacco product if the tobacco product were seized under subsection (a) may appeal the order to the Administrator. Within five days after such an appeal is filed, the Administrator, after providing opportunity for an informal hearing, shall confirm or terminate the order involved, and such confirmation by the Administrator shall be considered a final agency action for purposes of section 702 of title 5, United States Code. If during such five-day period the Administrator fails to provide such an opportunity, or to confirm or terminate such order, the order is deemed to be terminated.

(B) EFFECT OF INSTITUTING COURT ACTION.—The process under subparagraph (A) for the appeal of an order under paragraph (1) terminates if the Administrator institutes an action under subsection (a) or section 702 regarding the tobacco product involved.

SEC. 505. REPORT OF MINOR VIOLATIONS.

Nothing in this Act shall be construed as requiring the Administrator to report for prosecution, or for institution of libel or injunction proceedings, minor violations of this Act whenever the Administrator believes that the public interest will be adequately served by a suitable written notice or warning.

SEC. 506. INSPECTION.

(a) AUTHORITY TO INSPECT.—The Administrator shall have the power to inspect the premises of a tobacco product manufacturer for purposes of determining compliance with this Act, or the regulations promulgated under it. Officers of the Agency designated by the Administrator, upon presenting appropriate credentials and a written notice to the person in charge of the premises, are authorized to enter, at reasonable times, without a search warrant, any factory, warehouse, or other establishment in which tobacco products are manufactured, processed, packaged, or held for domestic distribution. Any such inspection shall be conducted within reasonable limits and in a reasonable manner, and shall be limited to examining only those things, including but not limited to records, relevant to determining whether violations of this Act, or regulations under it, have occurred. No inspection authorized by this section shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act), or research data. A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.

(b) REPORT OF OBSERVATIONS.—Before leaving the premises, the officer of the Agency who has supervised or conducted the inspection shall give to the person in charge of the premises a report in writing setting forth any conditions or practices that appear to manifest a violation of this Act, or the regulations under it.

(c) SAMPLES.—If the officer has obtained any sample in the course of inspection, prior to leaving the premises that officer shall give to the person in charge of the premises a receipt describing the samples obtained. As to each sample obtained, the officer shall furnish promptly to the person in charge of the premises a copy of the sample and of any analysis made upon the sample.

SEC. 507. EFFECT OF COMPLIANCE.

Compliance with the provisions of this Act and the regulations promulgated under it shall constitute a complete defense to any civil action, including but not limited to any products liability action, that seeks to recover damages, whether compensatory or punitive, based upon an alleged defect in the labeling or advertising of any tobacco product distributed for sale domestically.

SEC. 508. IMPORTS.

(a) IMPORTS; LIST OF REGISTERED FOREIGN ESTABLISHMENTS; SAMPLES FROM UNREGISTERED FOREIGN ESTABLISHMENTS; EXAMINATION AND REFUSAL OF ADMISSION.—The Secretary of Homeland Security shall deliver to the Administrator, upon request by the Administrator, samples of tobacco products that are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may appear before the Administrator and have the right to introduce testimony. The Administrator shall furnish to the Secretary of Homeland Security a list of establishments registered pursuant to subsection (d) of section 109 of this Act, and shall request that, if any tobacco products manufactured, prepared, or processed in an establishment not so registered are imported or offered for import into the United States, samples of such tobacco products be delivered to the Administrator, with notice of such delivery to the owner or consignee, who may appear before the Administrator and have the right to introduce testimony. If it appears from the examination of such samples or otherwise that (1) such tobacco product is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or (2) such tobacco product is adulterated, misbranded, or otherwise in violation of this Act, then such tobacco product shall be refused admission, except as provided in subsection (b) of this section. The Secretary of Homeland Security shall cause the destruction of any such tobacco product refused admission unless such tobacco product is exported, under regulations prescribed by the Secretary of Homeland Security, within ninety days of the date of notice of such refusal or within such additional time as may be permitted pursuant to such regulations.

(b) DISPOSITION OF REFUSED TOBACCO PRODUCTS.—Pending decision as to the admission of a tobacco product being imported or offered for import, the Secretary of Homeland Security may authorize delivery of such tobacco product to the owner or consignee upon the execution by such consignee of a good and sufficient bond providing for the payment of such liquidated damages in the event of default as may be required pursuant to regulations of the Secretary of Homeland Security. If it appears to the Administrator that a tobacco product included within the provisions of clause (3) of subsection (a) of this section can, by relabeling or other action, be brought into compliance with this Act or rendered other than a tobacco product, final determination as to admission of such tobacco product may be deferred and, upon filing of timely written application by the owner or consignee and the execution by such consignee of a bond as provided in the preceding provisions of this subsection, the Administrator may, in accordance with regulations, authorize the applicant to perform such relabeling or other action specified in such authorization (including destruction or export of rejected tobacco products or portions thereof, as may be specified in the Administrator's authorization). All such relabeling or other action pursuant to such authorization shall in accordance with regulations be under the supervision of an officer or employee of the Agency designated by the Administrator, or an officer or employee of the Department of Homeland Security designated by the Secretary of Homeland Security.

(c) CHARGES CONCERNING REFUSED TOBACCO PRODUCTS.—All expenses (including travel, per diem or subsistence, and salaries of officers or employees of the United States) in connection with the destruction provided for in subsection (a) of this section and the supervision of the relabeling or other action authorized under the provisions of subsection (b) of this section, the amount of such expenses to be determined in accordance with regulations, and all expenses in connection with the storage, cartage, or labor with respect to any tobacco product refused admission under subsection (a) of this section, shall be paid by the owner or consignee and, in default of such payment, shall

constitute a lien against any future importations made by such owner or consignee.

SEC. 509. TOBACCO PRODUCTS FOR EXPORT.

(a) EXEMPTION FOR TOBACCO PRODUCTS EXPORTED.—Except as provided in subsection (b), a tobacco product intended for export shall be exempt from this Act if—

(1) it is not in conflict with the laws of the country to which it is intended fore export, as shown by either (A) a document issued by the government of that country or (B) a document provided by a person knowledgeable with respect to the relevant laws of that country and qualified by training and experience to opine on whether the tobacco product is or is not in conflict with such laws;

(2) it is labeled on the outside of the shipping package that it is intended for export; and

(3) the particular units of tobacco product intended for export have not been sold or offered for sale in domestic commerce.

(b) PRODUCTS FOR U.S. ARMED FORCES OVERSEAS.—A tobacco product intended for export shall not be exempt from this Act if it is intended for sale or distribution to members or units of the Armed Forces of the United States located outside of the United States.

(c) This Act shall not apply to a person that manufactures and/or distributes tobacco products solely for export under subsection (a), except to the extent such tobacco products are subject to subsection (b).

TITLE VI—MISCELLANEOUS PROVISIONS

SEC. 601. USE OF PAYMENTS UNDER THE MASTER SETTLEMENT AGREEMENT AND INDIVIDUAL STATE SETTLEMENT AGREEMENTS.

(a) REDUCTION OF GRANT AMOUNTS.—(1) For fiscal year 2010 and each subsequent fiscal year, the Secretary shall reduce, as provided in subsection (b), the amount of any grant under section 1921 of the Public Health Service Act (42 U.S.C. § 300x–21) for any State that spends on tobacco control programs from the funds received by such State pursuant to the Master Settlement Agreement, the Florida Settlement Agreement, the Minnesota Settlement Agreement, the Mississippi Memorandum of Understanding, or the Texas Settlement Agreement, as applicable, less than 20 percent of the amounts received by that State from settlement payments.

(2) In the case of a State whose legislature does not convene a regular session in fiscal year 2009 or 2010, and in the case of a State whose legislature does not convene a regular session in fiscal year 2010, the requirement described in subsection (a)(1) as a condition of receipt of a grant under section 1921 of the Public Health Service Act shall apply only for fiscal year 2009 and subsequent fiscal years.

(b) DETERMINATION OF STATE SPENDING.—Before making a grant under section 1921 of the Public Health Service Act, section 300x–21 of title 42, United States Code, to a State for the first applicable fiscal year or any subsequent fiscal year, the Secretary shall make a determination of whether, during the immediately preceding fiscal year, the State has spent on tobacco control programs, from the funds received by such State pursuant to the Master Settlement Agreement, the Florida Settlement Agreement, the Minnesota Settlement Agreement, the Mississippi Memorandum of Understanding, or the Texas Settlement Agreement, as applicable, at least the amount referenced in (a)(1). If, after notice to the State and an opportunity for a hearing, the Secretary determines that the State has spent less than such amount, the Secretary shall reduce the amount of the allotment under section 300x–21 of title 42, United States Code, for the State for the fiscal year involved by an amount equal to—

(1) in the case of the first applicable fiscal year, 10 percent of the amount determined under section 300x–33 of title 42, United States Code, for the State for the fiscal year;

(2) in the case of the first fiscal year following such applicable fiscal year, 20 percent of the amount determined under section 300x–33 of title 42, United States Code, for the State for the fiscal year;

(3) in the case of the second such fiscal year, 30 percent of the amount determined under section 300x–33 of title 42, United States Code, for the State for the fiscal year; and

(4) in the case of the third such fiscal year or any subsequent fiscal year, 40 percent of the amount determined under section 300x–33 of title 42, United States Code, for the State for the fiscal year.

The Secretary shall not have authority or discretion to grant to any State a waiver of the terms and requirements of this subsection or subsection (a).

(c) DEFINITIONS.—For the purposes of this section—

(1) The term ''first applicable fiscal year'' means—

(A) fiscal year 2011, in the case of any State described in subsection (a)(2) of this section; and

(B) fiscal year 2010, in the case of any other State.

(2) The term ''Florida Settlement Agreement'' means the Settlement Agreement, together with the exhibits thereto, entered into on August 25, 1997, between the State of Florida and signatory tobacco product manufacturers, as specified therein.

(3) The term ''Master Settlement Agreement'' means the Master Settlement Agreement, together with the exhibits thereto, entered into on November 23, 1998, between the signatory States and signatory tobacco product manufacturers, as specified therein.

(4) The term ''Minnesota Settlement Agreement'' means the Settlement Agreement, together with the exhibits thereto, entered into on May 8, 1998, between the State of Minnesota and signatory tobacco product manufacturers, as specified therein.

(5) The term ''Mississippi Memorandum of Understanding'' means the Memorandum of Understanding, together with the exhibits thereto and Settlement Agreement contemplated therein, entered into on July 2, 1997, between the State of Mississippi and signatory tobacco product manufacturers, as specified therein.

(6) The term ''Secretary'' means the Secretary of Health and Human Services.

(7) The term ''Texas Settlement Agreement'' means the Settlement Agreement, together with the exhibits thereto, entered into on January 16, 1998, between the State of Texas and signatory tobacco product manufacturers, as specified therein.

SEC. 602. INSPECTION BY THE ALCOHOL AND TOBACCO TAX TRADE BUREAU OF RECORDS OF CERTAIN CIGARETTE AND SMOKELESS TOBACCO SELLERS.

(a) IN GENERAL.—Any officer of the Bureau of the Alcohol and Tobacco Tax Trade Bureau may, during normal business hours, enter the premises of any person described in subsection (b) for the purposes of inspecting—

(1) any records or information required to be maintained by such person under the provisions of law referred to in subsection (d); or

(2) any cigarettes or smokeless tobacco kept or stored by such person at such premises.

(b) COVERED PERSONS.—Subsection (a) applies to any person who engages in a delivery sale, and who ships, sells, distributes, or receives any quantity in excess of 10,000 cigarettes, or any quantity in excess of 500 single-unit consumer-sized cans or packages of smokeless tobacco, within a single month.

(c) RELIEF.—

(1) IN GENERAL.—The district courts of the United States shall have the authority in a civil action under this subsection to compel inspections authorized by subsection (a).

(2) VIOLATIONS.—Whoever violates subsection (a) or an order issued pursuant to paragraph (1) shall be subject to a civil penalty in an amount not to exceed $10,000 for each violation.

(d) COVERED PROVISIONS OF LAW.—The provisions of law referred to in this subsection are—

(1) the Act of October 19, 1949 (15 U.S.C. 375; commonly referred to as the ''Jenkins Act'');

(2) chapter 114 of title 18, United States Code; and

(3) this Act.

(e) DELIVERY SALE DEFINED.—In this section, the term ''delivery sale'' has the meaning given that term in 2343(e) of title 18, United States Code, as amended by this Act.

SEC. 603. SEVERABILITY.

If any provision of this Act, the amendments made by this Act, or the application of any provision of this Act to any person or circumstance is held to be invalid, the remainder of this Act, the amendments made by this Act, and the application of the provisions of this Act to any other person or circumstance shall not be affected, and shall continue to be enforced to the fullest extent possible.

TITLE VII—TOBACCO GROWER PROTECTION

SEC. 701. TOBACCO GROWER PROTECTION.

No provision in this Act shall allow the Administrator or any other person to require changes to traditional farming practices, including standard cultivation practices, curing processes, seed composition, tobacco type, fertilization, soil, record keeping, or any other requirement affecting farming practices.

TITLE VIII—RESTRICTIONS ON YOUTH ACCESS TO TOBACCO PRODUCTS AND EXPOSURE OF YOUTHS TO TOBACCO PRODUCT MARKETING AND ADVERTISING

SEC. 801. PROHIBITIONS ON YOUTH TARGETING.

Effective beginning on the date that is 18 months after the effective date of this Act, no person shall engage in any of the following activities or practices in the advertising, promotion, or marketing of any tobacco product:

(1) The use, or causing the use, of any cartoon in the advertising, promoting, packaging, or labeling of any tobacco product.

(2) The use, or causing the use, of any human image in the advertising, promoting, packaging, or labeling of any tobacco product, except for the following:

(A) The use, or continued use, in advertising, promoting, marketing, packaging, or labeling of any human image appearing on a tobacco product package before December 31, 2009.

(B) The use, or continued use, of a human image in the advertising, promoting, or marketing of a tobacco product, if conducted solely in an adult-only facility or facilities.

(C) The use, or continued use, of a human image in a tobacco product communication means directed solely to persons that the tobacco product manufacturer has a good-faith belief are age-verified adults.

(3) The advertising of tobacco products in any magazine or newspaper intended for distribution to the general public.

(4) The engaging in any brand name sponsorship in the United States, other than a brand name sponsorship occurring solely in an adult-only facility or facilities.

(5) The engaging in any brand name sponsorship of any event in the United States in which any paid participants or contestants are youths.

(6) The sponsoring of any athletic event between opposing teams in any football, basketball, baseball, soccer, or hockey league.

(7)(A) The securing of a right, by agreement, to name any stadium or arena located within the United States with a brand name; or

(B) otherwise causing a stadium or arena located within the United States to be named with a brand name.

(8) The securing of a right by agreement pursuant to which payment is made or other consideration is provided to use a brand name in association with any football, basketball, baseball, soccer, or hockey league, or any team involved in any such league.

(9) The use of, or causing the use of, by agreement requiring the payment of money or other consideration, a brand name with any nationally recognized or nationally established trade name or brand designation of any non-tobacco item or service, or any nationally recognized or nationally established sports team, entertainment group or individual celebrity for purposes of advertising, except for an agreement between or among persons that enter into such agreement for the sole purpose of avoiding infringement claims.

(10) The license, express authorization, or otherwise causing of any person to use or advertise within the United States any brand name in a manner that—

(A) does not pertain to a tobacco product; or

(B) causes that person to use the brand name to advertise, promote, package or label, distribute, or sell any product or service that is not a tobacco product.

(11) The marketing, distribution, offering, selling, licensing, or authorizing of, or the causing to be marketed, distributed, offered, sold, licensed, or authorized, any apparel or other merchandise (other than a tobacco product) bearing a brand name, except—

(A) apparel or other merchandise that is used by individuals representing a tobacco product manufacturer within an adult-only facility and that is not distributed, by sale or otherwise, to any member of the general public;

(B) apparel or merchandise provided to an adult employee of a tobacco product manufacturer for use by such employee;

(C) items or materials used to hold or display tobacco products at retail;

(D) items or materials the sole function of which is to advertise tobacco products;

(E) written or electronic publications;

(F) coupons or other items used by adults solely in connection with the purchase of tobacco products;

(G) that the composition, structure, form, or appearance of any tobacco product, package, label, or labeling shall not be affected by the prohibitions of this paragraph; and

(H) that no person shall be required to retrieve, collect or otherwise recover any item or material that was marketed, distributed, offered, sold, licensed, or caused to be marketed, distributed, offered, sold, or licensed by such person.

(12) The distribution, or causing the distribution, of any free sample domestically, except in an adult-only facility or facilities to individuals who are age-verified adults.

(13) The making of, or causing to be made, any payment or the payment of, or causing to be paid, any other consideration to any other person to use, display, make reference to, or use as a prop in any performance medium (for the purposes of this paragraph, the terms ''performance medium'' and ''performance media'' mean any motion picture, television show, theatrical production or other live performance, live or recorded performance of music, commercial film or video, or video game), any tobacco product, tobacco product package, advertisement for a tobacco product, or any other item bearing a brand name; except for the following:

(A) Performance media for which the audience or viewers are within one or more adult-only facilities, if such performance media are not audible or visible to persons outside such adult-only facility or facilities.

(B) Performance media not intended to be heard or viewed by the general public.

(C) Instructional performance media that concern tobacco products and their use, and that are intended to be heard or viewed only by, or provided only to, age-verified adults.

(D) Performance media used in tobacco product communications to age-verified adults.

(14) Engaging in outdoor advertising or transit advertisements of tobacco products within the United States, except for the following:

(A) Advertising that is within an adult-only facility.

(B) The use of outdoor advertising for purposes of identification of an adult-only facility, to the extent that such outdoor advertising is placed at the site, premises, or location of the adult-only facility.

(C) The use of outdoor advertising in identifying a brand name sponsorship at an adult-only facility, if such outdoor advertising—

(i) is placed at the site, premises, or location of the adult-only facility where such brand name sponsorship will occur no more than 30 days before the start of the initial sponsored event; and

(ii) is removed within 10 days after the end of the last sponsored event.

(15) The distribution or sale domestically of any package or other container of cigarettes containing fewer than 20 cigarettes.

(16) The advertising of tobacco products on any broadcast, cable, or satellite transmission to a television or radio receiver, or other medium of electronic communication subject to the jurisdiction of the Federal Communications Commission, except electronic communications—

(A) contained on log-in or home pages containing no tobacco product advertising other than brand name identification;

(B) in an adult-only facility or facilities; or

(C) through the Internet or other individual user-accessible electronic communication means, including websites accessible using the Internet, if the advertiser takes reasonable action to restrict access to individuals who are adults by—

(i) requiring individuals accessing such electronic communications to be age-verified adults, and

(ii) making good faith efforts to verify that such individuals are adults.

(17) The distribution or sale of tobacco products directly to consumers by mail or courier, unless the person receiving purchase requests for tobacco products takes reasonable action to prevent delivery to individuals who are not adults by—

(A) requiring that the addressees of the tobacco products be age-verified adults;

(B) making good faith efforts to verify that such addressees are adults; and

(C) addressing the tobacco products delivered by mail, courier or common carrier to a physical address and not a post office box.

(18) The providing of any gift of a non-tobacco product, except matches, in connection with the purchase of a tobacco product.

(19) The engaging in the sponsorship or promotion, or causing the sponsorship or promotion, of any consumer sweepstakes, contest, drawing, or similar activity resulting in the award of a prize in connection with advertising.

(20) The offering, promoting, conducting, or authorizing, or causing to be offered, promoted, conducted, or authorized, any consumer sweepstakes, drawing, contest, or other activity resulting in the award of a prize, based on redemption of a proof-of-purchase, coupon, or other item awarded as a result of the purchase or use of a tobacco product.

(21) The making of, or causing to be made, any payment or the payment of, or causing to be paid, any other consideration, to any other person with regard to the display or placement of any cigarettes, or any advertising for cigarettes, in any retail establishment that is not an adult-only facility.

TITLE IX—USER FEES

SEC. 901. USER FEES.

(a) ASSESSMENT OF USER FEES.—The Administrator shall assess an annual user fee for each fiscal year beginning in fiscal year 2010, in an amount calculated in accordance with this section, upon each tobacco product manufacturer (including each importer) that is subject to this Act.

(b) USE OF FEE.—The Administrator shall utilize an amount equal to the amount of user fees collected under this section in each fiscal year to pay for the costs of the activities of the Tobacco Regulatory Agency related to the regulation of tobacco products under this Act.

(c) AMOUNT OF FEE.—

(1) IN GENERAL.—Except as provided in paragraph (2), the total amount of user fees assessed for each fiscal year pursuant to this section shall be sufficient, and shall not exceed the amount necessary, to pay for the costs of the activities described in subsection (b) for that fiscal year.

(2) TOTAL.—The total assessment under this section—

(A) for fiscal years 2010, 2011, and 2012 shall be $100,000,000; and

(B) for each subsequent fiscal year, shall not exceed the limit on the assessment imposed during the previous fiscal year, as adjusted by the Administrator (after notice, published in the Federal Register) to be determined on the basis of both inflationary increases and guidance from the Scientific Advisory Committee—

(3) NOTIFICATION.—The Administrator shall notify each tobacco product manufacturer subject to this section of the amount of the annual assessment imposed on such tobacco product manufacturer under subsection (d). Such notifications shall occur not later than the July 31 prior to the beginning of the fiscal year for which such assessment is made, and payments of all assessments shall be made not later than 60 days after each such notification. Such notification shall contain a complete list of the assessments imposed on tobacco product manufacturers for that fiscal year.

(d) LIABILITY OF TOBACCO PRODUCT MANUFACTURERS FOR USER FEES.—

(1) IN GENERAL.—The user fee to be paid by each tobacco product manufacturer shall be determined in each fiscal year by multiplying—

(A) such tobacco product manufacturer's market share of tobacco products, as determined under regulations issued pursuant to subsection (e); by

(B) the total user fee assessment for such fiscal year, as determined under subsection (c).

(2) LIMITATION.—Except as provided in paragraph (3), no tobacco product manufacturer shall be required to pay a percentage of a total annual user fee for all tobacco product manufacturers that exceeds the market share of such manufacturer.

(3) FAILURE TO PAY.—If—

(A) a tobacco product manufacturer fails to pay its user fee share in full by the due date;

(B) the Administrator, after diligent inquiry, concludes that such manufacturer is unlikely to pay its user fee share in full by the time such payment will be needed by the Administrator; and

(C) the Administrator and the Department of Justice make diligent efforts to obtain payment in full from such tobacco product manufacturer;

the Administrator may re-allocate the unpaid amount owed by that tobacco product manufacturer to the other tobacco product manufacturers on the basis of their respective market shares. If the Administrator takes such action, the Administrator shall set a reasonable time, not less than 60 days from the date of the notice of the amount due, for payment of that amount. If and to the extent that the Administrator ultimately receives from that tobacco product manufacturer or any successor to such tobacco product manufacturer any payment in respect of the previously unpaid obligation, the Administrator shall credit such payment to the tobacco product manufacturers that paid portions of the re-allocated amount, in proportion to their respective payments of such amount.

(e) REGULATIONS.—Not later than 12 months after the date of enactment of this Act, the Administrator shall, by regulation, establish a system for determining the market shares of tobacco products for each tobacco product manufacturer subject to this section. In promulgating regulations under this subsection, the Administrator shall—

(1) take into account the differences between categories and subcategories of tobacco products in terms of sales, manner of unit packaging, and any other factors relevant to the calculation of market share for a tobacco product manufacturer;

(2) take into account that different tobacco product manufacturers rely to varying degrees on the sales of different categories and subcategories of tobacco products; and

(3) provide that the market share of tobacco products for each tobacco product manufacturer shall be recalculated on an annual basis.

SA 1247. Mr. DODD proposed an amendment to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; as follows:

Strike all after the enacting clause and insert the following:

DIVISION A—FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This division may be cited as the ''Family Smoking Prevention and Tobacco Control Act''.

(b) TABLE OF CONTENTS.—The table of contents of this division is as follows:

Sec. 1. Short title; table of contents.
Sec. 2. Findings.
Sec. 3. Purpose.
Sec. 4. Scope and effect.
Sec. 5. Severability.
Sec. 6. Modification of deadlines for Secretarial action.

TITLE I—AUTHORITY OF THE FOOD AND DRUG ADMINISTRATION

Sec. 101. Amendment of Federal Food, Drug, and Cosmetic Act.
Sec. 102. Final rule.
Sec. 103. Conforming and other amendments to general provisions.
Sec. 104. Study on raising the minimum age to purchase tobacco products.
Sec. 105. Enforcement action plan for advertising and promotion restrictions.
Sec. 106. Studies of progress and effectiveness.

TITLE II—TOBACCO PRODUCT WARNINGS; CONSTITUENT AND SMOKE CONSTITUENT DISCLOSURE

Sec. 201. Cigarette label and advertising warnings.
Sec. 202. Authority to revise cigarette warning label statements.
Sec. 203. State regulation of cigarette advertising and promotion.
Sec. 204. Smokeless tobacco labels and advertising warnings.
Sec. 205. Authority to revise smokeless tobacco product warning label statements.
Sec. 206. Tar, nicotine, and other smoke constituent disclosure to the public.

TITLE III—PREVENTION OF ILLICIT TRADE IN TOBACCO PRODUCTS

Sec. 301. Labeling, recordkeeping, records inspection.
Sec. 302. Study and report.

SEC. 2. FINDINGS.

The Congress finds the following:

(1) The use of tobacco products by the Nation's children is a pediatric disease of considerable proportions that results in new generations of tobacco-dependent children and adults.

(2) A consensus exists within the scientific and medical communities that tobacco products are inherently dangerous and cause cancer, heart disease, and other serious adverse health effects.

(3) Nicotine is an addictive drug.

(4) Virtually all new users of tobacco products are under the minimum legal age to purchase such products.

(5) Tobacco advertising and marketing contribute significantly to the use of nicotine-containing tobacco products by adolescents.

(6) Because past efforts to restrict advertising and marketing of tobacco products have failed adequately to curb tobacco use by adolescents, comprehensive restrictions on the sale, promotion, and distribution of such products are needed.

(7) Federal and State governments have lacked the legal and regulatory authority and resources they need to address comprehensively the public health and societal problems caused by the use of tobacco products.

(8) Federal and State public health officials, the public health community, and the public at large recognize that the tobacco industry should be subject to ongoing oversight.

(9) Under article I, section 8 of the Constitution, the Congress is vested with the responsibility for regulating interstate commerce and commerce with Indian tribes.

(10) The sale, distribution, marketing, advertising, and use of tobacco products are activities in and substantially affecting interstate commerce because they are sold, marketed, advertised, and distributed in interstate commerce on a nationwide basis, and have a substantial effect on the Nation's economy.

(11) The sale, distribution, marketing, advertising, and use of such products substantially affect interstate commerce through the health care and other costs attributable to the use of tobacco products.

(12) It is in the public interest for Congress to enact legislation that provides the Food and Drug Administration with the authority to regulate tobacco products and the advertising and promotion of such products. The benefits to the American people from enacting such legislation would be significant in human and economic terms.

(13) Tobacco use is the foremost preventable cause of premature death in America. It causes over 400,000 deaths in the United States each year, and approximately 8,600,000 Americans have chronic illnesses related to smoking.

(14) Reducing the use of tobacco by minors by 50 percent would prevent well over 10,000,000 of today's children from becoming regular, daily smokers, saving over 3,000,000 of them from premature death due to tobacco-induced disease. Such a reduction in youth smoking would also result in approximately $75,000,000,000 in savings attributable to reduced health care costs.

(15) Advertising, marketing, and promotion of tobacco products have been especially directed to attract young persons to use tobacco products, and these efforts have resulted in increased use of such products by youth. Past efforts to oversee these activities have not been successful in adequately preventing such increased use.

(16) In 2005, the cigarette manufacturers spent more than $13,000,000,000 to attract new users, retain current users, increase current consumption, and generate favorable long-term attitudes toward smoking and tobacco use.

(17) Tobacco product advertising often misleadingly portrays the use of tobacco as socially acceptable and healthful to minors.

(18) Tobacco product advertising is regularly seen by persons under the age of 18, and persons under the age of 18 are regularly exposed to tobacco product promotional efforts.

(19) Through advertisements during and sponsorship of sporting events, tobacco has become strongly associated with sports and has become portrayed as an integral part of sports and the healthy lifestyle associated with rigorous sporting activity.

(20) Children are exposed to substantial and unavoidable tobacco advertising that leads to favorable beliefs about tobacco use, plays a role in leading young people to overestimate the prevalence of tobacco use, and increases the number of young people who begin to use tobacco.

(21) The use of tobacco products in motion pictures and other mass media glamorizes its use for young people and encourages them to use tobacco products.

(22) Tobacco advertising expands the size of the tobacco market by increasing consumption of tobacco products including tobacco use by young people.

(23) Children are more influenced by tobacco marketing than adults: more than 80 percent of youth smoke three heavily marketed brands, while only 54 percent of adults, 26 and older, smoke these same brands.

(24) Tobacco company documents indicate that young people are an important and often crucial segment of the tobacco market. Children, who tend to be more price sensitive than adults, are influenced by advertising and promotion practices that result in drastically reduced cigarette prices.

(25) Comprehensive advertising restrictions will have a positive effect on the smoking rates of young people.

(26) Restrictions on advertising are necessary to prevent unrestricted tobacco advertising from undermining legislation prohibiting access to young people and providing for education about tobacco use.

(27) International experience shows that advertising regulations that are stringent and comprehensive have a greater impact on overall tobacco use and young people's use than weaker or less comprehensive ones.

(28) Text only requirements, although not as stringent as a ban, will help reduce underage use of tobacco products while preserving the informational function of advertising.

(29) It is in the public interest for Congress to adopt legislation to address the public health crisis created by actions of the tobacco industry.

(30) The final regulations promulgated by the Secretary of Health and Human Services in the August 28, 1996, issue of the Federal Register (61 Fed. Reg. 44615–44618) for inclusion as part 897 of title 21, Code of Federal Regulations, are consistent with the first amendment to the United States Constitution and with the standards set forth in the amendments made by this subtitle for the regulation of tobacco products by the Food and Drug Administration, and the restriction on the sale and distribution of, including access to and the advertising and promotion of, tobacco products contained in such regulations are substantially related to accomplishing the public health goals of this division.

(31) The regulations described in paragraph (30) will directly and materially advance the Federal Government's substantial interest in reducing the number of children and adolescents who use cigarettes and smokeless tobacco and in preventing the life-threatening health consequences associated with tobacco use. An overwhelming majority of Americans who use tobacco products begin using such products while they are minors and become addicted to the nicotine in those products before reaching the age of 18. Tobacco advertising and promotion play a crucial role in the decision of these minors to begin using tobacco products. Less restrictive and less comprehensive approaches have not and will not be effective in reducing the problems addressed by such regulations. The reasonable restrictions on the advertising and promotion of tobacco products contained in such regulations will lead to a significant decrease in the number of minors using and becoming addicted to those products.

(32) The regulations described in paragraph (30) impose no more extensive restrictions on communication by tobacco manufacturers and sellers than are necessary to reduce the number of children and adolescents who use cigarettes and smokeless tobacco and to prevent the life-threatening health consequences associated with tobacco use. Such regulations are narrowly tailored to restrict those advertising and promotional practices which are most likely to be seen or heard by youth and most likely to entice them into tobacco use, while affording tobacco manufacturers and sellers ample opportunity to convey information about their products to adult consumers.

(33) Tobacco dependence is a chronic disease, one that typically requires repeated interventions to achieve long-term or permanent abstinence.

(34) Because the only known safe alternative to smoking is cessation, interventions should target all smokers to help them quit completely.

(35) Tobacco products have been used to facilitate and finance criminal activities both domestically and internationally. Illicit trade of tobacco products has been linked to organized crime and terrorist groups.

(36) It is essential that the Food and Drug Administration review products sold or distributed for use to reduce risks or exposures associated with tobacco products and that it be empowered to review any advertising and labeling for such products. It is also essential that manufacturers, prior to marketing such products, be required to demonstrate that such products will meet a series of rigorous criteria, and will benefit the health of the population as a whole, taking into account both users of tobacco products and persons who do not currently use tobacco products.

(37) Unless tobacco products that purport to reduce the risks to the public of tobacco use actually reduce such risks, those products can cause substantial harm to the public health to the extent that the individuals, who would otherwise not consume tobacco products or would consume such products less, use tobacco products purporting to reduce risk. Those who use products sold or distributed as modified risk products that do not in fact reduce risk, rather than quitting or reducing their use of tobacco products, have a substantially increased likelihood of suffering disability and premature death. The costs to society of the widespread use of products sold or distributed as modified risk products that do not in fact reduce risk or that increase risk include thousands of unnecessary deaths and injuries and huge costs to our health care system.

(38) As the National Cancer Institute has found, many smokers mistakenly believe that ''low tar'' and ''light'' cigarettes cause fewer health problems than other cigarettes. As the National Cancer Institute has also found, mistaken beliefs about the health consequences of smoking ''low tar'' and ''light'' cigarettes can reduce the motivation to quit smoking entirely and thereby lead to disease and death.

(39) Recent studies have demonstrated that there has been no reduction in risk on a population-wide basis from ''low tar'' and ''light'' cigarettes, and such products may actually increase the risk of tobacco use.

(40) The dangers of products sold or distributed as modified risk tobacco products that do not in fact reduce risk are so high that there is a compelling governmental interest in ensuring that statements about modified risk tobacco products are complete, accurate, and relate to the overall disease risk of the product.

(41) As the Federal Trade Commission has found, consumers have misinterpreted advertisements in which one product is claimed to be less harmful than a comparable product, even in the presence of disclosures and advisories intended to provide clarification.

(42) Permitting manufacturers to make unsubstantiated statements concerning modified risk tobacco products, whether express or implied, even if accompanied by disclaimers would be detrimental to the public health.

(43) The only way to effectively protect the public health from the dangers of unsubstantiated modified risk tobacco products is to empower the Food and Drug Administration to require that products that tobacco manufacturers sold or distributed for risk reduction be reviewed in advance of marketing, and to require that the evidence relied on to support claims be fully verified.

(44) The Food and Drug Administration is a regulatory agency with the scientific expertise to identify harmful substances in products to which consumers are exposed, to design standards to limit exposure to those substances, to evaluate scientific studies supporting claims about the safety of products, and to evaluate the impact of labels, labeling, and advertising on consumer behavior in order to reduce the risk of harm and promote understanding of the impact of the product on health. In connection with its mandate to promote health and reduce the risk of harm, the Food and Drug Administration routinely makes decisions about whether and how products may be marketed in the United States.

(45) The Federal Trade Commission was created to protect consumers from unfair or deceptive acts or practices, and to regulate unfair methods of competition. Its focus is on those marketplace practices that deceive or mislead consumers, and those that give some competitors an unfair advantage. Its mission is to regulate activities in the marketplace. Neither the Federal Trade Commission nor any other Federal agency except the Food and Drug Administration possesses the scientific expertise needed to implement effectively all provisions of the Family Smoking Prevention and Tobacco Control Act.

(46) If manufacturers state or imply in communications directed to consumers through the media or through a label, labeling, or advertising, that a tobacco product is approved or inspected by the Food and Drug Administration or complies with Food and Drug Administration standards, consumers are likely to be confused and misled. Depending upon the particular language used and its context, such a statement could result in consumers being misled into believing that the product is endorsed by the Food and Drug Administration for use or in consumers being misled about the harmfulness of the product because of such regulation, inspection, approval, or compliance.

(47) In August 2006 a United States district court judge found that the major United States cigarette companies continue to target and market to youth. USA v. Philip Morris, USA, Inc., et al. (Civil Action No. 99–2496 (GK), August 17, 2006).

(48) In August 2006 a United States district court judge found that the major United States cigarette companies dramatically increased their advertising and promotional spending in ways that encourage youth to start smoking subsequent to the signing of the Master Settlement Agreement in 1998. USA v. Philip Morris, USA, Inc., et al. (Civil Action No. 99–2496 (GK), August 17, 2006).

(49) In August 2006 a United States district court judge found that the major United States cigarette companies have designed their cigarettes to precisely control nicotine delivery levels and provide doses of nicotine sufficient to create and sustain addiction while also concealing much of their nicotine-related research. USA v. Philip Morris, USA, Inc., et al. (Civil Action No. 99–2496 (GK), August 17, 2006).

SEC. 3. PURPOSE.

The purposes of this division are—

(1) to provide authority to the Food and Drug Administration to regulate tobacco products under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), by recognizing it as the primary Federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products as provided for in this division;

(2) to ensure that the Food and Drug Administration has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco;

(3) to authorize the Food and Drug Administration to set national standards controlling the manufacture of tobacco products and the identity, public disclosure, and amount of ingredients used in such products;

(4) to provide new and flexible enforcement authority to ensure that there is effective oversight of the tobacco industry's efforts to develop, introduce, and promote less harmful tobacco products;

(5) to vest the Food and Drug Administration with the authority to regulate the levels of tar, nicotine, and other harmful components of tobacco products;

(6) in order to ensure that consumers are better informed, to require tobacco product manufacturers to disclose research which has not previously been made available, as well as research generated in the future, relating to the health and dependency effects or safety of tobacco products;

(7) to continue to permit the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage purchasers;

(8) to impose appropriate regulatory controls on the tobacco industry;

(9) to promote cessation to reduce disease risk and the social costs associated with tobacco-related diseases; and

(10) to strengthen legislation against illicit trade in tobacco products.

SEC. 4. SCOPE AND EFFECT.

(a) INTENDED EFFECT.—Nothing in this division (or an amendment made by this division) shall be construed to—

(1) establish a precedent with regard to any other industry, situation, circumstance, or legal action; or

(2) affect any action pending in Federal, State, or tribal court, or any agreement, consent decree, or contract of any kind.

(b) AGRICULTURAL ACTIVITIES.—The provisions of this division (or an amendment made by this division) which authorize the Secretary to take certain actions with regard to tobacco and tobacco products shall not be construed to affect any authority of the Secretary of Agriculture under existing law regarding the growing, cultivation, or curing of raw tobacco.

(c) REVENUE ACTIVITIES.—The provisions of this division (or an amendment made by this division) which authorize the Secretary to take certain actions with regard to tobacco products shall not be construed to affect any authority of the Secretary of the Treasury under chapter 52 of the Internal Revenue Code of 1986.

SEC. 5. SEVERABILITY.

If any provision of this division, of the amendments made by this division, or of the regulations promulgated under this division (or under such amendments), or the application of any such provision to any person or circumstance is held to be invalid, the remainder of this division, such amendments and such regulations, and the application of such provisions to any other person or circumstance shall not be affected and shall continue to be enforced to the fullest extent possible.

SEC. 6. MODIFICATION OF DEADLINES FOR SECRETARIAL ACTION.

(a) DELAYED COMMENCEMENT OF DATES FOR SECRETARIAL ACTION.—

(1) IN GENERAL.—Except as provided in subsection (c), with respect to any time periods specified in this division (or in an amendment made by this division) that begin on the date of enactment of this Act, within which the Secretary of Health and Human Services is required to carry out and complete specified activities, the calculation of such time periods shall commence on the date described in subsection (b).

(2) LIMITATION.—Subsection (a) shall only apply with respect to obligations of the Secretary of Health and Human Services that must be completed within a specified time period and shall not apply to the obligations of any other person or to any other provision of this division (including the amendments made by this division) that do not create such obligations of the Secretary and are not contingent on actions by the Secretary.

(b) DATE DESCRIBED.—The date described in this subsection is the first day of the first fiscal quarter following the initial 2 consecutive fiscal quarters of fiscal year 2010 for which the Secretary of Health and Human Services has collected fees under section 919 of the Federal Food, Drug, and Cosmetic Act (as added by section 101).

(c) EXCEPTION.—Subsection (a) shall not apply to any time period (or date) contained—

(1) in section 102, except that the reference to ''180 days'' in subsection (a)(1) of such section shall be deemed to be ''270 days''; and

(2) in sections 201 through 204 (or the amendments made by any such sections).

(d) ADJUSTMENT.—The Secretary of Health and Human Services may extend or reduce the duration of one or more time periods to which subsection (a) applies if the Secretary determines appropriate, except that no such period shall be extended for more than 90 days.

TITLE I—AUTHORITY OF THE FOOD AND DRUG ADMINISTRATION

SEC. 101. AMENDMENT OF FEDERAL FOOD, DRUG, AND COSMETIC ACT.

(a) DEFINITION OF TOBACCO PRODUCTS.—Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following:

''(rr)(1) The term 'tobacco product' means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).

''(2) The term 'tobacco product' does not mean an article that is a drug under subsection (g)(1), a device under subsection (h), or a combination product described in section 503(g).

''(3) The products described in paragraph (2) shall be subject to chapter V of this Act.

''(4) A tobacco product shall not be marketed in combination with any other article or product regulated under this Act (including a drug, biologic, food, cosmetic, medical device, or a dietary supplement).''.

(b) FDA AUTHORITY OVER TOBACCO PRODUCTS.—The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is amended—

(1) by redesignating chapter IX as chapter X;

(2) by redesignating sections 901 through 910 as sections 1001 through 1010; and

(3) by inserting after chapter VIII the following:

''CHAPTER IX—TOBACCO PRODUCTS

''SEC. 900. DEFINITIONS.

''In this chapter:

''(1) ADDITIVE.—The term 'additive' means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), except that such term does not include tobacco or a pesticide chemical residue in or on raw tobacco or a pesticide chemical.

''(2) BRAND.—The term 'brand' means a variety of tobacco product distinguished by the tobacco used, tar content, nicotine content, flavoring used, size, filtration, packaging, logo, registered trademark, brand name, identifiable pattern of colors, or any combination of such attributes.

''(3) CIGARETTE.—The term 'cigarette'—

''(A) means a product that—

''(i) is a tobacco product; and

''(ii) meets the definition of the term 'cigarette' in section 3(1) of the Federal Cigarette Labeling and Advertising Act; and

''(B) includes tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco.

''(4) CIGARETTE TOBACCO.—The term 'cigarette tobacco' means any product that consists of loose tobacco that is intended for use by consumers in a cigarette. Unless otherwise stated, the requirements applicable to cigarettes under this chapter shall also apply to cigarette tobacco.

''(5) COMMERCE.—The term 'commerce' has the meaning given that term by section 3(2) of the Federal Cigarette Labeling and Advertising Act.

''(6) COUNTERFEIT TOBACCO PRODUCT.—The term 'counterfeit tobacco product' means a tobacco product (or the container or labeling of such a product) that, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a tobacco product listed in a registration under section 905(i)(1).

''(7) DISTRIBUTOR.—The term 'distributor' as regards a tobacco product means any person who furthers the distribution of a tobacco product, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Common carriers are not considered distributors for purposes of this chapter.

''(8) ILLICIT TRADE.—The term 'illicit trade' means any practice or conduct prohibited by law which relates to production, shipment, receipt, possession, distribution, sale, or purchase of tobacco products including any practice or conduct intended to facilitate such activity.

''(9) INDIAN COUNTRY.—The term 'Indian country' has the meaning given such term in section 1151 of title 18, United States Code.

''(10) INDIAN TRIBE.—The term 'Indian tribe' has the meaning given such term in section 4(e) of the Indian Self-Determination and Education Assistance Act.

''(11) LITTLE CIGAR.—The term 'little cigar' means a product that—

''(A) is a tobacco product; and

''(B) meets the definition of the term 'little cigar' in section 3(7) of the Federal Cigarette Labeling and Advertising Act.

''(12) NICOTINE.—The term 'nicotine' means the chemical substance named 3-(1-Methyl-2-pyrrolidinyl) pyridine or C[10]H[14]N[2], including any salt or complex of nicotine.

''(13) PACKAGE.—The term 'package' means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers.

''(14) RETAILER.—The term 'retailer' means any person, government, or entity who sells tobacco products to individuals for personal consumption, or who operates a facility where self-service displays of tobacco products are permitted.

''(15) ROLL-YOUR-OWN TOBACCO.—The term 'roll-your-own tobacco' means any tobacco product which, because of its appearance, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco for making cigarettes.

''(16) SMALL TOBACCO PRODUCT MANUFACTURER.—The term 'small tobacco product manufacturer' means a tobacco product manufacturer that employs fewer than 350 employees. For purposes of determining the number of employees of a manufacturer under the preceding sentence, the employees of a manufacturer are deemed to include the

employees of each entity that controls, is controlled by, or is under common control with such manufacturer.

''(17) SMOKE CONSTITUENT.—The term 'smoke constituent' means any chemical or chemical compound in mainstream or sidestream tobacco smoke that either transfers from any component of the cigarette to the smoke or that is formed by the combustion or heating of tobacco, additives, or other component of the tobacco product.

''(18) SMOKELESS TOBACCO.—The term 'smokeless tobacco' means any tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity.

''(19) STATE; TERRITORY.—The terms 'State' and 'Territory' shall have the meanings given to such terms in section 201.

''(20) TOBACCO PRODUCT MANUFACTURER.—The term 'tobacco product manufacturer' means any person, including any repacker or relabeler, who—

''(A) manufactures, fabricates, assembles, processes, or labels a tobacco product; or

''(B) imports a finished tobacco product for sale or distribution in the United States.

''(21) TOBACCO WAREHOUSE.—

''(A) Subject to subparagraphs (B) and (C), the term 'tobacco warehouse' includes any person—

''(i) who—

''(I) removes foreign material from tobacco leaf through nothing other than a mechanical process;

''(II) humidifies tobacco leaf with nothing other than potable water in the form of steam or mist; or

''(III) de-stems, dries, and packs tobacco leaf for storage and shipment;

''(ii) who performs no other actions with respect to tobacco leaf; and

''(iii) who provides to any manufacturer to whom the person sells tobacco all information related to the person's actions described in clause (i) that is necessary for compliance with this Act.

''(B) The term 'tobacco warehouse' excludes any person who—

''(i) reconstitutes tobacco leaf;

''(ii) is a manufacturer, distributor, or retailer of a tobacco product; or

''(iii) applies any chemical, additive, or substance to the tobacco leaf other than potable water in the form of steam or mist.

''(C) The definition of the term 'tobacco warehouse' in subparagraph (A) shall not apply to the extent to which the Secretary determines, through rulemaking, that regulation under this chapter of the actions described in such subparagraph is appropriate for the protection of the public health.

''(22) UNITED STATES.—The term 'United States' means the 50 States of the United States of America and the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, Johnston Atoll, the Northern Mariana Islands, and any other trust territory or possession of the United States.

"SEC. 901. FDA AUTHORITY OVER TOBACCO PRODUCTS.

''(a) IN GENERAL.—Tobacco products, including modified risk tobacco products for which an order has been issued in accordance with section 911, shall be regulated by the Secretary under this chapter and shall not be subject to the provisions of chapter V.

''(b) APPLICABILITY.—This chapter shall apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary by regulation deems to be subject to this chapter.

''(c) SCOPE.—

''(1) IN GENERAL.—Nothing in this chapter, or any policy issued or regulation promulgated thereunder, or in sections 101(a), 102, or 103 of title I, title II, or title III of the Family Smoking Prevention and Tobacco Control Act, shall be construed to affect, expand, or limit the Secretary's authority over (including the authority to determine whether products may be regulated), or the regulation of, products under this Act that are not tobacco products under chapter V or any other chapter.

''(2) LIMITATION OF AUTHORITY.—

''(A) IN GENERAL.—The provisions of this chapter shall not apply to tobacco leaf that is not in the possession of a manufacturer of tobacco products, or to the producers of tobacco leaf, including tobacco growers, tobacco warehouses, and tobacco grower cooperatives, nor shall any employee of the Food and Drug Administration have any authority to enter onto a farm owned by a producer of tobacco leaf without the written consent of such producer.

''(B) EXCEPTION.—Notwithstanding subparagraph (A), if a producer of tobacco leaf is also a tobacco product manufacturer or controlled by a tobacco product manufacturer, the producer shall be subject to this chapter in the producer's capacity as a manufacturer. The exception in this subparagraph shall not apply to a producer of tobacco leaf who grows tobacco under a contract with a tobacco product manufacturer and who is not otherwise engaged in the manufacturing process.

''(C) RULE OF CONSTRUCTION.—Nothing in this chapter shall be construed to grant the Secretary authority to promulgate regulations on any matter that involves the production of tobacco leaf or a producer thereof, other than activities by a manufacturer affecting production.

''(d) RULEMAKING PROCEDURES.—Each rulemaking under this chapter shall be in accordance with chapter 5 of title 5, United States Code. This subsection shall not be construed to affect the rulemaking provisions of section 102(a) of the Family Smoking Prevention and Tobacco Control Act.

''(e) CENTER FOR TOBACCO PRODUCTS.—Not later than 90 days after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall establish within the Food and Drug Administration the Center for Tobacco Products, which shall report to the Commissioner of Food and Drugs in the same manner as the other agency centers within the Food and Drug Administration. The Center shall be responsible for the implementation of this chapter and related matters assigned by the Commissioner.

''(f) OFFICE TO ASSIST SMALL TOBACCO PRODUCT MANUFACTURERS.—The Secretary shall establish within the Food and Drug Administration an identifiable office to provide technical and other nonfinancial assistance to small tobacco product manufacturers to assist them in complying with the requirements of this Act.

''(g) CONSULTATION PRIOR TO RULEMAKING.—Prior to promulgating rules under this chapter, the Secretary shall endeavor to consult with other Federal agencies as appropriate.

"SEC. 902. ADULTERATED TOBACCO PRODUCTS.

''A tobacco product shall be deemed to be adulterated if—

''(1) it consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise contaminated by any added poisonous or added deleterious substance that may render the product injurious to health;

''(2) it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health;

''(3) its package is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

''(4) the manufacturer or importer of the tobacco product fails to pay a user fee assessed to such manufacturer or importer pursuant to section 919 by the date specified in section 919 or by the 30th day after final agency action on a resolution of any dispute as to the amount of such fee;

''(5) it is, or purports to be or is represented as, a tobacco product which is subject to a tobacco product standard established under section 907 unless such tobacco product is in all respects in conformity with such standard;

''(6)(A) it is required by section 910(a) to have premarket review and does not have an order in effect under section 910(c)(1)(A)(i); or

''(B) it is in violation of an order under section 910(c)(1)(A);

''(7) the methods used in, or the facilities or controls used for, its manufacture, packing, or storage are not in conformity with applicable requirements under section 906(e)(1) or an applicable condition prescribed by an order under section 906(e)(2); or

''(8) it is in violation of section 911.

"SEC. 903. MISBRANDED TOBACCO PRODUCTS.

''(a) IN GENERAL.—A tobacco product shall be deemed to be misbranded—

''(1) if its labeling is false or misleading in any particular;

''(2) if in package form unless it bears a label containing—

''(A) the name and place of business of the tobacco product manufacturer, packer, or distributor;

''(B) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count;

''(C) an accurate statement of the percentage of the tobacco used in the product that is domestically grown tobacco and the percentage that is foreign grown tobacco; and

''(D) the statement required under section 920(a),

except that under subparagraph (B) reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary;

''(3) if any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, or designs in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

''(4) if it has an established name, unless its label bears, to the exclusion of any other nonproprietary name, its established name prominently printed in type as required by the Secretary by regulation;

''(5) if the Secretary has issued regulations requiring that its labeling bear adequate directions for use, or adequate warnings against use by children, that are necessary for the protection of users unless its labeling conforms in all respects to such regulations;

''(6) if it was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 905(b), 905(c), 905(d), or 905(h), if it was not included in a list required by section 905(i), if a notice or other information respecting it was not provided as required by such section or section 905(j), or if it does not bear such symbols from the uniform system for identification of tobacco products prescribed under section 905(e) as the Secretary by regulation requires;

''(7) if, in the case of any tobacco product distributed or offered for sale in any State—

''(A) its advertising is false or misleading in any particular; or

''(B) it is sold or distributed in violation of regulations prescribed under section 906(d);

''(8) unless, in the case of any tobacco product distributed or offered for sale in any State, the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that tobacco product—

''(A) a true statement of the tobacco product's established name as described in paragraph (4), printed prominently; and

''(B) a brief statement of—

''(i) the uses of the tobacco product and relevant warnings, precautions, side effects, and contraindications; and

''(ii) in the case of specific tobacco products made subject to a finding by the Secretary after notice and opportunity for comment that such action is appropriate to protect the public health, a full description of the components of such tobacco product or the formula showing quantitatively each ingredient of such tobacco product to the extent required in regulations which shall be issued by the Secretary after an opportunity for a hearing;

''(9) if it is a tobacco product subject to a tobacco product standard established under section 907, unless it bears such labeling as may be prescribed in such tobacco product standard; or

''(10) if there was a failure or refusal—

''(A) to comply with any requirement prescribed under section 904 or 908; or

''(B) to furnish any material or information required under section 909.

''(b) PRIOR APPROVAL OF LABEL STATEMENTS.—The Secretary may, by regulation, require prior approval of statements made on the label of a tobacco product to ensure that such statements do not violate the misbranding provisions of subsection (a) and that such statements comply with other provisions of the Family Smoking Prevention and Tobacco Control Act (including the amendments made by such Act). No regulation issued under this subsection may require prior approval by the Secretary of the content of any advertisement, except for modified risk tobacco products as provided in section 911. No advertisement of a tobacco product published after the date of enactment of the Family Smoking Prevention and Tobacco Control Act shall, with respect to the language of label statements as prescribed under section 4 of the Federal Cigarette Labeling and Advertising Act and section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 or the regulations issued under such sections, be subject to the provisions of sections 12 through 15 of the Federal Trade Commission Act.

''SEC. 904. SUBMISSION OF HEALTH INFORMATION TO THE SECRETARY.

''(a) REQUIREMENT.—Each tobacco product manufacturer or importer, or agents thereof, shall submit to the Secretary the following information:

''(1) Not later than 6 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, a listing of all ingredients, including tobacco, substances, compounds, and additives that are, as of such date, added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand and by quantity in each brand and subbrand.

''(2) A description of the content, delivery, and form of nicotine in each tobacco product measured in milligrams of nicotine in accordance with regulations promulgated by the Secretary in accordance with section 4(e) of the Federal Cigarette Labeling and Advertising Act.

''(3) Beginning 3 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, a listing of all constituents, including smoke constituents as applicable, identified by the Secretary as harmful or potentially harmful to health in each tobacco product, and as applicable in the smoke of each tobacco product, by brand and by quantity in each brand and subbrand. Effective beginning 3 years after such date of enactment, the manufacturer, importer, or agent shall comply with regulations promulgated under section 915 in reporting information under this paragraph, where applicable.

''(4) Beginning 6 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, all documents developed after such date of enactment that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives.

''(b) DATA SUBMISSION.—At the request of the Secretary, each tobacco product manufacturer or importer of tobacco products, or agents thereof, shall submit the following:

''(1) Any or all documents (including underlying scientific information) relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer (or agents thereof) on the health, toxicological, behavioral, or physiologic effects of tobacco products and their constituents (including smoke constituents), ingredients, components, and additives.

''(2) Any or all documents (including underlying scientific information) relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer (or agents thereof) that relate to the issue of whether a reduction in risk to health from tobacco products can occur upon the employment of technology available or known to the manufacturer.

''(3) Any or all documents (including underlying scientific or financial information) relating to marketing research involving the use of tobacco products or marketing practices and the effectiveness of such practices used by tobacco manufacturers and distributors.

An importer of a tobacco product not manufactured in the United States shall supply the information required of a tobacco product manufacturer under this subsection.

''(c) TIME FOR SUBMISSION.—

''(1) IN GENERAL.—At least 90 days prior to the delivery for introduction into interstate commerce of a tobacco product not on the market on the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the manufacturer of such product shall provide the information required under subsection (a).

''(2) DISCLOSURE OF ADDITIVE.—If at any time a tobacco product manufacturer adds to its tobacco products a new tobacco additive or increases the quantity of an existing tobacco additive, the manufacturer shall, except as provided in paragraph (3), at least 90 days prior to such action so advise the Secretary in writing.

''(3) DISCLOSURE OF OTHER ACTIONS.—If at any time a tobacco product manufacturer eliminates or decreases an existing additive, or adds or increases an additive that has by regulation been designated by the Secretary as an additive that is not a human or animal carcinogen, or otherwise harmful to health under intended conditions of use, the manufacturer shall within 60 days of such action so advise the Secretary in writing.

''(d) DATA LIST.—

''(1) IN GENERAL.—Not later than 3 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, and annually thereafter, the Secretary shall publish in a format that is understandable and not misleading to a lay person, and place on public display (in a manner determined by the Secretary) the list established under subsection (e).

''(2) CONSUMER RESEARCH.—The Secretary shall conduct periodic consumer research to ensure that the list published under paragraph (1) is not misleading to lay persons. Not later than 5 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall submit to the appropriate committees of Congress a report on the results of such research, together with recommendations on whether such publication should be continued or modified.

''(e) DATA COLLECTION.—Not later than 24 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall establish, and periodically revise as appropriate, a list of harmful and potentially harmful constituents, including smoke constituents, to health in each tobacco product by brand and by quantity in each brand and subbrand. The Secretary shall publish a public notice requesting the submission by interested persons of scientific and other information concerning the harmful and potentially harmful constituents in tobacco products and tobacco smoke.

''SEC. 905. ANNUAL REGISTRATION.

''(a) DEFINITIONS.—In this section:

''(1) MANUFACTURE, PREPARATION, COMPOUNDING, OR PROCESSING.—The term 'manufacture, preparation, compounding, or processing' shall include repackaging or otherwise changing the container, wrapper, or labeling of any tobacco product package in furtherance of the distribution of the tobacco product from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user.

''(2) NAME.—The term 'name' shall include in the case of a partnership the name of each partner and, in the case of a corporation, the name of each corporate officer and director, and the State of incorporation.

''(b) REGISTRATION BY OWNERS AND OPERATORS.—On or before December 31 of each year, every person who owns or operates any establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products shall register with the Secretary the name, places of business, and all such establishments of that person. If enactment of the Family Smoking Prevention and Tobacco Control Act occurs in the second half of the calendar year, the Secretary shall designate a date no later than 6 months into the subsequent calendar year by which registration pursuant to this subsection shall occur.

''(c) REGISTRATION BY NEW OWNERS AND OPERATORS.—Every person upon first engaging in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products in any establishment owned or operated in any State by that person shall immediately register with the Secretary that person's name, place of business, and such establishment.

''(d) REGISTRATION OF ADDED ESTABLISHMENTS.—Every person required to register under subsection (b) or (c) shall immediately register with the Secretary any additional establishment which that person owns or operates in any State and in which that person begins the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products.

''(e) UNIFORM PRODUCT IDENTIFICATION SYSTEM.—The Secretary may by regulation prescribe a uniform system for the identification of tobacco products and may require that persons who are required to list such tobacco products under subsection (i) shall list such tobacco products in accordance with such system.

''(f) PUBLIC ACCESS TO REGISTRATION INFORMATION.—The Secretary shall make available for inspection, to any person so requesting, any registration filed under this section.

''(g) BIENNIAL INSPECTION OF REGISTERED ESTABLISHMENTS.—Every establishment registered with the Secretary under this section shall be subject to inspection under section 704 or subsection (h), and every such establishment engaged in the manufacture, compounding, or processing of a tobacco product or tobacco products shall be so inspected by 1 or more officers or employees duly designated by the Secretary at least once in the 2-year period beginning with the date of registration of such establishment under this section and at least once in every successive 2-year period thereafter.

''(h) REGISTRATION BY FOREIGN ESTABLISHMENTS.—Any establishment within any foreign country engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products, shall register under this section under regulations promulgated by the Secretary. Such regulations shall require such establishment to provide the information required by subsection (i) and shall include provisions for registration of any such establishment upon condition that adequate and effective means are available, by arrangement with the government of such foreign country or otherwise, to enable the Secretary to determine from time to time whether tobacco products manufactured, prepared, compounded, or processed in such establishment, if imported or offered for import into the United States, shall be refused admission on any of the grounds set forth in section 801(a).

''(i) REGISTRATION INFORMATION.—

''(1) PRODUCT LIST.—Every person who registers with the Secretary under subsection (b), (c), (d), or (h) shall, at the time of registration under any such subsection, file with the Secretary a list of all tobacco products which are being manufactured, prepared, compounded, or processed by that person for commercial distribution and which have not been included in any list of tobacco products filed by that person with the Secretary under this paragraph or paragraph (2) before such time of registration. Such list shall be prepared in such form and manner as the Secretary may prescribe and shall be accompanied by—

''(A) in the case of a tobacco product contained in the applicable list with respect to which a tobacco product standard has been established under section 907 or which is subject to section 910, a reference to the authority for the marketing of such tobacco product and a copy of all labeling for such tobacco product;

''(B) in the case of any other tobacco product contained in an applicable list, a copy of all consumer information and other labeling for such tobacco product, a representative sampling of advertisements for such tobacco product, and, upon request made by the Secretary for good cause, a copy of all advertisements for a particular tobacco product; and

''(C) if the registrant filing a list has determined that a tobacco product contained in such list is not subject to a tobacco product standard established under section 907, a brief statement of the basis upon which the registrant made such determination if the Secretary requests such a statement with respect to that particular tobacco product.

''(2) CONSULTATION WITH RESPECT TO FORMS.—The Secretary shall consult with the Secretary of the Treasury in developing the forms to be used for registration under this section to minimize the burden on those persons required to register with both the Secretary and the Tax and Trade Bureau of the Department of the Treasury.

''(3) BIANNUAL REPORT OF ANY CHANGE IN PRODUCT LIST.—Each person who registers with the Secretary under this section shall report to the Secretary once during the month of June of each year and once during the month of December of each year the following:

''(A) A list of each tobacco product introduced by the registrant for commercial distribution which has not been included in any list previously filed by that person with the Secretary under this subparagraph or paragraph (1). A list under this subparagraph shall list a tobacco product by its established name and shall be accompanied by the other information required by paragraph (1).

''(B) If since the date the registrant last made a report under this paragraph that person has discontinued the manufacture, preparation, compounding, or processing for commercial distribution of a tobacco product included in a list filed under subparagraph (A) or paragraph (1), notice of such discontinuance, the date of such discontinuance, and the identity of its established name.

''(C) If since the date the registrant reported under subparagraph (B) a notice of discontinuance that person has resumed the manufacture, preparation, compounding, or processing for commercial distribution of the tobacco product with respect to which such notice of discontinuance was reported, notice of such resumption, the date of such resumption, the identity of such tobacco product by established name, and other information required by paragraph (1), unless the registrant has previously reported such resumption to the Secretary under this subparagraph.

''(D) Any material change in any information previously submitted under this paragraph or paragraph (1).

''(j) REPORT PRECEDING INTRODUCTION OF CERTAIN SUBSTANTIALLY EQUIVALENT PRODUCTS INTO INTERSTATE COMMERCE.—

''(1) IN GENERAL.—Each person who is required to register under this section and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a tobacco product intended for human use that was not commercially marketed (other than for test marketing) in the United States as of February 15, 2007, shall, at least 90 days prior to making such introduction or delivery, report to the Secretary (in such form and manner as the Secretary shall prescribe)—

''(A) the basis for such person's determination that—

''(i) the tobacco product is substantially equivalent, within the meaning of section 910, to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007, or to a tobacco product that the Secretary has previously determined, pursuant to subsection (a)(3) of section 910, is substantially equivalent and that is in compliance with the requirements of this Act; or

''(ii) the tobacco product is modified within the meaning of paragraph (3), the modifications are to a product that is commercially marketed and in compliance with the requirements of this Act, and all of the modifications are covered by exemptions granted by the Secretary pursuant to paragraph (3); and

''(B) action taken by such person to comply with the requirements under section 907 that are applicable to the tobacco product.

''(2) APPLICATION TO CERTAIN POST-FEBRUARY 15, 2007, PRODUCTS.—A report under this subsection for a tobacco product that was first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after February 15, 2007, and prior to the date that is 21 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act shall be submitted to the Secretary not later than 21 months after such date of enactment.

''(3) EXEMPTIONS.—

''(A) IN GENERAL.—The Secretary may exempt from the requirements of this subsection relating to the demonstration that a tobacco product is substantially equivalent within the meaning of section 910, tobacco products that are modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive, if the Secretary determines that—

''(i) such modification would be a minor modification of a tobacco product that can be sold under this Act;

''(ii) a report under this subsection is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for protection of the public health; and

''(iii) an exemption is otherwise appropriate.

''(B) REGULATIONS.—Not later than 15 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall issue regulations to implement this paragraph.

''SEC. 906. GENERAL PROVISIONS RESPECTING CONTROL OF TOBACCO PRODUCTS.

''(a) IN GENERAL.—Any requirement established by or under section 902, 903, 905, or 909 applicable to a tobacco product shall apply to such tobacco product until the applicability of the requirement to the tobacco product has been changed by action taken under section 907, section 910, section 911, or subsection (d) of this section, and any requirement established by or under section 902, 903, 905, or 909 which is inconsistent with a requirement imposed on such tobacco product under section 907, section 910, section 911, or subsection (d) of this section shall not apply to such tobacco product.

''(b) INFORMATION ON PUBLIC ACCESS AND COMMENT.—Each notice of proposed rulemaking or other notification under section 907, 908, 909, 910, or 911 or under this section, any other notice which is published in the Federal Register with respect to any other action taken under any such section and which states the reasons for such action, and each publication of findings required to be made in connection with rulemaking under any such section shall set forth—

''(1) the manner in which interested persons may examine data and other information on which the notice or findings is based; and

''(2) the period within which interested persons may present their comments on the notice or findings (including the need therefore) orally or in writing, which period shall be at least 60 days but may not exceed 90 days unless the time is extended by the Secretary by a notice published in the Federal Register stating good cause therefore.

''(c) LIMITED CONFIDENTIALITY OF INFORMATION.—Any information reported to or otherwise obtained by the Secretary or the Secretary's representative under section 903, 904, 907, 908, 909, 910, 911, or 704, or under subsection (e) or (f) of this section, which is exempt from disclosure under subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of that section shall be considered confidential and shall not be disclosed, except that the information

may be disclosed to other officers or employees concerned with carrying out this chapter, or when relevant in any proceeding under this chapter.

''(d) RESTRICTIONS.—

''(1) IN GENERAL.—The Secretary may by regulation require restrictions on the sale and distribution of a tobacco product, including restrictions on the access to, and the advertising and promotion of, the tobacco product, if the Secretary determines that such regulation would be appropriate for the protection of the public health. The Secretary may by regulation impose restrictions on the advertising and promotion of a tobacco product consistent with and to full extent permitted by the first amendment to the Constitution. The finding as to whether such regulation would be appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account—

''(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

''(B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

No such regulation may require that the sale or distribution of a tobacco product be limited to the written or oral authorization of a practitioner licensed by law to prescribe medical products.

''(2) LABEL STATEMENTS.—The label of a tobacco product shall bear such appropriate statements of the restrictions required by a regulation under subsection (a) as the Secretary may in such regulation prescribe.

''(3) LIMITATIONS.—

''(A) IN GENERAL.—No restrictions under paragraph (1) may—

''(i) prohibit the sale of any tobacco product in face-to-face transactions by a specific category of retail outlets; or

''(ii) establish a minimum age of sale of tobacco products to any person older than 18 years of age.

''(B) MATCHBOOKS.—For purposes of any regulations issued by the Secretary, matchbooks of conventional size containing not more than 20 paper matches, and which are customarily given away for free with the purchase of tobacco products, shall be considered as adult-written publications which shall be permitted to contain advertising. Notwithstanding the preceding sentence, if the Secretary finds that such treatment of matchbooks is not appropriate for the protection of the public health, the Secretary may determine by regulation that matchbooks shall not be considered adult-written publications.

''(4) REMOTE SALES.—

''(A) IN GENERAL.—The Secretary shall—

''(i) within 18 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, promulgate regulations regarding the sale and distribution of tobacco products that occur through means other than a direct, face-to-face exchange between a retailer and a consumer in order to prevent the sale and distribution of tobacco products to individuals who have not attained the minimum age established by applicable law for the purchase of such products, including requirements for age verification; and

''(ii) within 2 years after such date of enactment, issue regulations to address the promotion and marketing of tobacco products that are sold or distributed through means other than a direct, face-to-face exchange between a retailer and a consumer in order to protect individuals who have not attained the minimum age established by applicable law for the purchase of such products.

''(B) RELATION TO OTHER AUTHORITY.—Nothing in this paragraph limits the authority of the Secretary to take additional actions under the other paragraphs of this subsection.

''(e) GOOD MANUFACTURING PRACTICE REQUIREMENTS.—

''(1) METHODS, FACILITIES, AND CONTROLS TO CONFORM.—

''(A) IN GENERAL.—In applying manufacturing restrictions to tobacco, the Secretary shall, in accordance with subparagraph (B), prescribe regulations (which may differ based on the type of tobacco product involved) requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation (including a process to assess the performance of a tobacco product), packing, and storage of a tobacco product conform to current good manufacturing practice, or hazard analysis and critical control point methodology, as prescribed in such regulations to assure that the public health is protected and that the tobacco product is in compliance with this chapter. Such regulations may provide for the testing of raw tobacco for pesticide chemical residues regardless of whether a tolerance for such chemical residues has been established.

''(B) REQUIREMENTS.—The Secretary shall—

''(i) before promulgating any regulation under subparagraph (A), afford the Tobacco Products Scientific Advisory Committee an opportunity to submit recommendations with respect to the regulation proposed to be promulgated;

''(ii) before promulgating any regulation under subparagraph (A), afford opportunity for an oral hearing;

''(iii) provide the Tobacco Products Scientific Advisory Committee a reasonable time to make its recommendation with respect to proposed regulations under subparagraph (A);

''(iv) in establishing the effective date of a regulation promulgated under this subsection, take into account the differences in the manner in which the different types of tobacco products have historically been produced, the financial resources of the different tobacco product manufacturers, and the state of their existing manufacturing facilities, and shall provide for a reasonable period of time for such manufacturers to conform to good manufacturing practices; and

''(v) not require any small tobacco product manufacturer to comply with a regulation under subparagraph (A) for at least 4 years following the effective date established by the Secretary for such regulation.

''(2) EXEMPTIONS; VARIANCES.—

''(A) PETITION.—Any person subject to any requirement prescribed under paragraph (1) may petition the Secretary for a permanent or temporary exemption or variance from such requirement. Such a petition shall be submitted to the Secretary in such form and manner as the Secretary shall prescribe and shall—

''(i) in the case of a petition for an exemption from a requirement, set forth the basis for the petitioner's determination that compliance with the requirement is not required to assure that the tobacco product will be in compliance with this chapter;

''(ii) in the case of a petition for a variance from a requirement, set forth the methods proposed to be used in, and the facilities and controls proposed to be used for, the manufacture, packing, and storage of the tobacco product in lieu of the methods, facilities, and controls prescribed by the requirement; and

''(iii) contain such other information as the Secretary shall prescribe.

''(B) REFERRAL TO THE TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE.—The Secretary may refer to the Tobacco Products Scientific Advisory Committee any petition submitted under subparagraph (A). The Tobacco Products Scientific Advisory Committee shall report its recommendations to the Secretary with respect to a petition referred to it within 60 days after the date of the petition's referral. Within 60 days after—

''(i) the date the petition was submitted to the Secretary under subparagraph (A); or

''(ii) the day after the petition was referred to the Tobacco Products Scientific Advisory Committee,

whichever occurs later, the Secretary shall by order either deny the petition or approve it.

''(C) APPROVAL.—The Secretary may approve—

''(i) a petition for an exemption for a tobacco product from a requirement if the Secretary determines that compliance with such requirement is not required to assure that the tobacco product will be in compliance with this chapter; and

''(ii) a petition for a variance for a tobacco product from a requirement if the Secretary determines that the methods to be used in, and the facilities and controls to be used for, the manufacture, packing, and storage of the tobacco product in lieu of the methods, facilities, and controls prescribed by the requirement are sufficient to assure that the tobacco product will be in compliance with this chapter.

''(D) CONDITIONS.—An order of the Secretary approving a petition for a variance shall prescribe such conditions respecting the methods used in, and the facilities and controls used for, the manufacture, packing, and storage of the tobacco product to be granted the variance under the petition as may be necessary to assure that the tobacco product will be in compliance with this chapter.

''(E) HEARING.—After the issuance of an order under subparagraph (B) respecting a petition, the petitioner shall have an opportunity for an informal hearing on such order.

''(3) COMPLIANCE.—Compliance with requirements under this subsection shall not be required before the end of the 3-year period following the date of enactment of the Family Smoking Prevention and Tobacco Control Act.

''(f) RESEARCH AND DEVELOPMENT.—The Secretary may enter into contracts for research, testing, and demonstrations respecting tobacco products and may obtain tobacco products for research, testing, and demonstration purposes.

"SEC. 907. TOBACCO PRODUCT STANDARDS.

''(a) IN GENERAL.—

''(1) SPECIAL RULES.—

''(A) SPECIAL RULE FOR CIGARETTES.—Beginning 3 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, a cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke. Nothing in this subparagraph shall be construed to limit the Secretary's authority to take action under this section or other sections of this Act applicable to menthol or any artificial or natural flavor, herb, or spice not specified in this subparagraph.

''(B) ADDITIONAL SPECIAL RULE.—Beginning 2 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, a tobacco product manufacturer shall not use tobacco, including foreign grown tobacco, that contains a pesticide chemical residue that is at a level greater than is specified by any tolerance applicable under Federal law to domestically grown tobacco.

''(2) REVISION OF TOBACCO PRODUCT STANDARDS.—The Secretary may revise the tobacco product standards in paragraph (1) in accordance with subsection (c).

''(3) TOBACCO PRODUCT STANDARDS.—

''(A) IN GENERAL.—The Secretary may adopt tobacco product standards in addition to those in paragraph (1) if the Secretary finds that a tobacco product standard is appropriate for the protection of the public health.

''(B) DETERMINATIONS.—

''(i) CONSIDERATIONS.—In making a finding described in subparagraph (A), the Secretary shall consider scientific evidence concerning—

''(I) the risks and benefits to the population as a whole, including users and nonusers of tobacco products, of the proposed standard;

''(II) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

''(III) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

''(ii) ADDITIONAL CONSIDERATIONS.—In the event that the Secretary makes a determination, set forth in a proposed tobacco product standard in a proposed rule, that it is appropriate for the protection of public health to require the reduction or elimination of an additive, constituent (including a smoke constituent), or other component of a tobacco product because the Secretary has found that the additive, constituent, or other component is or may be harmful, any party objecting to the proposed standard on the ground that the proposed standard will not reduce or eliminate the risk of illness or injury may provide for the Secretary's consideration scientific evidence that demonstrates that the proposed standard will not reduce or eliminate the risk of illness or injury.

''(4) CONTENT OF TOBACCO PRODUCT STANDARDS.—A tobacco product standard established under this section for a tobacco product—

''(A) shall include provisions that are appropriate for the protection of the public health, including provisions, where appropriate—

''(i) for nicotine yields of the product;

''(ii) for the reduction or elimination of other constituents, including smoke constituents, or harmful components of the product; or

''(iii) relating to any other requirement under subparagraph (B);

''(B) shall, where appropriate for the protection of the public health, include—

''(i) provisions respecting the construction, components, ingredients, additives, constituents, including smoke constituents, and properties of the tobacco product;

''(ii) provisions for the testing (on a sample basis or, if necessary, on an individual basis) of the tobacco product;

''(iii) provisions for the measurement of the tobacco product characteristics of the tobacco product;

''(iv) provisions requiring that the results of each or of certain of the tests of the tobacco product required to be made under clause (ii) show that the tobacco product is in conformity with the portions of the standard for which the test or tests were required; and

''(v) a provision requiring that the sale and distribution of the tobacco product be restricted but only to the extent that the sale and distribution of a tobacco product may be restricted under a regulation under section 906(d);

''(C) shall, where appropriate, require the use and prescribe the form and content of labeling for the proper use of the tobacco product; and

''(D) shall require tobacco products containing foreign-grown tobacco to meet the same standards applicable to tobacco products containing domestically grown tobacco.

''(5) PERIODIC REEVALUATION OF TOBACCO PRODUCT STANDARDS.—The Secretary shall provide for periodic evaluation of tobacco product standards established under this section to determine whether such standards should be changed to reflect new medical, scientific, or other technological data. The Secretary may provide for testing under paragraph (4)(B) by any person.

''(6) INVOLVEMENT OF OTHER AGENCIES; INFORMED PERSONS.—In carrying out duties under this section, the Secretary shall endeavor to—

''(A) use personnel, facilities, and other technical support available in other Federal agencies;

''(B) consult with other Federal agencies concerned with standard setting and other nationally or internationally recognized standard-setting entities; and

''(C) invite appropriate participation, through joint or other conferences, workshops, or other means, by informed persons representative of scientific, professional, industry, agricultural, or consumer organizations who in the Secretary's judgment can make a significant contribution.

''(b) CONSIDERATIONS BY SECRETARY.—

''(1) TECHNICAL ACHIEVABILITY.—The Secretary shall consider information submitted in connection with a proposed standard regarding the technical achievability of compliance with such standard.

''(2) OTHER CONSIDERATIONS.—The Secretary shall consider all other information submitted in connection with a proposed standard, including information concerning the countervailing effects of the tobacco product standard on the health of adolescent tobacco users, adult tobacco users, or nontobacco users, such as the creation of a significant demand for contraband or other tobacco products that do not meet the requirements of this chapter and the significance of such demand.

''(c) PROPOSED STANDARDS.—

''(1) IN GENERAL.—The Secretary shall publish in the Federal Register a notice of proposed rulemaking for the establishment, amendment, or revocation of any tobacco product standard.

''(2) REQUIREMENTS OF NOTICE.—A notice of proposed rulemaking for the establishment or amendment of a tobacco product standard for a tobacco product shall—

''(A) set forth a finding with supporting justification that the tobacco product standard is appropriate for the protection of the public health;

''(B) invite interested persons to submit a draft or proposed tobacco product standard for consideration by the Secretary;

''(C) invite interested persons to submit comments on structuring the standard so that it does not advantage foreign-grown tobacco over domestically grown tobacco; and

''(D) invite the Secretary of Agriculture to provide any information or analysis which the Secretary of Agriculture believes is relevant to the proposed tobacco product standard.

''(3) FINDING.—A notice of proposed rulemaking for the revocation of a tobacco product standard shall set forth a finding with supporting justification that the tobacco product standard is no longer appropriate for the protection of the public health.

''(4) COMMENT.—The Secretary shall provide for a comment period of not less than 60 days.

''(d) PROMULGATION.—

''(1) IN GENERAL.—After the expiration of the period for comment on a notice of proposed rulemaking published under subsection (c) respecting a tobacco product standard and after consideration of comments submitted under subsections (b) and (c) and any report from the Tobacco Products Scientific Advisory Committee, the Secretary shall—

''(A) if the Secretary determines that the standard would be appropriate for the protection of the public health, promulgate a regulation establishing a tobacco product standard and publish in the Federal Register findings on the matters referred to in subsection (c); or

''(B) publish a notice terminating the proceeding for the development of the standard together with the reasons for such termination.

''(2) EFFECTIVE DATE.—A regulation establishing a tobacco product standard shall set forth the date or dates upon which the standard shall take effect, but no such regulation may take effect before 1 year after the date of its publication unless the Secretary determines that an earlier effective date is necessary for the protection of the public health. Such date or dates shall be established so as to minimize, consistent with the public health, economic loss to, and disruption or dislocation of, domestic and international trade. In establishing such effective date or dates, the Secretary shall consider information submitted in connection with a proposed product standard by interested parties, including manufacturers and tobacco growers, regarding the technical achievability of compliance with the standard, and including information concerning the existence of patents that make it impossible to comply in the timeframe envisioned in the proposed standard. If the Secretary determines, based on the Secretary's evaluation of submitted comments, that a product standard can be met only by manufacturers requiring substantial changes to the methods of farming the domestically grown tobacco used by the manufacturer, the effective date of that product standard shall be not less than 2 years after the date of publication of the final regulation establishing the standard.

''(3) LIMITATION ON POWER GRANTED TO THE FOOD AND DRUG ADMINISTRATION.—Because of the importance of a decision of the Secretary to issue a regulation—

''(A) banning all cigarettes, all smokeless tobacco products, all little cigars, all cigars other than little cigars, all pipe tobacco, or all roll-your-own tobacco products; or

''(B) requiring the reduction of nicotine yields of a tobacco product to zero,

the Secretary is prohibited from taking such actions under this Act.

''(4) AMENDMENT; REVOCATION.—

''(A) AUTHORITY.—The Secretary, upon the Secretary's own initiative or upon petition of an interested person, may by a regulation, promulgated in accordance with the requirements of subsection (c) and paragraph (2), amend or revoke a tobacco product standard.

''(B) EFFECTIVE DATE.—The Secretary may declare a proposed amendment of a tobacco product standard to be effective on and after its publication in the Federal Register and until the effective date of any final action taken on such amendment if the Secretary

determines that making it so effective is in the public interest.

''(5) REFERRAL TO ADVISORY COMMITTEE.—

''(A) IN GENERAL.—The Secretary may refer a proposed regulation for the establishment, amendment, or revocation of a tobacco product standard to the Tobacco Products Scientific Advisory Committee for a report and recommendation with respect to any matter involved in the proposed regulation which requires the exercise of scientific judgment.

''(B) INITIATION OF REFERRAL.—The Secretary may make a referral under this paragraph—

''(i) on the Secretary's own initiative; or

''(ii) upon the request of an interested person that—

''(I) demonstrates good cause for the referral; and

''(II) is made before the expiration of the period for submission of comments on the proposed regulation.

''(C) PROVISION OF DATA.—If a proposed regulation is referred under this paragraph to the Tobacco Products Scientific Advisory Committee, the Secretary shall provide the Advisory Committee with the data and information on which such proposed regulation is based.

''(D) REPORT AND RECOMMENDATION.—The Tobacco Products Scientific Advisory Committee shall, within 60 days after the referral of a proposed regulation under this paragraph and after independent study of the data and information furnished to it by the Secretary and other data and information before it, submit to the Secretary a report and recommendation respecting such regulation, together with all underlying data and information and a statement of the reason or basis for the recommendation.

''(E) PUBLIC AVAILABILITY.—The Secretary shall make a copy of each report and recommendation under subparagraph (D) publicly available.

''(e) MENTHOL CIGARETTES.—

''(1) REFERRAL; CONSIDERATIONS.—Immediately upon the establishment of the Tobacco Products Scientific Advisory Committee under section 917(a), the Secretary shall refer to the Committee for report and recommendation, under section 917(c)(4), the issue of the impact of the use of menthol in cigarettes on the public health, including such use among children, African-Americans, Hispanics, and other racial and ethnic minorities. In its review, the Tobacco Products Scientific Advisory Committee shall address the considerations listed in subsections (a)(3)(B)(i) and (b).

''(2) REPORT AND RECOMMENDATION.—Not later than 1 year after its establishment, the Tobacco Product Scientific Advisory Committee shall submit to the Secretary the report and recommendations required pursuant to paragraph (1).

''(3) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to limit the Secretary's authority to take action under this section or other sections of this Act applicable to menthol.

''(f) DISSOLVABLE TOBACCO PRODUCTS.—

''(1) REFERRAL; CONSIDERATIONS.—The Secretary shall refer to the Tobacco Products Scientific Advisory Committee for report and recommendation, under section 917(c)(4), the issue of the nature and impact of the use of dissolvable tobacco products on the public health, including such use among children. In its review, the Tobacco Products Scientific Advisory Committee shall address the considerations listed in subsection (a)(3)(B)(i).

''(2) REPORT AND RECOMMENDATION.—Not later than 2 years after its establishment, the Tobacco Product Scientific Advisory Committee shall submit to the Secretary the report and recommendations required pursuant to paragraph (1).

''(3) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to limit the Secretary's authority to take action under this section or other sections of this Act at any time applicable to any dissolvable tobacco product.

"SEC. 908. NOTIFICATION AND OTHER REMEDIES.

''(a) NOTIFICATION.—If the Secretary determines that—

''(1) a tobacco product which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm to the public health; and

''(2) notification under this subsection is necessary to eliminate the unreasonable risk of such harm and no more practicable means is available under the provisions of this chapter (other than this section) to eliminate such risk,

the Secretary may issue such order as may be necessary to assure that adequate notification is provided in an appropriate form, by the persons and means best suited under the circumstances involved, to all persons who should properly receive such notification in order to eliminate such risk. The Secretary may order notification by any appropriate means, including public service announcements. Before issuing an order under this subsection, the Secretary shall consult with the persons who are to give notice under the order.

''(b) NO EXEMPTION FROM OTHER LIABILITY.—Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided under such order shall be taken into account.

''(c) RECALL AUTHORITY.—

''(1) IN GENERAL.—If the Secretary finds that there is a reasonable probability that a tobacco product contains a manufacturing or other defect not ordinarily contained in tobacco products on the market that would cause serious, adverse health consequences or death, the Secretary shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the tobacco product) to immediately cease distribution of such tobacco product. The order shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order and on whether the order should be amended to require a recall of such tobacco product. If, after providing an opportunity for such a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

''(2) AMENDMENT OF ORDER TO REQUIRE RECALL.—

''(A) IN GENERAL.—If, after providing an opportunity for an informal hearing under paragraph (1), the Secretary determines that the order should be amended to include a recall of the tobacco product with respect to which the order was issued, the Secretary shall, except as provided in subparagraph (B), amend the order to require a recall. The Secretary shall specify a timetable in which the tobacco product recall will occur and shall require periodic reports to the Secretary describing the progress of the recall.

''(B) NOTICE.—An amended order under subparagraph (A)—

''(i) shall not include recall of a tobacco product from individuals; and

''(ii) shall provide for notice to persons subject to the risks associated with the use of such tobacco product.

In providing the notice required by clause (ii), the Secretary may use the assistance of retailers and other persons who distributed such tobacco product. If a significant number of such persons cannot be identified, the Secretary shall notify such persons under section 705(b).

''(3) REMEDY NOT EXCLUSIVE.—The remedy provided by this subsection shall be in addition to remedies provided by subsection (a).

"SEC. 909. RECORDS AND REPORTS ON TOBACCO PRODUCTS.

''(a) IN GENERAL.—Every person who is a tobacco product manufacturer or importer of a tobacco product shall establish and maintain such records, make such reports, and provide such information, as the Secretary may by regulation reasonably require to assure that such tobacco product is not adulterated or misbranded and to otherwise protect public health. Regulations prescribed under the preceding sentence—

''(1) may require a tobacco product manufacturer or importer to report to the Secretary whenever the manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed tobacco products may have caused or contributed to a serious unexpected adverse experience associated with the use of the product or any significant increase in the frequency of a serious, expected adverse product experience;

''(2) shall require reporting of other significant adverse tobacco product experiences as determined by the Secretary to be necessary to be reported;

''(3) shall not impose requirements unduly burdensome to a tobacco product manufacturer or importer, taking into account the cost of complying with such requirements and the need for the protection of the public health and the implementation of this chapter;

''(4) when prescribing the procedure for making requests for reports or information, shall require that each request made under such regulations for submission of a report or information to the Secretary state the reason or purpose for such request and identify to the fullest extent practicable such report or information;

''(5) when requiring submission of a report or information to the Secretary, shall state the reason or purpose for the submission of such report or information and identify to the fullest extent practicable such report or information; and

''(6) may not require that the identity of any patient or user be disclosed in records, reports, or information required under this subsection unless required for the medical welfare of an individual, to determine risks to public health of a tobacco product, or to verify a record, report, or information submitted under this chapter.

In prescribing regulations under this subsection, the Secretary shall have due regard for the professional ethics of the medical profession and the interests of patients. The prohibitions of paragraph (6) continue to apply to records, reports, and information concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

''(b) REPORTS OF REMOVALS AND CORRECTIONS.—

''(1) IN GENERAL.—Except as provided in paragraph (2), the Secretary shall by regulation require a tobacco product manufacturer or importer of a tobacco product to report promptly to the Secretary any corrective action taken or removal from the market of a

tobacco product undertaken by such manufacturer or importer if the removal or correction was undertaken—

''(A) to reduce a risk to health posed by the tobacco product; or

''(B) to remedy a violation of this chapter caused by the tobacco product which may present a risk to health.

A tobacco product manufacturer or importer of a tobacco product who undertakes a corrective action or removal from the market of a tobacco product which is not required to be reported under this subsection shall keep a record of such correction or removal.

''(2) EXCEPTION.—No report of the corrective action or removal of a tobacco product may be required under paragraph (1) if a report of the corrective action or removal is required and has been submitted under subsection (a).

''SEC. 910. APPLICATION FOR REVIEW OF CERTAIN TOBACCO PRODUCTS.

''(a) IN GENERAL.—

''(1) NEW TOBACCO PRODUCT DEFINED.—For purposes of this section the term 'new tobacco product' means—

''(A) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or

''(B) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

''(2) PREMARKET REVIEW REQUIRED.—

''(A) NEW PRODUCTS.—An order under subsection (c)(1)(A)(i) for a new tobacco product is required unless—

''(i) the manufacturer has submitted a report under section 905(j); and the Secretary has issued an order that the tobacco product—

''(I) is substantially equivalent to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007; and

''(II) is in compliance with the requirements of this Act; or

''(ii) the tobacco product is exempt from the requirements of section 905(j) pursuant to a regulation issued under section 905(j)(3).

''(B) APPLICATION TO CERTAIN POST-FEBRUARY 15, 2007, PRODUCTS.—Subparagraph (A) shall not apply to a tobacco product—

''(i) that was first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after February 15, 2007, and prior to the date that is 21 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act; and

''(ii) for which a report was submitted under section 905(j) within such 21-month period,

except that subparagraph (A) shall apply to the tobacco product if the Secretary issues an order that the tobacco product is not substantially equivalent.

''(3) SUBSTANTIALLY EQUIVALENT DEFINED.—

''(A) IN GENERAL.—In this section and section 905(j), the term 'substantially equivalent' or 'substantial equivalence' means, with respect to the tobacco product being compared to the predicate tobacco product, that the Secretary by order has found that the tobacco product—

''(i) has the same characteristics as the predicate tobacco product; or

''(ii) has different characteristics and the information submitted contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that it is not appropriate to regulate the product under this section because the product does not raise different questions of public health.

''(B) CHARACTERISTICS.—In subparagraph (A), the term 'characteristics' means the materials, ingredients, design, composition, heating source, or other features of a tobacco product.

''(C) LIMITATION.—A tobacco product may not be found to be substantially equivalent to a predicate tobacco product that has been removed from the market at the initiative of the Secretary or that has been determined by a judicial order to be misbranded or adulterated.

''(4) HEALTH INFORMATION.—

''(A) SUMMARY.—As part of a submission under section 905(j) respecting a tobacco product, the person required to file a premarket notification under such section shall provide an adequate summary of any health information related to the tobacco product or state that such information will be made available upon request by any person.

''(B) REQUIRED INFORMATION.—Any summary under subparagraph (A) respecting a tobacco product shall contain detailed information regarding data concerning adverse health effects and shall be made available to the public by the Secretary within 30 days of the issuance of a determination that such tobacco product is substantially equivalent to another tobacco product.

''(b) APPLICATION.—

''(1) CONTENTS.—An application under this section shall contain—

''(A) full reports of all information, published or known to, or which should reasonably be known to, the applicant, concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products;

''(B) a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such tobacco product;

''(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such tobacco product;

''(D) an identifying reference to any tobacco product standard under section 907 which would be applicable to any aspect of such tobacco product, and either adequate information to show that such aspect of such tobacco product fully meets such tobacco product standard or adequate information to justify any deviation from such standard;

''(E) such samples of such tobacco product and of components thereof as the Secretary may reasonably require;

''(F) specimens of the labeling proposed to be used for such tobacco product; and

''(G) such other information relevant to the subject matter of the application as the Secretary may require.

''(2) REFERRAL TO TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE.—Upon receipt of an application meeting the requirements set forth in paragraph (1), the Secretary—

''(A) may, on the Secretary's own initiative; or

''(B) may, upon the request of an applicant, refer such application to the Tobacco Products Scientific Advisory Committee for reference and for submission (within such period as the Secretary may establish) of a report and recommendation respecting the application, together with all underlying data and the reasons or basis for the recommendation.

''(c) ACTION ON APPLICATION.—

''(1) DEADLINE.—

''(A) IN GENERAL.—As promptly as possible, but in no event later than 180 days after the receipt of an application under subsection (b), the Secretary, after considering the report and recommendation submitted under subsection (b)(2), shall—

''(i) issue an order that the new product may be introduced or delivered for introduction into interstate commerce if the Secretary finds that none of the grounds specified in paragraph (2) of this subsection applies; or

''(ii) issue an order that the new product may not be introduced or delivered for introduction into interstate commerce if the Secretary finds (and sets forth the basis for such finding as part of or accompanying such denial) that 1 or more grounds for denial specified in paragraph (2) of this subsection apply.

''(B) RESTRICTIONS ON SALE AND DISTRIBUTION.—An order under subparagraph (A)(i) may require that the sale and distribution of the tobacco product be restricted but only to the extent that the sale and distribution of a tobacco product may be restricted under a regulation under section 906(d).

''(2) DENIAL OF APPLICATION.—The Secretary shall deny an application submitted under subsection (b) if, upon the basis of the information submitted to the Secretary as part of the application and any other information before the Secretary with respect to such tobacco product, the Secretary finds that—

''(A) there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health;

''(B) the methods used in, or the facilities or controls used for, the manufacture, processing, or packing of such tobacco product do not conform to the requirements of section 906(e);

''(C) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; or

''(D) such tobacco product is not shown to conform in all respects to a tobacco product standard in effect under section 907, and there is a lack of adequate information to justify the deviation from such standard.

''(3) DENIAL INFORMATION.—Any denial of an application shall, insofar as the Secretary determines to be practicable, be accompanied by a statement informing the applicant of the measures required to remove such application from deniable form (which measures may include further research by the applicant in accordance with 1 or more protocols prescribed by the Secretary).

''(4) BASIS FOR FINDING.—For purposes of this section, the finding as to whether the marketing of a tobacco product for which an application has been submitted is appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account—

''(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

''(B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

''(5) BASIS FOR ACTION.—

''(A) INVESTIGATIONS.—For purposes of paragraph (2)(A), whether permitting a tobacco product to be marketed would be appropriate for the protection of the public health shall, when appropriate, be determined on the basis of well-controlled investigations, which may include 1 or more clinical investigations by experts qualified by training and experience to evaluate the tobacco product.

''(B) OTHER EVIDENCE.—If the Secretary determines that there exists valid scientific evidence (other than evidence derived from investigations described in subparagraph (A)) which is sufficient to evaluate the tobacco product, the Secretary may authorize

that the determination for purposes of paragraph (2)(A) be made on the basis of such evidence.

''(d) WITHDRAWAL AND TEMPORARY SUSPENSION.—

''(1) IN GENERAL.—The Secretary shall, upon obtaining, where appropriate, advice on scientific matters from the Tobacco Products Scientific Advisory Committee, and after due notice and opportunity for informal hearing for a tobacco product for which an order was issued under subsection (c)(1)(A)(i), issue an order withdrawing the order if the Secretary finds—

''(A) that the continued marketing of such tobacco product no longer is appropriate for the protection of the public health;

''(B) that the application contained or was accompanied by an untrue statement of a material fact;

''(C) that the applicant—

''(i) has failed to establish a system for maintaining records, or has repeatedly or deliberately failed to maintain records or to make reports, required by an applicable regulation under section 909;

''(ii) has refused to permit access to, or copying or verification of, such records as required by section 704; or

''(iii) has not complied with the requirements of section 905;

''(D) on the basis of new information before the Secretary with respect to such tobacco product, evaluated together with the evidence before the Secretary when the application was reviewed, that the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or installation of such tobacco product do not conform with the requirements of section 906(e) and were not brought into conformity with such requirements within a reasonable time after receipt of written notice from the Secretary of nonconformity;

''(E) on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when the application was reviewed, that the labeling of such tobacco product, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary of such fact; or

''(F) on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when such order was issued, that such tobacco product is not shown to conform in all respects to a tobacco product standard which is in effect under section 907, compliance with which was a condition to the issuance of an order relating to the application, and that there is a lack of adequate information to justify the deviation from such standard.

''(2) APPEAL.—The holder of an application subject to an order issued under paragraph (1) withdrawing an order issued pursuant to subsection (c)(1)(A)(i) may, by petition filed on or before the 30th day after the date upon which such holder receives notice of such withdrawal, obtain review thereof in accordance with section 912.

''(3) TEMPORARY SUSPENSION.—If, after providing an opportunity for an informal hearing, the Secretary determines there is reasonable probability that the continuation of distribution of a tobacco product under an order would cause serious, adverse health consequences or death, that is greater than ordinarily caused by tobacco products on the market, the Secretary shall by order temporarily suspend the authority of the manufacturer to market the product. If the Secretary issues such an order, the Secretary shall proceed expeditiously under paragraph (1) to withdraw such application.

''(e) SERVICE OF ORDER.—An order issued by the Secretary under this section shall be served—

''(1) in person by any officer or employee of the department designated by the Secretary; or

''(2) by mailing the order by registered mail or certified mail addressed to the applicant at the applicant's last known address in the records of the Secretary.

''(f) RECORDS.—

''(1) ADDITIONAL INFORMATION.—In the case of any tobacco product for which an order issued pursuant to subsection (c)(1)(A)(i) for an application filed under subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, as the Secretary may by regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination of, whether there is or may be grounds for withdrawing or temporarily suspending such order.

''(2) ACCESS TO RECORDS.—Each person required under this section to maintain records, and each person in charge of custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

''(g) INVESTIGATIONAL TOBACCO PRODUCT EXEMPTION FOR INVESTIGATIONAL USE.—The Secretary may exempt tobacco products intended for investigational use from the provisions of this chapter under such conditions as the Secretary may by regulation prescribe.

''SEC. 911. MODIFIED RISK TOBACCO PRODUCTS.

''(a) IN GENERAL.—No person may introduce or deliver for introduction into interstate commerce any modified risk tobacco product unless an order issued pursuant to subsection (g) is effective with respect to such product.

''(b) DEFINITIONS.—In this section:

''(1) MODIFIED RISK TOBACCO PRODUCT.—The term 'modified risk tobacco product' means any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products.

''(2) SOLD OR DISTRIBUTED.—

''(A) IN GENERAL.—With respect to a tobacco product, the term 'sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products' means a tobacco product—

''(i) the label, labeling, or advertising of which represents explicitly or implicitly that—

''(I) the tobacco product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products;

''(II) the tobacco product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance; or

''(III) the tobacco product or its smoke does not contain or is free of a substance;

''(ii) the label, labeling, or advertising of which uses the descriptors 'light', 'mild', or 'low' or similar descriptors; or

''(iii) the tobacco product manufacturer of which has taken any action directed to consumers through the media or otherwise, other than by means of the tobacco product's label, labeling, or advertising, after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, respecting the product that would be reasonably expected to result in consumers believing that the tobacco product or its smoke may present a lower risk of disease or is less harmful than one or more commercially marketed tobacco products, or presents a reduced exposure to, or does not contain or is free of, a substance or substances.

''(B) LIMITATION.—No tobacco product shall be considered to be 'sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products', except as described in subparagraph (A).

''(C) SMOKELESS TOBACCO PRODUCT.—No smokeless tobacco product shall be considered to be 'sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products' solely because its label, labeling, or advertising uses the following phrases to describe such product and its use: 'smokeless tobacco', 'smokeless tobacco product', 'not consumed by smoking', 'does not produce smoke', 'smokefree', 'smokefree', 'without smoke', 'no smoke', or 'not smoke'.

''(3) EFFECTIVE DATE.—The provisions of paragraph (2)(A)(ii) shall take effect 12 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act for those products whose label, labeling, or advertising contains the terms described in such paragraph on such date of enactment. The effective date shall be with respect to the date of manufacture, provided that, in any case, beginning 30 days after such effective date, a manufacturer shall not introduce into the domestic commerce of the United States any product, irrespective of the date of manufacture, that is not in conformance with paragraph (2)(A)(ii).

''(c) TOBACCO DEPENDENCE PRODUCTS.—A product that is intended to be used for the treatment of tobacco dependence, including smoking cessation, is not a modified risk tobacco product under this section if it has been approved as a drug or device by the Food and Drug Administration and is subject to the requirements of chapter V.

''(d) FILING.—Any person may file with the Secretary an application for a modified risk tobacco product. Such application shall include—

''(1) a description of the proposed product and any proposed advertising and labeling;

''(2) the conditions for using the product;

''(3) the formulation of the product;

''(4) sample product labels and labeling;

''(5) all documents (including underlying scientific information) relating to research findings conducted, supported, or possessed by the tobacco product manufacturer relating to the effect of the product on tobacco-related diseases and health-related conditions, including information both favorable and unfavorable to the ability of the product to reduce risk or exposure and relating to human health;

''(6) data and information on how consumers actually use the tobacco product; and

''(7) such other information as the Secretary may require.

''(e) PUBLIC AVAILABILITY.—The Secretary shall make the application described in subsection (d) publicly available (except matters in the application which are trade secrets or otherwise confidential, commercial information) and shall request comments by interested persons on the information contained in the application and on the label, labeling, and advertising accompanying such application.

''(f) ADVISORY COMMITTEE.—

''(1) IN GENERAL.—The Secretary shall refer to the Tobacco Products Scientific Advisory Committee any application submitted under this section.

''(2) RECOMMENDATIONS.—Not later than 60 days after the date an application is referred to the Tobacco Products Scientific Advisory

Committee under paragraph (1), the Advisory Committee shall report its recommendations on the application to the Secretary.

''(g) MARKETING.—

''(1) MODIFIED RISK PRODUCTS.—Except as provided in paragraph (2), the Secretary shall, with respect to an application submitted under this section, issue an order that a modified risk product may be commercially marketed only if the Secretary determines that the applicant has demonstrated that such product, as it is actually used by consumers, will—

''(A) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and

''(B) benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.

''(2) SPECIAL RULE FOR CERTAIN PRODUCTS.—

''(A) IN GENERAL.—The Secretary may issue an order that a tobacco product may be introduced or delivered for introduction into interstate commerce, pursuant to an application under this section, with respect to a tobacco product that may not be commercially marketed under paragraph (1) if the Secretary makes the findings required under this paragraph and determines that the applicant has demonstrated that—

''(i) such order would be appropriate to promote the public health;

''(ii) any aspect of the label, labeling, and advertising for such product that would cause the tobacco product to be a modified risk tobacco product under subsection (b) is limited to an explicit or implicit representation that such tobacco product or its smoke does not contain or is free of a substance or contains a reduced level of a substance, or presents a reduced exposure to a substance in tobacco smoke;

''(iii) scientific evidence is not available and, using the best available scientific methods, cannot be made available without conducting long-term epidemiological studies for an application to meet the standards set forth in paragraph (1); and

''(iv) the scientific evidence that is available without conducting long-term epidemiological studies demonstrates that a measurable and substantial reduction in morbidity or mortality among individual tobacco users is reasonably likely in subsequent studies.

''(B) ADDITIONAL FINDINGS REQUIRED.—To issue an order under subparagraph (A) the Secretary must also find that the applicant has demonstrated that—

''(i) the magnitude of the overall reductions in exposure to the substance or substances which are the subject of the application is substantial, such substance or substances are harmful, and the product as actually used exposes consumers to the specified reduced level of the substance or substances;

''(ii) the product as actually used by consumers will not expose them to higher levels of other harmful substances compared to the similar types of tobacco products then on the market unless such increases are minimal and the reasonably likely overall impact of use of the product remains a substantial and measurable reduction in overall morbidity and mortality among individual tobacco users;

''(iii) testing of actual consumer perception shows that, as the applicant proposes to label and market the product, consumers will not be misled into believing that the product—

''(I) is or has been demonstrated to be less harmful; or

''(II) presents or has been demonstrated to present less of a risk of disease than 1 or more other commercially marketed tobacco products; and

''(iv) issuance of an order with respect to the application is expected to benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.

''(C) CONDITIONS OF MARKETING.—

''(i) IN GENERAL.—Applications subject to an order under this paragraph shall be limited to a term of not more than 5 years, but may be renewed upon a finding by the Secretary that the requirements of this paragraph continue to be satisfied based on the filing of a new application.

''(ii) AGREEMENTS BY APPLICANT.—An order under this paragraph shall be conditioned on the applicant's agreement to conduct postmarket surveillance and studies and to submit to the Secretary the results of such surveillance and studies to determine the impact of the order on consumer perception, behavior, and health and to enable the Secretary to review the accuracy of the determinations upon which the order was based in accordance with a protocol approved by the Secretary.

''(iii) ANNUAL SUBMISSION.—The results of such postmarket surveillance and studies described in clause (ii) shall be submitted annually.

''(3) BASIS.—The determinations under paragraphs (1) and (2) shall be based on—

''(A) the scientific evidence submitted by the applicant; and

''(B) scientific evidence and other information that is made available to the Secretary.

''(4) BENEFIT TO HEALTH OF INDIVIDUALS AND OF POPULATION AS A WHOLE.—In making the determinations under paragraphs (1) and (2), the Secretary shall take into account—

''(A) the relative health risks to individuals of the tobacco product that is the subject of the application;

''(B) the increased or decreased likelihood that existing users of tobacco products who would otherwise stop using such products will switch to the tobacco product that is the subject of the application;

''(C) the increased or decreased likelihood that persons who do not use tobacco products will start using the tobacco product that is the subject of the application;

''(D) the risks and benefits to persons from the use of the tobacco product that is the subject of the application as compared to the use of products for smoking cessation approved under chapter V to treat nicotine dependence; and

''(E) comments, data, and information submitted by interested persons.

''(h) ADDITIONAL CONDITIONS FOR MARKETING.—

''(1) MODIFIED RISK PRODUCTS.—The Secretary shall require for the marketing of a product under this section that any advertising or labeling concerning modified risk products enable the public to comprehend the information concerning modified risk and to understand the relative significance of such information in the context of total health and in relation to all of the diseases and health-related conditions associated with the use of tobacco products.

''(2) COMPARATIVE CLAIMS.—

''(A) IN GENERAL.—The Secretary may require for the marketing of a product under this subsection that a claim comparing a tobacco product to 1 or more other commercially marketed tobacco products shall compare the tobacco product to a commercially marketed tobacco product that is representative of that type of tobacco product on the market (for example the average value of the top 3 brands of an established regular tobacco product).

''(B) QUANTITATIVE COMPARISONS.—The Secretary may also require, for purposes of subparagraph (A), that the percent (or fraction) of change and identity of the reference tobacco product and a quantitative comparison of the amount of the substance claimed to be reduced shall be stated in immediate proximity to the most prominent claim.

''(3) LABEL DISCLOSURE.—

''(A) IN GENERAL.—The Secretary may require the disclosure on the label of other substances in the tobacco product, or substances that may be produced by the consumption of that tobacco product, that may affect a disease or health-related condition or may increase the risk of other diseases or health-related conditions associated with the use of tobacco products.

''(B) CONDITIONS OF USE.—If the conditions of use of the tobacco product may affect the risk of the product to human health, the Secretary may require the labeling of conditions of use.

''(4) TIME.—An order issued under subsection (g)(1) shall be effective for a specified period of time.

''(5) ADVERTISING.—The Secretary may require, with respect to a product for which an applicant obtained an order under subsection (g)(1), that the product comply with requirements relating to advertising and promotion of the tobacco product.

''(i) POSTMARKET SURVEILLANCE AND STUDIES.—

''(1) IN GENERAL.—The Secretary shall require, with respect to a product for which an applicant obtained an order under subsection (g)(1), that the applicant conduct postmarket surveillance and studies for such a tobacco product to determine the impact of the order issuance on consumer perception, behavior, and health, to enable the Secretary to review the accuracy of the determinations upon which the order was based, and to provide information that the Secretary determines is otherwise necessary regarding the use or health risks involving the tobacco product. The results of postmarket surveillance and studies shall be submitted to the Secretary on an annual basis.

''(2) SURVEILLANCE PROTOCOL.—Each applicant required to conduct a surveillance of a tobacco product under paragraph (1) shall, within 30 days after receiving notice that the applicant is required to conduct such surveillance, submit, for the approval of the Secretary, a protocol for the required surveillance. The Secretary, within 60 days of the receipt of such protocol, shall determine if the principal investigator proposed to be used in the surveillance has sufficient qualifications and experience to conduct such surveillance and if such protocol will result in collection of the data or other information designated by the Secretary as necessary to protect the public health.

''(j) WITHDRAWAL OF AUTHORIZATION.—The Secretary, after an opportunity for an informal hearing, shall withdraw an order under subsection (g) if the Secretary determines that—

''(1) the applicant, based on new information, can no longer make the demonstrations required under subsection (g), or the Secretary can no longer make the determinations required under subsection (g);

''(2) the application failed to include material information or included any untrue statement of material fact;

''(3) any explicit or implicit representation that the product reduces risk or exposure is no longer valid, including if—

''(A) a tobacco product standard is established pursuant to section 907;

''(B) an action is taken that affects the risks presented by other commercially marketed tobacco products that were compared to the product that is the subject of the application; or

''(C) any postmarket surveillance or studies reveal that the order is no longer consistent with the protection of the public health;

''(4) the applicant failed to conduct or submit the postmarket surveillance and studies required under subsection (g)(2)(C)(ii) or subsection (i); or

''(5) the applicant failed to meet a condition imposed under subsection (h).

''(k) CHAPTER IV OR V.—A product for which the Secretary has issued an order pursuant to subsection (g) shall not be subject to chapter IV or V.

''(l) IMPLEMENTING REGULATIONS OR GUIDANCE.—

''(1) SCIENTIFIC EVIDENCE.—Not later than 2 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall issue regulations or guidance (or any combination thereof) on the scientific evidence required for assessment and ongoing review of modified risk tobacco products. Such regulations or guidance shall—

''(A) to the extent that adequate scientific evidence exists, establish minimum standards for scientific studies needed prior to issuing an order under subsection (g) to show that a substantial reduction in morbidity or mortality among individual tobacco users occurs for products described in subsection (g)(1) or is reasonably likely for products described in subsection (g)(2);

''(B) include validated biomarkers, intermediate clinical endpoints, and other feasible outcome measures, as appropriate;

''(C) establish minimum standards for postmarket studies, that shall include regular and long-term assessments of health outcomes and mortality, intermediate clinical endpoints, consumer perception of harm reduction, and the impact on quitting behavior and new use of tobacco products, as appropriate;

''(D) establish minimum standards for required postmarket surveillance, including ongoing assessments of consumer perception;

''(E) require that data from the required studies and surveillance be made available to the Secretary prior to the decision on renewal of a modified risk tobacco product; and

''(F) establish a reasonable timetable for the Secretary to review an application under this section.

''(2) CONSULTATION.—The regulations or guidance issued under paragraph (1) shall be developed in consultation with the Institute of Medicine, and with the input of other appropriate scientific and medical experts, on the design and conduct of such studies and surveillance.

''(3) REVISION.—The regulations or guidance under paragraph (1) shall be revised on a regular basis as new scientific information becomes available.

''(4) NEW TOBACCO PRODUCTS.—Not later than 2 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall issue a regulation or guidance that permits the filing of a single application for any tobacco product that is a new tobacco product under section 910 and which the applicant seeks to commercially market under this section.

''(m) DISTRIBUTORS.—Except as provided in this section, no distributor may take any action, after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, with respect to a tobacco product that would reasonably be expected to result in consumers believing that the tobacco product or its smoke may present a lower risk of disease or is less harmful than one or more commercially marketed tobacco products, or presents a reduced exposure to, or does not contain or is free of, a substance or substances.

''SEC. 912. JUDICIAL REVIEW.

''(a) RIGHT TO REVIEW.—

''(1) IN GENERAL.—Not later than 30 days after—

''(A) the promulgation of a regulation under section 907 establishing, amending, or revoking a tobacco product standard; or

''(B) a denial of an application under section 910(c),

any person adversely affected by such regulation or denial may file a petition for judicial review of such regulation or denial with the United States Court of Appeals for the District of Columbia or for the circuit in which such person resides or has their principal place of business.

''(2) REQUIREMENTS.—

''(A) COPY OF PETITION.—A copy of the petition filed under paragraph (1) shall be transmitted by the clerk of the court involved to the Secretary.

''(B) RECORD OF PROCEEDINGS.—On receipt of a petition under subparagraph (A), the Secretary shall file in the court in which such petition was filed—

''(i) the record of the proceedings on which the regulation or order was based; and

''(ii) a statement of the reasons for the issuance of such a regulation or order.

''(C) DEFINITION OF RECORD.—In this section, the term 'record' means—

''(i) all notices and other matter published in the Federal Register with respect to the regulation or order reviewed;

''(ii) all information submitted to the Secretary with respect to such regulation or order;

''(iii) proceedings of any panel or advisory committee with respect to such regulation or order;

''(iv) any hearing held with respect to such regulation or order; and

''(v) any other information identified by the Secretary, in the administrative proceeding held with respect to such regulation or order, as being relevant to such regulation or order.

''(b) STANDARD OF REVIEW.—Upon the filing of the petition under subsection (a) for judicial review of a regulation or order, the court shall have jurisdiction to review the regulation or order in accordance with chapter 7 of title 5, United States Code, and to grant appropriate relief, including interim relief, as provided for in such chapter. A regulation or denial described in subsection (a) shall be reviewed in accordance with section 706(2)(A) of title 5, United States Code.

''(c) FINALITY OF JUDGMENT.—The judgment of the court affirming or setting aside, in whole or in part, any regulation or order shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of title 28, United States Code.

''(d) OTHER REMEDIES.—The remedies provided for in this section shall be in addition to, and not in lieu of, any other remedies provided by law.

''(e) REGULATIONS AND ORDERS MUST RECITE BASIS IN RECORD.—To facilitate judicial review, a regulation or order issued under section 906, 907, 908, 909, 910, or 916 shall contain a statement of the reasons for the issuance of such regulation or order in the record of the proceedings held in connection with its issuance.

''SEC. 913. EQUAL TREATMENT OF RETAIL OUTLETS.

''The Secretary shall issue regulations to require that retail establishments for which the predominant business is the sale of tobacco products comply with any advertising restrictions applicable to retail establishments accessible to individuals under the age of 18.

''SEC. 914. JURISDICTION OF AND COORDINATION WITH THE FEDERAL TRADE COMMISSION.

''(a) JURISDICTION.—

''(1) IN GENERAL.—Except where expressly provided in this chapter, nothing in this chapter shall be construed as limiting or diminishing the authority of the Federal Trade Commission to enforce the laws under its jurisdiction with respect to the advertising, sale, or distribution of tobacco products.

''(2) ENFORCEMENT.—Any advertising that violates this chapter or a provision of the regulations referred to in section 102 of the Family Smoking Prevention and Tobacco Control Act, is an unfair or deceptive act or practice under section 5(a) of the Federal Trade Commission Act and shall be considered a violation of a rule promulgated under section 18 of that Act.

''(b) COORDINATION.—With respect to the requirements of section 4 of the Federal Cigarette Labeling and Advertising Act and section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986—

''(1) the Chairman of the Federal Trade Commission shall coordinate with the Secretary concerning the enforcement of such Act as such enforcement relates to unfair or deceptive acts or practices in the advertising of cigarettes or smokeless tobacco; and

''(2) the Secretary shall consult with the Chairman of such Commission in revising the label statements and requirements under such sections.

''SEC. 915. REGULATION REQUIREMENT.

''(a) TESTING, REPORTING, AND DISCLOSURE.—Not later than 36 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall promulgate regulations under this Act that meet the requirements of subsection (b).

''(b) CONTENTS OF RULES.—The regulations promulgated under subsection (a)—

''(1) shall require testing and reporting of tobacco product constituents, ingredients, and additives, including smoke constituents, by brand and subbrand that the Secretary determines should be tested to protect the public health, provided that, for purposes of the testing requirements of this paragraph, tobacco products manufactured and sold by a single tobacco product manufacturer that are identical in all respects except the labels, packaging design, logo, trade dress, trademark, brand name, or any combination thereof, shall be considered as a single brand; and

''(2) may require that tobacco product manufacturers, packagers, or importers make disclosures relating to the results of the testing of tar and nicotine through labels or advertising or other appropriate means, and make disclosures regarding the results of the testing of other constituents, including smoke constituents, ingredients, or additives, that the Secretary determines should be disclosed to the public to protect the public health and will not mislead consumers about the risk of tobacco-related disease.

''(c) AUTHORITY.—The Secretary shall have the authority under this chapter to conduct or to require the testing, reporting, or disclosure of tobacco product constituents, including smoke constituents.

''(d) SMALL TOBACCO PRODUCT MANUFACTURERS.—

''(1) FIRST COMPLIANCE DATE.—The initial regulations promulgated under subsection (a) shall not impose requirements on small tobacco product manufacturers before the later of—

''(A) the end of the 2-year period following the final promulgation of such regulations; and

''(B) the initial date set by the Secretary for compliance with such regulations by

manufacturers that are not small tobacco product manufacturers.

''(2) TESTING AND REPORTING INITIAL COMPLIANCE PERIOD.—

''(A) 4-YEAR PERIOD.—The initial regulations promulgated under subsection (a) shall give each small tobacco product manufacturer a 4-year period over which to conduct testing and reporting for all of its tobacco products. Subject to paragraph (1), the end of the first year of such 4-year period shall coincide with the initial date of compliance under this section set by the Secretary with respect to manufacturers that are not small tobacco product manufacturers or the end of the 2-year period following the final promulgation of such regulations, as described in paragraph (1)(A). A small tobacco product manufacturer shall be required—

''(i) to conduct such testing and reporting for 25 percent of its tobacco products during each year of such 4-year period; and

''(ii) to conduct such testing and reporting for its largest-selling tobacco products (as determined by the Secretary) before its other tobacco products, or in such other order of priority as determined by the Secretary.

''(B) CASE-BY-CASE DELAY.—Notwithstanding subparagraph (A), the Secretary may, on a case-by-case basis, delay the date by which an individual small tobacco product manufacturer must conduct testing and reporting for its tobacco products under this section based upon a showing of undue hardship to such manufacturer. Notwithstanding the preceding sentence, the Secretary shall not extend the deadline for a small tobacco product manufacturer to conduct testing and reporting for all of its tobacco products beyond a total of 5 years after the initial date of compliance under this section set by the Secretary with respect to manufacturers that are not small tobacco product manufacturers.

''(3) SUBSEQUENT AND ADDITIONAL TESTING AND REPORTING.—The regulations promulgated under subsection (a) shall provide that, with respect to any subsequent or additional testing and reporting of tobacco products required under this section, such testing and reporting by a small tobacco product manufacturer shall be conducted in accordance with the timeframes described in paragraph (2)(A), except that, in the case of a new product, or if there has been a modification described in section 910(a)(1)(B) of any product of a small tobacco product manufacturer since the last testing and reporting required under this section, the Secretary shall require that any subsequent or additional testing and reporting be conducted in accordance with the same timeframe applicable to manufacturers that are not small tobacco product manufacturers.

''(4) JOINT LABORATORY TESTING SERVICES.—The Secretary shall allow any 2 or more small tobacco product manufacturers to join together to purchase laboratory testing services required by this section on a group basis in order to ensure that such manufacturers receive access to, and fair pricing of, such testing services.

''(e) EXTENSIONS FOR LIMITED LABORATORY CAPACITY.—

''(1) IN GENERAL.—The regulations promulgated under subsection (a) shall provide that a small tobacco product manufacturer shall not be considered to be in violation of this section before the deadline applicable under paragraphs (3) and (4), if—

''(A) the tobacco products of such manufacturer are in compliance with all other requirements of this chapter; and

''(B) the conditions described in paragraph (2) are met.

''(2) CONDITIONS.—Notwithstanding the requirements of this section, the Secretary may delay the date by which a small tobacco product manufacturer must be in compliance with the testing and reporting required by this section until such time as the testing is reported if, not later than 90 days before the deadline for reporting in accordance with this section, a small tobacco product manufacturer provides evidence to the Secretary demonstrating that—

''(A) the manufacturer has submitted the required products for testing to a laboratory and has done so sufficiently in advance of the deadline to create a reasonable expectation of completion by the deadline;

''(B) the products currently are awaiting testing by the laboratory; and

''(C) neither that laboratory nor any other laboratory is able to complete testing by the deadline at customary, nonexpedited testing fees.

''(3) EXTENSION.—The Secretary, taking into account the laboratory testing capacity that is available to tobacco product manufacturers, shall review and verify the evidence submitted by a small tobacco product manufacturer in accordance with paragraph (2). If the Secretary finds that the conditions described in such paragraph are met, the Secretary shall notify the small tobacco product manufacturer that the manufacturer shall not be considered to be in violation of the testing and reporting requirements of this section until the testing is reported or until 1 year after the reporting deadline has passed, whichever occurs sooner. If, however, the Secretary has not made a finding before the reporting deadline, the manufacturer shall not be considered to be in violation of such requirements until the Secretary finds that the conditions described in paragraph (2) have not been met, or until 1 year after the reporting deadline, whichever occurs sooner.

''(4) ADDITIONAL EXTENSION.—In addition to the time that may be provided under paragraph (3), the Secretary may provide further extensions of time, in increments of no more than 1 year, for required testing and reporting to occur if the Secretary determines, based on evidence properly and timely submitted by a small tobacco product manufacturer in accordance with paragraph (2), that a lack of available laboratory capacity prevents the manufacturer from completing the required testing during the period described in paragraph (3).

''(f) RULE OF CONSTRUCTION.—Nothing in subsection (d) or (e) shall be construed to authorize the extension of any deadline, or to otherwise affect any timeframe, under any provision of this Act or the Family Smoking Prevention and Tobacco Control Act other than this section.

"SEC. 916. PRESERVATION OF STATE AND LOCAL AUTHORITY.

''(a) IN GENERAL.—

''(1) PRESERVATION.—Except as provided in paragraph (2)(A), nothing in this chapter, or rules promulgated under this chapter, shall be construed to limit the authority of a Federal agency (including the Armed Forces), a State or political subdivision of a State, or the government of an Indian tribe to enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products that is in addition to, or more stringent than, requirements established under this chapter, including a law, rule, regulation, or other measure relating to or prohibiting the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of tobacco products by individuals of any age, information reporting to the State, or measures relating to fire safety standards for tobacco products. No provision of this chapter shall limit or otherwise affect any State, tribal, or local taxation of tobacco products.

''(2) PREEMPTION OF CERTAIN STATE AND LOCAL REQUIREMENTS.—

''(A) IN GENERAL.—No State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this chapter relating to tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products.

''(B) EXCEPTION.—Subparagraph (A) does not apply to requirements relating to the sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products by individuals of any age, or relating to fire safety standards for tobacco products. Information disclosed to a State under subparagraph (A) that is exempt from disclosure under section 552(b)(4) of title 5, United States Code, shall be treated as a trade secret and confidential information by the State.

''(b) RULE OF CONSTRUCTION REGARDING PRODUCT LIABILITY.—No provision of this chapter relating to a tobacco product shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.

"SEC. 917. TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE.

''(a) ESTABLISHMENT.—Not later than 6 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall establish a 12-member advisory committee, to be known as the Tobacco Products Scientific Advisory Committee (in this section referred to as the 'Advisory Committee').

''(b) MEMBERSHIP.—

''(1) IN GENERAL.—

''(A) MEMBERS.—The Secretary shall appoint as members of the Tobacco Products Scientific Advisory Committee individuals who are technically qualified by training and experience in medicine, medical ethics, science, or technology involving the manufacture, evaluation, or use of tobacco products, who are of appropriately diversified professional backgrounds. The committee shall be composed of—

''(i) 7 individuals who are physicians, dentists, scientists, or health care professionals practicing in the area of oncology, pulmonology, cardiology, toxicology, pharmacology, addiction, or any other relevant specialty;

''(ii) 1 individual who is an officer or employee of a State or local government or of the Federal Government;

''(iii) 1 individual as a representative of the general public;

''(iv) 1 individual as a representative of the interests of the tobacco manufacturing industry;

''(v) 1 individual as a representative of the interests of the small business tobacco manufacturing industry, which position may be filled on a rotating, sequential basis by representatives of different small business tobacco manufacturers based on areas of expertise relevant to the topics being considered by the Advisory Committee; and

''(vi) 1 individual as a representative of the interests of the tobacco growers.

''(B) NONVOTING MEMBERS.—The members of the committee appointed under clauses (iv), (v), and (vi) of subparagraph (A) shall serve as consultants to those described in clauses (i) through (iii) of subparagraph (A) and shall be nonvoting representatives.

''(C) CONFLICTS OF INTEREST.—No members of the committee, other than members appointed pursuant to clauses (iv), (v), and (vi) of subparagraph (A) shall, during the member's tenure on the committee or for the 18-

month period prior to becoming such a member, receive any salary, grants, or other payments or support from any business that manufactures, distributes, markets, or sells cigarettes or other tobacco products.

''(2) LIMITATION.—The Secretary may not appoint to the Advisory Committee any individual who is in the regular full-time employ of the Food and Drug Administration or any agency responsible for the enforcement of this Act. The Secretary may appoint Federal officials as ex officio members.

''(3) CHAIRPERSON.—The Secretary shall designate 1 of the members appointed under clauses (i), (ii), and (iii) of paragraph (1)(A) to serve as chairperson.

''(c) DUTIES.—The Tobacco Products Scientific Advisory Committee shall provide advice, information, and recommendations to the Secretary—

''(1) as provided in this chapter;

''(2) on the effects of the alteration of the nicotine yields from tobacco products;

''(3) on whether there is a threshold level below which nicotine yields do not produce dependence on the tobacco product involved; and

''(4) on its review of other safety, dependence, or health issues relating to tobacco products as requested by the Secretary.

''(d) COMPENSATION; SUPPORT; FACA.—

''(1) COMPENSATION AND TRAVEL.—Members of the Advisory Committee who are not officers or employees of the United States, while attending conferences or meetings of the committee or otherwise engaged in its business, shall be entitled to receive compensation at rates to be fixed by the Secretary, which may not exceed the daily equivalent of the rate in effect under the Senior Executive Schedule under section 5382 of title 5, United States Code, for each day (including travel time) they are so engaged; and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5, United States Code, for persons in the Government service employed intermittently.

''(2) ADMINISTRATIVE SUPPORT.—The Secretary shall furnish the Advisory Committee clerical and other assistance.

''(3) NONAPPLICATION OF FACA.—Section 14 of the Federal Advisory Committee Act does not apply to the Advisory Committee.

''(e) PROCEEDINGS OF ADVISORY PANELS AND COMMITTEES.—The Advisory Committee shall make and maintain a transcript of any proceeding of the panel or committee. Each such panel and committee shall delete from any transcript made under this subsection information which is exempt from disclosure under section 552(b) of title 5, United States Code.

''SEC. 918. DRUG PRODUCTS USED TO TREAT TOBACCO DEPENDENCE.

''(a) IN GENERAL.—The Secretary shall—

''(1) at the request of the applicant, consider designating products for smoking cessation, including nicotine replacement products as fast track research and approval products within the meaning of section 506;

''(2) consider approving the extended use of nicotine replacement products (such as nicotine patches, nicotine gum, and nicotine lozenges) for the treatment of tobacco dependence; and

''(3) review and consider the evidence for additional indications for nicotine replacement products, such as for craving relief or relapse prevention.

''(b) REPORT ON INNOVATIVE PRODUCTS.—

''(1) IN GENERAL.—Not later than 3 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary, after consultation with recognized scientific, medical, and public health experts (including both Federal agencies and nongovernmental entities, the Institute of Medicine of the National Academy of Sciences, and the Society for Research on Nicotine and Tobacco), shall submit to the Congress a report that examines how best to regulate, promote, and encourage the development of innovative products and treatments (including nicotine-based and non-nicotine-based products and treatments) to better achieve, in a manner that best protects and promotes the public health—

''(A) total abstinence from tobacco use;

''(B) reductions in consumption of tobacco; and

''(C) reductions in the harm associated with continued tobacco use.

''(2) RECOMMENDATIONS.—The report under paragraph (1) shall include the recommendations of the Secretary on how the Food and Drug Administration should coordinate and facilitate the exchange of information on such innovative products and treatments among relevant offices and centers within the Administration and within the National Institutes of Health, the Centers for Disease Control and Prevention, and other relevant agencies.

''SEC. 919. USER FEES.

''(a) ESTABLISHMENT OF QUARTERLY FEE.—Beginning on the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall in accordance with this section assess user fees on, and collect such fees from, each manufacturer and importer of tobacco products subject to this chapter. The fees shall be assessed and collected with respect to each quarter of each fiscal year, and the total amount assessed and collected for a fiscal year shall be the amount specified in subsection (b)(1) for such year, subject to subsection (c).

''(b) ASSESSMENT OF USER FEE.—

''(1) AMOUNT OF ASSESSMENT.—The total amount of user fees authorized to be assessed and collected under subsection (a) for a fiscal year is the following, as applicable to the fiscal year involved:

''(A) For fiscal year 2009, $85,000,000 (subject to subsection (e)).

''(B) For fiscal year 2010, $235,000,000.

''(C) For fiscal year 2011, $450,000,000.

''(D) For fiscal year 2012, $477,000,000.

''(E) For fiscal year 2013, $505,000,000.

''(F) For fiscal year 2014, $534,000,000.

''(G) For fiscal year 2015, $566,000,000.

''(H) For fiscal year 2016, $599,000,000.

''(I) For fiscal year 2017, $635,000,000.

''(J) For fiscal year 2018, $672,000,000.

''(K) For fiscal year 2019 and each subsequent fiscal year, $712,000,000.

''(2) ALLOCATIONS OF ASSESSMENT BY CLASS OF TOBACCO PRODUCTS.—

''(A) IN GENERAL.—The total user fees assessed and collected under subsection (a) each fiscal year with respect to each class of tobacco products shall be an amount that is equal to the applicable percentage of each class for the fiscal year multiplied by the amount specified in paragraph (1) for the fiscal year.

''(B) APPLICABLE PERCENTAGE.—

''(i) IN GENERAL.—For purposes of subparagraph (A), the applicable percentage for a fiscal year for each of the following classes of tobacco products shall be determined in accordance with clause (ii):

''(I) Cigarettes.

''(II) Cigars, including small cigars and cigars other than small cigars.

''(III) Snuff.

''(IV) Chewing tobacco.

''(V) Pipe tobacco.

''(VI) Roll-your-own tobacco.

''(ii) ALLOCATIONS.—The applicable percentage of each class of tobacco product described in clause (i) for a fiscal year shall be the percentage determined under section 625(c) of Public Law 108–357 for each such class of product for such fiscal year.

''(iii) REQUIREMENT OF REGULATIONS.—Notwithstanding clause (ii), no user fees shall be assessed on a class of tobacco products unless such class of tobacco products is listed in section 901(b) or is deemed by the Secretary in a regulation under section 901(b) to be subject to this chapter.

''(iv) REALLOCATIONS.—In the case of a class of tobacco products that is not listed in section 901(b) or deemed by the Secretary in a regulation under section 901(b) to be subject to this chapter, the amount of user fees that would otherwise be assessed to such class of tobacco products shall be reallocated to the classes of tobacco products that are subject to this chapter in the same manner and based on the same relative percentages otherwise determined under clause (ii).

''(3) DETERMINATION OF USER FEE BY COMPANY.—

''(A) IN GENERAL.—The total user fee to be paid by each manufacturer or importer of a particular class of tobacco products shall be determined for each quarter by multiplying—

''(i) such manufacturer's or importer's percentage share as determined under paragraph (4); by

''(ii) the portion of the user fee amount for the current quarter to be assessed on all manufacturers and importers of such class of tobacco products as determined under paragraph (2).

''(B) NO FEE IN EXCESS OF PERCENTAGE SHARE.—No manufacturer or importer of tobacco products shall be required to pay a user fee in excess of the percentage share of such manufacturer or importer.

''(4) ALLOCATION OF ASSESSMENT WITHIN EACH CLASS OF TOBACCO PRODUCT.—The percentage share of each manufacturer or importer of a particular class of tobacco products of the total user fee to be paid by all manufacturers or importers of that class of tobacco products shall be the percentage determined for purposes of allocations under subsections (e) through (h) of section 625 of Public Law 108–357.

''(5) ALLOCATION FOR CIGARS.—Notwithstanding paragraph (4), if a user fee assessment is imposed on cigars, the percentage share of each manufacturer or importer of cigars shall be based on the excise taxes paid by such manufacturer or importer during the prior fiscal year.

''(6) TIMING OF ASSESSMENT.—The Secretary shall notify each manufacturer and importer of tobacco products subject to this section of the amount of the quarterly assessment imposed on such manufacturer or importer under this subsection for each quarter of each fiscal year. Such notifications shall occur not later than 30 days prior to the end of the quarter for which such assessment is made, and payments of all assessments shall be made by the last day of the quarter involved.

''(7) MEMORANDUM OF UNDERSTANDING.—

''(A) IN GENERAL.—The Secretary shall request the appropriate Federal agency to enter into a memorandum of understanding that provides for the regular and timely transfer from the head of such agency to the Secretary of the information described in paragraphs (2)(B)(ii) and (4) and all necessary information regarding all tobacco product manufacturers and importers required to pay user fees. The Secretary shall maintain all disclosure restrictions established by the head of such agency regarding the information provided under the memorandum of understanding.

''(B) ASSURANCES.—Beginning not later than fiscal year 2015, and for each subsequent

fiscal year, the Secretary shall ensure that the Food and Drug Administration is able to determine the applicable percentages described in paragraph (2) and the percentage shares described in paragraph (4). The Secretary may carry out this subparagraph by entering into a contract with the head of the Federal agency referred to in subparagraph (A) to continue to provide the necessary information.

''(c) CREDITING AND AVAILABILITY OF FEES.—

''(1) IN GENERAL.—Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts, subject to paragraph (2)(D). Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation.

''(2) AVAILABILITY.—

''(A) IN GENERAL.—Fees appropriated under paragraph (3) are available only for the purpose of paying the costs of the activities of the Food and Drug Administration related to the regulation of tobacco products under this chapter and the Family Smoking Prevention and Tobacco Control Act (referred to in this subsection as 'tobacco regulation activities'), except that such fees may be used for the reimbursement specified in subparagraph (C).

''(B) PROHIBITION AGAINST USE OF OTHER FUNDS.—

''(i) IN GENERAL.—Except as provided in clause (ii), fees collected under subsection (a) are the only funds authorized to be made available for tobacco regulation activities.

''(ii) STARTUP COSTS.—Clause (i) does not apply until October 1, 2009. Until such date, any amounts available to the Food and Drug Administration (excluding user fees) shall be available and allocated as needed to pay the costs of tobacco regulation activities.

''(C) REIMBURSEMENT OF START-UP AMOUNTS.—

''(i) IN GENERAL.—Any amounts allocated for the start-up period pursuant to subparagraph (B)(ii) shall be reimbursed through any appropriated fees collected under subsection (a), in such manner as the Secretary determines appropriate to ensure that such allocation results in no net change in the total amount of funds otherwise available, for the period from October 1, 2008, through September 30, 2010, for Food and Drug Administration programs and activities (other than tobacco regulation activities) for such period.

''(ii) TREATMENT OF REIMBURSED AMOUNTS.—Amounts reimbursed under clause (i) shall be available for the programs and activities for which funds allocated for the start-up period were available, prior to such allocation, until September 30, 2010, notwithstanding any otherwise applicable limits on amounts for such programs or activities for a fiscal year.

''(D) FEE COLLECTED DURING START-UP PERIOD.—Notwithstanding the first sentence of paragraph (1), fees under subsection (a) may be collected through September 30, 2009 under subparagraph (B)(ii) and shall be available for obligation and remain available until expended. Such offsetting collections shall be credited to the salaries and expenses account of the Food and Drug Administration.

''(E) OBLIGATION OF START-UP COSTS IN ANTICIPATION OF AVAILABLE FEE COLLECTIONS.—Notwithstanding any other provision of law, following the enactment of an appropriation for fees under this section for fiscal year 2010, or any portion thereof, obligations for costs of tobacco regulation activities during the start-up period may be incurred in anticipation of the receipt of offsetting fee collections through procedures specified in section 1534 of title 31, United States Code.

''(3) AUTHORIZATION OF APPROPRIATIONS.—For fiscal year 2009 and each subsequent fiscal year, there is authorized to be appropriated for fees under this section an amount equal to the amount specified in subsection (b)(1) for the fiscal year.

''(d) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

''(e) APPLICABILITY TO FISCAL YEAR 2009.—If the date of enactment of the Family Smoking Prevention and Tobacco Control Act occurs during fiscal year 2009, the following applies, subject to subsection (c):

''(1) The Secretary shall determine the fees that would apply for a single quarter of such fiscal year according to the application of subsection (b) to the amount specified in paragraph (1)(A) of such subsection (referred to in this subsection as the 'quarterly fee amounts').

''(2) For the quarter in which such date of enactment occurs, the amount of fees assessed shall be a pro rata amount, determined according to the number of days remaining in the quarter (including such date of enactment) and according to the daily equivalent of the quarterly fee amounts. Fees assessed under the preceding sentence shall not be collected until the next quarter.

''(3) For the quarter following the quarter to which paragraph (2) applies, the full quarterly fee amounts shall be assessed and collected, in addition to collection of the pro rata fees assessed under paragraph (2).''.

(c) CONFORMING AMENDMENT.—Section 9(1) of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4408(i)) is amended to read as follows:

''(1) The term 'smokeless tobacco' has the meaning given such term by section 900(18) of the Federal Food, Drug, and Cosmetic Act.''.

SEC. 102. FINAL RULE.

(a) CIGARETTES AND SMOKELESS TOBACCO.—

(1) IN GENERAL.—On the first day of publication of the Federal Register that is 180 days or more after the date of enactment of this Act, the Secretary of Health and Human Services shall publish in the Federal Register a final rule regarding cigarettes and smokeless tobacco, which—

(A) is deemed to be issued under chapter 9 of the Federal Food, Drug, and Cosmetic Act, as added by section 101 of this division; and

(B) shall be deemed to be in compliance with all applicable provisions of chapter 5 of title 5, United States Code, and all other provisions of law relating to rulemaking procedures.

(2) CONTENTS OF RULE.—Except as provided in this subsection, the final rule published under paragraph (1), shall be identical in its provisions to part 897 of the regulations promulgated by the Secretary of Health and Human Services in the August 28, 1996, issue of the Federal Register (61 Fed. Reg. 44615–44618). Such rule shall—

(A) provide for the designation of jurisdictional authority that is in accordance with this subsection in accordance with this division and the amendments made by this division;

(B) strike Subpart C—Labels and section 897.32(c);

(C) strike paragraphs (a), (b), and (i) of section 897.3 and insert definitions of the terms ''cigarette'', ''cigarette tobacco'', and ''smokeless tobacco'' as defined in section 900 of the Federal Food, Drug, and Cosmetic Act;

(D) insert ''or roll-your-own paper'' in section 897.34(a) after ''other than cigarettes or smokeless tobacco'';

(E) include such modifications to section 897.30(b), if any, that the Secretary determines are appropriate in light of governing First Amendment case law, including the decision of the Supreme Court of the United States in Lorillard Tobacco Co. v. Reilly (533 U.S. 525 (2001));

(F) become effective on the date that is 1 year after the date of enactment of this Act; and

(G) amend paragraph (d) of section 897.16 to read as follows:

''(d)(1) Except as provided in subparagraph (2), no manufacturer, distributor, or retailer may distribute or cause to be distributed any free samples of cigarettes, smokeless tobacco, or other tobacco products (as such term is defined in section 201 of the Federal Food, Drug, and Cosmetic Act).

''(2)(A) Subparagraph (1) does not prohibit a manufacturer, distributor, or retailer from distributing or causing to be distributed free samples of smokeless tobacco in a qualified adult-only facility.

''(B) This subparagraph does not affect the authority of a State or local government to prohibit or otherwise restrict the distribution of free samples of smokeless tobacco.

''(C) For purposes of this paragraph, the term 'qualified adult-only facility' means a facility or restricted area that—

''(i) requires each person present to provide to a law enforcement officer (whether on or off duty) or to a security guard licensed by a governmental entity government-issued identification showing a photograph and at least the minimum age established by applicable law for the purchase of smokeless tobacco;

''(ii) does not sell, serve, or distribute alcohol;

''(iii) is not located adjacent to or immediately across from (in any direction) a space that is used primarily for youth-oriented marketing, promotional, or other activities;

''(iv) is a temporary structure constructed, designated, and operated as a distinct enclosed area for the purpose of distributing free samples of smokeless tobacco in accordance with this subparagraph;

''(v) is enclosed by a barrier that—

''(I) is constructed of, or covered with, an opaque material (except for entrances and exits);

''(II) extends from no more than 12 inches above the ground or floor (which area at the bottom of the barrier must be covered with material that restricts visibility but may allow airflow) to at least 8 feet above the ground or floor (or to the ceiling); and

''(III) prevents persons outside the qualified adult-only facility from seeing into the qualified adult-only facility, unless they make unreasonable efforts to do so; and

''(vi) does not display on its exterior—

''(I) any tobacco product advertising;

''(II) a brand name other than in conjunction with words for an area or enclosure to identify an adult-only facility; or

''(III) any combination of words that would imply to a reasonable observer that the manufacturer, distributor, or retailer has a sponsorship that would violate section 897.34(c).

''(D) Distribution of samples of smokeless tobacco under this subparagraph permitted to be taken out of the qualified adult-only facility shall be limited to 1 package per adult consumer containing no more than 0.53 ounces (15 grams) of smokeless tobacco. If such package of smokeless tobacco contains individual portions of smokeless tobacco, the

individual portions of smokeless tobacco shall not exceed 8 individual portions and the collective weight of such individual portions shall not exceed 0.53 ounces (15 grams). Any manufacturer, distributor, or retailer who distributes or causes to be distributed free samples also shall take reasonable steps to ensure that the above amounts are limited to one such package per adult consumer per day.

''(3) Notwithstanding subparagraph (2), no manufacturer, distributor, or retailer may distribute or cause to be distributed any free samples of smokeless tobacco—

''(A) to a sports team or entertainment group; or

''(B) at any football, basketball, baseball, soccer, or hockey event or any other sporting or entertainment event determined by the Secretary to be covered by this subparagraph.

''(4) The Secretary shall implement a program to ensure compliance with this paragraph and submit a report to the Congress on such compliance not later than 18 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act.

''(5) Nothing in this paragraph shall be construed to authorize any person to distribute or cause to be distributed any sample of a tobacco product to any individual who has not attained the minimum age established by applicable law for the purchase of such product.''.

(3) AMENDMENTS TO RULE.—Prior to making amendments to the rule published under paragraph (1), the Secretary shall promulgate a proposed rule in accordance with chapter 5 of title 5, United States Code.

(4) RULE OF CONSTRUCTION.—Except as provided in paragraph (3), nothing in this section shall be construed to limit the authority of the Secretary to amend, in accordance with chapter 5 of title 5, United States Code, the regulation promulgated pursuant to this section, including the provisions of such regulation relating to distribution of free samples.

(5) ENFORCEMENT OF RETAIL SALE PROVISIONS.—The Secretary of Health and Human Services shall ensure that the provisions of this division, the amendments made by this division, and the implementing regulations (including such provisions, amendments, and regulations relating to the retail sale of tobacco products) are enforced with respect to the United States and Indian tribes.

(6) QUALIFIED ADULT-ONLY FACILITY.—A qualified adult-only facility (as such term is defined in section 897.16(d) of the final rule published under paragraph (1)) that is also a retailer and that commits a violation as a retailer shall not be subject to the limitations in section 103(q) and shall be subject to penalties applicable to a qualified adult-only facility.

(7) CONGRESSIONAL REVIEW PROVISIONS.—Section 801 of title 5, United States Code, shall not apply to the final rule published under paragraph (1).

(b) LIMITATION ON ADVISORY OPINIONS.—As of the date of enactment of this Act, the following documents issued by the Food and Drug Administration shall not constitute advisory opinions under section 10.85(d)(1) of title 21, Code of Federal Regulations, except as they apply to tobacco products, and shall not be cited by the Secretary of Health and Human Services or the Food and Drug Administration as binding precedent:

(1) The preamble to the proposed rule in the document titled ''Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents'' (60 Fed. Reg. 41314–41372 (August 11, 1995)).

(2) The document titled ''Nicotine in Cigarettes and Smokeless Tobacco Products is a Drug and These Products Are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act'' (60 Fed. Reg. 41453–41787 (August 11, 1995)).

(3) The preamble to the final rule in the document titled ''Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents'' (61 Fed. Reg. 44396–44615 (August 28, 1996)).

(4) The document titled ''Nicotine in Cigarettes and Smokeless Tobacco is a Drug and These Products are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act; Jurisdictional Determination'' (61 Fed. Reg. 44619–45318 (August 28, 1996)).

SEC. 103. CONFORMING AND OTHER AMENDMENTS TO GENERAL PROVISIONS.

(a) AMENDMENT OF FEDERAL FOOD, DRUG, AND COSMETIC ACT.—Except as otherwise expressly provided, whenever in this section an amendment is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference is to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(b) SECTION 301.—Section 301 (21 U.S.C. 331) is amended—

(1) in subsection (a), by inserting ''tobacco product,'' after ''device,'';

(2) in subsection (b), by inserting ''tobacco product,'' after ''device,'';

(3) in subsection (c), by inserting ''tobacco product,'' after ''device,'';

(4) in subsection (e)—

(A) by striking the period after ''572(i)''; and

(B) by striking ''or 761 or the refusal to permit access to'' and inserting ''761, 909, or 920 or the refusal to permit access to'';

(5) in subsection (g), by inserting ''tobacco product,'' after ''device,'';

(6) in subsection (h), by inserting ''tobacco product,'' after ''device,'';

(7) in subsection (j)—

(A) by striking the period after ''573''; and

(B) by striking ''708, or 721'' and inserting ''708, 721, 904, 905, 906, 907, 908, 909, or 920(b)'';

(8) in subsection (k), by inserting ''tobacco product,'' after ''device,'';

(9) by striking subsection (p) and inserting the following:

''(p) The failure to register in accordance with section 510 or 905, the failure to provide any information required by section 510(j), 510(k), 905(i), or 905(j), or the failure to provide a notice required by section 510(j)(2) or 905(i)(3).'';

(10) by striking subsection (q)(1) and inserting the following:

''(q)(1) The failure or refusal—

''(A) to comply with any requirement prescribed under section 518, 520(g), 903(b), 907, 908, or 915;

''(B) to furnish any notification or other material or information required by or under section 519, 520(g), 904, 909, or 920; or

''(C) to comply with a requirement under section 522 or 913.'';

(11) in subsection (q)(2), by striking ''device,'' and inserting ''device or tobacco product,'';

(12) in subsection (r), by inserting ''or tobacco product'' after the term ''device'' each time that such term appears; and

(13) by adding at the end the following:

''(oo) The sale of tobacco products in violation of a no-tobacco-sale order issued under section 303(f).

''(pp) The introduction or delivery for introduction into interstate commerce of a tobacco product in violation of section 911.

''(qq)(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp (including tax stamp), tag, label, or other identification device upon any tobacco product or container or labeling thereof so as to render such tobacco product a counterfeit tobacco product.

''(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other item that is designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any tobacco product or container or labeling thereof so as to render such tobacco product a counterfeit tobacco product.

''(3) The doing of any act that causes a tobacco product to be a counterfeit tobacco product, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit tobacco product.

''(rr) The charitable distribution of tobacco products.

''(ss) The failure of a manufacturer or distributor to notify the Attorney General and the Secretary of the Treasury of their knowledge of tobacco products used in illicit trade.

''(tt) Making any express or implied statement or representation directed to consumers with respect to a tobacco product, in a label or labeling or through the media or advertising, that either conveys, or misleads or would mislead consumers into believing, that—

''(1) the product is approved by the Food and Drug Administration;

''(2) the Food and Drug Administration deems the product to be safe for use by consumers;

''(3) the product is endorsed by the Food and Drug Administration for use by consumers; or

''(4) the product is safe or less harmful by virtue of—

''(A) its regulation or inspection by the Food and Drug Administration; or

''(B) its compliance with regulatory requirements set by the Food and Drug Administration;

including any such statement or representation rendering the product misbranded under section 903.''.

(c) SECTION 303.—Section 303(f) (21 U.S.C. 333(f)) is amended—

(1) in paragraph (5)—

(A) by striking ''paragraph (1), (2), (3), or (4)'' each place such appears and inserting ''paragraph (1), (2), (3), (4), or (9)'';

(B) in subparagraph (A)—

(i) by striking ''assessed'' the first time it appears and inserting ''assessed, or a no-tobacco-sale order may be imposed,''; and

(ii) by striking ''penalty'' the second time it appears and inserting ''penalty, or upon whom a no-tobacco-sale order is to be imposed,'';

(C) in subparagraph (B)—

(i) by inserting after ''penalty,'' the following: ''or the period to be covered by a no-tobacco-sale order,''; and

(ii) by adding at the end the following: ''A no-tobacco-sale order permanently prohibiting an individual retail outlet from selling tobacco products shall include provisions that allow the outlet, after a specified period of time, to request that the Secretary compromise, modify, or terminate the order.''; and

(D) by adding at the end the following:

''(D) The Secretary may compromise, modify, or terminate, with or without conditions, any no-tobacco-sale order.'';

(2) in paragraph (6)—

(A) by inserting ''or the imposition of a no-tobacco-sale order'' after the term ''penalty'' each place such term appears; and

(B) by striking ''issued.'' and inserting ''issued, or on which the no-tobacco-sale order was imposed, as the case may be.''; and

(3) by adding at the end the following:

''(8) If the Secretary finds that a person has committed repeated violations of restrictions promulgated under section 906(d) at a particular retail outlet then the Secretary may impose a no-tobacco-sale order on that person prohibiting the sale of tobacco products in that outlet. A no-tobacco-sale order may be imposed with a civil penalty under paragraph (1). Prior to the entry of a no-sale order under this paragraph, a person shall be entitled to a hearing pursuant to the procedures established through regulations of the Food and Drug Administration for assessing civil money penalties, including at a retailer's request a hearing by telephone, or at the nearest regional or field office of the Food and Drug Administration, or at a Federal, State, or county facility within 100 miles from the location of the retail outlet, if such a facility is available.

''(9) CIVIL MONETARY PENALTIES FOR VIOLATION OF TOBACCO PRODUCT REQUIREMENTS.—

''(A) IN GENERAL.—Subject to subparagraph (B), any person who violates a requirement of this Act which relates to tobacco products shall be liable to the United States for a civil penalty in an amount not to exceed $15,000 for each such violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding.

''(B) ENHANCED PENALTIES.—

''(i) Any person who intentionally violates a requirement of section 902(5), 902(6), 904, 908(c), or 911(a), shall be subject to a civil monetary penalty of—

''(I) not to exceed $250,000 per violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding; or

''(II) in the case of a violation that continues after the Secretary provides written notice to such person, $250,000 for the first 30-day period (or any portion thereof) that the person continues to be in violation, and such amount shall double for every 30-day period thereafter that the violation continues, not to exceed $1,000,000 for any 30-day period, and not to exceed $10,000,000 for all such violations adjudicated in a single proceeding.

''(ii) Any person who violates a requirement of section 911(g)(2)(C)(ii) or 911(i)(1), shall be subject to a civil monetary penalty of—

''(I) not to exceed $250,000 per violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding; or

''(II) in the case of a violation that continues after the Secretary provides written notice to such person, $250,000 for the first 30-day period (or any portion thereof) that the person continues to be in violation, and such amount shall double for every 30-day period thereafter that the violation continues, not to exceed $1,000,000 for any 30-day period, and not to exceed $10,000,000 for all such violations adjudicated in a single proceeding.

''(iii) In determining the amount of a civil penalty under clause (i)(II) or (ii)(II), the Secretary shall take into consideration whether the person is making efforts toward correcting the violation of the requirements of the section for which such person is subject to such civil penalty.''.

(d) SECTION 304.—Section 304 (21 U.S.C. 334) is amended—

(1) in subsection (a)(2)—

(A) by striking ''and'' before ''(D)''; and

(B) by striking ''device.'' and inserting the following: ''device, and (E) Any adulterated or misbranded tobacco product.'';

(2) in subsection (d)(1), by inserting ''tobacco product,'' after ''device,'';

(3) in subsection (g)(1), by inserting ''or tobacco product'' after the term ''device'' each place such term appears; and

(4) in subsection (g)(2)(A), by inserting ''or tobacco product'' after ''device''.

(e) SECTION 505.—Section 505(n)(2) (21 U.S.C. 355(n)(2)) is amended by striking ''section 904'' and inserting ''section 1004''.

(f) SECTION 523.—Section 523(b)(2)(D) (21 U.S.C. 360m(b)(2)(D)) is amended by striking ''section 903(g)'' and inserting ''section 1003(g)''.

(g) SECTION 702.—Section 702(a)(1) (U.S.C. 372(a)(1)) is amended—

(1) by striking ''(a)(1)'' and inserting ''(a)(1)(A)''; and

(2) by adding at the end the following:

''(B)(i) For a tobacco product, to the extent feasible, the Secretary shall contract with the States in accordance with this paragraph to carry out inspections of retailers within that State in connection with the enforcement of this Act.

''(ii) The Secretary shall not enter into any contract under clause (i) with the government of any of the several States to exercise enforcement authority under this Act on Indian country without the express written consent of the Indian tribe involved.''.

(h) SECTION 703.—Section 703 (21 U.S.C. 373) is amended—

(1) by inserting ''tobacco product,'' after the term ''device,'' each place such term appears; and

(2) by inserting ''tobacco products,'' after the term ''devices,'' each place such term appears.

(i) SECTION 704.—Section 704 (21 U.S.C. 374) is amended—

(1) in subsection (a)(1)—

(A) by striking ''devices, or cosmetics'' each place it appears and inserting ''devices, tobacco products, or cosmetics'';

(B) by striking ''or restricted devices'' each place it appears and inserting ''restricted devices, or tobacco products''; and

(C) by striking ''and devices and subject to'' and all that follows through ''other drugs or devices'' and inserting ''devices, and tobacco products and subject to reporting and inspection under regulations lawfully issued pursuant to section 505 (i) or (k), section 519, section 520(g), or chapter IX and data relating to other drugs, devices, or tobacco products'';

(2) in subsection (b), by inserting ''tobacco product,'' after ''device,''; and

(3) in subsection (g)(13), by striking ''section 903(g)'' and inserting ''section 1003(g)''.

(j) SECTION 705.—Section 705(b) (21 U.S.C. 375(b)) is amended by inserting ''tobacco products,'' after ''devices,''.

(k) SECTION 709.—Section 709 (21 U.S.C. 379a) is amended by inserting ''tobacco product,'' after ''device,''.

(l) SECTION 801.—Section 801 (21 U.S.C. 381) is amended—

(1) in subsection (a)—

(A) by inserting ''tobacco products,'' after the term ''devices,'';

(B) by inserting ''or section 905(h)'' after ''section 510''; and

(C) by striking the term ''drugs or devices'' each time such term appears and inserting ''drugs, devices, or tobacco products'';

(2) in subsection (e)(1)—

(A) by inserting ''tobacco product'' after ''drug, device,''; and

(B) by inserting '', and a tobacco product intended for export shall not be deemed to be in violation of section 906(e), 907, 911, or 920(a),'' before ''if it—''; and

(3) by adding at the end the following:

''(p)(1) Not later than 36 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report regarding—

''(A) the nature, extent, and destination of United States tobacco product exports that do not conform to tobacco product standards established pursuant to this Act;

''(B) the public health implications of such exports, including any evidence of a negative public health impact; and

''(C) recommendations or assessments of policy alternatives available to Congress and the executive branch to reduce any negative public health impact caused by such exports.

''(2) The Secretary is authorized to establish appropriate information disclosure requirements to carry out this subsection.''.

(m) SECTION 1003.—Section 1003(d)(2)(C) (as redesignated by section 101(b)) is amended—

(1) by striking ''and'' after ''cosmetics,''; and

(2) inserting '', and tobacco products'' after ''devices''.

(n) SECTION 1009.—Section 1009(b) (as redesignated by section 101(b)) is amended by striking ''section 908'' and inserting ''section 1008''.

(o) SECTION 409 OF THE FEDERAL MEAT INSPECTION ACT.—Section 409(a) of the Federal Meat Inspection Act (21 U.S.C. 679(a)) is amended by striking ''section 902(b)'' and inserting ''section 1002(b)''.

(p) RULE OF CONSTRUCTION.—Nothing in this section is intended or shall be construed to expand, contract, or otherwise modify or amend the existing limitations on State government authority over tribal restricted fee or trust lands.

(q) GUIDANCE AND EFFECTIVE DATES.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall issue guidance—

(A) defining the term ''repeated violation'', as used in section 303(f)(8) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)(8)) as amended by subsection (c), as including at least 5 violations of particular requirements over a 36-month period at a particular retail outlet that constitute a repeated violation and providing for civil penalties in accordance with paragraph (2);

(B) providing for timely and effective notice by certified or registered mail or personal delivery to the retailer of each alleged violation at a particular retail outlet prior to conducting a followup compliance check, such notice to be sent to the location specified on the retailer's registration or to the retailer's registered agent if the retailer has provider such agent information to the Food and Drug Administration prior to the violation;

(C) providing for a hearing pursuant to the procedures established through regulations of the Food and Drug Administration for assessing civil money penalties, including at a retailer's request a hearing by telephone or at the nearest regional or field office of the Food and Drug Administration, and providing for an expedited procedure for the administrative appeal of an alleged violation;

(D) providing that a person may not be charged with a violation at a particular retail outlet unless the Secretary has provided notice to the retailer of all previous violations at that outlet;

(E) establishing that civil money penalties for multiple violations shall increase from one violation to the next violation pursuant to paragraph (2) within the time periods provided for in such paragraph;

(F) providing that good faith reliance on the presentation of a false government-issued photographic identification that contains a date of birth does not constitute a violation of any minimum age requirement for the sale of tobacco products if the retailer has taken effective steps to prevent such violations, including—

(i) adopting and enforcing a written policy against sales to minors;

(ii) informing its employees of all applicable laws;

(iii) establishing disciplinary sanctions for employee noncompliance; and

(iv) requiring its employees to verify age by way of photographic identification or electronic scanning device; and

(G) providing for the Secretary, in determining whether to impose a no-tobacco-sale order and in determining whether to compromise, modify, or terminate such an order, to consider whether the retailer has taken effective steps to prevent violations of the minimum age requirements for the sale of tobacco products, including the steps listed in subparagraph (F).

(2) PENALTIES FOR VIOLATIONS.—

(A) IN GENERAL.—The amount of the civil penalty to be applied for violations of restrictions promulgated under section 906(d), as described in paragraph (1), shall be as follows:

(i) With respect to a retailer with an approved training program, the amount of the civil penalty shall not exceed—

(I) in the case of the first violation, $0.00 together with the issuance of a warning letter to the retailer;

(II) in the case of a second violation within a 12-month period, $250;

(III) in the case of a third violation within a 24-month period, $500;

(IV) in the case of a fourth violation within a 24-month period, $2,000;

(V) in the case of a fifth violation within a 36-month period, $5,000; and

(VI) in the case of a sixth or subsequent violation within a 48-month period, $10,000 as determined by the Secretary on a case-by-case basis.

(ii) With respect to a retailer that does not have an approved training program, the amount of the civil penalty shall not exceed—

(I) in the case of the first violation, $250;

(II) in the case of a second violation within a 12-month period, $500;

(III) in the case of a third violation within a 24-month period, $1,000;

(IV) in the case of a fourth violation within a 24-month period, $2,000;

(V) in the case of a fifth violation within a 36-month period, $5,000; and

(VI) in the case of a sixth or subsequent violation within a 48-month period, $10,000 as determined by the Secretary on a case-by-case basis.

(B) TRAINING PROGRAM.—For purposes of subparagraph (A), the term ''approved training program'' means a training program that complies with standards developed by the Food and Drug Administration for such programs.

(C) CONSIDERATION OF STATE PENALTIES.—The Secretary shall coordinate with the States in enforcing the provisions of this Act and, for purposes of mitigating a civil penalty to be applied for a violation by a retailer of any restriction promulgated under section 906(d), shall consider the amount of any penalties paid by the retailer to a State for the same violation.

(3) GENERAL EFFECTIVE DATE.—The amendments made by paragraphs (2), (3), and (4) of subsection (c) shall take effect upon the issuance of guidance described in paragraph (1) of this subsection.

(4) SPECIAL EFFECTIVE DATE.—The amendment made by subsection (c)(1) shall take effect on the date of enactment of this Act.

(5) PACKAGE LABEL REQUIREMENTS.—The package label requirements of paragraphs (3) and (4) of section 903(a) of the Federal Food, Drug, and Cosmetic Act (as amended by this division) shall take effect on the date that is 12 months after the date of enactment of this Act. The package label requirements of paragraph (2) of such section 903(a) for cigarettes shall take effect on the date that is 15 months after the issuance of the regulations required by section 4(d) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333), as amended by section 201 of this division. The package label requirements of paragraph (2) of such section 903(a) for tobacco products other than cigarettes shall take effect on the date that is 12 months after the date of enactment of this Act. The effective date shall be with respect to the date of manufacture, provided that, in any case, beginning 30 days after such effective date, a manufacturer shall not introduce into the domestic commerce of the United States any product, irrespective of the date of manufacture, that is not in conformance with section 903(a) (2), (3), and (4) and section 920(a) of the Federal Food, Drug, and Cosmetic Act.

(6) ADVERTISING REQUIREMENTS.—The advertising requirements of section 903(a)(8) of the Federal Food, Drug, and Cosmetic Act (as amended by this division) shall take effect on the date that is 12 months after the date of enactment of this Act.

SEC. 104. STUDY ON RAISING THE MINIMUM AGE TO PURCHASE TOBACCO PRODUCTS.

The Secretary of Health and Human Services shall—

(1) convene an expert panel to conduct a study on the public health implications of raising the minimum age to purchase tobacco products; and

(2) not later than 5 years after the date of enactment of this Act, submit a report to the Congress on the results of such study.

SEC. 105. ENFORCEMENT ACTION PLAN FOR ADVERTISING AND PROMOTION RESTRICTIONS.

(a) ACTION PLAN.—

(1) DEVELOPMENT.—Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall develop and publish an action plan to enforce restrictions adopted pursuant to section 906 of the Federal Food, Drug, and Cosmetic Act, as added by section 101(b) of this division, or pursuant to section 102(a) of this division, on promotion and advertising of menthol and other cigarettes to youth.

(2) CONSULTATION.—The action plan required by paragraph (1) shall be developed in consultation with public health organizations and other stakeholders with demonstrated expertise and experience in serving minority communities.

(3) PRIORITY.—The action plan required by paragraph (1) shall include provisions designed to ensure enforcement of the restrictions described in paragraph (1) in minority communities.

(b) STATE AND LOCAL ACTIVITIES.—

(1) INFORMATION ON AUTHORITY.—Not later than 3 months after the date of enactment of this Act, the Secretary shall inform State, local, and tribal governments of the authority provided to such entities under section 5(c) of the Federal Cigarette Labeling and Advertising Act, as added by section 203 of this division, or preserved by such entities under section 916 of the Federal Food, Drug, and Cosmetic Act, as added by section 101(b) of this division.

(2) COMMUNITY ASSISTANCE.—At the request of communities seeking assistance to prevent underage tobacco use, the Secretary shall provide such assistance, including assistance with strategies to address the prevention of underage tobacco use in communities with a disproportionate use of menthol cigarettes by minors.

SEC. 106. STUDIES OF PROGRESS AND EFFECTIVENESS.

(a) FDA REPORT.—Not later than 3 years after the date of enactment of this Act, and not less than every 2 years thereafter, the Secretary of Health and Human Services shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report concerning—

(1) the progress of the Food and Drug Administration in implementing this division, including major accomplishments, objective measurements of progress, and the identification of any areas that have not been fully implemented;

(2) impediments identified by the Food and Drug Administration to progress in implementing this division and to meeting statutory timeframes;

(3) data on the number of new product applications received under section 910 of the Federal Food, Drug, and Cosmetic Act and modified risk product applications received under section 911 of such Act, and the number of applications acted on under each category; and

(4) data on the number of full time equivalents engaged in implementing this division.

(b) GAO REPORT.—Not later than 5 years after the date of enactment of this Act, the Comptroller General of the United States shall conduct a study of, and submit to the Committees described in subsection (a) a report concerning—

(1) the adequacy of the authority and resources provided to the Secretary of Health and Human Services for this division to carry out its goals and purposes; and

(2) any recommendations for strengthening that authority to more effectively protect the public health with respect to the manufacture, marketing, and distribution of tobacco products.

(c) PUBLIC AVAILABILITY.—The Secretary of Health and Human Services and the Comptroller General of the United States, respectively, shall make the reports required under subsection (a) and (b) available to the public, including by posting such reports on the respective Internet websites of the Food and Drug Administration and the Government Accountability Office.

TITLE II—TOBACCO PRODUCT WARNINGS; CONSTITUENT AND SMOKE CONSTITUENT DISCLOSURE

SEC. 201. CIGARETTE LABEL AND ADVERTISING WARNINGS.

(a) AMENDMENT.—Section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) is amended to read as follows:

''SEC. 4. LABELING.

''(a) LABEL REQUIREMENTS.—

''(1) IN GENERAL.—It shall be unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any cigarettes the package of which fails to bear, in accordance with the requirements of this section, one of the following labels:

''WARNING: Cigarettes are addictive.

''WARNING: Tobacco smoke can harm your children.

''WARNING: Cigarettes cause fatal lung disease.

''WARNING: Cigarettes cause cancer.

''WARNING: Cigarettes cause strokes and heart disease.

''WARNING: Smoking during pregnancy can harm your baby.

''WARNING: Smoking can kill you.

''WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.

''WARNING: Quitting smoking now greatly reduces serious risks to your health.

''(2) PLACEMENT; TYPOGRAPHY; ETC.—Each label statement required by paragraph (1) shall be located in the upper portion of the front and rear panels of the package, directly on the package underneath the cellophane or other clear wrapping. Each label statement shall comprise the top 50 percent of the front and rear panels of the package. The word

'WARNING' shall appear in capital letters and all text shall be in conspicuous and legible 17-point type, unless the text of the label statement would occupy more than 70 percent of such area, in which case the text may be in a smaller conspicuous and legible type size, provided that at least 60 percent of such area is occupied by required text. The text shall be black on a white background, or white on a black background, in a manner that contrasts, by typography, layout, or color, with all other printed material on the package, in an alternating fashion under the plan submitted under subsection (c).

''(3) DOES NOT APPLY TO FOREIGN DISTRIBUTION.—The provisions of this subsection do not apply to a tobacco product manufacturer or distributor of cigarettes which does not manufacture, package, or import cigarettes for sale or distribution within the United States.

''(4) APPLICABILITY TO RETAILERS.—A retailer of cigarettes shall not be in violation of this subsection for packaging that—

''(A) contains a warning label;

''(B) is supplied to the retailer by a license- or permit-holding tobacco product manufacturer, importer, or distributor; and

''(C) is not altered by the retailer in a way that is material to the requirements of this subsection.

''(b) ADVERTISING REQUIREMENTS.—

''(1) IN GENERAL.—It shall be unlawful for any tobacco product manufacturer, importer, distributor, or retailer of cigarettes to advertise or cause to be advertised within the United States any cigarette unless its advertising bears, in accordance with the requirements of this section, one of the labels specified in subsection (a).

''(2) TYPOGRAPHY, ETC.—Each label statement required by subsection (a) in cigarette advertising shall comply with the standards set forth in this paragraph. For press and poster advertisements, each such statement and (where applicable) any required statement relating to tar, nicotine, or other constituent (including a smoke constituent) yield shall comprise at least 20 percent of the area of the advertisement and shall appear in a conspicuous and prominent format and location at the top of each advertisement within the trim area. The Secretary may revise the required type sizes in such area in such manner as the Secretary determines appropriate. The word 'WARNING' shall appear in capital letters, and each label statement shall appear in conspicuous and legible type. The text of the label statement shall be black if the background is white and white if the background is black, under the plan submitted under subsection (c). The label statements shall be enclosed by a rectangular border that is the same color as the letters of the statements and that is the width of the first downstroke of the capital 'W' of the word 'WARNING' in the label statements. The text of such label statements shall be in a typeface pro rata to the following requirements: 45-point type for a whole-page broadsheet newspaper advertisement; 39-point type for a half-page broadsheet newspaper advertisement; 39-point type for a whole-page tabloid newspaper advertisement; 27-point type for a half-page tabloid newspaper advertisement; 31.5-point type for a double page spread magazine or whole-page magazine advertisement; 22.5-point type for a 28 centimeter by 3 column advertisement; and 15-point type for a 20 centimeter by 2 column advertisement. The label statements shall be in English, except that—

''(A) in the case of an advertisement that appears in a newspaper, magazine, periodical, or other publication that is not in English, the statements shall appear in the predominant language of the publication; and

''(B) in the case of any other advertisement that is not in English, the statements shall appear in the same language as that principally used in the advertisement.

''(3) MATCHBOOKS.—Notwithstanding paragraph (2), for matchbooks (defined as containing not more than 20 matches) customarily given away with the purchase of tobacco products, each label statement required by subsection (a) may be printed on the inside cover of the matchbook.

''(4) ADJUSTMENT BY SECRETARY.—The Secretary may, through a rulemaking under section 553 of title 5, United States Code, adjust the format and type sizes for the label statements required by this section; the text, format, and type sizes of any required tar, nicotine yield, or other constituent (including smoke constituent) disclosures; or the text, format, and type sizes for any other disclosures required under the Federal Food, Drug, and Cosmetic Act. The text of any such label statements or disclosures shall be required to appear only within the 20 percent area of cigarette advertisements provided by paragraph (2). The Secretary shall promulgate regulations which provide for adjustments in the format and type sizes of any text required to appear in such area to ensure that the total text required to appear by law will fit within such area.

''(c) MARKETING REQUIREMENTS.—

''(1) RANDOM DISPLAY.—The label statements specified in subsection (a)(1) shall be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer and approved by the Secretary.

''(2) ROTATION.—The label statements specified in subsection (a)(1) shall be rotated quarterly in alternating sequence in advertisements for each brand of cigarettes in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer to, and approved by, the Secretary.

''(3) REVIEW.—The Secretary shall review each plan submitted under paragraph (2) and approve it if the plan—

''(A) will provide for the equal distribution and display on packaging and the rotation required in advertising under this subsection; and

''(B) assures that all of the labels required under this section will be displayed by the tobacco product manufacturer, importer, distributor, or retailer at the same time.

''(4) APPLICABILITY TO RETAILERS.—This subsection and subsection (b) apply to a retailer only if that retailer is responsible for or directs the label statements required under this section except that this paragraph shall not relieve a retailer of liability if the retailer displays, in a location open to the public, an advertisement that does not contain a warning label or has been altered by the retailer in a way that is material to the requirements of this subsection and subsection (b).

''(d) GRAPHIC LABEL STATEMENTS.—Not later than 24 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall issue regulations that require color graphics depicting the negative health consequences of smoking to accompany the label statements specified in subsection (a)(1). The Secretary may adjust the type size, text and format of the label statements specified in subsections (a)(2) and (b)(2) as the Secretary determines appropriate so that both the graphics and the accompanying label statements are clear, conspicuous, legible and appear within the specified area.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect 15 months after the issuance of the regulations required by subsection (a). Such effective date shall be with respect to the date of manufacture, provided that, in any case, beginning 30 days after such effective date, a manufacturer shall not introduce into the domestic commerce of the United States any product, irrespective of the date of manufacture, that is not in conformance with section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333), as amended by subsection (a).

SEC. 202. AUTHORITY TO REVISE CIGARETTE WARNING LABEL STATEMENTS.

(a) PREEMPTION.—Section 5(a) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1334(a)) is amended by striking ''No'' and inserting ''Except to the extent the Secretary requires additional or different statements on any cigarette package by a regulation, by an order, by a standard, by an authorization to market a product, or by a condition of marketing a product, pursuant to the Family Smoking Prevention and Tobacco Control Act (and the amendments made by that Act), or as required under section 903(a)(2) or section 920(a) of the Federal Food, Drug, and Cosmetic Act, no''.

(b) CHANGE IN REQUIRED STATEMENTS.—Section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333), as amended by section 201, is further amended by adding at the end the following:

''(d) CHANGE IN REQUIRED STATEMENTS.—The Secretary through a rulemaking conducted under section 553 of title 5, United States Code, may adjust the format, type size, color graphics, and text of any of the label requirements, or establish the format, type size, and text of any other disclosures required under the Federal Food, Drug, and Cosmetic Act, if the Secretary finds that such a change would promote greater public understanding of the risks associated with the use of tobacco products.''.

SEC. 203. STATE REGULATION OF CIGARETTE ADVERTISING AND PROMOTION.

Section 5 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1334) is amended by adding at the end the following:

''(c) EXCEPTION.—Notwithstanding subsection (b), a State or locality may enact statutes and promulgate regulations, based on smoking and health, that take effect after the effective date of the Family Smoking Prevention and Tobacco Control Act, imposing specific bans or restrictions on the time, place, and manner, but not content, of the advertising or promotion of any cigarettes.''.

SEC. 204. SMOKELESS TOBACCO LABELS AND ADVERTISING WARNINGS.

(a) AMENDMENT.—Section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4402) is amended to read as follows:

''SEC. 3. SMOKELESS TOBACCO WARNING.

''(a) GENERAL RULE.—

''(1) It shall be unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any smokeless tobacco product unless the product package bears, in accordance with the requirements of this Act, one of the following labels:

''WARNING: This product can cause mouth cancer.

''WARNING: This product can cause gum disease and tooth loss.

''WARNING: This product is not a safe alternative to cigarettes.

''WARNING: Smokeless tobacco is addictive.

''(2) Each label statement required by paragraph (1) shall be—

''(A) located on the 2 principal display panels of the package, and each label statement shall comprise at least 30 percent of each such display panel; and

''(B) in 17-point conspicuous and legible type and in black text on a white background, or white text on a black background, in a manner that contrasts by typography, layout, or color, with all other printed material on the package, in an alternating fashion under the plan submitted under subsection (b)(3), except that if the text of a label statement would occupy more than 70 percent of the area specified by subparagraph (A), such text may appear in a smaller type size, so long as at least 60 percent of such warning area is occupied by the label statement.

''(3) The label statements required by paragraph (1) shall be introduced by each tobacco product manufacturer, packager, importer, distributor, or retailer of smokeless tobacco products concurrently into the distribution chain of such products.

''(4) The provisions of this subsection do not apply to a tobacco product manufacturer or distributor of any smokeless tobacco product that does not manufacture, package, or import smokeless tobacco products for sale or distribution within the United States.

''(5) A retailer of smokeless tobacco products shall not be in violation of this subsection for packaging that—

''(A) contains a warning label;

''(B) is supplied to the retailer by a license- or permit-holding tobacco product manufacturer, importer, or distributor; and

''(C) is not altered by the retailer in a way that is material to the requirements of this subsection.

''(b) REQUIRED LABELS.—

''(1) It shall be unlawful for any tobacco product manufacturer, packager, importer, distributor, or retailer of smokeless tobacco products to advertise or cause to be advertised within the United States any smokeless tobacco product unless its advertising bears, in accordance with the requirements of this section, one of the labels specified in subsection (a).

''(2)(A) Each label statement required by subsection (a) in smokeless tobacco advertising shall comply with the standards set forth in this paragraph.

''(B) For press and poster advertisements, each such statement and (where applicable) any required statement relating to tar, nicotine, or other constituent yield shall comprise at least 20 percent of the area of the advertisement.

''(C) The word 'WARNING' shall appear in capital letters, and each label statement shall appear in conspicuous and legible type.

''(D) The text of the label statement shall be black on a white background, or white on a black background, in an alternating fashion under the plan submitted under paragraph (3).

''(E) The label statements shall be enclosed by a rectangular border that is the same color as the letters of the statements and that is the width of the first downstroke of the capital 'W' of the word 'WARNING' in the label statements.

''(F) The text of such label statements shall be in a typeface pro rata to the following requirements: 45-point type for a whole-page broadsheet newspaper advertisement; 39-point type for a half-page broadsheet newspaper advertisement; 39-point type for a whole-page tabloid newspaper advertisement; 27-point type for a half-page tabloid newspaper advertisement; 31.5-point type for a double page spread magazine or whole-page magazine advertisement; 22.5-point type for a 28 centimeter by 3 column advertisement; and 15-point type for a 20 centimeter by 2 column advertisement.

''(G) The label statements shall be in English, except that—

''(i) in the case of an advertisement that appears in a newspaper, magazine, periodical, or other publication that is not in English, the statements shall appear in the predominant language of the publication; and

''(ii) in the case of any other advertisement that is not in English, the statements shall appear in the same language as that principally used in the advertisement.

''(3)(A) The label statements specified in subsection (a)(1) shall be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer and approved by the Secretary.

''(B) The label statements specified in subsection (a)(1) shall be rotated quarterly in alternating sequence in advertisements for each brand of smokeless tobacco product in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer to, and approved by, the Secretary.

''(C) The Secretary shall review each plan submitted under subparagraphs (A) and (B) and approve it if the plan—

''(i) will provide for the equal distribution and display on packaging and the rotation required in advertising under this subsection; and

''(ii) assures that all of the labels required under this section will be displayed by the tobacco product manufacturer, importer, distributor, or retailer at the same time.

''(D) This paragraph applies to a retailer only if that retailer is responsible for or directs the label statements under this section, unless the retailer displays, in a location open to the public, an advertisement that does not contain a warning label or has been altered by the retailer in a way that is material to the requirements of this subsection.

''(4) The Secretary may, through a rulemaking under section 553 of title 5, United States Code, adjust the format and type sizes for the label statements required by this section; the text, format, and type sizes of any required tar, nicotine yield, or other constituent disclosures; or the text, format, and type sizes for any other disclosures required under the Federal Food, Drug, and Cosmetic Act. The text of any such label statements or disclosures shall be required to appear only within the 20 percent area of advertisements provided by paragraph (2). The Secretary shall promulgate regulations which provide for adjustments in the format and type sizes of any text required to appear in such area to ensure that the total text required to appear by law will fit within such area.

''(c) TELEVISION AND RADIO ADVERTISING.—It is unlawful to advertise smokeless tobacco on any medium of electronic communications subject to the jurisdiction of the Federal Communications Commission.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect 12 months after the date of enactment of this Act. Such effective date shall be with respect to the date of manufacture, provided that, in any case, beginning 30 days after such effective date, a manufacturer shall not introduce into the domestic commerce of the United States any product, irrespective of the date of manufacture, that is not in conformance with section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4402), as amended by subsection (a).

SEC. 205. AUTHORITY TO REVISE SMOKELESS TOBACCO PRODUCT WARNING LABEL STATEMENTS.

(a) IN GENERAL.—Section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4402), as amended by section 204, is further amended by adding at the end the following:

''(d) AUTHORITY TO REVISE WARNING LABEL STATEMENTS.—The Secretary may, by a rulemaking conducted under section 553 of title 5, United States Code, adjust the format, type size, and text of any of the label requirements, require color graphics to accompany the text, increase the required label area from 30 percent up to 50 percent of the front and rear panels of the package, or establish the format, type size, and text of any other disclosures required under the Federal Food, Drug, and Cosmetic Act, if the Secretary finds that such a change would promote greater public understanding of the risks associated with the use of smokeless tobacco products.''.

(b) PREEMPTION.—Section 7(a) of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4406(a)) is amended by striking ''No'' and inserting ''Except as provided in the Family Smoking Prevention and Tobacco Control Act (and the amendments made by that Act), no''.

SEC. 206. TAR, NICOTINE, AND OTHER SMOKE CONSTITUENT DISCLOSURE TO THE PUBLIC.

Section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333), as amended by sections 201 and 202, is further amended by adding at the end the following:

''(e) TAR, NICOTINE, AND OTHER SMOKE CONSTITUENT DISCLOSURE.—

''(1) IN GENERAL.—The Secretary shall, by a rulemaking conducted under section 553 of title 5, United States Code, determine (in the Secretary's sole discretion) whether cigarette and other tobacco product manufacturers shall be required to include in the area of each cigarette advertisement specified by subsection (b) of this section, or on the package label, or both, the tar and nicotine yields of the advertised or packaged brand. Any such disclosure shall be in accordance with the methodology established under such regulations, shall conform to the type size requirements of subsection (b) of this section, and shall appear within the area specified in subsection (b) of this section.

''(2) RESOLUTION OF DIFFERENCES.—Any differences between the requirements established by the Secretary under paragraph (1) and tar and nicotine yield reporting requirements established by the Federal Trade Commission shall be resolved by a memorandum of understanding between the Secretary and the Federal Trade Commission.

''(3) CIGARETTE AND OTHER TOBACCO PRODUCT CONSTITUENTS.—In addition to the disclosures required by paragraph (1), the Secretary may, under a rulemaking conducted under section 553 of title 5, United States Code, prescribe disclosure requirements regarding the level of any cigarette or other tobacco product constituent including any smoke constituent. Any such disclosure may be required if the Secretary determines that disclosure would be of benefit to the public health, or otherwise would increase consumer awareness of the health consequences of the use of tobacco products, except that no such prescribed disclosure shall be required on the face of any cigarette package or advertisement. Nothing in this section shall prohibit the Secretary from requiring such prescribed disclosure through a cigarette or other tobacco product package or advertisement insert, or by any other means under the Federal Food, Drug, and Cosmetic Act.

''(4) RETAILERS.—This subsection applies to a retailer only if that retailer is responsible for or directs the label statements required under this section.''.

TITLE III—PREVENTION OF ILLICIT TRADE IN TOBACCO PRODUCTS

SEC. 301. LABELING, RECORDKEEPING, RECORDS INSPECTION.

Chapter IX of the Federal Food, Drug, and Cosmetic Act, as added by section 101, is further amended by adding at the end the following:

''SEC. 920. LABELING, RECORDKEEPING, RECORDS INSPECTION.

''(a) ORIGIN LABELING.—

''(1) REQUIREMENT.—Beginning 1 year after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the label, packaging, and shipping containers of tobacco products other than cigarettes for introduction or delivery for introduction into interstate commerce in the United States shall bear the statement 'sale only allowed in the United States'. Beginning 15 months after the issuance of the regulations required by section 4(d) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333), as amended by section 201 of Family Smoking Prevention and Tobacco Control Act, the label, packaging, and shipping containers of cigarettes for introduction or delivery for introduction into interstate commerce in the United States shall bear the statement 'Sale only allowed in the United States'.

''(2) EFFECTIVE DATE.—The effective date specified in paragraph (1) shall be with respect to the date of manufacture, provided that, in any case, beginning 30 days after such effective date, a manufacturer shall not introduce into the domestic commerce of the United States any product, irrespective of the date of manufacture, that is not in conformance with such paragraph.

''(b) REGULATIONS CONCERNING RECORDKEEPING FOR TRACKING AND TRACING.—

''(1) IN GENERAL.—The Secretary shall promulgate regulations regarding the establishment and maintenance of records by any person who manufactures, processes, transports, distributes, receives, packages, holds, exports, or imports tobacco products.

''(2) INSPECTION.—In promulgating the regulations described in paragraph (1), the Secretary shall consider which records are needed for inspection to monitor the movement of tobacco products from the point of manufacture through distribution to retail outlets to assist in investigating potential illicit trade, smuggling, or counterfeiting of tobacco products.

''(3) CODES.—The Secretary may require codes on the labels of tobacco products or other designs or devices for the purpose of tracking or tracing the tobacco product through the distribution system.

''(4) SIZE OF BUSINESS.—The Secretary shall take into account the size of a business in promulgating regulations under this section.

''(5) RECORDKEEPING BY RETAILERS.—The Secretary shall not require any retailer to maintain records relating to individual purchasers of tobacco products for personal consumption.

''(c) RECORDS INSPECTION.—If the Secretary has a reasonable belief that a tobacco product is part of an illicit trade or smuggling or is a counterfeit product, each person who manufactures, processes, transports, distributes, receives, holds, packages, exports, or imports tobacco products shall, at the request of an officer or employee duly designated by the Secretary, permit such officer or employee, at reasonable times and within reasonable limits and in a reasonable manner, upon the presentation of appropriate credentials and a written notice to such person, to have access to and copy all records (including financial records) relating to such article that are needed to assist the Secretary in investigating potential illicit trade, smuggling, or counterfeiting of tobacco products. The Secretary shall not authorize an officer or employee of the government of any of the several States to exercise authority under the preceding sentence on Indian country without the express written consent of the Indian tribe involved.

''(d) KNOWLEDGE OF ILLEGAL TRANSACTION.—

''(1) NOTIFICATION.—If the manufacturer or distributor of a tobacco product has knowledge which reasonably supports the conclusion that a tobacco product manufactured or distributed by such manufacturer or distributor that has left the control of such person may be or has been—

''(A) imported, exported, distributed, or offered for sale in interstate commerce by a person without paying duties or taxes required by law; or

''(B) imported, exported, distributed, or diverted for possible illicit marketing,

the manufacturer or distributor shall promptly notify the Attorney General and the Secretary of the Treasury of such knowledge.

''(2) KNOWLEDGE DEFINED.—For purposes of this subsection, the term 'knowledge' as applied to a manufacturer or distributor means—

''(A) the actual knowledge that the manufacturer or distributor had; or

''(B) the knowledge which a reasonable person would have had under like circumstances or which would have been obtained upon the exercise of due care.

''(e) CONSULTATION.—In carrying out this section, the Secretary shall consult with the Attorney General of the United States and the Secretary of the Treasury, as appropriate.''.

SEC. 302. STUDY AND REPORT.

(a) STUDY.—The Comptroller General of the United States shall conduct a study of cross-border trade in tobacco products to—

(1) collect data on cross-border trade in tobacco products, including illicit trade and trade of counterfeit tobacco products and make recommendations on the monitoring of such trade;

(2) collect data on cross-border advertising (any advertising intended to be broadcast, transmitted, or distributed from the United States to another country) of tobacco products and make recommendations on how to prevent or eliminate, and what technologies could help facilitate the elimination of, cross-border advertising; and

(3) collect data on the health effects (particularly with respect to individuals under 18 years of age) resulting from cross-border trade in tobacco products, including the health effects resulting from—

(A) the illicit trade of tobacco products and the trade of counterfeit tobacco products; and

(B) the differing tax rates applicable to tobacco products.

(b) REPORT.—Not later than 18 months after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the study described in subsection (a).

(c) DEFINITION.—In this section:

(1) The term ''cross-border trade'' means trade across a border of the United States, a State or Territory, or Indian country.

(2) The term ''Indian country'' has the meaning given to such term in section 1151 of title 18, United States Code.

(3) The terms ''State'' and ''Territory'' have the meanings given to those terms in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

DIVISION B—FEDERAL RETIREMENT REFORM ACT

SEC. 100. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This division may be cited as the ''Federal Retirement Reform Act of 2009''.

(b) TABLE OF CONTENTS.—The table of contents for this division is as follows:

DIVISION B—FEDERAL RETIREMENT REFORM ACT

Sec. 100. Short title; table of contents.

TITLE I—PROVISIONS RELATING TO FEDERAL EMPLOYEES RETIREMENT

Sec. 101. Short title.
Sec. 102. Automatic enrollments and immediate employing agency contributions.
Sec. 103. Qualified Roth contribution program.
Sec. 104. Authority to establish mutual fund window.
Sec. 105. Reporting requirements.
Sec. 106. Acknowledgment of risk.
Sec. 107. Subpoena authority.
Sec. 108. Amounts in Thrift Savings Funds subject to legal proceedings.
Sec. 109. Accounts for surviving spouses.
Sec. 110. Treatment of members of the uniformed services under the Thrift Savings Plan.

TITLE II—SPECIAL SURVIVOR INDEMNITY ALLOWANCE FOR SURVIVING SPOUSES OF ARMED FORCES MEMBERS

Sec. 201. Increase in monthly amount of special survivor indemnity allowance for widows and widowers of deceased members of the Armed Forces affected by required Survivor Benefit Plan annuity offset for dependency and indemnity compensation.

TITLE I—PROVISIONS RELATING TO FEDERAL EMPLOYEES RETIREMENT

SEC. 101. SHORT TITLE.

This title may be cited as the ''Thrift Savings Plan Enhancement Act of 2009''.

SEC. 102. AUTOMATIC ENROLLMENTS AND IMMEDIATE EMPLOYING AGENCY CONTRIBUTIONS.

(a) IN GENERAL.—Section 8432(b) of title 5, United States Code, is amended by striking paragraphs (2) through (4) and inserting the following:

''(2)(A) The Executive Director shall by regulation provide for an eligible individual to be automatically enrolled to make contributions under subsection (a) at the default percentage of basic pay.

''(B) For purposes of this paragraph, the default percentage shall be equal to 3 percent or such other percentage, not less than 2 percent nor more than 5 percent, as the Board may prescribe.

''(C) The regulations shall include provisions under which any individual who would otherwise be automatically enrolled in accordance with subparagraph (A) may—

''(i) modify the percentage or amount to be contributed pursuant to automatic enrollment, effective not later than the first full pay period following receipt of the election by the appropriate processing entity; or

''(ii) decline automatic enrollment altogether.

''(D)(i) Except as provided in clause (ii), for purposes of this paragraph, the term 'eligible individual' means any individual who, after any regulations under subparagraph (A) first take effect, is appointed, transferred, or reappointed to a position in which that individual becomes eligible to contribute to the Thrift Savings Fund.

''(ii) Members of the uniformed services shall not be eligible individuals for purposes of this paragraph.

''(E) Sections 8351(a)(1), 8440a(a)(1), 8440b(a)(1), 8440c(a)(1), 8440d(a)(1), and 8440e(a)(1) shall be applied in a manner consistent with the purposes of this paragraph.''.

(b) TECHNICAL AMENDMENT.—Section 8432(b)(1) of title 5, United States Code, is amended by striking the parenthetical matter in subparagraph (B).

SEC. 103. QUALIFIED ROTH CONTRIBUTION PROGRAM.

(a) IN GENERAL.—Subchapter III of chapter 84 of title 5, United States Code, is amended by inserting after section 8432c the following:

''§ 8432d. Qualified Roth contribution program

''(a) DEFINITIONS.—For purposes of this section—

''(1) the term 'qualified Roth contribution program' means a program described in paragraph (1) of section 402A(b) of the Internal Revenue Code of 1986 which meets the requirements of paragraph (2) of such section; and

''(2) the terms 'designated Roth contribution' and 'elective deferral' have the meanings given such terms in section 402A of the Internal Revenue Code of 1986.

''(b) AUTHORITY TO ESTABLISH.—The Executive Director shall by regulation provide for the inclusion in the Thrift Savings Plan of a qualified Roth contribution program, under such terms and conditions as the Board may prescribe.

''(c) REQUIRED PROVISIONS.—The regulations under subsection (b) shall include—

''(1) provisions under which an election to make designated Roth contributions may be made—

''(A) by any individual who is eligible to make contributions under section 8351, 8432(a), 8440a, 8440b, 8440c, 8440d, or 8440e; and

''(B) by any individual, not described in subparagraph (A), who is otherwise eligible to make elective deferrals under the Thrift Savings Plan;

''(2) any provisions which may, as a result of enactment of this section, be necessary in order to clarify the meaning of any reference to an 'account' made in section 8432(f), 8433, 8434(d), 8435, 8437, or any other provision of law; and

''(3) any other provisions which may be necessary to carry out this section.''.

(b) CLERICAL AMENDMENT.—The analysis for chapter 84 of title 5, United States Code, is amended by inserting after the item relating to section 8432c the following:

''8432d. Qualified Roth contribution program.''.

SEC. 104. AUTHORITY TO ESTABLISH MUTUAL FUND WINDOW.

(a) IN GENERAL.—Section 8438(b)(1) of title 5, United States Code, is amended—

(1) in subparagraph (D), by striking ''and'' at the end;

(2) in subparagraph (E), by striking the period and inserting ''; and''; and

(3) by adding after subparagraph (E) the following:

''(F) a service that enables participants to invest in mutual funds, if the Board authorizes the mutual fund window under paragraph (5).''.

(b) REQUIREMENTS.—Section 8438(b) of title 5, United States Code, is amended by adding at the end the following:

''(5)(A) The Board may authorize the addition of a mutual fund window under the Thrift Savings Plan if the Board determines that such addition would be in the best interests of participants.

''(B) The Board shall ensure that any expenses charged for use of the mutual fund window are borne solely by the participants who use such window.

''(C) The Board may establish such other terms and conditions for the mutual fund window as the Board considers appropriate to protect the interests of participants, including requirements relating to risk disclosure.

''(D) The Board shall consult with the Employee Thrift Advisory Council (established under section 8473) before authorizing the addition of a mutual fund window or establishing a service that enables participants to invest in mutual funds.''.

(c) TECHNICAL AND CONFORMING AMENDMENT.—Section 8438(d)(1) of title 5, United States Code, is amended by inserting ''and options'' after ''investment funds''.

SEC. 105. REPORTING REQUIREMENTS.

(a) ANNUAL REPORT.—The Board shall, not later than June 30 of each year, submit to Congress an annual report on the operations of the Thrift Savings Plan. Such report shall include, for the prior calendar year, information on the number of participants as of the last day of such prior calendar year, the median balance in participants' accounts as of such last day, demographic information on participants, the percentage allocation of amounts among investment funds or options, the status of the development and implementation of the mutual fund window, the diversity demographics of any company, investment adviser, or other entity retained to invest and manage the assets of the Thrift Savings Fund, and such other information as the Board considers appropriate. A copy of each annual report under this subsection shall be made available to the public through an Internet website.

(b) REPORTING OF FEES AND OTHER INFORMATION.—

(1) IN GENERAL.—The Board shall include in the periodic statements provided to participants under section 8439(c) of title 5, United States Code, the amount of the investment management fees, administrative expenses, and any other fees or expenses paid with respect to each investment fund and option under the Thrift Savings Plan. Any such statement shall also provide a statement notifying participants as to how they may access the annual report described in subsection (a), as well as any other information concerning the Thrift Savings Plan that might be useful.

(2) USE OF ESTIMATES.—For purposes of providing the information required under this subsection, the Board may provide a reasonable and representative estimate of any fees or expenses described in paragraph (1) and shall indicate any such estimate as being such an estimate. Any such estimate shall be based on the previous year's experience.

(c) DEFINITIONS.—For purposes of this section—

(1) the term ''Board'' has the meaning given such term by 8401(5) of title 5, United States Code;

(2) the term ''participant'' has the meaning given such term by section 8471(3) of title 5, United States Code; and

(3) the term ''account'' means an account established under section 8439 of title 5, United States Code.

SEC. 106. ACKNOWLEDGMENT OF RISK.

(a) IN GENERAL.—Section 8439(d) of title 5, United States Code, is amended—

(1) by striking the matter after ''who elects to invest in'' and before ''shall sign an acknowledgment'' and inserting ''any investment fund or option under this chapter, other than the Government Securities Investment Fund,''; and

(2) by striking ''either such Fund'' and inserting ''any such fund or option''.

(b) COORDINATION WITH PROVISIONS RELATING TO FIDUCIARY RESPONSIBILITIES, LIABILITIES, AND PENALTIES.—Section 8477(e)(1)(C) of title 5, United States Code, is amended—

(1) by redesignating subparagraph (C) as subparagraph (C)(i); and

(2) by adding at the end the following:

''(ii) A fiduciary shall not be liable under subparagraph (A), and no civil action may be brought against a fiduciary—

''(I) for providing for the automatic enrollment of a participant in accordance with section 8432(b)(2)(A);

''(II) for enrolling a participant in a default investment fund in accordance with section 8438(c)(2); or

''(III) for allowing a participant to invest through the mutual fund window or for establishing restrictions applicable to participants' ability to invest through the mutual fund window.''.

SEC. 107. SUBPOENA AUTHORITY.

(a) IN GENERAL.—Chapter 84 of title 5, United States Code, is amended by inserting after section 8479 the following:

''§ 8480. Subpoena authority

''(a) In order to carry out the responsibilities specified in this subchapter and subchapter III of this chapter, the Executive Director may issue subpoenas commanding each person to whom the subpoena is directed to produce designated books, documents, records, electronically stored information, or tangible materials in the possession or control of that individual.

''(b) Notwithstanding any Federal, State, or local law, any person, including officers, agents, and employees, receiving a subpoena under this section, who complies in good faith with the subpoena and thus produces the materials sought, shall not be liable in any court of any State or the United States to any individual, domestic or foreign corporation or upon a partnership or other unincorporated association for such production.

''(c) When a person fails to obey a subpoena issued under this section, the district court of the United States for the district in which the investigation is conducted or in which the person failing to obey is found, shall on proper application issue an order directing that person to comply with the subpoena. The court may punish as contempt any disobedience of its order.

''(d) The Executive Director shall prescribe regulations to carry out subsection (a).''.

(b) TECHNICAL AND CONFORMING AMENDMENT.—The table of sections for chapter 84 of title 5, United States Code, is amended by inserting after the item relating to section 8479 the following:

''8480. Subpoena authority.''.

SEC. 108. AMOUNTS IN THRIFT SAVINGS FUNDS SUBJECT TO LEGAL PROCEEDINGS.

Section 8437(e)(3) of title 5, United States Code, is amended in the first sentence by striking ''or relating to the enforcement of a judgment for the physically, sexually, or emotionally abusing a child as provided under section 8467(a)'' and inserting ''the enforcement of an order for restitution under section 3663A of title 18, forfeiture under section 8432(g)(5) of this title, or an obligation of the Executive Director to make a payment to another person under section 8467 of this title''.

SEC. 109. ACCOUNTS FOR SURVIVING SPOUSES.

Section 8433(e) of title 5, United States Code, is amended—

(1) by inserting ''(1)'' after ''(e)''; and

(2) by adding at the end the following:

''(2) Notwithstanding section 8424(d), if an employee, Member, former employee, or former Member dies and has designated as sole or partial beneficiary his or her spouse at the time of death, or, if an employee, Member, former employee, or former Member, dies with no designated beneficiary and

is survived by a spouse, the spouse may maintain the portion of the employee's or Member's account to which the spouse is entitled in accordance with the following terms:

''(A) Subject to the limitations of subparagraph (B), the spouse shall have the same withdrawal options under subsection (b) as the employee or Member were the employee or Member living.

''(B) The spouse may not make withdrawals under subsection (g) or (h).

''(C) The spouse may not make contributions or transfers to the account.

''(D) The account shall be disbursed upon the death of the surviving spouse. A beneficiary or surviving spouse of a deceased spouse who has inherited an account is ineligible to maintain the inherited spousal account.

''(3) The Executive Director shall prescribe regulations to carry out this subsection.''.

SEC. 110. TREATMENT OF MEMBERS OF THE UNIFORMED SERVICES UNDER THE THRIFT SAVINGS PLAN.

(a) SENSE OF CONGRESS.—It is the sense of Congress that—

(1) members of the uniformed services should have a retirement system that is at least as generous as the one which is available to Federal civilian employees; and

(2) Federal civilian employees receive matching contributions from their employing agencies for their contributions to the Thrift Savings Fund, but the costs of requiring such a matching contribution from the Department of Defense could be significant.

(b) REPORTING REQUIREMENT.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Defense shall report to Congress on—

(1) the cost to the Department of Defense of providing a matching payment with respect to contributions made to the Thrift Savings Fund by members of the Armed Forces;

(2) the effect that requiring such a matching payment would have on recruitment and retention; and

(3) any other information that the Secretary of Defense considers appropriate.

TITLE II—SPECIAL SURVIVOR INDEMNITY ALLOWANCE FOR SURVIVING SPOUSES OF ARMED FORCES MEMBERS

SEC. 201. INCREASE IN MONTHLY AMOUNT OF SPECIAL SURVIVOR INDEMNITY ALLOWANCE FOR WIDOWS AND WIDOWERS OF DECEASED MEMBERS OF THE ARMED FORCES AFFECTED BY REQUIRED SURVIVOR BENEFIT PLAN ANNUITY OFFSET FOR DEPENDENCY AND INDEMNITY COMPENSATION.

(a) PAYMENT AMOUNT PER FISCAL YEAR.—Paragraph (2) of section 1450(m) of title 10, United States Code, is amended—

(1) in subparagraph (E), by striking ''and'' after the semicolon; and

(2) by striking subparagraph (F) and inserting the following new subparagraphs:

''(F) for months during fiscal year 2014, $150;

''(G) for months during fiscal year 2015, $200;

''(H) for months during fiscal year 2016, $275; and

''(I) for months during fiscal year 2017, $310.''.

(b) DURATION.—Paragraph (6) of such section is amended—

(1) by striking ''February 28, 2016'' and inserting ''September 30, 2017''; and

(2) by striking ''March 1, 2016'' both places it appears and inserting ''October 1, 2017''.

SA 1248. Mrs. FEINSTEIN (for herself, Mr. BROWNBACK, and Ms. STABENOW) submitted an amendment intended to be proposed by her to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place in division A, insert the following:

TITLE ____—REDUCING LUNG CANCER

SEC. ____1. SHORT TITLE.

This title may be cited as the ''Lung Cancer Mortality Reduction Act of 2009''.

SEC. ____2. SENSE OF THE SENATE CONCERNING INVESTMENT IN LUNG CANCER RESEARCH.

It is the sense of the Senate that—

(1) lung cancer mortality reduction should be made a national public health priority; and

(2) a comprehensive mortality reduction program coordinated by the Secretary of Health and Human Services is justified and necessary to adequately address and reduce lung cancer mortality.

SEC. ____3. LUNG CANCER MORTALITY REDUCTION PROGRAM.

(a) IN GENERAL.—Subpart 1 of part C of title IV of the Public Health Service Act (42 U.S.C. 285 et seq.) is amended by adding at the end the following:

''SEC. 417G. LUNG CANCER MORTALITY REDUCTION PROGRAM.

''(a) IN GENERAL.—Not later than 6 months after the date of enactment of the Lung Cancer Mortality Reduction Act of 2009, the Secretary, in consultation with the Secretary of Defense, the Secretary of Veterans Affairs, the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, the Commissioner of the Food and Drug Administration, the Administrator of the Centers for Medicare & Medicaid Services, the Director of the National Center on Minority Health and Health Disparities, and other members of the Lung Cancer Advisory Board established under section ____6 of the Lung Cancer Mortality Reduction Act of 2009, shall implement a comprehensive program to achieve a 50 percent reduction in the mortality rate of lung cancer by 2016.

''(b) REQUIREMENTS.—The program implemented under subsection (a) shall include at least the following:

''(1) With respect to the National Institutes of Health—

''(A) a strategic review and prioritization by the National Cancer Institute of research grants to achieve the goal of the program in reducing lung cancer mortality;

''(B) the provision of funds to enable the Airway Biology and Disease Branch of the National Heart, Lung, and Blood Institute to expand its research programs to include predispositions to lung cancer, the interrelationship between lung cancer and other pulmonary and cardiac disease, and the diagnosis and treatment of these interrelationships;

''(C) the provision of funds to enable the National Institute of Biomedical Imaging and Bioengineering to expand its Quantum Grant Program and Image-Guided Interventions programs to expedite the development of computer assisted diagnostic, surgical, treatment, and drug testing innovations to reduce lung cancer mortality; and

''(D) the provision of funds to enable the National Institute of Environmental Health Sciences to implement research programs relative to lung cancer incidence.

''(2) With respect to the Food and Drug Administration—

''(A) the establishment of a lung cancer mortality reduction drug program under subchapter G of chapter V of the Federal Food, Drug, and Cosmetic Act; and

''(B) compassionate access activities under section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb).

''(3) With respect to the Centers for Disease Control and Prevention, the establishment of a lung cancer mortality reduction program under section 1511.

''(4) With respect to the Agency for Healthcare Research and Quality, the conduct of a biannual review of lung cancer screening, diagnostic and treatment protocols, and the issuance of updated guidelines.

''(5) The cooperation and coordination of all minority and health disparity programs within the Department of Health and Human Services to ensure that all aspects of the Lung Cancer Mortality Reduction Program adequately address the burden of lung cancer on minority and rural populations.

''(6) The cooperation and coordination of all tobacco control and cessation programs within agencies of the Department of Health and Human Services to achieve the goals of the Lung Cancer Mortality Reduction Program with particular emphasis on the coordination of drug and other cessation treatments with early detection protocols.

''(c) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section—

''(1) $25,000,000 for fiscal year 2010 for the activities described in subsection (b)(1)(B), and such sums as may be necessary for each of fiscal years 2011 through 2014;

''(2) $25,000,000 for fiscal year 2010 for the activities described in subsection (b)(1)(C), and such sums as may be necessary for each of fiscal years 2011 through 2014;

''(3) $10,000,000 for fiscal year 2010 for the activities described in subsection (b)(1)(D), and such sums as may be necessary for each of fiscal years 2011 through 2014; and

''(4) $15,000,000 for fiscal year 2010 for the activities described in subsection (b)(3), and such sums as may be necessary for each of fiscal years 2011 through 2014.''.

(b) FOOD, DRUG, AND COSMETIC ACT.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

''Subchapter G—Lung Cancer Mortality Reduction Programs

''SEC. 581. LUNG CANCER MORTALITY REDUCTION PROGRAM.

''(a) IN GENERAL.—The Secretary shall implement a program to provide incentives of the type provided for in subchapter B of this chapter for the development of chemoprevention drugs for precancerous conditions of the lung, drugs for targeted therapeutic treatments and vaccines for lung cancer, and new agents to curtail or prevent nicotine addiction. The Secretary shall model the program implemented under this section on the program provided for under subchapter B of this chapter with respect to certain drugs.

''(b) APPLICATION OF PROVISIONS.—The Secretary shall apply the provisions of subchapter B of this chapter to drugs, biological products, and devices for the prevention or treatment of lung cancer, including drugs, biological products, and devices for chemoprevention of precancerous conditions of the lungs, vaccination against the development of lung cancer, and therapeutic treatment for lung cancer.

''(c) BOARD.—The Board established under section ____6 of the Lung Cancer Mortality

Reduction Act of 2009 shall monitor the program implemented under this section.''.

(c) ACCESS TO UNAPPROVED THERAPIES.—Section 561(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb(e)) is amended by inserting before the period the following: ''and shall include providing compassionate access to drugs, biological products, and devices under the program under section 581, with substantial consideration being given to whether the totality of information available to the Secretary regarding the safety and effectiveness of an investigational drug, as compared to the risk of morbidity and death from the disease, indicates that a patient may obtain more benefit than risk if treated with the drug, biological product, or device.''.

(d) CDC.—Title XV of the Public Health Service Act (42 U.S.C. 300k et seq.) is amended by adding at the end the following:

''SEC. 1511. LUNG CANCER MORTALITY REDUCTION PROGRAM.

''(a) IN GENERAL.—The Secretary shall establish and implement an early disease research and management program targeted at the high incidence and mortality rates among minority and low-income populations.

''(b) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated, such sums as may be necessary to carry out this section.''.

SEC. ___4. DEPARTMENT OF DEFENSE AND THE DEPARTMENT OF VETERANS AFFAIRS.

The Secretary of Defense and the Secretary of Veterans Affairs shall coordinate with the Secretary of Health and Human Services—

(1) in the development of the Lung Cancer Mortality Reduction Program under section 417E of part C of title IV of the Public Health Service Act, as amended by section ___4;

(2) in the implementation within the Department of Defense and the Department of Veterans Affairs of an early detection and disease management research program for military personnel and veterans whose smoking history and exposure to carcinogens during active duty service has increased their risk for lung cancer; and

(3) in the implementation of coordinated care programs for military personnel and veterans diagnosed with lung cancer.

SEC. ___5. LUNG CANCER ADVISORY BOARD.

(a) IN GENERAL.—The Secretary of Health and Human Services shall establish a Lung Cancer Advisory Board (referred to in this section as the ''Board'') to monitor the programs established under this title (and the amendments made by this title), and provide annual reports to Congress concerning benchmarks, expenditures, lung cancer statistics, and the public health impact of such programs.

(b) COMPOSITION.—The Board shall be composed of—

(1) the Secretary of Health and Human Services;

(2) the Secretary of Defense;

(3) the Secretary of Veterans Affairs; and

(4) two representatives each from the fields of—

(A) clinical medicine focused on lung cancer;

(B) lung cancer research;

(C) imaging;

(D) drug development; and

(E) lung cancer advocacy,

to be appointed by the Secretary of Health and Human Services.

SEC. ___6. AUTHORIZATION OF APPROPRIATIONS.

For the purpose of carrying out the programs under this title (and the amendments made by this title), there is authorized to be appropriated such sums as may be necessary for each of fiscal years 2010 through 2014.

SA 1249. Mrs. HAGAN submitted an amendment intended to be proposed by her to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

In section 907(a) of the Federal Food, Drug, and Cosmetic Act (as added by section 101), insert after paragraph (4) the following:

''(5) TECHNOLOGICAL FEASABILITY.—A tobacco product standard adopted under this section shall be based on a finding by the Secretary that technology is available to achieve the reductions required by such standard.''.

SA 1250. Mrs. HAGAN submitted an amendment intended to be proposed by her to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

In section 102(a)(2)(D), insert ''and other components and accessories necessary for the assembly of roll-your-own cigarettes'' after ''paper''.

SA 1251. Mrs. HAGAN submitted an amendment intended to be proposed by her to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

In section 900 of the Federal Food, Drug, and Cosmetic Act (as added by section 101) strike paragraph (16) and insert the following:

''(16) SMALL TOBACCO PRODUCT MANUFACTURER.—The term 'small tobacco product manufacturer' includes any farmer owned tobacco cooperative or a tobacco product manufacturer other than a cooperative that employs fewer than 350 employees. For purposes of determining the number of employees of a manufacturer under the preceding sentence, the employees of a manufacturer are deemed to include the employees of each entity that controls, is controlled by, or is under common control with such manufacture.''.

SA 1252. Mrs. HAGAN submitted an amendment intended to be proposed by her to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

In section 907(a)(4) of the Federal Food, Drug, and Cosmetic Act (as added by section 101(b)), strike clause (ii) of subparagraph (B) and all that follows through clause (v) of such subparagraph, and insert the following:

''(ii) provisions for the testing in a laboratory located in the United States (on a sample basis or, if necessary, on an individual basis) of the tobacco product;

''(iii) provisions for the measurement of the tobacco product characteristics of the tobacco product;

''(iv) provisions requiring that the results of each or of certain of the tests of the tobacco product required to be made under clause (ii) show that the tobacco product is in conformity with the portions of the standard for which the test or tests were required; and

''(v) a provision requiring that the sale and distribution of the tobacco product be restricted but only to the extent that the sale and distribution of a tobacco product may be restricted under a regulation under section 906(d);

''(C) shall require all tobacco product testing on domestic and foreign manufacturers' products to be performed in a laboratory located in the United States to ensure compliance with Federal law;

SA 1253. Mrs. HAGAN submitted an amendment intended to be proposed by her to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

In section 901(c)(2)(C) of the Federal Food, Drug, and Cosmetic Act (as added by section 101), strike '', other than activities by a manufacturer affecting production''.

SA 1254. Mrs. HAGAN submitted an amendment intended to be proposed by her to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

At the end of section 907 of the Federal Food, Drug, and Cosmetic Act (as added by section 101) add the following:

''(f) TECHNOLOGY REQUIRED TO MEET STANDARD.—It shall not be an act of infringement under section 271 of title 35, United States Code, for a tobacco product manufacturer to make use of a patented technology if such technology is used for the purpose of meeting any standard established under this section.''.

SA 1255. Ms. STABENOW (for herself, Mr. BROWNBACK, Ms. MIKULSKI, Mr. VOINOVICH, Mrs. SHAHEEN, Mr. BOND,

Mr. BURRIS, Mr. DURBIN, Mr. LEVIN, and Mr. BROWN) submitted an amendment intended to be proposed by her to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

DIVISION ____—DRIVE AMERICA FORWARD PROGRAM

SEC. __01. SHORT TITLE.

This division may be cited as the ''Drive America Forward Act of 2009''.

SEC. __02. DRIVE AMERICA FORWARD PROGRAM.

(a) ESTABLISHMENT.—There is established in the National Highway Traffic Safety Administration a voluntary program to be known as the ''Drive America Forward Program'' through which the Secretary, in accordance with this section and the regulations promulgated under subsection (d), shall—

(1) authorize the issuance of an electronic voucher, subject to the specifications set forth in subsection (c), to offset the purchase price or lease price for a qualifying lease of a new fuel efficient automobile upon the surrender of an eligible trade-in vehicle to a dealer participating in the Program;

(2) certify dealers for participation in the Program and require all participating dealers—

(A) to accept vouchers as provided in this section as partial payment or down payment for the purchase or qualifying lease of any new fuel efficient automobile offered for sale or lease by that dealer; and

(B) in accordance with subsection (c)(2), to transfer each eligible trade-in vehicle surrendered to the dealer under the Program to an entity for disposal;

(3) in consultation with the Secretary of the Treasury, make electronic payments to dealers for vouchers accepted by such dealers, in accordance with the regulations issued under subsection (d); and

(4) in consultation with the Secretary of the Treasury and the Inspector General of the Department of Transportation, establish and provide for the enforcement of measures to prevent and penalize fraud under the Program.

(b) QUALIFICATIONS FOR AND VALUE OF VOUCHERS.—A voucher issued under the Program shall have a value that may be applied to offset the purchase price or lease price for a qualifying lease of a new fuel efficient automobile as follows:

(1) $3,500 VALUE.—The voucher may be used to offset the purchase price or lease price of the new fuel efficient automobile by $3,500 if—

(A) the new fuel efficient automobile is a passenger automobile and the combined fuel economy value of such automobile is at least 4 miles per gallon higher than the combined fuel economy value of the eligible trade-in vehicle;

(B) the new fuel efficient automobile is a category 1 truck and the combined fuel economy value of such truck is at least 2 miles per gallon higher than the combined fuel economy value of the eligible trade-in vehicle;

(C) the new fuel efficient automobile is a category 2 truck that has a combined fuel economy value of at least 15 miles per gallon and—

(i) the eligible trade-in vehicle is a category 2 truck and the combined fuel economy value of the new fuel efficient automobile is at least 1 mile per gallon higher than the combined fuel economy value of the eligible trade-in vehicle; or

(ii) the eligible trade-in vehicle is a category 3 truck of model year 2001 or earlier; or

(D) the new fuel efficient automobile is a category 3 truck and the eligible trade-in vehicle is a category 3 truck of model year of 2001 or earlier and is of similar size or larger than the new fuel efficient automobile as determined in a manner prescribed by the Secretary.

(2) $4,500 VALUE.—The voucher may be used to offset the purchase price or lease price of the new fuel efficient automobile by $4,500 if—

(A) the new fuel efficient automobile is a passenger automobile and the combined fuel economy value of such automobile is at least 10 miles per gallon higher than the combined fuel economy value of the eligible trade-in vehicle;

(B) the new fuel efficient automobile is a category 1 truck and the combined fuel economy value of such truck is at least 5 miles per gallon higher than the combined fuel economy value of the eligible trade-in vehicle; or

(C) the new fuel efficient automobile is a category 2 truck that has a combined fuel economy value of at least 15 miles per gallon and the combined fuel economy value of such truck is at least 2 miles per gallon higher than the combined fuel economy value of the eligible trade-in vehicle and the eligible trade-in vehicle is a category 2 truck.

(c) PROGRAM SPECIFICATIONS.—

(1) LIMITATIONS.—

(A) GENERAL PERIOD OF ELIGIBILITY.—A voucher issued under the Program shall be used only for the purchase or qualifying lease of new fuel efficient automobiles that occur between—

(i) the date of the enactment of this Act; and

(ii) the day that is 1 year after the date on which the regulations promulgated under subsection (d) are implemented.

(B) NUMBER OF VOUCHERS PER PERSON AND PER TRADE-IN VEHICLE.—Not more than 1 voucher may be issued for a single person and not more than 1 voucher may be issued for the joint registered owners of a single eligible trade-in vehicle.

(C) NO COMBINATION OF VOUCHERS.—Only 1 voucher issued under the Program may be applied toward the purchase or qualifying lease of a single new fuel efficient automobile.

(D) CAP ON FUNDS FOR CATEGORY 3 TRUCKS.—Not more than 7.5 percent of the total funds made available for the Program shall be used for vouchers for the purchase or qualifying lease of category 3 trucks.

(E) COMBINATION WITH OTHER INCENTIVES PERMITTED.—The availability or use of a Federal, State, or local incentive or a State-issued voucher for the purchase or lease of a new fuel efficient automobile shall not limit the value or issuance of a voucher under the Program to any person otherwise eligible to receive such a voucher.

(F) NO ADDITIONAL FEES.—A dealer participating in the program may not charge a person purchasing or leasing a new fuel efficient automobile any additional fees associated with the use of a voucher under the Program.

(G) NUMBER AND AMOUNT.—The total number and value of vouchers issued under the Program may not exceed the amounts appropriated for such purpose.

(2) DISPOSITION OF ELIGIBLE TRADE-IN VEHICLES.—

(A) IN GENERAL.—For each eligible trade-in vehicle surrendered to a dealer under the Program, the dealer shall certify to the Secretary, in such manner as the Secretary shall prescribe by rule, that the dealer—

(i) has not and will not sell, lease, exchange, or otherwise dispose of the vehicle for use as an automobile in the United States or in any other country; and

(ii) will transfer the vehicle (including the engine block), in such manner as the Secretary prescribes, to an entity that will ensure that the vehicle—

(I) will be crushed or shredded within such period and in such manner as the Secretary prescribes; and

(II) has not been, and will not be, sold, leased, exchanged, or otherwise disposed of for use as an automobile in the United States or in any other country.

(B) SAVINGS PROVISION.—Nothing in subparagraph (A) may be construed to preclude a person who dismantles or disposes of the vehicle from—

(i) selling any parts of the disposed vehicle other than the engine block and drive train (unless the transmission, drive shaft, or rear end are sold as separate parts); or

(ii) retaining the proceeds from such sale.

(C) COORDINATION.—The Secretary shall coordinate with the Attorney General to ensure that the National Motor Vehicle Title Information System and other publicly accessible systems are appropriately updated on a timely basis to reflect the crushing or shredding of vehicles under this section and appropriate reclassification of the vehicles' titles. The commercial market shall also have electronic and commercial access to the vehicle identification numbers of vehicles that have been disposed of on a timely basis.

(d) REGULATIONS.—Notwithstanding the requirements of section 553 of title 5, United States Code, the Secretary shall promulgate final regulations to implement the Program not later than 30 days after the date of the enactment of this Act. Such regulations shall—

(1) provide for a means of certifying dealers for participation in the Program;

(2) establish procedures for the reimbursement of dealers participating in the Program to be made through electronic transfer of funds for both the amount of the vouchers and any reasonable administrative costs incurred by the dealer as soon as practicable but no longer than 10 days after the submission of a voucher for the new fuel efficient automobile to the Secretary;

(3) require the dealer to use the voucher in addition to any other rebate or discount advertised by the dealer or offered by the manufacturer for the new fuel efficient automobile and prohibit the dealer from using the voucher to offset any such other rebate or discount;

(4) require dealers to disclose to the person trading in an eligible trade-in vehicle the best estimate of the scrappage value of such vehicle and to permit the dealer to retain $50 of any amounts paid to the dealer for scrappage of the automobile as payment for any administrative costs to the dealer associated with participation in the Program;

(5) consistent with subsection (c)(2), establish requirements and procedures for the disposal of eligible trade-in vehicles and provide such information as may be necessary to entities engaged in such disposal to ensure that such vehicles are disposed of in accordance with such requirements and procedures, including—

(A) requirements for the removal and appropriate disposition of refrigerants, antifreeze, lead products, mercury switches, and such other toxic or hazardous vehicle components prior to the crushing or shredding of

an eligible trade-in vehicle, in accordance with rules established by the Secretary in consultation with the Administrator of the Environmental Protection Agency, and in accordance with other applicable Federal or State requirements;

(B) a mechanism for dealers to certify to the Secretary that each eligible trade-in vehicle will be transferred to an entity that will ensure that the vehicle is disposed of, in accordance with such requirements and procedures, and to submit the vehicle identification numbers of the vehicles disposed of and the new fuel efficient automobile purchased with each voucher; and

(C) a list of entities to which dealers may transfer eligible trade-in vehicles for disposal; and

(6) provide for the enforcement of the penalties described in subsection (e).

(e) ANTI-FRAUD PROVISIONS.—

(1) VIOLATION.—It shall be unlawful for any person to violate any provision under this section or any regulations issued pursuant to subsection (d) (other than by making a clerical error).

(2) PENALTIES.—Any person who commits a violation described in paragraph (1) shall be liable to the United States Government for a civil penalty of not more than $15,000 for each violation. In determining the amount of the civil penalty, the severity of the violation and the intent and history of the person committing the violation shall be taken into account.

(f) INFORMATION TO CONSUMERS AND DEALERS.—Not later than 30 days after the date of the enactment of this Act, and promptly upon the update of any relevant information, the Secretary, in consultation with the Administrator of the Environmental Protection Agency, shall make available on an Internet website and through other means determined by the Secretary information about the Program, including—

(1) how to determine if a vehicle is an eligible trade-in vehicle;

(2) how to participate in the Program, including how to determine participating dealers; and

(3) a comprehensive list, by make and model, of new fuel efficient automobiles meeting the requirements of the Program.

Once such information is available, the Secretary shall conduct a public awareness campaign to inform consumers about the Program and where to obtain additional information.

(g) RECORDKEEPING AND REPORT.—

(1) DATABASE.—The Secretary shall maintain a database of the vehicle identification numbers of all new fuel efficient vehicles purchased or leased and all eligible trade-in vehicles disposed of under the Program.

(2) REPORT ON EFFICACY OF THE PROGRAM.—Not later than 60 days after the termination date described in subsection (c)(1)(A)(ii), the Secretary shall submit a report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Commerce, Science, and Transportation of the Senate describing the efficacy of the Program, including—

(A) a description of Program results, including—

(i) the total number and amount of vouchers issued for purchase or lease of new fuel efficient automobiles by manufacturer (including aggregate information concerning the make, model, model year) and category of automobile;

(ii) aggregate information regarding the make, model, model year, and manufacturing location of vehicles traded in under the Program; and

(iii) the location of sale or lease;

(B) an estimate of the overall increase in fuel efficiency in terms of miles per gallon, total annual oil savings, and total annual greenhouse gas reductions, as a result of the Program; and

(C) an estimate of the overall economic and employment effects of the Program.

(h) EXCLUSION OF VOUCHERS FROM INCOME.—

(1) FOR PURPOSES OF ALL FEDERAL AND STATE PROGRAMS.—A voucher issued under the Program shall not be regarded as income and shall not be regarded as a resource for the month of receipt of the voucher and the following 12 months, for purposes of determining the eligibility of the recipient of the voucher (or the recipient's spouse or other family or household members) for benefits or assistance, or the amount or extent of benefits or assistance, under any Federal or State program.

(2) FOR PURPOSES OF TAXATION.—A voucher issued under the Program shall not be considered as gross income for purposes of the Internal Revenue Code of 1986.

(i) DEFINITIONS.—As used in this section—

(1) the term ''passenger automobile'' means a passenger automobile, as defined in section 32901(a)(18) of title 49, United States Code, that has a combined fuel economy value of at least 22 miles per gallon;

(2) the term ''category 1 truck'' means a nonpassenger automobile, as defined in section 32901(a)(17) of title 49, United States Code, that has a combined fuel economy value of at least 18 miles per gallon, except that such term does not include a category 2 truck;

(3) the term ''category 2 truck'' means a large van or a large pickup, as categorized by the Secretary using the method used by the Environmental Protection Agency and described in the report entitled ''Light-Duty Automotive Technology and Fuel Economy Trends: 1975 through 2008'';

(4) the term ''category 3 truck'' means a work truck, as defined in section 32901(a)(19) of title 49, United States Code;

(5) the term ''combined fuel economy value'' means—

(A) with respect to a new fuel efficient automobile, the number, expressed in miles per gallon, centered below the words ''Combined Fuel Economy'' on the label required to be affixed or caused to be affixed on a new automobile pursuant to subpart D of part 600 of title 40, Code of Federal Regulations;

(B) with respect to an eligible trade-in vehicle, the equivalent of the number described in subparagraph (A), and posted under the words ''Estimated New EPA MPG'' and above the word ''Combined'' for vehicles of model year 1984 through 2007, or posted under the words ''New EPA MPG'' and above the word ''Combined'' for vehicles of model year 2008 or later on the fueleconomy.gov website of the Environmental Protection Agency for the make, model, and year of such vehicle; or

(C) with respect to an eligible trade-in vehicle manufactured between model years 1978 through 1984, the equivalent of the number described in subparagraph (A) as determined by the Secretary (and posted on the website of the National Highway Traffic Safety Administration) using data maintained by the Environmental Protection Agency for the make, model, and year of such vehicle;

(6) the term ''dealer'' means a person licensed by a State who engages in the sale of new automobiles to ultimate purchasers;

(7) the term ''eligible trade-in vehicle'' means an automobile or a work truck (as such terms are defined in section 32901(a) of title 49, United States Code) that, at the time it is presented for trade-in under this section—

(A) is in drivable condition;

(B) has been continuously insured consistent with the applicable State law and registered to the same owner for a period of not less than 1 year immediately prior to such trade-in;

(C) was manufactured less than 25 years before the date of the trade-in; and

(D) in the case of an automobile, has a combined fuel economy value of 18 miles per gallon or less;

(8) the term ''new fuel efficient automobile'' means an automobile described in paragraph (1), (2), (3), or (4)—

(A) the equitable or legal title of which has not been transferred to any person other than the ultimate purchaser;

(B) that carries a manufacturer's suggested retail price of $45,000 or less;

(C) that—

(i) in the case of passenger automobiles, category 1 trucks, or category 2 trucks, is certified to applicable standards under section 86.1811–04 of title 40, Code of Federal Regulations; or

(ii) in the case of category 3 trucks, is certified to the applicable vehicle or engine standards under section 86.1816–08, 86.007–11, or 86.008–10 of title 40, Code of Federal Regulations; and

(D) that has the combined fuel economy value of at least—

(i) 22 miles per gallon for a passenger automobile;

(ii) 18 miles per gallon for a category 1 truck; or

(iii) 15 miles per gallon for a category 2 truck;

(9) the term ''Program'' means the Drive America Forward Program established by this section;

(10) the term ''qualifying lease'' means a lease of an automobile for a period of not less than 5 years;

(11) the term ''scrappage value'' means the amount received by the dealer for a vehicle upon transferring title of such vehicle to the person responsible for ensuring the dismantling and destroying the vehicle;

(12) the term ''Secretary'' means the Secretary of Transportation acting through the National Highway Traffic Safety Administration;

(13) the term ''ultimate purchaser'' means, with respect to any new automobile, the first person who in good faith purchases such automobile for purposes other than resale; and

(14) the term ''vehicle identification number'' means the 17-character number used by the automobile industry to identify individual automobiles.

SEC. __03. REALLOCATION OF APPROPRIATIONS.

The Director of the Office of Management and Budget may reallocate not more than $4,000,000,000 from the amounts appropriated under the American Recovery and Reinvestment Act of 2009 (Public Law 111–5) to carry out the Drive America Forward Program established under this division if the Director notifies the Committee on Appropriations of the Senate and the Committee on Appropriations of the House of Representatives not less than 15 days before reallocating any such amounts.

SEC. __04. EMERGENCY DESIGNATION.

For purposes of House and Senate enforcement, this division is designated as an emergency requirement and necessary to meet emergency needs pursuant to—

(1) clause 10 of rule XXI of the Rules of the House of Representatives for the 111th Congress for purposes of pay-as-you-go principles; and

(2) section 403 of S. Con. Res. 13 (111th Congress), the concurrent resolution on the budget for fiscal year 2010.

SA 1256. Mr. SCHUMER (for Mr. LIEBERMAN (for himself, Ms. COLLINS, Mr. AKAKA, and Mr. VOINOVICH)) proposed an amendment to amendment

1247 proposed by Mr. DODD to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

At the end of title I of division B, add the following:

Subtitle B—Other Retirement-Related Provisions

SEC. 111. CREDIT FOR UNUSED SICK LEAVE.

(a) IN GENERAL.—Section 8415 of title 5, United States Code, is amended—

(1) by redesignating the second subsection (k) and subsection (l) as subsections (l) and (m), respectively; and

(2) in subsection (l) (as so redesignated by paragraph (1))—

(A) by striking ''(l) In computing'' and inserting ''(l)(1) In computing''; and

(B) by adding at the end the following:

''(2) Except as provided in paragraph (1), in computing an annuity under this subchapter, the total service of an employee who retires on an immediate annuity or who dies leaving a survivor or survivors entitled to annuity includes the days of unused sick leave to his credit under a formal leave system and for which days the employee has not received payment, except that these days will not be counted in determining average pay or annuity eligibility under this subchapter. For purposes of this subsection, in the case of any such employee who is excepted from subchapter I of chapter 63 under section 6301(2)(x) through (xiii), the days of unused sick leave to his credit include any unused sick leave standing to his credit when he was excepted from such subchapter.''.

(b) EXCEPTION FROM DEPOSIT REQUIREMENT.—Section 8422(d)(2) of title 5, United States Code, is amended by striking ''section 8415(k)'' and inserting ''paragraph (1) or (2) of section 8415(l)''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to annuities computed based on separations occurring on or after the date of enactment of this Act.

SEC. 112. LIMITED EXPANSION OF THE CLASS OF INDIVIDUALS ELIGIBLE TO RECEIVE AN ACTUARIALLY REDUCED ANNUITY UNDER THE CIVIL SERVICE RETIREMENT SYSTEM.

(a) IN GENERAL.—Section 8334(d)(2)(A)(i) of title 5, United States Code, is amended by striking ''October 1, 1990'' each place it appears and inserting ''March 1, 1991''.

(b) APPLICABILITY.—The amendment made by subsection (a) shall be effective with respect to any annuity, entitlement to which is based on a separation from service occurring on or after the date of enactment of this Act.

SEC. 113. COMPUTATION OF CERTAIN ANNUITIES BASED ON PART-TIME SERVICE.

(a) IN GENERAL.—Section 8339(p) of title 5, United States Code, is amended by adding at the end the following:

''(3) In the administration of paragraph (1)—

''(A) subparagraph (A) of such paragraph shall apply with respect to service performed before, on, or after April 7, 1986; and

''(B) subparagraph (B) of such paragraph—

''(i) shall apply with respect to that portion of any annuity which is attributable to service performed on or after April 7, 1986; and

''(ii) shall not apply with respect to that portion of any annuity which is attributable to service performed before April 7, 1986.''.

(b) APPLICABILITY.—The amendment made by subsection (a) shall be effective with respect to any annuity, entitlement to which is based on a separation from service occurring on or after the date of enactment of this Act.

SEC. 114. AUTHORITY TO DEPOSIT REFUNDS UNDER FERS.

(a) DEPOSIT AUTHORITY.—Section 8422 of title 5, United States Code, is amended by adding at the end the following:

''(i)(1) Each employee or Member who has received a refund of retirement deductions under this or any other retirement system established for employees of the Government covering service for which such employee or Member may be allowed credit under this chapter may deposit the amount received, with interest. Credit may not be allowed for the service covered by the refund until the deposit is made.

''(2) Interest under this subsection shall be computed in accordance with paragraphs (2) and (3) of section 8334(e) and regulations prescribed by the Office. The option under the third sentence of section 8334(e)(2) to make a deposit in one or more installments shall apply to deposits under this subsection.

''(3) For the purpose of survivor annuities, deposits authorized by this subsection may also be made by a survivor of an employee or Member.''.

(b) TECHNICAL AND CONFORMING AMENDMENTS.—

(1) DEFINITIONAL AMENDMENT.—Section 8401(19)(C) of title 5, United States Code, is amended by striking ''8411(f);'' and inserting ''8411(f) or 8422(i);''.

(2) CREDITING OF DEPOSITS.—Section 8422(c) of title 5, United States Code, is amended by adding at the end the following: ''Deposits made by an employee, Member, or survivor also shall be credited to the Fund.''.

(3) SECTION HEADING.—(A) The heading for section 8422 of title 5, United States Code, is amended to read as follows:

''§ 8422. Deductions from pay; contributions for other service; deposits''.

(B) The analysis for chapter 84 of title 5, United States Code, is amended by striking the item relating to section 8422 and inserting the following:

''8422. Deductions from pay; contributions for other service; deposits.''.

(4) RESTORATION OF ANNUITY RIGHTS.—The last sentence of section 8424(a) of title 5, United States Code, is amended by striking ''based.'' and inserting ''based, until the employee or Member is reemployed in the service subject to this chapter.''.

SEC. 115. RETIREMENT CREDIT FOR SERVICE OF CERTAIN EMPLOYEES TRANSFERRED FROM DISTRICT OF COLUMBIA SERVICE TO FEDERAL SERVICE.

(a) RETIREMENT CREDIT.—

(1) IN GENERAL.—Any individual who is treated as an employee of the Federal Government for purposes of chapter 83 or chapter 84 of title 5, United States Code, on or after the date of enactment of this Act who performed qualifying District of Columbia service shall be entitled to have such service included in calculating the individual's creditable service under sections 8332 or 8411 of title 5, United States Code, but only for purposes of the following provisions of such title:

(A) Sections 8333 and 8410 (relating to eligibility for annuity).

(B) Sections 8336 (other than subsections (d), (h), and (p) thereof) and 8412 (relating to immediate retirement).

(C) Sections 8338 and 8413 (relating to deferred retirement).

(D) Sections 8336(d), 8336(h), 8336(p), and 8414 (relating to early retirement).

(E) Section 8341 and subchapter IV of chapter 84 (relating to survivor annuities).

(F) Section 8337 and subchapter V of chapter 84 (relating to disability benefits).

(2) TREATMENT OF DETENTION OFFICER SERVICE AS LAW ENFORCEMENT OFFICER SERVICE.—Any portion of an individual's qualifying District of Columbia service which consisted of service as a detention officer under section 2604(2) of the District of Columbia Government Comprehensive Merit Personnel Act of 1978 (sec. 1–626.04(2), D.C. Official Code) shall be treated as service as a law enforcement officer under sections 8331(20) or 8401(17) of title 5, United States Code, for purposes of applying paragraph (1) with respect to the individual.

(3) SERVICE NOT INCLUDED IN COMPUTING AMOUNT OF ANY ANNUITY.—Qualifying District of Columbia service shall not be taken into account for purposes of computing the amount of any benefit payable out of the Civil Service Retirement and Disability Fund.

(b) QUALIFYING DISTRICT OF COLUMBIA SERVICE DEFINED.—In this section, ''qualifying District of Columbia service'' means any of the following:

(1) Service performed by an individual as a nonjudicial employee of the District of Columbia courts—

(A) which was performed prior to the effective date of the amendments made by section 11246(b) of the Balanced Budget Act of 1997; and

(B) for which the individual did not ever receive credit under the provisions of subchapter III of chapter 83 or chapter 84 of title 5, United States Code (other than by virtue of section 8331(1)(iv) of such title).

(2) Service performed by an individual as an employee of an entity of the District of Columbia government whose functions were transferred to the Pretrial Services, Parole, Adult Supervision, and Offender Supervision Trustee under section 11232 of the Balanced Budget Act of 1997—

(A) which was performed prior to the effective date of the individual's coverage as an employee of the Federal Government under section 11232(f) of such Act; and

(B) for which the individual did not ever receive credit under the provisions of subchapter III of chapter 83 or chapter 84 of title 5, United States Code (other than by virtue of section 8331(1)(iv) of such title).

(3) Service performed by an individual as an employee of the District of Columbia Public Defender Service—

(A) which was performed prior to the effective date of the amendments made by section 7(e) of the District of Columbia Courts and Justice Technical Corrections Act of 1998; and

(B) for which the individual did not ever receive credit under the provisions of subchapter III of chapter 83 or chapter 84 of title 5, United States Code (other than by virtue of section 8331(1)(iv) of such title).

(4) In the case of an individual who was an employee of the District of Columbia Department of Corrections who was separated from service as a result of the closing of the Lorton Correctional Complex and who was appointed to a position with the Bureau of Prisons, the District of Columbia courts, the Pretrial Services, Parole, Adult Supervision, and Offender Supervision Trustee, the United States Parole Commission, or the District of Columbia Public Defender Service, service performed by the individual as an employee of the District of Columbia Department of Corrections—

(A) which was performed prior to the effective date of the individual's coverage as an employee of the Federal Government; and

(B) for which the individual did not ever receive credit under the provisions of subchapter III of chapter 83 or chapter 84 of title 5, United States Code (other than by virtue of section 8331(1)(iv) of such title).

(c) CERTIFICATION OF SERVICE.—The Office of Personnel Management shall accept the certification of the appropriate personnel official of the government of the District of Columbia or other independent employing entity concerning whether an individual performed qualifying District of Columbia service and the length of the period of such service the individual performed.

SEC. 116. RETIREMENT TREATMENT OF CERTAIN SECRET SERVICE EMPLOYEES.

(a) DEFINITION.—In this section the term ''covered employee'' means an individual who—

(1) was hired as a member of the United States Secret Service Division during the period beginning on January 1, 1984 through December 31, 1986;

(2) has actively performed duties other than clerical for 10 or more years directly related to the protection mission of the United States Secret Service described under section 3056 of title 18, United States Code;

(3) is serving as a member of the United States Secret Service Division or the United States Secret Service Uniform Division (or any successor entity) on the effective date of this section; and

(4) files an election to be a covered employee under subsection (b)(1).

(b) ELECTION OF COVERAGE.—

(1) IN GENERAL.—Not later than 60 days after the date of enactment of this Act, an individual described under subsection (a)(1), (2), and (3) may file an election with the United States Secret Service to be a covered employee and to transition to the District of Columbia Police and Fire Fighter Retirement and Disability System.

(2) NOTIFICATION.—Not later than 30 days after the date of enactment of this Act, the Office of Personnel Management and the United States Secret Service shall notify each individual described under subsection (a)(1), (2), and (3) that the individual is qualified to file an election under paragraph (1).

(c) RETIREMENT COVERAGE CONVERSION.—

(1) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, and in consultation with the Secretary of Homeland Security and the Thrift Savings Board, the Office of Personnel Management shall prescribe regulations to carry out the responsibilities of the Federal Government under this section. The regulations prescribed under this paragraph shall provide for transition of covered employees from the Federal Employees' Retirement System to the Civil Service Retirement System.

(2) TREATMENT OF COVERED EMPLOYEES.—

(A) ELECTION OF COVERAGE.—

(i) IN GENERAL.—If a covered employee files an election under subsection (b)(1), the covered employee shall, subject to clause (ii), be converted from the Federal Employees' Retirement System to the Civil Service Retirement System.

(ii) COVERAGE IN DISTRICT OF COLUMBIA RETIREMENT SYSTEM.—

(I) IN GENERAL.—Chapter 7 of title 5 of the District of Columbia Code shall apply with respect to a covered employee on the date on which the covered employee transitions to the Civil Service Retirement System.

(II) AUTHORIZATION FOR DISTRICT OF COLUMBIA.—The government of the District of Columbia shall provide for the coverage of covered employees in the District of Columbia Police and Fire Fighter Retirement and Disability System in accordance with this section.

(B) THRIFT SAVINGS PLAN.—A covered employee shall forfeit, under procedures prescribed by the Executive Director of the Federal Retirement Thrift Investment Board, all Thrift Savings Plan contributions and associated earnings made by an employing agency pursuant to section 8432(c) of title 5, United States Code. Any amounts remaining in the Thrift Savings Plan account of the covered employee may be transferred to a private account or the District of Columbia Police and Firefighter Retirement and Disability System.

(C) FORFEITURE OF SOCIAL SECURITY BENEFITS.—

(i) CONTRIBUTIONS.—Upon conversion into the Civil Service Retirement System, a covered employee shall forfeit all contributions made under title II of the Social Security Act while employed by the United States Secret Service. All forfeited funds shall remain in the Federal Old-Age and Survivors Insurance Trust Fund and the Federal Disability Insurance Trust Fund, as applicable .

(ii) BENEFITS.—A covered employee shall not be entitled to any benefit based on any contribution forfeited under clause (i).

(3) IMPLEMENT.—The Office of Personnel Management, the Department of Homeland Security, the Social Security Administration, and the Thrift Savings Board shall take such actions as necessary to provide for the implementation of this section.

(d) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided under paragraph (2), this section shall take effect on the first day of the first applicable pay period that begins 180 days after the date of enactment of this Act.

(2) ELECTIONS AND IMPLEMENTATION.—Subsections (b) and (c)(1) and (3) shall take effect on the date of enactment of this Act.

TITLE _____—NON-FOREIGN AREA RETIREMENT EQUITY ASSURANCE

SEC. __01. SHORT TITLE.

This title may be cited as the ''Non-Foreign Area Retirement Equity Assurance Act of 2009'' or the ''Non-Foreign AREA Act of 2009''.

SEC. __02. EXTENSION OF LOCALITY PAY.

(a) LOCALITY-BASED COMPARABILITY PAYMENTS.—Section 5304 of title 5, United States Code, is amended—

(1) in subsection (f)(1), by striking subparagraph (A) and inserting the following:

''(A) each General Schedule position in the United States, as defined under section 5921(4), and its territories and possessions, including the Commonwealth of Puerto Rico and the Commonwealth of the Northern Mariana Islands, shall be included within a pay locality;'';

(2) in subsection (g)—

(A) in paragraph (2)—

(i) in subparagraph (A), by striking ''and'' after the semicolon;

(ii) in subparagraph (B) by striking the period and inserting ''; and''; and

(iii) by adding after subparagraph (B) the following:

''(C) positions under subsection (h)(1)(C) not covered by appraisal systems certified under section 5382; and''; and

(B) by adding at the end the following:

''(3) The applicable maximum under this subsection shall be level II of the Executive Schedule for positions under subsection (h)(1)(C) covered by appraisal systems certified under section 5307(d).''; and

(3) in subsection (h)(1)—

(A) in subparagraph (B) by striking ''and'' after the semicolon;

(B) by redesignating subparagraph (C) as subparagraph (D);

(C) by inserting after subparagraph (B) the following:

''(C) a Senior Executive Service position under section 3132 or 3151 or a senior level position under section 5376 stationed within the United States, but outside the 48 contiguous States and the District of Columbia in which the incumbent was an individual who on the day before the date of enactment of the Non-Foreign Area Retirement Equity Assurance Act of 2009 was eligible to receive a cost-of-living allowance under section 5941; and'';

(D) in clause (iv) in the matter following subparagraph (D), by inserting '', except for members covered by subparagraph (C)'' before the semicolon; and

(E) in clause (v) in the matter following subparagraph (D), by inserting '', except for members covered by subparagraph (C)'' before the semicolon.

(b) ALLOWANCES BASED ON LIVING COSTS AND CONDITIONS OF ENVIRONMENT.—Section 5941 of title 5, United States Code, is amended—

(1) in subsection (a), by adding after the last sentence ''Notwithstanding any preceding provision of this subsection, the cost-of-living allowance rate based on paragraph (1) shall be the cost-of-living allowance rate in effect on the date of enactment of the Non-Foreign Area Retirement Equity Assurance Act of 2009, except as adjusted under subsection (c).'';

(2) by redesignating subsection (b) as subsection (d); and

(3) by inserting after subsection (a) the following:

''(b) This section shall apply only to areas that are designated as cost-of-living allowance areas as in effect on December 31, 2009.

''(c)(1) The cost-of-living allowance rate payable under this section shall be adjusted on the first day of the first applicable pay period beginning on or after—

''(A) January 1, 2010; and

''(B) January 1 of each calendar year in which a locality-based comparability adjustment takes effect under section __04 (2) and (3) of the Non-Foreign Area Retirement Equity Assurance Act of 2009.

''(2)(A) In this paragraph, the term 'applicable locality-based comparability pay percentage' means, with respect to calendar year 2010 and each calendar year thereafter, the applicable percentage under section __04 (1), (2), or (3) of Non-Foreign Area Retirement Equity Assurance Act of 2009.

''(B) Each adjusted cost-of-living allowance rate under paragraph (1) shall be computed by—

''(i) subtracting 65 percent of the applicable locality-based comparability pay percentage from the cost-of-living allowance percentage rate in effect on December 31, 2009; and

''(ii) dividing the resulting percentage determined under clause (i) by the sum of—

''(I) one; and

''(II) the applicable locality-based comparability payment percentage expressed as a numeral.

''(3) No allowance rate computed under paragraph (2) may be less than zero.

''(4) Each allowance rate computed under paragraph (2) shall be paid as a percentage of basic pay (including any applicable locality-based comparability payment under section 5304 or similar provision of law and any applicable special rate of pay under section 5305 or similar provision of law).''.

SEC. __03. ADJUSTMENT OF SPECIAL RATES.

(a) IN GENERAL.—Each special rate of pay established under section 5305 of title 5, United States Code, and payable in an area designated as a cost-of-living allowance area under section 5941(a) of that title, shall be adjusted, on the dates prescribed by section __04 of this title, in accordance with regulations prescribed by the Director of the Office of Personnel Management under section __08 of this title.

(b) AGENCIES WITH STATUTORY AUTHORITY.—

(1) IN GENERAL.—Each special rate of pay established under an authority described under paragraph (2) and payable in a location designated as a cost-of-living allowance area under section 5941(a)(1) of title 5, United States Code, shall be adjusted in accordance with regulations prescribed by the applicable head of the agency that are consistent with the regulations issued by the Director of the Office of Personnel Management under subsection (a).

(2) STATUTORY AUTHORITY.—The authority referred to under paragraph (1), is any statutory authority that—

(A) is similar to the authority exercised under section 5305 of title 5, United States Code;

(B) is exercised by the head of an agency when the head of the agency determines it to be necessary in order to obtain or retain the services of persons specified by statute; and

(C) authorizes the head of the agency to increase the minimum, intermediate, or maximum rates of basic pay authorized under applicable statutes and regulations.

(c) TEMPORARY ADJUSTMENT.—Regulations issued under subsection (a) or (b) may provide that statutory limitations on the amount of such special rates may be temporarily raised to a higher level during the transition period described in section __04 ending on the first day of the first pay period beginning on or after January 1, 2012, at which time any special rate of pay in excess of the applicable limitation shall be converted to a retained rate under section 5363 of title 5, United States Code.

SEC. __04. TRANSITION SCHEDULE FOR LOCALITY-BASED COMPARABILITY PAYMENTS.

Notwithstanding any other provision of this title or section 5304 or 5304a of title 5, United States Code, in implementing the amendments made by this title, for each non-foreign area determined under section 5941(b) of that title, the applicable rate for the locality-based comparability adjustment that is used in the computation required under section 5941(c) of that title shall be adjusted effective on the first day of the first pay period beginning on or after January 1—

(1) in calendar year 2010, by using ⅓ of the locality pay percentage for the rest of United States locality pay area;

(2) in calendar year 2011, by using ⅔ of the otherwise applicable comparability payment approved by the President for each non-foreign area; and

(3) in calendar year 2012 and each subsequent year, by using the full amount of the applicable comparability payment approved by the President for each non-foreign area.

SEC. __05. SAVINGS PROVISION.

(a) SENSE OF CONGRESS.—It is the sense of Congress that—

(1) the application of this title to any employee should not result in a decrease in the take home pay of that employee;

(2) in calendar year 2012 and each subsequent year, no employee shall receive less than the Rest of the U.S. locality pay rate;

(3) concurrent with the surveys next conducted under the provisions of section 5304(d)(1)(A) of title 5, United States Code, beginning after the date of the enactment of this Act, the Bureau of Labor Statistics should conduct separate surveys to determine the extent of any pay disparity (as defined by section 5302 of that title) that may exist with respect to positions located in the State of Alaska, the State of Hawaii, and the United States territories, including American Samoa, Guam, Commonwealth of the Northern Mariana Islands, Commonwealth of Puerto Rico, and the United States Virgin Islands;

(4) if the surveys under paragraph (3) indicate that the pay disparity determined for the State of Alaska, the State of Hawaii, or any 1 of the United States territories including American Samoa, Guam, Commonwealth of the Northern Mariana Islands, Commonwealth of Puerto Rico, and the United States Virgin Islands exceeds the pay disparity determined for the locality which (for purposes of section 5304 of that title) is commonly known as the ''Rest of the United States'', the President's Pay Agent should take appropriate measures to provide that each such surveyed area be treated as a separate pay locality for purposes of that section; and

(5) the President's Pay Agent will establish 1 locality area for the entire State of Hawaii and 1 locality area for the entire State of Alaska.

(b) SAVINGS PROVISIONS.—

(1) IN GENERAL.—During the period described under section __04 of this title, an employee paid a special rate under 5305 of title 5, United States Code, who the day before the date of enactment of this Act was eligible to receive a cost-of-living allowance under section 5941 of title 5, United States Code, and who continues to be officially stationed in an allowance area, shall receive an increase in the employee's special rate consistent with increases in the applicable special rate schedule. For employees in allowance areas, the minimum step rate for any grade of a special rate schedule shall be increased at the time of an increase in the applicable locality rate percentage for the allowance area by not less than the dollar increase in the locality-based comparability payment for a non-special rate employee at the same minimum step provided under section __04 of this title, and corresponding increases shall be provided for all step rates of the given pay range.

(2) CONTINUATION OF COST OF LIVING ALLOWANCE RATE.—If an employee, who the day before the date of enactment of this Act was eligible to receive a cost-of-living allowance under section 5941 of title 5, United States Code, would receive a rate of basic pay and applicable locality-based comparability payment which is in excess of the maximum rate limitation set under section 5304(g) of title 5, United States Code, for his position (but for that maximum rate limitation) due to the operation of this title, the employee shall continue to receive the cost-of-living allowance rate in effect on December 31, 2009 without adjustment until—

(A) the employee leaves the allowance area or pay system; or

(B) the employee is entitled to receive basic pay (including any applicable locality-based comparability payment or similar supplement) at a higher rate,

but, when any such position becomes vacant, the pay of any subsequent appointee thereto shall be fixed in the manner provided by applicable law and regulation.

(3) LOCALITY-BASED COMPARABILITY PAYMENTS.—Any employee covered under paragraph (2) shall receive any applicable locality-based comparability payment extended under section __04 of this title which is not in excess of the maximum rate set under section 5304(g) of title 5, United States Code, for his position including any future increase to statutory pay limitations under 5318 of title 5, United States Code. Notwithstanding paragraph (2), to the extent that an employee covered under that paragraph receives any amount of locality-based comparability payment, the cost-of-living allowance rate under that paragraph shall be reduced accordingly, as provided under section 5941(c)(2)(B) of title 5, United States Code.

SEC. __06. APPLICATION TO OTHER ELIGIBLE EMPLOYEES.

(a) IN GENERAL.—

(1) DEFINITION.—In this subsection, the term ''covered employee'' means—

(A) any employee who—

(i) on the day before the date of enactment of this Act—

(I) was eligible to be paid a cost-of-living allowance under 5941 of title 5, United States Code; and

(II) was not eligible to be paid locality-based comparability payments under 5304 or 5304a of that title; or

(ii) on or after the date of enactment of this Act becomes eligible to be paid a cost-of-living allowance under 5941 of title 5, United States Code; or

(B) any employee who—

(i) on the day before the date of enactment of this Act—

(I) was eligible to be paid an allowance under section 1603(b) of title 10, United States Code;

(II) was eligible to be paid an allowance under section 1005(b) of title 39, United States Code;

(III) was employed by the Transportation Security Administration of the Department of Homeland Security and was eligible to be paid an allowance based on section 5941 of title 5, United States Code; or

(IV) was eligible to be paid under any other authority a cost-of-living allowance that is equivalent to the cost-of-living allowance under section 5941 of title 5, United States Code; or

(ii) on or after the date of enactment of this Act—

(I) becomes eligible to be paid an allowance under section 1603(b) of title 10, United States Code;

(II) becomes eligible to be paid an allowance under section 1005(b) of title 39, United States Code;

(III) is employed by the Transportation Security Administration of the Department of Homeland Security and becomes eligible to be paid an allowance based on section 5941 of title 5, United States Code; or

(IV) is eligible to be paid under any other authority a cost-of-living allowance that is equivalent to the cost-of-living allowance under section 5941 of title 5, United States Code.

(2) APPLICATION TO COVERED EMPLOYEES.—

(A) IN GENERAL.—Notwithstanding any other provision of law, for purposes of this title (including the amendments made by this title) any covered employee shall be treated as an employee to whom section 5941 of title 5, United States Code (as amended by section __02 of this title), and section __04 of this title apply.

(B) PAY FIXED BY STATUTE.—Pay to covered employees under section 5304 or 5304a of title 5, United States Code, as a result of the application of this title shall be considered to be fixed by statute.

(C) PERFORMANCE APPRAISAL SYSTEM.—With respect to a covered employee who is subject to a performance appraisal system no part of pay attributable to locality-based comparability payments as a result of the application of this title including section 5941 of title 5, United States Code (as amended by section __02 of this title), may be reduced on the basis of the performance of that employee.

(b) POSTAL EMPLOYEES IN NON-FOREIGN AREAS.—

(1) IN GENERAL.—Section 1005(b) of title 39, United States Code, is amended—

(A) by inserting ''(1)'' after ''(b)'';

(B) by striking ''Section 5941,'' and inserting ''Except as provided under paragraph (2), section 5941'';

(C) by striking ''For purposes of such section,'' and inserting ''Except as provided under paragraph (2), for purposes of section 5941 of that title,''; and

(D) by adding at the end the following:

''(2) On and after the date of enactment of the Non-Foreign Area Retirement Equity Assurance Act of 2009—

''(A) the provisions of that Act and section 5941 of title 5 shall apply to officers and employees covered by section 1003 (b) and (c) whose duty station is in a nonforeign area; and

''(B) with respect to officers and employees of the Postal Service (other than those officers and employees described under subparagraph (A)) of section __06(b)(2) of that Act shall apply.''.

(2) CONTINUATION OF COST OF LIVING ALLOWANCE.—

(A) IN GENERAL.—Notwithstanding any other provision of this title, any employee of the Postal Service (other than an employee covered by section 1003 (b) and (c) of title 39, United States Code, whose duty station is in a nonforeign area) who is paid an allowance under section 1005(b) of that title shall be treated for all purposes as if the provisions of this title (including the amendments made by this title) had not been enacted, except that the cost-of-living allowance rate paid to that employee—

(i) may result in the allowance exceeding 25 percent of the rate of basic pay of that employee; and

(ii) shall be the greater of—

(I) the cost-of-living allowance rate in effect on December 31, 2009 for the applicable area; or

(II) the applicable locality-based comparability pay percentage under section __04.

(B) RULE OF CONSTRUCTION.—Nothing in this title shall be construed to—

(i) provide for an employee described under subparagraph (A) to be a covered employee as defined under subsection (a); or

(ii) authorize an employee described under subparagraph (A) to file an election under section __07 of this title.

SEC. __07. ELECTION OF ADDITIONAL BASIC PAY FOR ANNUITY COMPUTATION BY EMPLOYEES.

(a) DEFINITION.—In this section the term ''covered employee'' means any employee—

(1) to whom section __04 applies;

(2) who is separated from service by reason of retirement under chapter 83 or 84 of title 5, United States Code, during the period of January 1, 2010, through December 31, 2012; and

(3) who files an election with the Office of Personnel Management under subsection (b).

(b) ELECTION.—

(1) IN GENERAL.—An employee described under subsection (a) (1) and (2) may file an election with the Office of Personnel Management to be covered under this section.

(2) DEADLINE.—An election under this subsection may be filed not later than December 31, 2012.

(c) COMPUTATION OF ANNUITY.—

(1) IN GENERAL.—Except as provided under paragraph (2), for purposes of the computation of an annuity of a covered employee any cost-of-living allowance under section 5941 of title 5, United States Code, paid to that employee during the first applicable pay period beginning on or after January 1, 2010 through the first applicable pay period ending on or after December 31, 2012, shall be considered basic pay as defined under section 8331(3) or 8401(4) of that title.

(2) LIMITATION.—The amount of the cost-of-living allowance which may be considered basic pay under paragraph (1) may not exceed the amount of the locality-based comparability payments the employee would have received during that period for the applicable pay area if the limitation under section __04 of this title did not apply.

(d) CIVIL SERVICE RETIREMENT AND DISABILITY RETIREMENT FUND.—

(1) EMPLOYEE CONTRIBUTIONS.—A covered employee shall pay into the Civil Service Retirement and Disability Retirement Fund—

(A) an amount equal to the difference between—

(i) employee contributions that would have been deducted and withheld from pay under section 8334 or 8422 of title 5, United States Code, during the period described under subsection (c) of this section if the cost-of-living allowances described under that subsection had been treated as basic pay under section 8331(3) or 8401(4) of title 5, United States Code; and

(ii) employee contributions that were actually deducted and withheld from pay under section 8334 or 8422 of title 5, United States Code, during that period; and

(B) interest as prescribed under section 8334(e) of title 5, United States Code, based on the amount determined under subparagraph (A).

(2) AGENCY CONTRIBUTIONS.—

(A) IN GENERAL.—The employing agency of a covered employee shall pay into the Civil Service Retirement and Disability Retirement Fund an amount for applicable agency contributions based on payments made under paragraph (1).

(B) SOURCE.—Amounts paid under this paragraph shall be contributed from the appropriation or fund used to pay the employee.

(3) REGULATIONS.—The Office of Personnel Management may prescribe regulations to carry out this section.

SEC. __08. REGULATIONS.

(a) IN GENERAL.—The Director of the Office of Personnel Management shall prescribe regulations to carry out this title, including—

(1) rules for special rate employees described under section __03;

(2) rules for adjusting rates of basic pay for employees in pay systems administered by the Office of Personnel Management when such employees are not entitled to locality-based comparability payments under section 5304 of title 5, United States Code, without regard to otherwise applicable statutory pay limitations during the transition period described in section __04 ending on the first day of the first pay period beginning on or after January 1, 2012; and

(3) rules governing establishment and adjustment of saved or retained rates for any employee whose rate of pay exceeds applicable pay limitations on the first day of the first pay period beginning on or after January 1, 2012.

(b) OTHER PAY SYSTEMS.—With the concurrence of the Director of the Office of Personnel Management, the administrator of a pay system not administered by the Office of Personnel Management shall prescribe regulations to carry out this title with respect to employees in such pay system, consistent with the regulations prescribed by the Office under subsection (a). With respect to employees not entitled to locality-based comparability payments under section 5304 of title 5, United States Code, regulations prescribed under this subsection may provide for special payments or adjustments for employees who were eligible to receive a cost-of-living allowance under section 5941 of that title on the date before the date of enactment of this Act.

SEC. __09. EFFECTIVE DATES.

(a) IN GENERAL.—Except as provided by subsection (b), this title (including the amendments made by this title) shall take effect on the date of enactment of this Act.

(b) LOCALITY PAY AND SCHEDULE.—The amendments made by section __02 and the provisions of section __04 shall take effect on the first day of the first applicable pay period beginning on or after January 1, 2010.

TITLE _____—PART-TIME REEMPLOYMENT OF ANNUITANTS

SEC. ___1. SHORT TITLE.

This title may be cited as the ''Part-Time Reemployment of Annuitants Act of 2009''.

SEC. ___2. PART-TIME REEMPLOYMENT.

(a) CIVIL SERVICE RETIREMENT SYSTEM.—Section 8344 of title 5, United States Code, is amended—

(1) by redesignating subsection (l) as subsection (m);

(2) by inserting after subsection (k) the following:

''(l)(1) For purposes of this subsection—

''(A) the term 'head of an agency' means—

''(i) the head of an Executive agency, other than the Department of Defense or the Government Accountability Office;

''(ii) the head of the United States Postal Service;

''(iii) the Director of the Administrative Office of the United States Courts, with respect to employees of the judicial branch; and

''(iv) any employing authority described under subsection (k)(2), other than the Government Accountability Office; and

''(B) the term 'limited time appointee' means an annuitant appointed under a temporary appointment limited to 1 year or less.

''(2) The head of an agency may waive the application of subsection (a) or (b) with respect to any annuitant who is employed in such agency as a limited time appointee, if the head of the agency determines that the employment of the annuitant is necessary to—

''(A) fulfill functions critical to the mission of the agency, or any component of that agency;

''(B) assist in the implementation or oversight of the American Recovery and Reinvestment Act of 2009 (Public Law 111–5) or the Troubled Asset Relief Program under title I of the Emergency Economic Stabilization Act of 2008 (12 U.S.C. 5201 et seq.);

''(C) assist in the development, management, or oversight of agency procurement actions;

''(D) assist the Inspector General for that agency in the performance of the mission of that Inspector General;

''(E) promote appropriate training or mentoring programs of employees;

''(F) assist in the recruitment or retention of employees; or

''(G) respond to an emergency involving a direct threat to life of property or other unusual circumstances.

''(3) The head of an agency may not waive the application of subsection (a) or (b) with respect to an annuitant—

''(A) for more than 520 hours of service performed by that annuitant during the period ending 6 months following the individual's annuity commencing date;

''(B) for more than 1040 hours of service performed by that annuitant during any 12-month period; or

''(C) for more than a total of 3120 hours of service performed by that annuitant.

''(4)(A) The total number of annuitants to whom a waiver by the head of an agency under this subsection or section 8468(i) applies may not exceed 2.5 percent of the total number of full-time employees of that agency.

''(B) If the total number of annuitants to whom a waiver by the head of an agency under this subsection or section 8468(i) applies exceeds 1 percent of the total number of full-time employees of that agency, the head of that agency shall submit to the Committee on Homeland Security and Governmental Affairs of the Senate, the Committee on Oversight and Government Reform of the House of Representatives, and the Office of Personnel Management—

''(i) a report with an explanation that justifies the need for the waivers in excess of that percentage; and

''(ii) not later than 180 days after submitting the report under clause (i), a succession plan.

''(5)(A) The Director of the Office of Personnel Management may promulgate regulations providing for the administration of this subsection.

''(B) Any regulations promulgated under subparagraph (A) may—

''(i) provide standards for the maintenance and form of necessary records of employment under this subsection;

''(ii) to the extent not otherwise expressly prohibited by law, require employing agencies to provide records of such employment to the Office of Personnel Management or other employing agencies as necessary to ensure compliance with paragraph (3);

''(iii) authorize other administratively convenient periods substantially equivalent to 12 months, such as 26 pay periods, to be used in determining compliance with paragraph (3)(B);

''(iv) include such other administrative requirements as the Director of the Office of Personnel Management may find appropriate to provide for the effective operation of, or to ensure compliance with, this subsection; and

''(v) encourage the training and mentoring of employees by any limited time appointee employed under this subsection.

''(6)(A) Any hours of training or mentoring of employees by any limited time appointee employed under this subsection shall not be included in the hours of service performed for purposes of paragraph (3), but those hours of training or mentoring may not exceed 520 hours.

''(B) If the primary service performed by any limited time appointee employed under this subsection is training or mentoring of employees, the hours of that service shall be included in the hours of service performed for purposes of paragraph (3).

''(7) The authority of the head of an agency under this subsection to waive the application of subsection (a) or (b) shall terminate 5 years after the date of enactment of the Part-Time Reemployment of Annuitants Act of 2009.''; and

(3) in subsection (m) (as so redesignated)—

(A) in paragraph (1), by striking ''(k)'' and inserting ''(l)''; and

(B) in paragraph (2), by striking ''or (k)'' and inserting ''(k), or (l)''.

(b) FEDERAL EMPLOYEE RETIREMENT SYSTEM.—Section 8468 of title 5, United States Code, is amended—

(1) by redesignating subsection (i) as subsection (j);

(2) by inserting after subsection (h) the following:

''(i)(1) For purposes of this subsection—

''(A) the term 'head of an agency' means—

''(i) the head of an Executive agency, other than the Department of Defense or the Government Accountability Office;

''(ii) the head of the United States Postal Service;

''(iii) the Director of the Administrative Office of the United States Courts, with respect to employees of the judicial branch; and

''(iv) any employing authority described under subsection (h)(2), other than the Government Accountability Office; and

''(B) the term 'limited time appointee' means an annuitant appointed under a temporary appointment limited to 1 year or less.

''(2) The head of an agency may waive the application of subsection (a) with respect to any annuitant who is employed in such agency as a limited time appointee, if the head of the agency determines that the employment of the annuitant is necessary to—

''(A) fulfill functions critical to the mission of the agency, or any component of that agency;

''(B) assist in the implementation or oversight of the American Recovery and Reinvestment Act of 2009 (Public Law 111–5) or the Troubled Asset Relief Program under title I of the Emergency Economic Stabilization Act of 2008 (12 U.S.C. 5201 et seq.);

''(C) assist in the development, management, or oversight of agency procurement actions;

''(D) assist the Inspector General for that agency in the performance of the mission of that Inspector General;

''(E) promote appropriate training or mentoring programs of employees;

''(F) assist in the recruitment or retention of employees; or

''(G) respond to an emergency involving a direct threat to life of property or other unusual circumstances.

''(3) The head of an agency may not waive the application of subsection (a) with respect to an annuitant—

''(A) for more than 520 hours of service performed by that annuitant during the period ending 6 months following the individual's annuity commencing date;

''(B) for more than 1040 hours of service performed by that annuitant during any 12-month period; or

''(C) for more than a total of 3120 hours of service performed by that annuitant.

''(4)(A) The total number of annuitants to whom a waiver by the head of an agency under this subsection or section 8344(l) applies may not exceed 2.5 percent of the total number of full-time employees of that agency.

''(B) If the total number of annuitants to whom a waiver by the head of an agency under this subsection or section 8344(l) applies exceeds 1 percent of the total number of full-time employees of that agency, the head of that agency shall submit to the Committee on Homeland Security and Governmental Affairs of the Senate, the Committee on Oversight and Government Reform of the House of Representatives, and the Office of Personnel Management—

''(i) a report with an explanation that justifies the need for the waivers in excess of that percentage; and

''(ii) not later than 180 days after submitting the report under clause (i), a succession plan.

''(5)(A) The Director of the Office of Personnel Management may promulgate regulations providing for the administration of this subsection.

''(B) Any regulations promulgated under subparagraph (A) may—

''(i) provide standards for the maintenance and form of necessary records of employment under this subsection;

''(ii) to the extent not otherwise expressly prohibited by law, require employing agencies to provide records of such employment to the Office or other employing agencies as necessary to ensure compliance with paragraph (3);

''(iii) authorize other administratively convenient periods substantially equivalent to 12 months, such as 26 pay periods, to be used in determining compliance with paragraph (3)(B);

''(iv) include such other administrative requirements as the Director of the Office of Personnel Management may find appropriate to provide for effective operation of, or to ensure compliance with, this subsection; and

''(v) encourage the training and mentoring of employees by any limited time appointee employed under this subsection.

''(6)(A) Any hours of training or mentoring of employees by any limited time appointee employed under this subsection shall not be included in the hours of service performed for purposes of paragraph (3), but those hours of training or mentoring may not exceed 520 hours.

''(B) If the primary service performed by any limited time appointee employed under this subsection is training or mentoring of employees, the hours of that service shall be included in the hours of service performed for purposes of paragraph (3).

''(7) The authority of the head of an agency under this subsection to waive the application of subsection (a) shall terminate 5 years after the date of enactment of the Part-Time Reemployment of Annuitants Act of 2009.''; and

(3) in subsection (j) (as so redesignated)—

(A) in paragraph (1), by striking ''(h)'' and inserting ''(i)''; and

(B) in paragraph (2), by striking ''or (h)'' and inserting ''(h), or (i)''.

(c) RULE OF CONSTRUCTION.—Nothing in the amendments made by this section may be construed to authorize the waiver of the hiring preferences under chapter 33 of title 5, United States Code in selecting annuitants to employ in an appointive or elective position.

(d) TECHNICAL AND CONFORMING AMENDMENTS.—Section 1005(d)(2) of title 39, United States Code, is amended—

(1) by striking ''(l)(2)'' and inserting ''(m)(2)''; and

(2) by striking ''(i)(2)'' and inserting ''(j)(2)''.

SEC. ___3. GENERAL ACCOUNTABILITY OFFICE REPORT.

(a) IN GENERAL.—Not later than 3 years after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Homeland Security and Governmental Affairs of the Senate and the Committee on Oversight and Government Reform of the House of Representatives a report regarding the use of the authority under the amendments made by section ___2.

(b) CONTENTS.—The report submitted under subsection (a) shall—

(1) include the number of annuitants for whom a waiver was made under subsection (l) of section 8344 of title 5, United States Code, as amended by this title, or subsection (i) of section 8468 of title 5, United States Code, as amended by this title; and

(2) identify each agency that used the authority described in paragraph (1).

(c) AGENCY DATA.—Each head of an agency (as defined under sections 8344(l)(1) and 8468(i)(1)(A) of title 5, United States Code, as added by section ___2 of this title) shall—

(1) collect and maintain data necessary for purposes of the Comptroller General report submitted under subsection (a); and

(2) submit to the Comptroller General that data as the Comptroller General requires in a timely fashion.

AUTHORITY FOR COMMITTEES TO MEET

COMMITTEE ON BANKING, HOUSING, AND URBAN AFFAIRS

Mr. MERKLEY. Mr. President, I ask unanimous consent that the Committee on Banking, Housing, and Urban Affairs be authorized to meet during the session of the Senate on June 3, 2009 at 2 p.m. to conduct a hearing entitled ''A Fresh Start For New Starts.''

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION

Mr. MERKLEY. Mr. President, I ask unanimous consent that the Committee on Commerce, Science, and Transportation be authorized to meet during the session of the Senate on Wednesday, June 3, 2009, at 2:30 p.m., in room 106 of the Dirksen Senate office building.

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON FOREIGN RELATIONS

Mr. MERKLEY. Mr. President, I ask unanimous consent that the Committee on Foreign Relations be authorized to meet during the session of the Senate on Wednesday, June 3, 2009, at 11 a.m.

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON FOREIGN RELATIONS

Mr. MERKLEY. Mr. President, I ask unanimous consent that the Committee on Foreign Relations be authorized to meet during the session of the Senate on Wednesday, June 3, 2009 at 2:30 p.m.

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

Mr. MERKLEY. Mr. President, I ask unanimous consent that the Committee on Homeland security and Governmental Affairs be authorized to meet during the session of the Senate on Wednesday, June 3, 2009, at 10 a.m.

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON THE JUDICIARY

Mr. MERKLEY. Mr. President, I ask unanimous consent that the Committee on the Judiciary be authorized to meet during the session of the Senate on June 3, 2009, at 10 a.m. in room SD–226 of the Dirksen Senate Office Building, to conduct a hearing entitled ''The Uniting American Families Act: Addressing Inequality in Federal Immigration Law.''

The PRESIDING OFFICER. Without objection, it is so ordered.

PERSONNEL SUBCOMMITTEE

Mr. MERKLEY. Mr. President, I ask unanimous consent that the Personnel Subcommittee of the Committee on Armed Services be authorized to meet during the session of the Senate on Wednesday, June 3, 2009, at 2:30 p.m.

The PRESIDING OFFICER. Without objection, it is so ordered.

AD HOC SUBCOMMITTEE ON STATE, LOCAL, AND PRIVATE SECTOR PREPAREDNESS AND INTEGRATION

Mr. MERKLEY. Mr. President, I ask unanimous consent that the Ad Hoc Subcommittee on State, Local, and Private Sector Preparedness and Integration of the Committee on Homeland Security and Governmental Affairs be authorized to meet during the session of the Senate on Wednesday, June 3, 2009, at 2 p.m. to conduct a hearing entitled, ''Pandemic Flu: Closing the Gaps.''

The PRESIDING OFFICER. Without objection, it is so ordered.

SUBCOMMITTEE ON READINESS AND MANAGEMENT SUPPORT

Mr. MERKLEY. Mr. President, I ask unanimous consent that the Committee on Armed Services Subcommittee on Readiness and Management Support be authorized to meet during the session of the Senate on Wednesday, June 3, 2009, at 10 a.m.

The PRESIDING OFFICER. Without objection, it is so ordered.

SUBCOMMITTEE ON STRATEGIC FORCE

Mr. MERKLEY. Mr. President, I ask unanimous consent that the Subcommittee on Strategic Forces of the Committee on Armed Services be authorized to meet during the session of the Senate on Wednesday, June 3, 2009, at 2:30 p.m.

The PRESIDING OFFICER. Without objection, it is so ordered.

SPECIAL COMMITTEE ON AGING

Mr. MERKLEY. Mr. President, I ask unanimous consent that the Special Committee on Aging be authorized to meet during the session of the Senate on June 3, 2009, from 2 p.m. to 4 p.m. in Hart 216 for the purpose of conducting a hearing.

The PRESIDING OFFICER. Without objection, it is so ordered.

DISCHARGE AND REFERRAL—S. 1144

Mr. SCHUMER. Mr. President, I ask unanimous consent that the bill S. 1144 be discharged from the Committee on Commerce, Science, and Transportation and that it be referred to the Committee on Banking, Housing, and Urban Affairs.

The PRESIDING OFFICER. Without objection, it is so ordered.

ORDERS FOR THURSDAY, JUNE 4, 2009

Mr. SCHUMER. Mr. President, I ask unanimous consent that when the Senate completes its business today, it adjourn until 9:30 a.m., tomorrow, Thursday, June 4; that following the prayer and pledge, the Journal of proceedings be approved to date, the morning hour be deemed expired, the time for the two leaders be reserved for their use later in the day, and there be a period of morning business for 1 hour, with Senators permitted to speak for up to 10 minutes each with the time equally divided and controlled between the two leaders or their designees, with the Republicans controlling the first half and the majority controlling the second half; further, I ask following morning business the Senate resume consideration of H.R. 1256, the Family Smoking Prevention and Tobacco Control Act.

The PRESIDING OFFICER. Without objection, it is so ordered.

PROGRAM

Mr. SCHUMER. Mr. President, tomorrow we will resume consideration of the tobacco regulation bill; the Burr-Hagan substitute amendment is pending and we hope to reach agreement to vote in relation to it tomorrow morning. Senators will be notified when any votes are scheduled.

ADJOURNMENT UNTIL 9:30 A.M. TOMORROW

Mr. SCHUMER. If there is no further business to come before the Senate, I ask unanimous consent it adjourn under the previous order.

There being no objection, the Senate, at 7:55 p.m., adjourned until Thursday, June 4, 2009, at 9:30 a.m.

NOMINATIONS

Executive nominations received by the Senate:

DEPARTMENT OF STATE

LAURIE SUSAN FULTON, OF VIRGINIA, TO BE AMBASSADOR EXTRAORDINARY AND PLENIPOTENTIARY OF THE UNITED STATES OF AMERICA TO DENMARK.

DEPARTMENT OF THE TREASURY

DANIEL M. TANGHERLINI, OF THE DISTRICT OF COLUMBIA, TO BE AN ASSISTANT SECRETARY OF THE TREASURY, VICE PETER B. MCCARTHY, RESIGNED.

DANIEL M. TANGHERLINI, OF THE DISTRICT OF COLUMBIA, TO BE CHIEF FINANCIAL OFFICER, DEPARTMENT OF THE TREASURY, VICE PETER B. MCCARTHY, RESIGNED.

DEPARTMENT OF LABOR

RAYMOND M. JEFFERSON, OF HAWAII, TO BE ASSISTANT SECRETARY OF LABOR FOR VETERANS' EMPLOYMENT AND TRAINING, VICE CHARLES S. CICCOLELLA, RESIGNED.