

Whereas Medicaid provides a care coordination benefit that supports at-risk children by coordinating State health services, thereby furthering the ability of States to effectively coordinate medical and social services that are provided by multiple organizations and agencies;

Whereas administrative spending is lower in Medicaid than through private insurance;

Whereas Medicaid is critical for ensuring that children have access to safety-net providers in their local communities and for training health care professionals, including pediatricians; and

Whereas Medicaid provides low-income children with the full complement of services they need to meet their unique health and developmental needs: Now, therefore, be it

Resolved, That it is the sense of the Senate that—

(1) Congress should ensure that reform of our Nation's health care system shall benefit all children and that no child shall be worse off, particularly the most vulnerable low-income children and children with disabilities; and

(2) strengthening our Nation's Medicaid program should be a priority and that low-income children should not be moved into a health care exchange system that could disrupt and diminish their benefits, cost-sharing protections, availability of care standards and protections, and access to supports, services, and safety-net providers.

Mr. CASEY. S. Res. 170 is cosponsored by Senators DODD, ROCKEFELLER, BROWN, WHITEHOUSE, and SANDERS. I will highlight some of the features of it.

First, it starts with a recognition that the Medicaid Program is a cornerstone of the Nation's health insurance infrastructure. It notes in the resolution that Medicaid covers a quarter of all children in the country—one-quarter—and half of all poor children. It notes as well that Medicaid has been shown to reduce racial and ethnic disparities in health care and provides coverage for two out of every five African-American and Hispanic children.

Medicaid is a comprehensive benefit package. It provides developmental assessments for infants and young children. It has care coordination benefits in support of at-risk children, and Medicaid's administrative spending is lower than that through private insurance.

Here is the end of the resolution, and I am summarizing here: It is the intent of this resolution to say that the Nation's health care system shall benefit all children—all children—and that no child shall be worse off at the end of this debate. Low-income children should not be moved into a health care exchange system that could disrupt and diminish their benefits. That is S. Res. 170.

I believe it is critically important to emphasize this idea, that no child should be worse off as a result of health care reform—not a single child—and in particular, those who have special needs or who happen to be poor.

We know from our research that children are not small adults. They have different challenges. They have developmental and health care needs that are very different from adults. The

challenges they have, the problems they encounter can be exacerbated if children face economic challenges or have any kind of special needs. These needs must be met, and if they are not met, the whole trajectory for the future of that child will be changed for the worse.

Let me say in conclusion, we have seen throughout our history that there are some people who cannot do something on their own, that they need the help of a program, they need the help of a government, and thank goodness we made the determination a long time ago that our health care system is part of that equation. When I think about health care and when we think about the health care of children, no matter what income level their family happens to be in, but especially if they are poor or have special needs, and you think of the love of a mother, with the kind of love that a mother provides to a child, there are so many things that one mother can provide for her child. She can help with that child's education. She can provide nurturing and care and love to make sure that child develops in the way we would hope. She can even help somewhat in that child's health care. But no matter how much a mother loves her child, no matter how skilled she is, no matter how dedicated she is to the welfare of her child, and no matter how much she loves that child, she cannot—cannot—provide the kind of protections that health insurance provides and the kind of medical attention that a good hospital or a good doctor or a good health care professional can provide.

So we have a choice. We can have health reform legislation, and everyone will pat each other on the back and we will all be happy we got it done. That would be wonderful. But if we get this bill passed and we have fallen short with regard to our children, especially those who are poor and have special needs, I think we will have failed not only those children, of course, but we will have failed the obligation we have to make sure that every child comes through this with the kind of protections and the kind of help they should have a right to expect, and that that mother can have a sense that this country, this government has made a full commitment—not a partial commitment but a full commitment—to children.

Let us, as we go forward, remember the love that a mother has for her child and the limitations—no matter how much that mother loves that child and what she is able to do—that we must help her with in this debate. Let us not forget, and let us make sure that the legislation we pass on health care reform has as one of its ironclad promises: no child worse off.

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

The PRESIDING OFFICER. The clerk will call the roll.

The bill clerk proceeded to call the roll.

Mr. DODD. 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. DODD. Mr. President, what is the business before the Senate?

CONCLUSION OF MORNING BUSINESS

The PRESIDING OFFICER. Morning business is closed.

FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT

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

The bill 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.

The PRESIDING OFFICER. Under the previous order, the time until 2:30 p.m. will be equally divided and controlled between the Senator from Connecticut, Mr. DODD, and the Senator from Wyoming, Mr. ENZI, or their designees.

Mr. DODD. Mr. President, I see my friend from Ohio, Senator BROWN, who has been a champion of this issue, not only as a Member of this body but as a former Member of the other body. He has spoken eloquently on this already. I will defer to him whatever time he may wish to use. I am told Senator ENZI will be here shortly. We will go back and forth between now and 2:30.

The PRESIDING OFFICER. The Senator from Ohio is recognized.

Mr. BROWN. I thank the Senator.

Mr. President, I have watched with great admiration Senator DODD's work on this bill. I also worked on this bill with HENRY WAXMAN in the House of Representatives. Senators KENNEDY, DODD, DURBIN, and Congressman WAXMAN have helped to bring these issues forward, and they have never given up.

I boil this issue down to basically almost one sentence. I remember sitting in front of the Health Subcommittee in the House years ago and seeing the tobacco company executives swear to tell the truth, and they didn't exactly tell the truth when they talked about nicotine not being an addiction. I learned one simple concept at that hearing—and we have known this for a number of years—which is that 400,000 Americans die every year from tobacco-related illnesses. On average, that means more than 1,000 Americans die every day from tobacco-related illnesses.

If you are a tobacco executive, you think about this: You have lost 400,000 customers every year, more than a thousand customers every day, and you

need to replenish your customer base. What do you do? You need to find 400,000 new customers every year. You don't go to people of Senator DODD's and my generation; you don't even go to my children's age group; they are in their late twenties. You aim your marketing campaign at the young men and women sitting in front of me, the pages on the steps in front of the Presiding Officer's chair. You aim at people 14, 15, 16, 17, 18 years old. You have to find 400,000 new customers every year and more than 1,000 customers every day. And they are pretty successful at it.

I heard Senator DODD talk a few minutes ago in another meeting, and he said something like 3,000 new young people start smoking every day. Of those 3,000, for many it becomes a life-long habit and many will die as a result of smoking. So the key point about this legislation—what makes the legislation Chairman DODD brought forward today so important—is to have the FDA finally be involved in tobacco-related illness and regulation. What makes it so important is we need somebody to stand between the very well-paid drug company marketing executives and these 13-, 14-, 15-, and 16-year-olds who aren't nearly as sophisticated. We need some assistance in making sure those targeting efforts cannot get those young people addicted.

One thousand Americans every day die from tobacco-related illnesses. They need 1,000 new customers every day to replenish their customer base. This legislation will help stop that. That is why this is important, and the Senate needs to pass this legislation. That is why this 15-year effort to do this right finally is coming to fruition. We need to pass this and get it to the President. He is eager to sign it. It will matter greatly in affecting America's public health in the decades ahead.

I yield the floor.

The PRESIDING OFFICER. The Senator from Connecticut is recognized.

Mr. DODD. I thank my colleague from Ohio for his remarks and for his efforts over the years. This has been a long journey. It goes back 50 years. Back then, the Surgeon General of the United States warned of the health effects of smoking—a half century ago.

I know we will have a big vote at 2:30, and that is great news. Sometimes a large vote such as this minimizes the impact of the decision. This has been a very long battle. Somebody told me the other day the issue to ban smoking on airplanes only passed the Congress by one vote. Imagine today if somebody tried to restore the right, or privilege, to smoke on airplanes. I doubt you would find one vote in favor. Even smokers object to smoking on airplanes today. So only by a one-vote margin did Congress vote to ban that practice.

On Monday, we had a cloture vote. People can vote for a lot of different reasons. I don't suggest that everybody who voted against cloture was in favor of continuing to allow the tobacco in-

dustry to be unregulated. But by a 1-vote margin, basically, 61 votes, on a bipartisan basis, we terminated that debate, which is bringing us to the vote in 20 minutes. While it may seem like another vote on this day, June 11, 2009, it is a significant vote. I don't know of another vote in the last number of years as important as this one. We are going to start a markup in the next week—my friend from Wyoming has been involved in this and is passionate about the issue of smoking. We are going to mark up bills and fashion a major health care reform debate in this country. What better way to begin that debate than by the vote we are going to take in a few minutes.

For the first time in the history of our country, we will insist that tobacco products be regulated by the FDA. To put this into perspective, the FDA regulates not only all the food and other products we ingest, it regulates cosmetics, mascara, lipstick, and all sorts of products that we not only ingest but that we also use on our bodies. It also controls the products your pets consume, such as cat food, dog food, hamsters, and whatever else; the FDA has the power to regulate that.

But for 50 years, the tobacco industry has successfully fought the ability to regulate tobacco products. Yet 3,000 to 4,000 kids start smoking every day in this country; 400,000 a year die, as you have heard from Senator BROWN. It is incredible to me that for more years than many want to believe or count, we have had an industry that has gone basically unregulated. Of course, the idea that you can put cherry flavors and strawberry flavors in a cigarette and use cartoon figures to market it, that is not aimed at the 30- and 40-year-old tobacco user, it is aimed at children. One thousand of those children become addicted every day, and one-third that number will die prematurely from smoking.

I will guarantee you there is not an adult smoker who wishes their child would begin smoking. I guarantee you that virtually 100 percent of adult smokers have many wishes for their children and one is that their children never start the habit that they did. We are told by health officials, experts, that the average person who smokes and tries to quit, tries seven times before effectively kicking the habit. I am a former smoker. Let me tell you, it is hard. I know others have not smoked, and my colleague from Wyoming talks about his own family smoking. He never did, but he grew up in a family that did. My mother smoked cigarettes and my father smoked cigars and pipes in our house with six children. Many of my siblings smoked growing up, all of whom have stopped. But it is hard.

Today, in the name of my colleague from Massachusetts, Senator KENNEDY, who for four decades championed this, as well as HENRY WAXMAN in the House, DICK DURBIN of Illinois, SHERROD BROWN of Ohio, MIKE ENZI of Wyoming, and many others who have fought this

battle, we will vote at 2:30. It will go through overwhelmingly, and we will go on to the next matter.

Our leader, HARRY REID, insisted we stay on this matter. That is leadership. He could have easily said let's move on to another issue, it is taking too long—3 weeks to get it done. But because HARRY REID and DICK DURBIN and MIKE ENZI stayed with us and insisted we go through a normal process, which is right to do in our committee, with the good staff people who have worked hard on this, we are going to get this done today. We might move on to the next issue then.

For the first time, we will make a difference by requiring that the FDA regulate the production, the sale, and the marketing of these products. That is history. I cannot tell you how proud I am to be involved in it, in the name of TED KENNEDY and the others who came before us, including Mike DeWine of Ohio, Tom Davis, HENRY WAXMAN and many others and the thousands of organizations that joined us in this effort today.

Mr. DURBIN. Will the Senator yield?

Mr. DODD. Yes.

Mr. DURBIN. I thank the Senator from Connecticut for his leadership on this issue. Just a few weeks ago, he had the legislation on credit card reform.

I thank Senator ENZI for making this a true bipartisan effort. We would not be here today without his cooperative effort.

I thank Senator DODD for invoking the name of our great hero, TED KENNEDY, who started this fight.

In just a few minutes, this Senate will make a historic decision, and I think it will make the right decision. Joe Camel will be given a life sentence and put away forever, and we are going to give our kids and families across America a fighting chance for a better life.

This bill is historic. It has been a long time coming. I thank my colleagues for all their work to make it possible.

Mr. DODD. I yield the floor.

The PRESIDING OFFICER. The Senator from Wyoming.

Mr. ENZI. Mr. President, I rise today in support of the Family Smoking Prevention and Tobacco Control Act. I have thought long and hard about this legislation, and after a lot of work and a few good improvements, I believe this bill is the only bill we will consider seriously that will make it difficult for kids to get tobacco, make it difficult for them to start smoking, and that is the important point.

I want to be clear, I still do not think there is enough in this bill to stop smoking. One smoker is too many. But maintaining the current state of tobacco regulations is not acceptable to me.

One issue we have not discussed much is the cost of tobacco use to non-smokers. Many smokers say it is their business what they put into their bodies. Ordinarily, they would be right.

But when it comes to tobacco, we all pay for what smokers put into their bodies and breathe out into the air. We all bear the increased financial costs of the diminished health of smokers. When one of your colleagues smokes, health insurance premiums go up for everybody. Every senior who uses tobacco creates a further strain on Medicare, and since you pay for that, too, through your taxes, it puts a strain on your wallet.

If smokers were the only ones who paid the price for smoking, we would not be having this debate at all. But since the extra costs get shifted to the rest of us, it becomes our problem too. Secondhand smoke penalizes those who do not smoke, particularly the families of smokers. I hope they listen to that and realize that.

Unfortunately, I know a lot about this since my parents' smoking impacted me. My mom, we thought, quit, but she became a closet smoker, which goes with Senator DODD's comment that it is hard to give it up, and I understand how hard it is to give it up. When she quit smoking and was not smoking around me, my doctor told me he was glad I quit smoking. I said I never did. He showed me the lung x rays he had taken the year before at my athletic physical and that year at my athletic physical. When they quit smoking around me, I also got over extreme hay fever.

Nearly 22 million U.S. children aged 3 to 11 are exposed to secondhand smoke. Approximately 30 percent of indoor workers in the United States are not covered by smoke-free workplace policies. Those numbers are just too high. We cannot keep paying that price.

I also have concerns about the long-term financial health of this new center at FDA. The bill gives FDA increases in funding for this program for the first 10 years but leaves it flat after that. I think Congress will have to revisit that issue or this program will wither on the vine and we will not have meaningful tobacco regulation. We cannot let that happen.

This bill does contain three important provisions for which I fought; increased fines on tobacco companies, larger color graphic warning labels, and reporting to Congress on how the program is going. I would like to talk about each of these for a moment.

We know from decades of experience that the tobacco companies are not inclined to follow the law. They do not have a history of being forthcoming with the health information in their possession. Just 2 weeks ago, the U.S. Court of Appeals for the District of Columbia found that the tobacco companies were guilty of ". . . a decades-long conspiracy to deceive the American public about the health effects and addictiveness of smoking cigarettes."

I am pleased I was able to add a measure to the bill that increased civil penalties for violations of the new law and sends a strong message that we are serious about expecting compliance from the tobacco industry.

The new larger color graphic warning labels provision I authored will do a lot to reduce smoking. Everyone from the World Health Organization to the Congressional Budget Office says these warnings work. Research shows these warnings have a big impact. One-fifth of the participants reported smoking less as a result of the labels. Only 1 percent reported smoking more.

We should want kids who are thinking about taking up this deadly habit to have a bit of a shock just by looking at the package. We should want smokers to think about these health issues each time they light up. Any tool in our arsenal that makes people think twice about taking up tobacco should not be an option, it should be a requirement. Now these labels are a requirement.

Finally, we now require reports on the performance of FDA's tobacco center and on the financial situation of the program. Without this regular reporting, Congress would have little insight into the operation and status of this new program. These reports play an important role in establishing the health of the programs and FDA's performance in carrying out the law.

I want to make sure the agency is doing what it is supposed to do and that the fees are paying for FDA's tobacco control activities. These reports will help us do just exactly that.

I have always stood against tobacco. The footing would have been better if changes such as my phase-out amendment to reduce tobacco use over 100 years was accepted. I know how addictive it is. I did not want to make it too short a period of time. I thought 100 years was plenty reasonable. We did not have a chance to debate that or look at it. I actually offered that a little more than a year ago. It was a new amendment then. New amendments have trouble getting traction, except in New Zealand. New Zealand liked this approach to stopping smoking and looked at it in their legislature. They even called it the Enzi bill. Of course, you have to realize that is how it sounds and that is the way they spelled it, but in New Zealand, "NZ" stands for their country. I think they were talking about their country's bill rather than something I had written. It was kind of fun to watch anyway.

I think we need to look at some approaches such as that idea where the tobacco companies have to reduce the number of cigarettes they are selling each and every year or purchase a number from another company to make up for the increase in cigarettes they sold, which would reduce smoking at least in one part and over a long period of time would eliminate this problem.

This bill is just one step toward the goal I know we all share, which is reducing the public health toll of tobacco use. I urge my colleagues not to rest on their laurels and think this bill is enough to combat tobacco. I intend to continue the fight against tobacco, and I ask my colleagues to join me.

I thank Senator DODD, who has been chairing this effort and working on this bill with me, for giving us a voice and taking the bill through the whole process. It was extremely important, extremely valuable. The floor discussion took longer but with less debate than I anticipated. I know some parliamentary issues got in the way of that. We could have had more success, but there were some additional amendments that could not be resolved.

I always ask people to do relevant or germane amendments to the bills. When they talk about doing other ones, it sometimes slows our process down dramatically and usually does not result in any of those amendments happening anyway.

I also wish to thank all the staff who worked on this bill. They, too, have been very diligent, have looked at everything, have done tremendous research. I particularly thank Amy Muhlberg for her efforts on this legislation. I think she knows the tobacco bill and other proposals better than probably anybody. She has real diligence and passion for it. I also thank Greg Dean of my staff for his efforts. He has a legal mind that helps us on these issues.

I thank Senator BURR for his hard work during this process. Although he ultimately was not successful, his efforts helped advance the debate and highlight some areas where improvement is needed. He put considerable time and energy into preparing a viable alternative, and I appreciate the way he created options.

Chris Wall of Senator BURR's staff was extremely helpful during the markup and floor debate, and I thank him and compliment his work with my staff and others on this bill. Jeff Teitz and Ben Olinsky of Senator KENNEDY's staff, and Jim Fenton and Jeremy Sharp of Senator DODD's staff were also critical to our progress on this bill. Finally, Megan Hauck from the Republican leader's office and the floor staff for their assistance.

I do intend to continue the fight against tobacco. I ask my colleagues to join me in this fight. I thank Senator DODD for all of his efforts. There is true passion.

I yield the floor.

REGULATING TOBACCO WAREHOUSES

Mr. WARNER. Mr. President, the bill before us grants standby authority to the Secretary of Health and Human Services to regulate "tobacco warehouses." Because the bill already draws a bright line between tobacco companies that actually manufacture tobacco products and those, including growers and "tobacco warehouses," that do not manufacture, I would expect that the Secretary would utilize the standby authority to regulate tobacco warehouses only under unforeseen and unanticipated circumstances that give rise to public health concerns.

Mr. DODD. That is my general understanding of the provision.

Mr. WARNER. I thank the Senator.

PESTICIDE REGULATION

Mr. CHAMBLISS. Mr. President, the EPA's Office of Pesticide Programs has been protecting the environment, agricultural workers and the public health by regulating pesticides for many years. These chemicals are commonly used in agriculture, including the production of tobacco leaf. EPA approves the use of all pesticides in the United States under the authority of the Federal Insecticide, Fungicide and Rodenticide Act—FIFRA. I would ask Senator HARKIN if this bill would in any way limit the authority of the Administrator of the Environmental Protection Agency to regulate pesticides under FIFRA.

Mr. HARKIN. I would respond to the Senator from Georgia that it is my understanding that nothing in the Family Smoking Prevention and Tobacco Control Act would restrict the Administrator's authority provided under FIFRA.

Mr. DODD. I agree with my colleagues from the Committee on Agriculture, Nutrition and Forestry.

Mr. AKAKA. Mr. President, I support the Family Smoking Prevention and Tobacco Control Act. Tobacco products kill approximately 400,000 people each year. The Food and Drug Administration, FDA, must be provided with the authority to regulate deadly tobacco products, restrict advertising, and further restrict access of tobacco to children.

The Campaign for Tobacco-Free Kids estimates that almost 10 percent of Hawaii high school students smoke. Flavored cigarettes are one of the repulsive methods used by tobacco companies to get children and teenagers to start smoking. In 2004, R.J. Reynolds Tobacco Company tried to exploit images of my home state of Hawaii and the name of one of our islands in an attempt to make smoking more attractive. One of the cigarettes, which was named Kauai Kolada, was flavored with hints of pineapple and coconut. Another lime-flavored cigarette was featured in the predatory marketing campaign. It was extraordinarily offensive that a manufacturer of such a deadly product would exploit and taint the images and names from Hawaii in an attempt to attract young smokers. This is just one example of some of the products and marketing used to attract young people to become smokers.

This legislation includes a long overdue prohibition on fruit and candy flavored cigarettes. It also will permit the FDA to restrict advertising, marketing, and sales practices in an attempt to further limit the access of tobacco products to children. This bill will help protect our children and improve the public health of our country. We must prevent tobacco companies from cultivating another generation of smokers so that they can increase sales and reap more profits at the expense of the health and well-being of our families.

In order to supplement the loss in revenue from this bill, the House added

provisions to increase revenue through the introduction of a Roth-like option for Thrift Savings Plan participants. The additional revenue also covered a number of annuity enhancement, correction, and equity provisions for Federal employees. The Lieberman amendment included these provisions as well as the Non-Foreign Area Retirement Equity Assurance Act, to provide Federal employees in Alaska, Hawaii, and the territories locality pay. I strongly supported the Lieberman amendment and all the Federal employee annuitant provisions, and I am very disappointed that a lack of cooperation for this bipartisan amendment led to its defeat. I am hopeful that we will be able to address these critical issues to Federal employees very soon.

I appreciate all of the work done on this important issue by my friend from Massachusetts, Senator KENNEDY, and my friends from Connecticut, Senators DODD and LIEBERMAN. I look forward to the enactment of this vital legislation.

Mr. LEAHY. Mr. President, I am pleased the Senate is moving once again to pass legislation to regulate tobacco products in the United States. Senator KENNEDY's lifetime efforts to improve the public's health are exemplified in his fight to pass the Family Smoking Prevention and Tobacco Control Act. Despite many setbacks, Senator KENNEDY has worked tirelessly to pass this legislation and I am proud to join him again as a cosponsor of this bill. This legislation is long overdue and I look forward to it being signed into law.

The health risks associated with smoking are undisputed and cost hundreds of thousands of Americans their lives every year. Tobacco products will kill one out of three long-term smokers, leading to over 400,000 deaths per year. The Surgeon General has determined that smoking causes lung cancer, heart disease, and other serious illnesses. Deaths from tobacco products exceed deaths from HIV/AIDS, illegal drug use, alcohol use, car accidents, suicides, and murders combined.

Despite the dangers of smoking, we have seen that children have the greatest risk of becoming addicted to tobacco. Each day more than 3,500 children will try a cigarette for the first time and 1000 of those kids will become regular smokers. Among adult smokers, 90 percent started smoking as children and teens under the age of 18. In my home State of Vermont, more than 18 percent of high school students smoke. According to the Campaign for Tobacco-Free Kids, 12,000 children in Vermont will ultimately die from smoking if smoking rates remain unchanged.

These statistics are horrifying but perhaps not surprising given the historic lack of regulation of the tobacco industry. At a congressional hearing as late as 1994, tobacco industry chairmen and CEOs testified that nicotine is not addictive, even though decades of evidence showed otherwise. In fact, the to-

bacco industry has increased the nicotine levels in cigarettes by more than 11 percent from 1998 to 2005, increasing the risk of cigarette addiction. If enhanced nicotine levels in cigarettes is not enough to convince us that the tobacco industry should be regulated, a new study released this spring showed that changes the tobacco industry has made to cigarette design over the years has increased the risk of lung cancer for those who smoke.

In addition to making their products more potent and addictive, study after study has shown how the tobacco industry continues to successfully target advertising to minors to get them hooked for life on smoking. Each year, the tobacco industry spends over \$13 billion in advertising—that is \$36 million every day. Studies have showed that children are three times more sensitive to tobacco advertising than adults and are more likely to be influenced to start smoking by cigarette marketing than by peer pressure.

This bill addresses these shameful business practices by giving the United States Food and Drug Administration the authority for the first time to regulate the sale, distribution, and advertising of cigarettes and smokeless tobacco. It will require manufacturers to better disclose the contents and consequences of their products in new, stronger warning labels on packages. It will also prohibit cigarette companies from labeling their brands as reduced risk "lite" or "ultra-lite" unless the government can certify that those claims are true. The very purpose of the Food and Drug Administration is to protect the interests and safety of consumers and this legislation will finally allow the FDA to hold the tobacco industry accountable for their products.

A recent ruling by the District of Columbia Circuit Court highlights the need for serious regulation of the tobacco industry. The DC Appeals Court confirmed the district court's ruling, which found that the tobacco industry had for decades engaged in deceptive marketing tactics to conceal the negative health impacts of smoking. The ruling confirmed that tobacco companies had not changed the way their products were marketed in response to the Master Settlement Agreement, and instead the industry has more than doubled spending on marketing campaigns that included spurious claims of "healthier" cigarettes that are "light" or "low-tar." The ruling did not, however, require that the tobacco industry surrender profits that resulted in the misleading advertising or stop the industry from adding flavors to make products more appealing to kids or to manipulate nicotine levels to increase addictiveness and harm. The tobacco industry must be regulated to create transparency in the contents of tobacco products and to help stop hundreds of thousands of preventable deaths each year.

For far too long, the tobacco industry has been given free rein to mislead

the public and encourage children and teens to take up smoking. The passage of this bill will give the FDA the authority it needs to effectively protect children from smoking and improve consumer awareness of tobacco industry practices, which will in turn save American lives. I urge all Senators to support passage of the Family Smoking Prevention and Tobacco Control Act.

The PRESIDING OFFICER. The Senator from Connecticut.

Mr. DODD. Mr. President, I thank my colleagues. We are getting close to the time of the vote. I would be remiss if I did not also mention our staff. I often say in a time such as this, Senators get the opportunity to stand at a podium and be heard, but there are literally dozens of people whose names most Americans will never know who make these moments happen. They deserve public recognition because they worked tirelessly, late nights, weekends, around the clock negotiating, working with each other trying to iron out provisions of the bill.

On Senator KENNEDY's staff: Jeff Teitz, Michael Myers, Ben Olinsky, Terri Roney, Shawn Daugherty, and Portia Wu. Some are in the Chamber. I thank them immensely on behalf of Senator KENNEDY.

Senator DURBIN's staff: Tom Falletti and Sara Singleton have been terrific in this effort. We thank Tom and Sara for their work.

Senator ENZI's staff: Greg Dean and Amy Muhlberg. We thank them immensely. They worked hard on this bill.

Finally I want to thank Jim Fenton from my office, Rachael Holt, Jeremy Sharp, who is sitting next to me, and Monica Feit. I have gotten a lot of help in this effort, with Senator KENNEDY's staff and Senator ENZI's staff.

There are members of the majority leader's staff who deserve our thanks as well. We always have to thank Lula, Tim, and others who make it all possible. We thank them all very much for what they do.

Again, as Senator DURBIN said, and Senator ENZI and others have said, this is a historic moment for our Chamber to be able to do something. Fifty years ago the Surgeon General warned us of tobacco use, and a half century later we are about to insist the agency in charge of food, drugs, cosmetics, and pet food also be able to include tobacco. We are about to do that.

The House and Senate bills are similar, and I believe we will have a Presidential signature on this legislation very quickly.

On behalf of millions of families across this country and as the father of a 4-year-old and a 7-year-old who do not know anything about tobacco yet, and whose mother does not smoke, never did, and a father who did but stopped, on behalf of my children and millions of children around this country, we are told by the Congressional Budget Office that an 11-percent reduc-

tion in youth smoking can happen immediately with the passage of this bill. That may not seem like much, but it is a beginning. We may just reach the goal of my colleague from Wyoming of a 100-percent reduction of young people smoking. My hope is that certainly will be the case.

Mr. President, with a little bit of time remaining, I am prepared to yield back the time, and at the appropriate moment, I will ask for the yeas and nays.

The PRESIDING OFFICER. The Senator's time has expired. The Senator from Wyoming has 3 minutes 30 seconds remaining.

Mr. ENZI. Mr. President, I yield back the remainder of my time.

Mr. DODD. Mr. President, I ask for the yeas and nays.

The PRESIDING OFFICER. Is there a sufficient second?

There is a sufficient second. Under the previous order, the bill having been read the third time, the question is, Shall the bill, as amended, pass?

The clerk will call the roll. The legislative clerk called the roll.

Mr. DURBIN. I announce that the Senator from West Virginia (Mr. BYRD) and the Senator from Massachusetts (Mr. KENNEDY) are necessarily absent.

Mr. KYL. The following Senator is necessarily absent: the Senator from Missouri (Mr. BOND).

Further, if present and voting, the Senator from Missouri (Mr. BOND) would have voted "nay."

The PRESIDING OFFICER. Are there any other Senators in the Chamber desiring to vote?

The result was announced—yeas 79, nays 17, as follows:

[Rollcall Vote No. 207 Leg.]
YEAS—79

Akaka	Grassley	Nelson (FL)
Barrasso	Gregg	Pryor
Baucus	Harkin	Reed
Bayh	Hutchison	Reid
Begich	Inouye	Risch
Bennet	Johanns	Rockefeller
Bingaman	Johnson	Sanders
Boxer	Kaufman	Schumer
Brown	Kerry	Sessions
Burr	Klobuchar	Shaheen
Cantwell	Kohl	Shelby
Cardin	Landrieu	Snowe
Carper	Lautenberg	Specter
Casey	Leahy	Stabenow
Cochran	Levin	Tester
Collins	Lieberman	Thune
Conrad	Lincoln	Udall (CO)
Corker	Lugar	Udall (NM)
Cornyn	Martinez	Vitter
Crapo	McCain	Voinovich
Dodd	McCaskill	Warner
Dorgan	Menendez	Webb
Durbin	Merkley	Whitehouse
Enzi	Mikulski	Wicker
Feingold	Murkowski	Wyden
Feinstein	Murray	
Gillibrand	Nelson (NE)	

NAYS—17

Alexander	Coburn	Inhofe
Bennett	DeMint	Isakson
Brownback	Ensign	Kyl
Bunning	Graham	McConnell
Burr	Hagan	Roberts
Chambliss	Hatch	

NOT VOTING—3

Bond	Byrd	Kennedy
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The bill (H.R. 1256), as amended, was passed, as follows:

H.R. 1256

Resolved, That the bill from the House of Representatives (H.R. 1256) entitled "An Act 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.", do pass with the following amendment:

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 non-proprietary 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) **BIENNIAL 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 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’, ‘smoke-free’, ‘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 enact-

ment 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; FACAS.**—

“(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 FACAS.**—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)”; and

(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)”;

(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)”;

(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”;

(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—”;

(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,”;

(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 follow-up 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 provided 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 consulta-

tion 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 al-

tered 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:

“(i) 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”.

Mr. DODD. Mr. President, I move to reconsider the vote.

Mr. DURBIN. I move to lay that motion on the table.

The motion to lay on the table was agreed to.

ORDER OF BUSINESS

Mr. REID. Mr. President, this will be the last vote of the week. We have a lot of work going on in the committees and that will continue on Monday. The next vote will be Tuesday morning. I will confer with the distinguished Republican leader as to what time we will do that and what it is going to be on for sure. We think we know, but there will be a vote Tuesday morning.

Everyone has been notified, but to make sure that people understand, when we come back after the July 4 recess, we are going to be in session for 5 weeks. The House will be in session for only 4 weeks. We have 5 weeks and we are going to work very hard during that period of time. I have had requests from the managers of the bill, the health care bill, Senator BAUCUS and DODD, that we need every day of that break so there is only going to be 1 day that there will be no votes—Mondays and Fridays there will be votes—which is Friday, July 17.

The first day we get back we are going to have a Monday morning vote, to show everybody we are serious about this. So the day we get back there will be a Monday morning vote. We have a tremendous amount of work to do. We not only have health care, which is going to take so much of our time, but

we are in the appropriations process. The House is going to pass all their appropriations bills by the end of the July recess. I don't know if we can meet that schedule—it is somewhat doubtful—but we are going to pass some bills. We are going to try to get to one this work period.

Without going into more detail, the next work period is going to be extremely long, arduous, and extremely important.

I suggest the absence of a quorum.

The PRESIDING OFFICER. Will the leader withhold his request for a quorum call?

Mr. REID. I withhold.

The PRESIDING OFFICER. The Senator from New Mexico is recognized.

UNANIMOUS CONSENT REQUEST—EXECUTIVE CALENDAR

Mr. BINGAMAN. Mr. President, I wish to propound a unanimous consent request. I ask unanimous consent the Senate proceed to executive session to consider Calendar No. 97, the nomination of Hilary Chandler Tompkins to be Solicitor of the Department of Interior, the nomination be confirmed, the motion to reconsider be laid on the table with no further motion to be in order, that any statements related to the nomination be printed in the RECORD, and upon confirmation the President be immediately notified of the Senate's action and the Senate then resume legislative session.

The PRESIDING OFFICER. Is there objection?

Mr. CORNYN. Mr. President, reserving the right to object.

The PRESIDING OFFICER. The Senator from Texas is recognized.

Mr. CORNYN. With all due respect to my colleague from New Mexico, I am advised that the nomination has not yet been cleared on this side. We are going to keep working on it, but at this time I must object and I do object.

The PRESIDING OFFICER. Objection is noted.

The majority leader is recognized.

MORNING BUSINESS

Mr. REID. Mr. President, I know my friend, the distinguished Senator from Texas, wishes to speak for up to 20 minutes, is that right?

Mr. CORNYN. That is my wish.

Mr. REID. We have Senators on this side. What I would ask consent to do is have Senator BINGAMAN be recognized for up to 3 minutes, Senator CORNYN be recognized for up to 20 minutes, and then I will be recognized following his statement. Following me, Senator DORGAN be recognized.

I ask we proceed to a period of morning business, with Senators permitted to speak for up to 10 minutes, with the exceptions I noted.

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

The Senator from New Mexico is recognized.

NOMINATION OF HILARY CHANDLER TOMPKINS

Mr. BINGAMAN. Mr. President, let me state I am disappointed to see the objection still raised to the confirmation of Hilary Chandler Tompkins to be the Solicitor for the Department of Interior. She is extremely well qualified. No one has raised any question about her qualifications. Our former colleague, now Secretary Salazar, needs a Solicitor in the Department of Interior.

We reported her nomination out of our committee on April 30, nearly 6 weeks ago now. There has been something of a rolling hold on her nomination.

I know Senator BENNETT had an objection at one point; that has been satisfied. Senator COBURN had an objection; that has been satisfied. Senator BUNNING had an objection; that has been satisfied. Now I am informed there are additional objections.

I hope very much my colleagues on the Republican side will go ahead and approve her for confirmation quickly so that Secretary Salazar can get on with the important business of the Department of Interior.

I yield the floor.

The PRESIDING OFFICER. The Senator from Texas is recognized.

HEALTH CARE REFORM

Mr. CORNYN. Mr. President, I want to spend a few minutes talking about the importance and challenge of health care reform, something that is on the fast track in the Senate.

Recently, as I traveled my State of 24 million people, I heard many similar themes from my constituents. What they told me is that our top priority ought to be reducing the cost of health care because, of course, by reducing the cost it becomes more affordable by more people and we attack what is one of the other principal concerns, and certainly one of mine, and that is too many people who are uninsured in this country.

We know cost is one reason why 46 million people are not insured in this country, some of whom have good jobs that pay well, but if they are young they would rather put the money in their pocket than pay for health care. Others have different circumstances, maybe small businesses that are priced out of the market.

It is a fact that American families have seen their health care premiums double over the last 10 years. My constituents and the American people generally are also very concerned about our future. As they see so much borrowing and so much spending here in Washington, they worry about the fact that Medicare, which is the health care program for seniors, has an unfunded liability of \$38 trillion. So, to understand, while we have roughly \$2 trillion in annual deficits running, we also have \$38 trillion in unfunded Federal liabilities for Medicare and the trust