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Senate

The Senate met at 9:30 a.m. and was called to order by the Honorable DANIEL K. AKAKA, a Senator from the State of Hawaii.

PRAYER

The Chaplain, Dr. Lloyd John Ogilvie, offered the following prayer:

Gracious Father, our morning prayer is like being amazed by deposits in our checking account from unexpected sources. We are astounded by Your goodness. You know what we will need for today and You deposit the required amounts of insight, discernment, and vision in our minds. You fill the wells of our hearts to overflowing with the added courage and determination that are necessary for the demands of today. Even now, we feel the fresh strength of Your Spirit energizing our bodies. We should not be surprised. You have promised that,

"As your days, so shall your strength be".—(Deuteronomy 33:25).

Bless the women and men of this Senate and all who work with and for them that this will be a day in which we draw on Your limitless resources for dynamic leadership. You are our Lord and Saviour. Amen.

PLEDGE OF ALLEGIANCE

The Honorable DANIEL K. AKAKA, a Senator from the State of Hawaii, led the Pledge of Allegiance, as follows:

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

APPOINTMENT OF ACTING PRESIDENT PRO TEMPORE

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

The legislative clerk read the following letter:

U.S. SENATE,
PRESIDENT PRO TEMPORE,
Washington, DC, July 19, 2002.

To the Senate:

Under the provisions of rule I, paragraph 3, of the Standing Rules of the Senate, I hereby appoint the Honorable DANIEL K. AKAKA, a Senator from the State of Hawaii, to perform the duties of the Chair.

ROBERT C. BYRD,
President pro tempore.

Mr. AKAKA thereupon assumed the Chair as Acting President pro tempore.

RESERVATION OF LEADER TIME

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

MORNING BUSINESS

The ACTING PRESIDENT pro tempore. Under the previous order, there will be a period for the transaction of morning business, not to extend beyond the hour of 11:30 a.m., with Senators permitted to speak therein for up to 10 minutes each, with the time to be equally divided between the two leaders or their designees.

In my capacity as the Senator from the State of Hawaii, I suggest the absence of a quorum. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

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

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

The Senator from Wyoming is recognized.

Mr. ENZI. I thank the Chair.

(The remarks of Mr. ENZI pertaining to the introduction of S. 2760 are located in today's RECORD under "Statements on Introduced Bills and Joint Resolutions.")

21ST CENTURY MEDICARE ACT OF 2002

Mr. ENZI. Mr. President, since I still have time remaining under morning business, I will comment on another issue that I am sure will be commented on throughout the day and later next week. Later this morning I will be at a conference meeting on the accounting reform bill. I have had a considerable role in that process and will be doing that when we get to the actual debate on this bill. I see that as a top priority as well.

Today I rise in support of the tripartisan 21st Century Medicare Act, which was introduced on July 15 by Senators GRASSLEY, SNOWE, JEFFORDS, BREAUX, and HATCH. This bill is a giant step forward for seniors in this country and it demonstrates a sincere commitment to future beneficiaries, by taking steps to preserve, improve, and modernize the Medicare Program. No other proposal before the Senate can deliver on such a promise.

Some of them have not been introduced yet. In fact, we have been a little disappointed that bills have not been introduced so that a more direct discussion can be done on that.

I should say, not only no other proposal is before the Senate, no other proposal that is being talked about out there can deliver on the promise that this bill does.

This bill very likely has the support of the majority of the Senate. Of course, we would need a supermajority, or support of 60 Members, to adopt the bill. It raises a very important and interesting question. It is a budget question, because the score of the tripartisan bill exceeds by \$70 billion the \$300 billion Congress reserved last year for Medicare; there is a budget point of order that can be raised against the bill.

Essentially, if a Senator votes against removing or bypassing the budget point of order, they will be saying this bill costs taxpayers too much,

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



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so I will not support it. But what is really interesting is that many of those who oppose this bill are actually supporting a proposal that is significantly more costly to the taxpayers. So I suggest people take a look to see who votes against this bill on the basis it exceeds the amount of money we have set aside by \$70 billion and then perhaps votes for a bill that is \$700 billion, \$800 billion, \$900 billion—or a trillion dollars—perhaps twice or three times the cost of this bill.

My point is a number of my colleagues could find themselves in the position of voting against one bill because it costs too much only to turn around and support a competing bill that is two or three times more costly.

Beyond cost to taxpayers, there are other important policy differences between the two Medicare drug benefit proposals. I believe the most important is that the tripartisan bill stretches Federal dollars further than any other proposal and provides a permanent, comprehensive drug benefit that's affordable for seniors and taxpayers. This is a critical achievement.

And, the bill does even more. It provides seniors with the option of an expanded fee-for-service plan, including drug coverage, that will serve as the first modernization of the scope of benefits under Medicare since the program was created almost 40 years ago.

Lastly, while Medicare managed care plans—known as Medicare Plus Choice plans—are not serving Wyoming, millions of seniors across the country made the "choice" to enroll in those plans, and this bill makes long overdue improvements to how those plans compete for seniors' business. My colleagues from more populous and urban states undoubtedly know that seniors who have Medicare Plus Choice plans as an option now want to keep that option and want to see it expanded and improved.

All of this sounds like a lot. And it is. But I won't stand here and tell my constituents in Wyoming that this is everything they might dream of in a prescription drug benefit. It is a giant step forward and it will absolutely reduce the drug costs seniors bear today. It won't make those costs disappear, but it will dramatically reduce them. And, it's a benefit we can afford to enact for seniors today and keep our promise to implement it in 2005. The proponents of the Daschle bill are also making seniors promises about a great new drug benefit. Except we can't afford it, so it's a hollow promise.

The opponents of the tripartisan bill will say that our bill doesn't provide a real benefit to seniors. Well, here's the skinny on our bill and what it will save seniors in out-of-pocket costs. The Congressional Budget Office (CBO) determined that Medicare beneficiaries will spend an average of \$3,059 per year on drugs in 2005. If enacted, this bill would cut those costs by 53%—a savings of over \$1600. That is real money. CBO also determined that the bill

would cut costs for lower-income beneficiaries at or below 135% of poverty by 98%, a savings of \$2,988! The estimated out-of-pocket cost per prescription among the 50 most-prescribed medications would be \$21. And, every beneficiary would have at least 2 drug plans to choose from when selecting the plan that best fits their health care needs.

The Democrat bill, on the other hand, has a statutorily prescribed cost sharing for all drugs that the government decides to include in the plan, and every senior must participate in that one-size-fits-all plan. That's a concerning and very significant difference from the tripartisan bill. All of us in this body have numerous choices of health plans both at and above the standard benefit package under the Federal Employees Health Benefit Program. I do not believe seniors should be—by law—without a choice in their own health coverage. Unlike the tripartisan bill, the Daschle bill completely misses the opportunity to improve Medicare through expanded choices for seniors when selecting the right drug coverage.

To restate another distinction I raised earlier, the tripartisan bill has been officially scored by the CBO to cost \$370 billion over 10 years. The sponsors of the Daschle bill have not provided us with an official score, but the unofficial scores are as high as \$1 trillion over 10 years. More importantly, the drug benefit is not permanent under the Daschle bill. It would sunset in the year 2010. That is to hold costs down as much as possible. There are rumors of a 4th iteration of the bill that would not sunset the benefit, but that bill has not been introduced and will be much more costly.

Since I'm talking about the cost of the Daschle bill to taxpayers, I would be remiss if I did not talk about the cost of the bill to seniors themselves. Because the bill would cement in Federal law fixed co-payment amounts for all drugs, seniors will actually pay more for certain drugs than they would if the bill allowed drug plans to offer lower co-payments. The CBO analysis and score of the tripartisan bill proves that it employs this logic and essentially proved that drugs will be provided in a more cost-effective way under the tripartisan model.

I have mentioned it before, but I just want to say again that, in addition to the very high profile issue of needing to provide a drug benefit, Medicare has many other shortcomings. It is crying out for updating and improvements. No one in this chamber can possibly be satisfied with the program's status quo. Every day—literally—I either meet with or hear from my constituents who interact with the Medicare program or beneficiaries. They are all complaining, and rightly so. The program was created with the best of intentions. But since that day some 40 years ago, the rest of the health care world has evolved and improved, from standards of care to technology to dis-

ease management. Not to mention how providers are reimbursed and empowered in the delivery of health care services. I question whether any of this progress has penetrated the morass of the Medicare program. In fact, all I seem to hear from my constituents is that things are pretty bad with Medicare right now. That is before the new program is started.

I am astonished that only one of the two major bills—the tripartisan bill—tries to address the other problems with Medicare. The foundation of the program desperately needs reinforcement; simply building on its weak foundation the way the Daschle bill does is dangerous and falls short of our obligation to do our best for seniors where all of their health care is concerned. Where the tripartisan bill has an enhanced fee-for-service option and improvements to the existing Medicare Plus Choice option, the Daschle bill is eerily silent. Such an absence of reform will only cost seniors more money in patch jobs down the road.

I guess I have come full circle. This debate is all about giving seniors additional coverage options and saving them money. Many seniors currently lack drug coverage. All of the bills will give them coverage and cost them less out-of-pocket than what they pay right now. But only the tripartisan bill will give them flexibility in their coverage choices and buy them and taxpayers the most that a dollar will buy. That takes competition and modernization. The tripartisan bill has both. The Daschle bill prohibits competition in its statutory language and does not entertain even modest improvements to the rest of the Medicare program.

The choice is clear to me and, I imagine, will be crystal clear to the American people. For that reason, Mr. President, I would ask unanimous consent that I be added as a cosponsor of the 21st Century Medicare Act.

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

Mr. ENZI. Mr. President, I yield the floor.

I suggest the absence of a quorum. The PRESIDING OFFICER. The clerk will call the roll.

The senior assistant bill clerk proceeded to call the roll.

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

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

The Senator from Colorado is recognized.

Mr. ALLARD. Mr. President, I ask unanimous consent that I be allowed to speak for 20 minutes in morning business.

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

THE SENATE HAS NOT PASSED A BUDGET

Mr. ALLARD. Mr. President, I wish to express to the Senate my sincere

disappointment that we have not passed a budget. It has been 27 years since we have had this budget process in place in the Senate. This is the first time we have not had a budget plan passed out of the Senate.

If we are going to begin to talk about the need for various programs, it would certainly be helpful if we had some idea of where our limits were. I happen to believe we need to work to eliminate our deficit spending. We need to work to make sure we are trying to hold down the growth in our total debt.

MEDICARE PRESCRIPTION DRUG BENEFIT

Mr. ALLARD. Mr. President, I think it is vitally important that the Senate pass a Medicare prescription drug benefit plan now. Our seniors need it, our seniors have been waiting for years for it, and our seniors deserve it now.

Medicare is a health care entitlement program for the elderly. Since Medicare was established in 1965, Congress has considered adding a prescription drug benefit to the program. In the 106th Congress, the Senate got serious about enacting a benefit but was unsuccessful in their efforts.

I hope the Senate is successful now. I am concerned, however, that the legislative process has been derailed. The majority leader decided to bring to the floor S. 812, the Greater Access to Affordable Pharmaceuticals Act. This legislation did not proceed through the Committee on Finance. In order for a revenue measure to not face a Budget Act point-of-order, legislation must proceed through the Committee on Finance. S. 812 did not. As a result, the Senate is left with assuming budget points-of-order against any and all revenue legislation as we continue debate this week.

This is unacceptable. Seniors need drug coverage now. But the Senate majority has stalled the process. I hope seniors across the United States realize what has happened. This faulty procedure is robbing seniors of their drug benefit, which Congress and the President support but which the Senate is denying. Politics is superseding policy and that is simply unacceptable.

Because S. 812 did not proceed through the Committee on Finance, next week the Senate will take up the Graham-Miller, tripartisan, Hagel-Ensign, and Smith-Allard amendments in an attempt to provide a prescription drug benefit. We can only hope that the Senate will waive the budget point-of-order raised against these measures.

I have serious concerns about the legislation introduced by Senators GRAHAM and MILLER. Graham-Miller would be a temporary drug benefit, without secure financing. Graham-Miller would raise drug prices significantly, and Graham-Miller would not be able to be implemented as proposed. Graham-Miller would have an immeasurable and possibly unlimited cost.

Senator GRAHAM's bill does not even have a CBO score. That is another con-

cern I have. Preliminary estimates are that it would cost at least \$400 billion to \$800 billion over only 6 years. With two-thirds of seniors already obtaining their prescription drugs independent of Government, the Graham plan, frankly, is too generous at a time when Social Security solvency is at risk. According to CBO, Medicare beneficiaries will utilize \$1.8 trillion worth of drugs over the next 10 years. But \$1.1 trillion of this \$1.8 trillion will be paid by third parties, such as employers, States, and Medicare+Choice plans. Drug benefit proposals should focus on reducing the \$700 billion that will be paid by beneficiaries, not shifting the remaining \$1.1 trillion to the Federal budget. Seniors and taxpayers need a plan that provides a benefit that does not blanket seniors with costs completely covered and that does not break the Nation's bank. Graham-Miller's cost alone is reason to oppose it.

Other Senate drug proposals are less expensive. The tripartisan 21st Century Medicare Act of 2002, introduced by Senators GRASSLEY, SNOWE, BREAU, JEFFORDS, and HATCH, is estimated to cost about \$350 billion from the years 2005 to 2012. For days, weeks, and months, the Senate Finance Committee members and staff have worked tirelessly to write a bill that expands drug plan options for seniors and refines and enhances Medicare+Choice, Medigap, and other programs. This tripartisan bill will establish a universal, voluntary prescription drug benefit with affordable premiums and special protections for low-income seniors. The tripartisan bill would add a new voluntary fee-for-service option to fit modern health benefit packages, and it will strengthen another drug option under Medicare+Choice.

I am pleased that this tripartisan group of Republican, Democrat, and Independent Senators have joined together to provide a Medicare prescription drug benefit. The tripartisan plan expands drug options for seniors so they can choose a plan that fits their needs.

I also laud the work of Senators HAGEL, ENSIGN, GRAMM, and LUGAR who introduced the Medicare Prescription Drug Discount and Security Act. The Hagel-Ensign plan would offer beneficiaries a voluntary drug discount card that they could use to purchase prescription drugs. The bill would cover catastrophic drug costs for beneficiaries under 600 percent of the Federal poverty level, so that seniors making less than about \$53,000 will pay no more than \$1,500 to \$5,500 in out-of-pocket expenses. The bill also does not require monthly premiums, deductibles, or benefit caps. This bill is fiscally responsible, costing about \$150 billion over 10 years. I commend Senators HAGEL and ENSIGN for their work in offering this voluntary plan for seniors who need it most.

Senator SMITH and I also have introduced an amendment to S. 812 that would provide a Medicare prescription

drug benefit. Under our plan, the voluntary Medicare prescription drug plan, a Medicare beneficiary already enrolled in Medicare Parts A and B will have the option of choosing a new, voluntary prescription drug plan called Rx Option. This would cover 50 percent of their prescription drug costs toward the first \$5,000 worth of prescriptions that the senior purchases.

Currently, Medicare Part A has a \$812 deductible and Part B has a \$100 deductible. The Smith-Allard plan would create one deductible for Part A and Part B of \$675 that would apply to all hospital costs, doctor visits, and prescription drug costs. Once this \$675 deductible is met by the Medicare recipient, Medicare will pay 50 percent of the cost toward the first \$5,000 worth of prescription drugs that the senior purchases.

In addition, there is no benefit premium that would be required. Our plan is revenue-neutral. It is voluntary and will lower Medigap premiums by \$550 per year.

According to the National Bipartisan Commission on the Future of Medicare, the Federal Government pays about \$1,400 more per senior if the senior has a Medigap plan that covers his Part A and Part B deductibles. This generally is attributed to the fact there is overutilization of hospital and doctor visits by the senior because no deductible is required under Medigap, and seniors are more inclined to visit the hospital or doctor without having to pay a deductible.

The Smith-Allard plan would require seniors pay a deductible. As a result, Medigap utilization will decrease and savings are achieved. In other words, there is an incentive created for the senior to go to the doctor when he needs to and not simply because it cost him nothing.

The Smith-Allard plan would work as a stand-alone drug benefit or as a complementing, additional drug benefit in conjunction with the other drug options about which I talked earlier. Our plan has a number of features that both the Graham-Miller plan and the House-passed Medicare Modernization and Prescription Drug Act do not have.

I would like to take a minute to go over a chart I put together on Smith-Allard. This is the Smith-Allard proposal as compared to current law, as compared to the Democrat plan referred to as Graham-Kennedy, and as compared to the House GOP plan for prescription drugs.

This is assuming the senior has Medigap supplemental insurance. Under current law, there is no deductible with the doctor or the hospital when they have Medigap insurance coverage.

With the Smith-Allard plan, there would be a \$675 deductible that would combine for both Part A and Part B of Medicare. Under the Democrat plan, there is no deductible, and in the House plan there is no deductible.

The prescription drug deductible is not covered in current law. It is combined in the Smith-Allard plan. There is no deductible in the Democrat plan and the House plan.

The average supplemental insurance premium under current law is \$1,611. Under the Smith-Allard plan, this comes to \$1,061. This remains the same under both the Graham-Kennedy and House GOP plan.

Prescription drug premium: Under current law, there is no coverage. Under the Smith-Allard plan, the prescription drug premium would be zero. Under the Democrat plan, the monthly charge that is talked about as \$25 a month, this amounts to a \$300-a-year premium, and the House GOP plan, which is \$30 a month, amounts to an annual premium of \$420.

Total annual premiums and deductible: Under current law, we stay at the \$1,611 level. Under the Smith-Allard plan, it is \$1,736. Under the Democrat plan, the Graham-Kennedy proposal, it is \$1,911. And the House GOP plan is \$2,281.

Let's look at the 10-year cost to the Medicare Program. Obviously, we do not have anything under current law. The Smith-Allard plan would remain at zero. The 10-year cost of the Medicare Program to the taxpayer is zero.

The Graham-Kennedy plan gets up to \$600 billion, and some estimates are running between \$400 billion and \$800 billion; \$600 billion is the number we use on this chart.

The House GOP plan comes in at \$350 billion. Some are estimating \$370 billion currently.

Who provides the drug benefit? Under current law, it is not covered. Under the Smith-Allard plan, Medicare provides that drug benefit. In the Graham-Kennedy bill, Medicare provides it. And under the House GOP, it is provided by the private insurance industry.

What is the comparison of drug coverage? Currently, there is no coverage. In the Smith-Allard plan, there is 50 percent coverage of all drugs up to \$5,000. In the Graham-Kennedy plan, the senior pays \$10 for generic drugs and \$40 for brand name drugs. Then in the House GOP, there is 20 to 30 percent coverage up to \$1,000 the senior pays, and then 50 percent between \$1,000 and \$2,250, and 100 percent over the \$2,250, up to \$5,000.

Let's look at the catastrophic coverage under these various plans. Under the Smith-Allard proposal, it is optional. Seniors can decide whether they want to take it or not. Coverage could be provided with savings if they decide to take that optional provision. In the Graham-Kennedy plan, it is over \$4,000, and in the House GOP plan, it is over \$5,000.

The nice thing about the Smith-Allard plan and one reason I am presenting it to the Senate today and have introduced the legislation with Senator SMITH is because it provides another option, and it is compatible with these other drug plans, particularly the first

one we talked about, the tripartisan plan, with an Independent, Democrats, and Republicans supporting the plan. Our bill is very compatible with that kind of a plan.

The amendment I will be offering with Senator SMITH is simply to provide seniors with an option so that as we move forward with this, it may be they do not want to pay the \$25-a-month premium or the \$30-a-month premium. They can say: I will offset that by increasing my deductibles in Part A and Part B on Medicare. I think it is the kind of choice we ought to offer seniors. It will balance any of the plans that happen to pass the Senate, and we ought to pass it in the Senate in order to give seniors some choice.

I am pleased the Senate is working to pass a prescription drug benefit for Medicare's 40 million enrollees. The Senate should be pleased that many Members have worked hard in recent years to add a drug benefit. We should be pleased that we are debating various proposals now. But our efforts are in vain if we do not pass a drug benefit this year. Our efforts are in vain, I repeat, if we do not pass a drug benefit this year. I urge my colleagues to set aside politics and pass a Medicare prescription drug benefit now.

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

The PRESIDING OFFICER. The clerk will call the roll.

The senior assistant bill clerk proceeded to call the roll.

Mr. KYL. 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. KYL. Mr. President, I ask unanimous consent to speak until the hour of 11:20 a.m. in morning business.

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

AMERICA'S SENIORS NEED PRESCRIPTION DRUG COVERAGE

Mr. KYL. Mr. President, I want to talk about the delivery of prescription drugs to America's seniors. It is a subject that Senators have been talking about pretty much all week long, but people tuning in might wonder whether we are really making any progress toward getting a bill passed. That is what I would like to address this morning.

For quite a long time now, we have appreciated the fact that when Medicare was created, treating people with medications was not the preferred or first or primary method of treatment. So much of what Medicare covers today is the cost of invasive surgery, and the cost of just about every other kind of treatment except treatment through the use of medication or prescription drugs. Over the last 25 years, it has become increasingly common for physicians first to treat with medications, if possible. It seems second nature to us now. When Medicare was first established, that was not the case.

As a result, most prescription drugs were not covered as part of Medicare.

Over the years, people learned how to receive supplemental drug coverage through Medigap insurance and other ways to pay for prescription drugs, but the combination of the fact that Medicare itself did not set out to cover those drugs and, second, that the cost of drugs has obviously increased over the years has made it more difficult for some seniors to be able to pay for their prescription drugs, especially since, again, this is what their physicians are prescribing as the best way to treat them in many cases.

Add to that the fact that people are, fortunately, living longer today, but that the longer one lives, the more likely they are going to need to take various kinds of drugs, and we have a situation in which clearly it is time for Congress to respond with an inclusion of a Medicare drug benefit for all of America's seniors. We have been working on that now for quite a long time.

I find it interesting that on the Republican side there are three or four very good, somewhat different, ways of approaching this because Members on our side have been working hard to try to fashion a set of benefits we can afford and which will also provide the kind of care we want for our senior citizens, and now we have a number of options.

I sit on the Finance Committee. Last year, when Senator GRASSLEY chaired the Finance Committee, we began working legislation through the Finance Committee to try to bring to the Senate floor so we could provide a prescription drug benefit to Medicare. Then the control of the Senate changed.

Toward the end of last year, Republican members continued to meet and, in fact, began reaching across the aisle to meet with the Democratic members of the Finance Committee and also with the Independent Member of the Senate, Senator JEFFORDS, who had left the Republican Party and caucused with the Democrats but is identified as an Independent, and over the months, representatives of the Republican Party, the Democratic Party, and Senator JEFFORDS have come together on an approach that has now acquired the name, the tripartisan approach—because it is not just the two parties but, it is actually three parties—an approach that actually will deliver a very good prescription drug benefit to our seniors and a plan that actually is unique among all of the different ideas that have been brought to the floor because it can actually pass the Senate.

It has more than 51 votes in the full Senate, we believe, and it could pass the Finance Committee. Senator BREAU is one of the leaders in this coalition, and he has been a leader in the Finance Committee in support of this. So a great deal of work has been done to try to develop the kind of reform that is necessary to provide prescription drugs to our seniors.

Then why the discussion on the Senate floor and what is going to happen next week? Well, at the early part of next week, we are finally going to have a chance to vote on some alternatives. There will be at least two. One will be this tripartisan plan I mentioned that has been offered by Senators GRASSLEY, HATCH, SNOWE, JEFFORDS, BREAUX, and others, and the other will be a competing plan brought by some members of the Democratic Party, led by BOB GRAHAM from the State of Florida. The two proposals approach the prescription drug issue in fairly different ways. I am hoping we will have a good debate about the difference between those two approaches.

There are also approaches from other Republican colleagues who are even more different and in some ways provide a very direct benefit to seniors at a much lower cost than either of the two bills I just described. The problem is that at the end of next week, it is doubtful the Senate will have passed any of these bills.

How can that be if, as I said, there is majority support at least for one of the bills? I fear the problem is a political one, that there are some people who would rather have an issue than a bill, a problem rather than a solution, because of course the problem can continue to be talked about in a campaign context. I would rather have a bill that provides the benefit we can all take credit for, but if politics is the primary motivation, then clearly doing something is a good way to appeal to voters. But of course the whole point is it is the right thing to do.

It is past time that we provided a drug benefit to our seniors. Why is it that my prediction is what it is? Ordinarily, if the Finance Committee brought a bill to the floor, we would vote on it and the majority would prevail. It either wins or it loses. But in this case, even though the Finance Committee has been working very hard under the chairmanship of Senator BAUCUS's and Senator GRASSLEY's leadership on the Republican side, we are close to being able to mark up the bill in the Finance Committee and bring it to the floor. It is clear that the Senate majority leader has, according to Senator BAUCUS, indicated the bill would have to be acceptable to him in order for it to come out of the Finance Committee and brought to the floor. That was not the case with the so-called tripartisan bill. The legislation that has been brought to the floor by the majority leader is not legislation that would have come out of the Finance Committee.

Why is that important? Because a point of order lies against legislation that does not come out of committee. In practical terms, that means you have to have 60 votes on the Senate floor to pass it.

What has been set up is a process that is set up to fail. By not allowing the Finance Committee to bring its bill to the floor and be voted on by a ma-

majority of 51, we are setting up a requirement that any bill has to pass with 60 votes because it did not come out of committee; 60 votes will be very difficult to achieve because the Senate is divided roughly 50/50 among the two parties.

We have different approaches to this solution, this problem. The only bill that likely would pass is the so-called tripartisan compromise. But if it has to have 60 votes, that is a stretch, as well. I am not sure we can get 60 votes.

At the end of the day, by virtue of the process that has been created, we are not likely to end up with any legislation at the end of next week. Then what will we do? Point fingers: It is your fault. No, it is your fault.

The bottom line will be that the American people end up the losers. Our seniors will not have a prescription drug benefit because the Senate decided to operate in a way that guaranteed that conclusion.

The House of Representatives has passed a bill that is a good bill. It is not exactly what I would do, but it is a good start. The Senate should act in the same way.

Let me describe a little bit about what this tripartisan bill does. Even though it is not a bill I would have written, I am willing to support it, primarily because it does have a number of good ideas, and it can be passed and we can move on, get a bill to conference and to the President for signature to begin providing Medicare drug benefits for our seniors.

The tripartisan plan is a comprehensive plan. It is a permanent plan with respect to providing drugs to all Medicare beneficiaries. It also has another feature that the other plans, by and large, do not, in that it provides reforms of Medicare that will ensure that as the program continues on out into the future, it will actually work. The problem with both Social Security and Medicare today is without serious modernizations neither one can provide the benefits that have been promised. Those are commitments that we should be ensuring we can keep.

Under this plan, Medicare beneficiaries will have a new drug benefit option. They can keep their current Medicare plan and do nothing, or they can buy into the new drug plan provided for them. If they sign up for the new plan, it is completely voluntary on their part. If they sign up for the new plan, they will have choices so that they can pick what best suits them. They would pay a premium that is estimated to be about \$24 a month, very similar to the monthly premium seniors now pay for Medicare Part B. They would be able to choose between competing plans. The plans would compete for their business and therefore would offer the best possible arrangements for each individual senior. The plans generally would have an annual deductible of \$250. This is similar to the Part B deductible seniors now pay which is currently \$100.

A key difference is after \$3,700 in out-of-pocket drug spending by the beneficiary, the Government would pay 90 percent of the costs, and the beneficiary would only pay 10 percent. As Medicare beneficiaries know, traditional fee-for-service Medicare does not have this type of important stop-loss coverage for the benefits it provides; stop-loss meaning after you pay a certain amount you do not have to pay anymore, the Government would begin paying the bulk at that point. It is important to protect the beneficiaries from high drug costs, particularly those who have a significant illness, or a longstanding illness that will require them to pay for drugs over a long period of time.

Another important aspect of the proposal is it is affordable. The CBO has estimated the cost, what we call scoring, will be \$370 billion over 10 years. Given it is estimated the alternative offered by the House Democrats cost in the neighborhood of \$800 billion to \$900 billion over 10 years, and the Graham-Miller proposal will cost almost \$600 billion over 10 years, we clearly have an inability to fund that kind of a program. I believe the tripartisan plan is a much more affordable and practical plan.

In an artificial attempt to keep down their costs, the Graham-Miller plan sunsets after just 6 years. The proponents of this plan claim the reason they sunset their legislation after 6 years, in the year 2010, is they want the ability to look to see whether changes are necessary. The fact is, it is a very expensive plan, about \$600 billion over 10 years, if enacted on a permanent basis, making it undesirable from a political point of view. That is one of the reasons that plan should not be supported.

Let me also say we can examine legislation at any time, whether or not it sunsets, and we can review legislation every year and propose amendments to it. We do not need to sunset this legislation.

I mentioned the fact that traditional fee-for-service Medicare does not have the stop-loss provision so people can continue to pay for high-cost drugs on and on. Under the tripartisan plan, beneficiaries will have a chance to join this new fee-for-service option instead of joining Medicare Part A and Part B, as they do now. It would have a combined deductible, instead of two separate deductibles that beneficiaries have to deal with today.

Additionally, it would eliminate the beneficiary cost sharing for preventive benefits, such as breast cancer screening, prostate cancer screening, and screening for glaucoma. This allows Medicare beneficiaries to receive these benefits without having to pay a so-called copay.

One of the important aspects of the new option is the ultimate \$6,000 stop-loss coverage, especially important if a Medicare beneficiary has a long hospital stay. As I said, there are those

who have serious illnesses that simply cannot afford to pay more than that. This new option is a complete benefits package as opposed to just a prescription drug package. Instead of just trying to address the issue of providing drugs, the tripartisan bill puts it into a new option in the traditional Medicare Program that currently exists so people will know what they have a comprehensive plan. They can make an intelligent choice and know that it is all there for them together.

I will comment on another important part of the plan, and that is that it uses the current market system that seniors are familiar with to deliver the benefits. The alternative is a strictly Government plan that has to be run by Government bureaucrats. They will make the rules. They would establish exactly what the benefits are over time and what the costs of those are. By using the market that is currently used, there is competition to provide the product that is the best for seniors at the lowest cost, so that seniors' needs will actually keep the costs down and keep the benefit structure positive, as opposed to the Government bureaucrats making those decisions.

The tripartisan plan includes coverage for drugs within all therapeutic categories and classes, and provides timely appeals if there is any denial of drug coverage in a particular case. This allows the beneficiary to continue to have access to the needed drug and to call on outside experts to review any decision that would deny them those drugs.

The plans that participate in the program will have to meet access and quality standards that are decided by the Department of Health and Human Services, including pharmacy access standards. We want to make sure in the rural areas Medicare beneficiaries have access to pharmacies they can go to and get good advice. In rare cases, where beneficiaries may not have a choice of at least two of these plans, the legislation guarantees they would have an option of a fallback plan.

Providing affordable drug coverage is the goal of the tripartisan plan. That is why it subsidizes private plans to provide this drug benefit. Using this delivery method, as I said before, will both provide competition to hold down the costs and maintain the kind of program benefit that seniors are used to at the present time.

The CBO has told the authors of the tripartisan plan that using this delivery method not only ensures Medicare beneficiaries access to the new drug plans but also the most effective use of taxpayer dollars. We know the plan will become more expensive over time. Seniors care just as much about taxes as anyone else and they want to know it is affordable. The more affordable it is, the more likely they can expand the benefit to seniors. So that is in their interests, as well.

In contrast, the Graham-Miller plan uses government contractors to admin-

ister their drug benefit. These contractors would have little interest in holding down the cost of prescription drugs for Medicare beneficiaries. We all know what the ultimate result of this would be: the federal government would establish price controls on prescription drugs to hold down the costs. This would have a devastating impact on prescription drugs. Let me offer a real life example of what will happen here.

In some major cities today you have price controls, or rent controls on housing. We all know what happens when you have these rent controls. The bottom line is the prices either go up or the conditions of the tenements go down because the people who own them are no longer in a position to continue to upgrade them because they cannot make a profit on them.

What happens is that a severe shortage of housing is created and most people who do not have access to rent controlled housing have to pay very large amounts just to live in a small apartment. We are familiar with this in the area of housing.

The same thing would happen with respect to drugs. If you use the alternative plan, which will ultimately lead to an attempt by the Government to control the prices—whenever you try to control the price of something, you get less of it. That is exactly what would happen here. People who do not have access will pay extremely high costs. Just as there is no incentive to build new rental housing units in areas with price controls, there will be no incentive to create new prescription drugs. After all, if you cannot make a profit with a new drug that you create, why would you go to the effort and expend the money to try to develop that new drug and put it on the market? It is just not worthwhile to spend the amount of money necessary to create a product when you cannot even cover the costs when you sell it.

If we just think about price controls, if they had existed on prescription drugs over the last 20 years, you are probably not likely to have seen the creation of the fantastic new drugs we all have the benefit of today—to control cholesterol levels, like Lipitor; to help people with allergies; to help people with diabetes; and the list goes on. This could be the result of the Democratic alternative which would try to impose price controls without providing an incentive to create these new drugs. Over time, that will result in inferior medical care because fewer and fewer drugs are being brought to market that will help seniors as well as everyone else.

This is another reason we should support the tripartisan plan that essentially builds on the system we have today, that gives seniors at least two types of choices. Medicare beneficiaries can either continue in the existing Medicare system or get to choose the new options. If you get into the new options, you are going to have at least two plans to choose from. So there is a

lot of choice at the same time that it is also very similar to the current system private employees and federal workers have to receive their health care.

Let me finally talk about how much the Government is paying Medicare providers to serve Medicare beneficiaries. It is a very serious concern. At some point we are going to have to deal with it. In the House of Representatives there was, I think, \$30 billion added to their prescription drug benefit legislation to ensure that physicians and hospitals and other providers would receive the money they need literally to stay in business.

We have emergency rooms around the country that are closing because they are not being paid. It is going to be necessary for us to provide some supplemental funding to the hospitals and other health care providers literally to continue to provide the benefits we are promising through programs such as Medicare and Medicaid. If there are not doctors and hospitals to serve people, we can pass all the laws we want, but it is not going to do people any good. So we are going to have to address this issue, whether it is on this legislation or legislation down the road.

My colleagues may appreciate that by Federal law, under the Medicare Program, physicians will receive a 17-percent cut over the next 4 years in what Medicare pays them to see a Medicare patient. Since private plans frequently base their reimbursements on what the Government Medicare plan reimburses, the effect is, for virtually all physicians, that they are seeing this kind of drastic cut in what they are reimbursed, either by the Government—which provides about 50 percent of the health care—or by the private plans, which provide the remainder.

According to a March 12, 2002, New York Times story, 17 percent of family doctors are not taking new Medicare patients because of this problem. They are simply not getting paid enough to cover their overhead costs.

Last year, Senators JEFFORDS and BREAUX and I introduced legislation that would have partially fixed this problem. This legislation now has 80 cosponsors in the Senate. That means virtually everybody in the Senate has said we need to adopt this legislation. It would help to fix this problem of declining reimbursements for providers.

Additionally, Home health care agencies will be taking a 15-percent reduction in payments starting October 1, skilled nursing facilities will experience a 17-percent cut in some of their Medicare rates, and these are just a few of the examples of payment reductions. So we are not going to be able to provide quality care under Medicare if we are not able to sustain the experts who are providing that care today.

I am looking forward to working with my colleagues to ensure that through the reimbursements we will add, whether in this legislation or

some other legislation this year, we will be able to provide that supplemental help to them until we are able to straighten out the payment formulas under which Congress reimburses the hospitals and other providers that are providing care called for by Medicare.

Let me summarize the point about the difference between the two prescription drug proposals and how we are likely to pass a drug bill that will actually be signed into law. If we had been able to pass a bill out of the Finance Committee, we would only have to have a bare majority—51 votes. The tripartisan bill has support on both sides of the aisle, Democrat and Republican as well as Senator JEFFORDS, another cosponsor, to be able to pass. We could actually get together with the House of Representatives, make the changes, the compromises between the House bill that has already been passed and this bill, and get it to the President for his signature, and by the beginning of the fiscal year we could actually be implementing a new drug for our seniors that they do not currently have.

But because that does not fit in with the plans of the majority leader, we are now in a situation where any bill that is brought here is going to have to have 60 votes to pass. Because of the realities of the political environment in which we operate, it is unfortunately the case that it is going to be very difficult to get 60 votes for any plan.

The one that has the best chance is the tripartisan plan that I alluded to earlier. It is not the bill I would have written, but I am willing to support it because it is a good proposal that has the best chance we have to actually get something passed and deliver a real benefit to our seniors. We will have time to work the issues in the conference committee. We will have time to continue to modify the legislation after it is passed and signed into law. But we have to act, and every year we do not act is a year in which more and more seniors are denied the benefit that they need, that their physicians are prescribing for them and, unfortunately, many of them cannot afford.

It seems to me we should put ideologies and politics aside and try to do something good for the seniors of our country and lay those differences aside to the extent that we can actually pass a bill. It is a good bill. It is a very good bill in terms of providing the benefits. It is costly, but with the reforms in Medicare that are included within it, I think over time we will be able to afford these costs. After all, it is a commitment that we should be satisfying for our seniors.

I urge my colleagues, when the time comes early next week, to lay aside partisan differences, to support the tripartisan bill, the only bill that has a chance of succeeding here, and move on with the political process so we can work with the House of Representatives, pass it on to the President, who

I am quite sure will sign it, and begin providing a prescription drug benefit to our seniors.

Going all the way back to when Medicare was created, we treated people differently. Today we know medications are the primary method of treatment. We have to recognize that here in the Senate, something that all seniors understand very well. Let's recognize the reality, let's provide this drug benefit and really keep faith with the seniors we represent.

I suggest the absence of a quorum.

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

The legislative clerk proceeded to call the roll.

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

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

PRESCRIPTION DRUGS

Mrs. LINCOLN. Mr. President, in all the rhetoric and grandstanding about who has the best prescription drug plan, I truly do not want us to forget who we are trying to help.

I cannot possibly forget the 436,000 Medicare beneficiaries in Arkansas who struggle every single day to pay for the prescription drugs to control blood pressure, their heart, and help them cope with chronic diseases.

Yes, some seniors are eligible for Medicaid. Some have Medigap. But most of them fall through the cracks. In Arkansas, we don't have the tools that other States might have to help our seniors pay for their prescription drugs. Medicare+Choice has left our State. Medigap plans cost a lot more than the national average—almost 20 percent higher, to be exact, a year.

Employer-sponsored retiree health plans are extremely rare. On top of that, 60 percent of our seniors live in rural areas. So how do our seniors afford their prescription drugs, which rise in cost absolutely every year? The sad fact is, they don't.

The best way to combat this problem is add a prescription drug benefit to the Medicare Program. That is why I am so disappointed that neither of the Medicare prescription drug plans we will consider this next week seem to have the 60 votes they need to pass.

I am disappointed we are at a standstill in the Senate, and I am disappointed we have been unable to forge a compromise in the Senate Finance Committee. As a member of that committee, I would prefer to be debating these plans in that committee. However, I understand that the urgency of the issue and the timing of the Senate schedule has brought us here today.

In years past, I have been a cosponsor of Senator BOB GRAHAM's Medicare prescription drug bill. My colleague from Florida has invested a tremendous amount of time and effort in designing a benefit that senior citizens desire.

And he has done well. My constituents have told me how much they like the benefit package and the extra assistance for low-income beneficiaries. They like that the premium will be guaranteed at \$25 a month and will not vary State by State or region by region. This is good because in States such as Arkansas, we usually—almost always—get the short end of the stick when that happens. They like that the benefit is stable and universal and that it does not have a gap in coverage and is straightforward and simple.

Although I favor this plan, I did not cosponsor the bill this year in the hopes that I could help my colleagues on the Finance Committee forge a compromise that would work for seniors and that would have enough votes to pass the Senate. Unfortunately, that effort seems to have failed. I commend my chairman, Senator BAUCUS, for his efforts to try to shape a compromise between these two competing plans that we have before us today.

I also thank my friend from Louisiana, Senator JOHN BREAUX. Senator BREAUX, through serving on the National Bipartisan Commission on the Future of Medicare in 1997 and shaping the debate in Congress, has played a leading role in the national effort to improve the Medicare Program.

I appreciate the many meetings we have had on this issue and hope we have the ability to continue to work in that bipartisan fashion, working to forge compromises as we move forward on the Senate floor, as well as in conference.

I also want to recognize the tremendous amount of staff work that has been done, particularly and especially by my staff, Elizabeth MacDonald, all of the staff on the Finance Committee, as well as the Members who have had plans.

However, despite the changes Senator BREAUX, Senator GRASSLEY, and others have made to the tripartisan bill, I believe the bill still fails to offer an acceptable model to deliver prescription drugs to seniors in rural States such as Arkansas.

I cannot in good conscience vote for a plan that relies on the untried, untested delivery system laid out in the tripartisan plan. The private insurer model will require significant taxpayer subsidies to attract insurers into a drug-only insurance market, something we have never tried before. The insurance companies have told me they are hesitant to assume the risk for this type of plan unless they are heavily subsidized, and I do not think this is a proper use of our taxpayers' dollars. Nor can I support a plan that does not entitle seniors to any particular drug benefit but, rather, only a suggested benefit.

Consider for a moment the story of Mrs. Mildred Owens of Havana, AR. Mildred is 70 years old, and she worked for 35 years before retiring 5 years ago. Now widowed, Mildred receives about \$830 a month in Social Security and about \$125 a month in retirement.

Mildred takes prescription drugs which cost about \$200 a month. After paying her Medicare premium and drug expenses, she has spent well over 27 percent of her income. She said that she and her two sisters, Evalee and Betty, who each make about \$600 a month, do not even go to the doctor anymore because they cannot even afford the prescription drugs the doctor would prescribe. Sometimes Mildred and her sisters must rely on their children to help pay for some of their medications.

If the tripartisan plan were law and if Mildred and her sisters asked me what their monthly premium was going to be and what their benefits would be for prescription drug coverage under Medicare, I would have to say to them, actually, I do not know; I cannot give you a specific; we will have to wait and see what actually happens in our area. Mildred may, in fact, end up paying a different premium for prescription drugs than her friends pay in California or Florida or New York or other States. Yet they both paid taxes into Medicare all of their lives and therefore should be entitled to the same Medicare benefit.

The point is, we do not know yet what private plans might offer in different regions of the country. We do not know what their benefits would be. We do not know if private plans would want to participate. We do not know how much they would charge for it. And there is absolutely no guarantee that seniors would be able to depend on the same plan or benefit structure from year to year. These are just too many unknowns, and for seniors, nothing is more frightening than the unknown.

Why do we want to force our parents and grandparents into an untested delivery system that is unlike any other system in American health care as we know it?

Why should seniors in rural Arkansas, who are older and sicker and more likely to use prescription drugs, be in the dark about what their premiums will be until the Federal Government entices the private insurers to compete in their area of the country?

Why should we risk forcing them to pay higher premiums than those in urban areas?

Show me where it has worked. I ask my colleagues: Show me a study, show me a demonstration project. If the sponsors of the tripartisan plan are so confident that their delivery model will work, then I propose a compromise that could garner the 60 votes needed to pass a Medicare prescription drug plan.

Let's put a demonstration project in the home State of the bill's chief architects and use the Graham delivery model in Arkansas and the rest of the country so that we can be assured of what we are going to get until we know what works. Let's see if this untested delivery model works in a few States before we take it nationwide and put everyone at risk.

Why subject our seniors to a vast social experiment? Why should we subsidize private insurance companies when we should instead empower our seniors with the ability to afford the prescription drugs they need?

I am also concerned that the tripartisan bill has a gap in coverage, albeit a much smaller one than originally proposed. How can I tell seniors in my State that they will not receive any coverage for their drug costs between \$3,451 and \$5,300?

Although the tripartisan plan says it only contains a gap of \$250, in reality it is actually a gap of \$1,850 because the first threshold includes the combined expenditures of seniors and the Government, while the second only refers to the senior's out-of-pocket expenses.

How can I explain to Mildred Owens that no other American but Medicare beneficiaries will have this gap in coverage? Members of Congress and Federal employees do not face a gap in prescription drug coverage, nor do non-Federal retirees or employees. This gap in coverage for seniors who use more prescription drugs than any other population group in our country is not only unfair, it is simply unreasonable.

Further, this gap in coverage is opposed by the AARP, which counts about 350,000 Arkansans in their nationwide membership. AARP has surveyed their membership on the value of a prescription drug benefit and has identified five characteristics that any prescription drug benefit must include in order to attract the enrollees it needs. One of those characteristics is a benefit that does not expose beneficiaries to a gap in insurance coverage.

Mr. President, I ask unanimous consent to print a letter from the Arkansas AARP State chapter in the RECORD that shows how the tripartisan bill fails to meet the kitchen-table test that their Members will likely use when determining if the drug benefit is a good buy.

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

AARP,
Washington, DC, July 12, 2002.

HON. BLANCHE L. LINCOLN,
U.S. Senate,
Washington, DC.

DEAR SENATOR LINCOLN: Medicare beneficiaries cannot wait any longer for protection against the increasing cost of prescription drugs. The 439,000 Medicare beneficiaries in Arkansas need an affordable prescription drug benefit enacted into law this year.

Currently, about 13 million Medicare beneficiaries nationwide lack prescription drug coverage for the entire year and about 16 million lack coverage for some point during the year. State pharmacy assistance programs often provide some prescription drug benefits to low to moderate-income beneficiaries. However, as you know, Arkansas does not even have such a program to help meet the needs of low-income beneficiaries in the state.

The prescription drug legislation recently passed by the House of Representatives begins to move the Medicare program one step closer to providing millions of older Ameri-

cans and people with disabilities with some help against the rising costs of prescription drugs. But more needs to be done.

We know from our membership that they will assess the value of a prescription drug benefit by adding up the premium, coinsurance and deductible to determine if it is a good buy. We believe that in order for a voluntary Medicare prescription drug benefit to pass this "kitchen table test" and attract enough enrollee it should:

Provide an affordable benefit as a permanent part of Medicare's benefit package;

Keep the monthly premium to no more than \$35;

Ensure reasonable and stable cost-sharing for beneficiaries;

Ensure that there are no gaps in coverage that leave beneficiaries vulnerable;

Be voluntary and available to all beneficiaries no matter where they live;

Help to bring down the soaring costs of prescription drugs; and

Protect low-income beneficiaries.

It is critical that the Senate pass a Medicare prescription drug bill this month that meets these goals. The 205,000 AARP households in Arkansas are counting on your support for a prescription drug benefit at least as good as the Graham-Miller proposal.

If you have any questions please call one of us or have your staff call David Certner, Director of our Federal Affairs Department, at (202) 434-3750.

Sincerely,

WILLIAM D. NOVELLI,
Executive Director and
CEO.

Cecil Malone,
AARP Arkansas State
President.

MARIA REYNOLDS-DIAZ,
AARP Arkansas State
Director.

Mrs. LINCOLN. Mr. President, I am also hopeful that a compromise on the Medicare prescription drug benefit is imminent. I am ever optimistic that we can all agree on a good basic solution at the end of the day. We must not fall into the trap of all talk and no action once again. For the almost 4 years I have served in the Senate, I have continually gone home to my State of Arkansas, talked to seniors across our great State, and assured them that the Senate would act on a prescription drug package.

I can no longer in good faith continue to simply talk about the benefit that is so needed. Our parents and our grandparents are depending on us. It would be a national tragedy to let them all down.

We have talked and talked about it for years. Let us act this year and in this session. Let us not adjourn until we pass a Medicare prescription drug benefit that is meaningful and affordable for all seniors across this great country, no matter where they live.

ADDITIONAL STATEMENTS

FIFTIETH ANNIVERSARY OF THE ESTONIAN AMERICAN NATIONAL COUNCIL

● Ms. MIKULSKI. Mr. President, today I pay tribute to the 50th anniversary of the Estonian American National Council. On July 19, 1952, Estonian Americans founded this Council to preserve

the Estonian cultural heritage. For 50 years, it has provided an independent voice for the Estonian people in their successful campaign for human rights and democracy in their homeland.

The Estonian American National Council combined the strong spirits of America and Estonia in its fight for Estonian independence. Forcibly annexed and occupied by the Soviet Union in 1940, Estonians could not speak freely for themselves in their own homeland. But as the leader of the free world, the United States never recognized the Soviet Union's oppressive regimes in Estonia or its Baltic neighbors, Latvia, and Lithuania. So with the start of the cold war, Americans of Estonian descent established their own organization.

Half a century later, I visited Estonia. I was so happy to see the tremendous strides the country was making toward developing its democratic and market-based systems. Estonia is proving its abilities through high-tech initiatives in everything from cellular phones to paperless government. I also appreciate the Baltic States' renewed senses of culture while respecting the rights of Russian-speaking minorities.

As a founding member of the Senate Baltic Freedom Caucus, I applaud the work of the Estonian American National Council, a critical member of the Joint Baltic American National Committee. Together, America, Estonia and the other Baltic States are doing all they can in the war against terrorism. With America's support, Estonia, Lithuania, and Latvia are already contributing to our mutual security by developing modern armed forces, air surveillance systems, and participating in peacekeeping activities. I believe Estonia and its Baltic partners will make a wonderful contribution to NATO.

Since Estonia achieved independence in 1991, the Estonian American National Council has been instrumental in bringing America and Estonia together to make both countries more secure. The council has funded scholarships, schools, cultural activities, youth programs and exchange missions that have enhanced the ties that it began to build between America and Estonia many years ago. I am proud of the partnerships Maryland had built with Estonia through our National Guard and their Armed Forces, and the trade between our great cities and ports.

Everywhere I look, America's interest in strengthening its ties with Estonia and the other Baltic States is growing. I congratulate the council on its 50th anniversary, and I send my best wishes to the Estonia American community in Maryland and nationwide. You can count on me to continue to help promote a closer and more comprehensive relationship between the United States and Estonia. I ask my colleagues to join me in congratulating the Estonian American National Council on its contributions to America and Estonia for the last 50 years.●

LOCAL LAW ENFORCEMENT ACT OF 2001

● Mr. SMITH of Oregon. Mr. President, I rise today to speak about hate crimes legislation I introduced with Senator KENNEDY in March of last year. The Local Law Enforcement Act of 2001 would add new categories to current hate crimes legislation sending a signal that violence of any kind is unacceptable in our society.

I would like to describe a terrible crime that occurred September 17, 1997, in Chicago, IL. Two minors pushed a gay man down a flight of stairs because of his sexual orientation. The assailants used anti-gay obscenities during the attack.

I believe that government's first duty is to defend its citizens, to defend them against the harms that come out of hate. The Local Law Enforcement Enhancement Act of 2001 is now a symbol that can become substance. I believe that by passing this legislation and changing current law, we can change hearts and minds as well.●

MEASURES REFERRED

The following bill was read the first and the second times by unanimous consent, and referred as indicated:

H.R. 5118. An act to provide for enhanced penalties for accounting and auditing improprieties at publicly traded companies, and for other purposes; to the Committee on the Judiciary.

EXECUTIVE AND OTHER COMMUNICATIONS

The following communications were laid before the Senate, together with accompanying papers, reports, and documents, which were referred as indicated:

EC-8005. A communication from the Director, Office of Personnel Management, transmitting, pursuant to law, the Report on Federal Agencies' Use of the Physicians' Comparability Allowance (PCA) Program for 2002; to the Committee on Governmental Affairs.

EC-8006. A communication from the Chair of the Board of Directors, Corporation for Public Broadcasting, transmitting, pursuant to law, the report of the Office of the Inspector General for the period October 1, 2001 through March 31, 2002; to the Committee on Governmental Affairs.

EC-8007. A communication from Chairman of the Federal Housing Finance Board, transmitting, pursuant to law, the report of the Office of the Inspector General for the period from October 1, 2001 through March 31, 2002; to the Committee on Governmental Affairs.

EC-8008. A communication from the Chairman of the Council of the District of Columbia, transmitting, pursuant to law, a report on D.C. Act 14-404, "Tax Clarity and Recorder of Deeds Temporary Act of 2002"; to the Committee on Governmental Affairs.

EC-8009. A communication from the Chairman of the Broadcasting Board of Governors, transmitting, pursuant to law, the report of the Office of the Inspector General for the period from October 1, 2001 through March 31, 2002; to the Committee on Governmental Affairs.

EC-8010. A communication from the Director, Regulations Policy and Management

Staff, Food and Drug Administration, Department of Health and Human Services, transmitting, pursuant to law, the report of a rule entitled "Sunscreen Drug Products for Over-the-Counter Human Use; Final Monograph; Technical Amendment" (RIN0910-AA01) received on July 16, 2002; to the Committee on Health, Education, Labor, and Pensions.

EC-8011. A communication from the Director, Corporation Policy and Research Department, Pension Benefit Guaranty Corporation, transmitting, pursuant to law, the report of a rule entitled "Benefits Payable in Terminated Single-Employer Plans; Allocation of Assets in Single-Employer Plans; Interest Assumptions for Valuing and Paying Benefits" received on July 16, 2002; to the Committee on Health, Education, Labor, and Pensions.

EC-8012. A communication from the Chief Executive Officer, Corporation for National and Community Service, transmitting, pursuant to law, the report of a vacancy in the position of Inspector General, received on June 26, 2002 referred jointly, pursuant to the order of January 30, 1975 as modified by the order of April 11, 1986, to the Committees on Health, Education, Labor, and Pensions; and Governmental Affairs.

EC-8013. A communication from the Chief of the Regulations Branch, Customs Service, Department of the Treasury, transmitting, pursuant to law, the report of a rule entitled "Import Restrictions Imposed on Pre-Classical and Classical Archaeological Material Originating in Cyprus" (RIN1515-AC86) received on July 16, 2002; to the Committee on Finance.

EC-8014. A communication from the Chief of the Regulations Unit, Internal Revenue Service, Department of the Treasury, transmitting, pursuant to law, the report of a rule entitled "Modification of Rev. Proc. 96-13" (Rev. Proc. 2002-52) received on July 14, 2002; to the Committee on Finance.

EC-8015. A communication from the Acting Director, Office of Regulatory Law, Board of Veterans' Affairs, Department of Veterans' Affairs, transmitting, pursuant to law, the report of a rule entitled "Board of Veterans' Appeals: Rules of Practice—Effect of Procedural Defects in Motions for Revision of Decisions on the Grounds of Clear and Unmistakable Error" (RIN2900-AK74) received on July 14, 2002; to the Committee on Veterans' Affairs.

EC-8016. A communication from the Acting Director, Office of Regulatory Law, Board of Veterans' Affairs, Department of Veterans' Affairs, transmitting, pursuant to law, the report of a rule entitled "Adjudication; Fiduciary Activities—Nomenclature Changes" (RIN2900-AL10) received on July 14, 2002; to the Committee on Veterans' Affairs.

EC-8017. A communication from the Acting Director, Office of Regulatory Law, Board of Veterans' Affairs, Department of Veterans' Affairs, transmitting, pursuant to law, the report of a rule entitled "Policy Regarding Participation in Natural Practitioner Data Bank" (RIN2900-AJ76) received on July 14, 2002; to the Committee on Veterans' Affairs.

EC-8018. A communication from the Director, Office of Standards, Regulations and Variances, Mine Safety and Health Administration, transmitting, pursuant to law, the report of a rule entitled "Hazard Communication (HazCom)" (RIN1219-AA47) received on July 14, 2002; to the Committee on Energy and Natural Resources.

EC-8019. A communication from the Assistant Secretary, Land and Minerals Management, Engineering and Operations Division, Minerals Management Service, Department of the Interior, transmitting, pursuant to law, the report of a rule entitled "Prospecting for Minerals Other Than Oil,

Gas, and Sulphur on the Outer Continental Shelf” (RIN1010-AC48) received on July 16, 2002; to the Committee on Energy and Natural Resources.

EC-8020. A communication from the Assistant Secretary, Land and Minerals Management, Engineering and Operations Division, Minerals Management Service, Department of the Interior, transmitting, pursuant to law, the report of a rule entitled “Oil and Gas and Sulphur Operations in the Outer Continental Shelf—Document Incorporated by Reference—API RP 14C” (RIN1010-AC93) received on July 16, 2002; to the Committee on Energy and Natural Resources.

EC-8021. A communication from the Secretary of the Interior, transmitting, pursuant to law, the 2001 Annual Report of the Office of Surface Mining (OSM); to the Committee on Energy and Natural Resources.

EC-8022. A communication from the Register Liaison Officer, Office of the Secretary, Department of Defense, transmitting, pursuant to law, the report of a rule entitled “TRICARE Partial Implementation of Pharmacy Benefits; Implementation of National Defense Authorization Act for Fiscal Year 2001” (RIN0720-AA62) received on July 16, 2002; to the Committee on Armed Services.

EC-8023. A communication from the Deputy Secretary of Defense, transmitting, pursuant to law, a report on outreach to Gulf War veterans, the revision of Physical Evaluation Board criteria and the review of records and re-evaluation of the ratings of previously discharged Gulf War veterans for calendar year 2001; to the Committee on Armed Services.

EC-8024. A communication from the Chief, Programs and Legislation Division, Office of Legislative Liaison, Department of the Air Force, transmitting, pursuant to law, a report relative to initiating a standard cost comparison of the Aircraft Maintenance and Support Activities at Edwards Air Force Base, California; to the Committee on Armed Services.

EC-8025. A communication from the Under Secretary of Defense, Acquisition, Technology, and Logistics, transmitting, pursuant to law, reports that set out the current amount of outstanding contingent liabilities of the United States for vessels insured under the authority of title XII of the Merchant Marine Act of 1936, and for aircraft insured under the authority of chapter 433 of Title 49, United States Code; to the Committee on Armed Services.

EC-8026. A communication from the Under Secretary of Defense, Acquisition, Technology, and Logistics, transmitting, pursuant to law, the annual report detailing test and evaluation activities of the Foreign Comparative Testing (FCT) Program for Fiscal Year 2001; to the Committee on Armed Services.

EC-8027. A communication from the Chief of Regulations and Administrative Law, United States Coast Guard, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled “Safety/Security Zone Regulations; Captain of the Port Chicago Zone, Lake Michigan” (RIN2115-AA97)(2002-0142) received on July 16, 2002; to the Committee on Commerce, Science, and Transportation.

EC-8028. A communication from the Chief of Regulations and Administrative Law, United States Coast Guard, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled “Safety/Security Zone Regulations; Seabrook Nuclear Power Plant, Seabrook, NH” (RIN2115-AA97)(2002-0136) received on July 16, 2002; to the Committee on Commerce, Science, and Transportation.

EC-8029. A communication from the Chief of Regulations and Administrative Law,

United States Coast Guard, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled “Safety/Security Zone Regulations; High Interest Vessel Transits, Narragansett Bay, Providence River, and Tounton River, Rhode Island” ((RIN2115-AA97)(2002-0137)) received on July 16, 2002; to the Committee on Commerce, Science, and Transportation.

EC-8030. A communication from the Chief of Regulations and Administrative Law, United States Coast Guard, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled “Safety/Security Zone Regulations; Captain of the Port of Detroit Zone, Selfridge Air National Guard Base, Lake St. Clair” ((RIN2115-AA97)(2002-0138)) received on July 16, 2002; to the Committee on Commerce, Science, and Transportation.

EC-8031. A communication from the Chief of Regulations and Administrative Law, United States Coast Guard, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled “Safety/Security Zone Regulations; Annual Fireworks Event in the Captain of the Port Milwaukee Zone” ((RIN2115-AA97)(2002-0139)) received on July 16, 2002; to the Committee on Commerce, Science, and Transportation.

EC-8032. A communication from the Chief of Regulations and Administrative Law, United States Coast Guard, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled “Safety/Security Zone Regulations; Limited Service Domestic Voyage Load Lines for River Barges on Lake Michigan” ((RIN2115-AA97)(2002-0132)) received on July 16, 2002; to the Committee on Commerce, Science, and Transportation.

EC-8033. A communication from the Chief of Regulations and Administrative Law, United States Coast Guard, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled “Safety/Security Zone Regulations; Waters Adjacent to San Onofre, San Diego County, CA” ((RIN2115-AA97)(2002-0133)) received on July 16, 2002; to the Committee on Commerce, Science, and Transportation.

EC-8034. A communication from the Chief of Regulations and Administrative Law, United States Coast Guard, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled “Safety/Security Zone Regulations; Ports of Houston and Galveston, TX” ((RIN2115-AA97)(2002-0134)) received on July 16, 2002; to the Committee on Commerce, Science, and Transportation.

EC-8035. A communication from the Chief of Regulations and Administrative Law, United States Coast Guard, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled “Safety/Security Zone Regulations; St. Croix, U.S. Virgin Islands” ((RIN2115-AA97)(2002-0135)) received on July 16, 2002; to the Committee on Commerce, Science, and Transportation.

EC-8036. A communication from the Chief of Regulations and Administrative Law, United States Coast Guard, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled “Safety/Security Zone Regulations; Missouri River, Mile Marker 646.0 to 645.6, Fort Calhoun, Nebraska” ((RIN2115-AA97)(2002-0153)) received on July 16, 2002; to the Committee on Commerce, Science, and Transportation.

EC-8037. A communication from the Chief of Regulations and Administrative Law, United States Coast Guard, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled “Safety/Security Zone Regulations; Upper Mississippi River, Mile Marker 507.3 to 506.3, Left Descending Bank, Cordova, IL” ((RIN2115-

AA97)(2002-0152)) received on July 16, 2002; to the Committee on Commerce, Science, and Transportation.

EC-8038. A communication from the Chief of Regulations and Administrative Law, United States Coast Guard, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled “Safety/Security Zone Regulations; San Francisco Bay, San Francisco, CA” ((RIN2115-AA97)(2002-0151)) received on July 16, 2002; to the Committee on Commerce, Science, and Transportation.

EC-8039. A communication from the Chief, Regulations and Administrative Law, United States Coast Guard, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled “Safety/Security Zone Regulations; Captain of the Port Toledo Zone, Lake Erie” ((RIN2115-AA97)(2002-0164)) received on July 16, 2002; to the Committee on Commerce, Science, and Transportation.

EC-8040. A communication from the Chief, Regulations and Administrative Law, United States Coast Guard, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled “Drawbridge Regulations; Pelican Island Causeway, Calveston Channel, TX” ((RIN2115-AE47)(2002-0068)) received on July 16, 2002; to the Committee on Commerce, Science, and Transportation.

EC-8041. A communication from the Chief, Regulations and Administrative Law, United States Coast Guard, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled “Regatta Regulations; Beaufort Water Festival July 12th Fireworks Display, Beaufort River, Beaufort, SC” ((RIN2115-AE46)(2002-0025)) received on July 16, 2002; to the Committee on Commerce, Science, and Transportation.

EC-8042. A communication from the Chief, Regulations and Administrative Law, United States Coast Guard, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled “Safety/Security Zone Regulations; High Interest Vessels—Boston Harbor, Waymouth Fore River, and Salem Harbor, Massachusetts” ((RIN2115-AA97)(2002-0141)) received on July 16, 2002; to the Committee on Commerce, Science, and Transportation.

EC-8043. A communication from the Chief, Regulations and Administrative Law, United States Coast Guard, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled “Safety/Security Zone Regulations; Lake Ontario, Oswego, NY” ((RIN2115-AA97)(2002-0154)) received on July 16, 2002; to the Committee on Commerce, Science, and Transportation.

EC-8044. A communication from the Chief, Regulations and Administrative Law, United States Coast Guard, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled “Safety/Security Zone Regulations; Liquefied Natural Gas Carrier Transits and Anchorage Operations, Boston Marine Inspection Zone and Captain of the Port Zone” ((RIN2115-AA97)(2002-0140)) received on July 16, 2002; to the Committee on Commerce, Science, and Transportation.

EC-8045. A communication from the Chief, Regulations and Administrative Law, United States Coast Guard, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled “Safety/Security Zone Regulations; Sag Harbor Fireworks Display, Sag Harbor, NY” ((RIN2115-AA97)(2002-0143)) received on July 16, 2002; to the Committee on Commerce, Science, and Transportation.

EC-8046. A communication from the Chief, Regulations and Administrative Law, United States Coast Guard, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled “Drawbridge Regulations; Chicago River” ((RIN2115-

AE47)(2002-0066)) received on July 16, 2002; to the Committee on Commerce, Science, and Transportation.

EC-8047. A communication from the Chief, Regulations and Administrative Law, United States Coast Guard, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled "Drawbridge Regulations; Lady's Island Bridge, Atlantic Intracoastal Waterway (AIWW), Beaufort, SC" ((RIN2115-AE47)(2002-0067)) received on July 16, 2002; to the Committee on Commerce, Science, and Transportation.

EC-8048. A communication from the Chief, Regulations and Administrative Law, United States Coast Guard, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled "Safety/Security Zone Regulations; Lake Huron, Harbor Beach, MI" ((RIN2115-AA97)(2002-0147)) received on July 16, 2002; to the Committee on Commerce, Science, and Transportation.

EC-8049. A communication from the Chief, Regulations and Administrative Law, United States Coast Guard, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled "Safety/Security Zone Regulations; Ohio River Miles 355.5 to 356.5, Portsmouth, Ohio" ((RIN2115-AA97)(2002-0148)) received on July 16, 2002; to the Committee on Commerce, Science, and Transportation.

EC-8050. A communication from the Chief, Regulations and Administrative Law, United States Coast Guard, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled "Safety/Security Zone Regulations; Port Hueneme Harbor, Ventura County, CA" ((RIN2115-AA97)(2002-0149)) received on July 16, 2002; to the Committee on Commerce, Science, and Transportation.

EC-8051. A communication from the Chief, Regulations and Administrative Law, United States Coast Guard, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled "Safety/Security Zone Regulations; Missouri River, Mile Marker 532.9 to 532.5, Brownsville, Nebraska" ((RIN2115-AA97)(2002-0150)) received on July 16, 2002; to the Committee on Commerce, Science, and Transportation.

EC-8052. A communication from the Chief, Regulations and Administrative Law, United States Coast Guard, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled "Safety/Security Zone Regulations; Boston and Salem Harbors, MA" ((RIN2115-AA97)(2002-0145)) received on July 16, 2002; to the Committee on Commerce, Science, and Transportation.

EC-8053. A communication from the Chief, Regulations and Administrative Law, United States Coast Guard, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled "Safety/Security Zone Regulations; Port of Palm Beach, Palm Beach, FL; Port Everglades, Fort Lauderdale, FL; Port of Miami, Miami, FL, and Port of Key West, Key West, FL; Hutchinson Island Power Plant, St. Lucie, FL, and Turkey Point Power Plant, Florida City, FL" ((RIN2115-AA97)(2002-0144)) received on July 16, 2002; to the Committee on Commerce, Science, and Transportation.

EC-8054. A communication from the Chief, Regulations and Administrative Law, United States Coast Guard, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled "Safety/Security Zone Regulations; Seafair Blue Angels Performance, Lake Washington, WA" ((RIN2115-AA97)(2002-0146)) received on July 16, 2002; to the Committee on Commerce, Science, and Transportation.

EC-8055. A communication from the Chief, Regulations and Administrative Law, United States Coast Guard, Department of Trans-

portation, transmitting, pursuant to law, the report of a rule entitled "Regatta Regulations; Deerfield Beach Super Boat Race, Deerfield Beach, FL" ((RIN2115-AE46)(2002-0026)) received on July 16, 2002; to the Committee on Commerce, Science, and Transportation.

EC-8056. A communication from the Chief, Regulations and Administrative Law, United States Coast Guard, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled "Safety/Security Zone Regulations; Lake Michigan, Point Beach Nuclear Power Plant" ((RIN2115-AA97)(2002-0157)) received on July 16, 2002; to the Committee on Commerce, Science, and Transportation.

EC-8057. A communication from the Chief, Regulations and Administrative Law, United States Coast Guard, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled "Revise Options for Responding to Notices of Violations" ((RIN2115-AG15)(2002-0001)) received on July 16, 2002; to the Committee on Commerce, Science, and Transportation.

EC-8058. A communication from the Chief, Regulations and Administrative Law, United States Coast Guard, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled "Safety/Security Zone Regulations; Saint Lawrence River, Massena, NY" ((RIN2115-AA97)(2002-0155)) received on July 16, 2002; to the Committee on Commerce, Science, and Transportation.

EC-8059. A communication from the Chief, Regulations and Administrative Law, United States Coast Guard, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled "Safety/Security Zone Regulations; Lake Michigan, Kewaunee Nuclear Power Plant" ((RIN2115-AA97)(2002-0156)) received on July 16, 2002; to the Committee on Commerce, Science, and Transportation.

EC-8060. A communication from the Chief, Regulations and Administrative Law, United States Coast Guard, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled "Safety/Security Zone Regulations; New York Marine Inspection Zone and Captain of the Port Zone" ((RIN2115-AA97)(2002-0161)) received on July 16, 2002; to the Committee on Commerce, Science, and Transportation.

EC-8061. A communication from the Chief, Regulations and Administrative Law, United States Coast Guard, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled "Safety/Security Zone Regulations; Cruise Ships, Port of San Diego, CA" ((RIN2115-AA97)(2002-0160)) received on July 16, 2002; to the Committee on Commerce, Science, and Transportation.

EC-8062. A communication from the Chief, Regulations and Administrative Law, United States Coast Guard, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled "Safety/Security Zone Regulations; Calvert Cliffs Nuclear Power Plant, Chesapeake Bay, Calvert County, MD" ((RIN2115-AA97)(2002-0159)) received on July 16, 2002; to the Committee on Commerce, Science, and Transportation.

EC-8063. A communication from the Chief, Regulations and Administrative Law, United States Coast Guard, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled "Safety/Security Zone Regulations; Lake Ontario, Rochester, NY" ((RIN2115-AA97)(2002-0158)) received on July 16, 2002; to the Committee on Commerce, Science, and Transportation.

EC-8064. A communication from the Chief, Regulations and Administrative Law, United States Coast Guard, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled "Drawbridge Regu-

lations; Inner Harbor Navigation Canal, LA" ((RIN2115-AE47)(2002-0071)) received on July 16, 2002; to the Committee on Commerce, Science, and Transportation.

EC-8065. A communication from the Chief, Regulations and Administrative Law, United States Coast Guard, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled "Drawbridge Regulations; Sanibel Causeway Bridge, Okeechobee Waterway, Punta Rassa, FL" ((RIN2115-AE47)(2002-0070)) received on July 16, 2002; to the Committee on Commerce, Science, and Transportation.

EC-8066. A communication from the Chief, Regulations and Administrative Law, United States Coast Guard, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled "Drawbridge Regulations; Commercial Boulevard Bridge (SR 870), Atlantic Intracoastal Waterway, Mile 1059.0, Lauderdale-by-the-Sea, Broward County, FL" ((RIN2115-AE47)(2002-0069)) received on July 16, 2002; to the Committee on Commerce, Science, and Transportation.

EC-8067. A communication from the Chief, Regulations and Administrative Law, United States Coast Guard, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled "Wearing of Personal Flotation Devices (PFDs) by Certain Children aboard Recreational Vessels" ((RIN2115-AG04)(2002-0003)) received on July 16, 2002; to the Committee on Commerce, Science, and Transportation.

EC-8068. A communication from the Chief, Regulations and Administrative Law, United States Coast Guard, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled "Wearing of Personal Flotation Devices (PFDs) by Certain Children aboard Recreational Vessels" ((RIN2115-AG04)(2002-0002)) received on July 16, 2002; to the Committee on Commerce, Science, and Transportation.

EC-8069. A communication from the Chief, Regulations and Administrative Law, United States Coast Guard, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled "Safety/Security Zone Regulations; Gary Air and Water Show, Lake Michigan, Gary, IN" ((RIN2115-AA97)(2002-0163)) received on July 16, 2002; to the Committee on Commerce, Science, and Transportation.

REPORTS OF COMMITTEES

The following reports of committees were submitted:

By Mr. BYRD, from the Committee on Appropriations, without amendment:

S. Res. 304. An original resolution encouraging the Senate Committee on Appropriations to report thirteen, fiscally responsible, bipartisan appropriations bills to the Senate not later than July 31, 2002.

INTRODUCTION OF BILLS AND JOINT RESOLUTIONS

The following bills and joint resolutions were introduced, read the first and second times by unanimous consent, and referred as indicated:

By Mr. ENZI (for himself, Mr. LIEBERMAN, Mr. ALLEN, Mrs. BOXER, Mr. BURNS, Mr. FRIST, and Mr. ENSIGN):

S. 2760. A bill to direct the Securities and Exchange Commission to conduct a study and make recommendations regarding the accounting treatment of stock options for purposes of the Federal securities laws; to the Committee on Banking, Housing, and Urban Affairs.

By Mr. FEINGOLD:

S. 2761. A bill to amend the Internal Revenue Code of 1986 to provide that reimbursements for costs of using passenger automobiles for charitable and other organizations are excluded from gross income, and for other purposes; to the Committee on Finance.

By Mr. THOMAS (for himself, Mr. ENZI, and Mr. HAGEL):

S. 2762. A bill to amend the Internal Revenue Code of 1986 to provide involuntary conversion tax relief for producers forced to sell livestock due to weather-related conditions or Federal land management agency policy or action, and for other purposes; to the Committee on Finance.

By Mrs. FEINSTEIN (for herself, Mr. HUTCHINSON, and Mr. KOHL):

S. 2763. A bill to respond to the illegal production, distribution, and use of methamphetamines in the United States, and for other purposes; to the Committee on the Judiciary.

By Mr. MILLER:

S. 2764. A bill to eliminate the Federal quota and price support programs for tobacco, to compensate quota holder and active producers for the loss of tobacco quota asset value, to establish a permanent advisory board to determine and describe the physical characteristics of domestic and imported tobacco, and for other purposes; to the Committee on Finance.

SUBMISSION OF CONCURRENT AND SENATE RESOLUTIONS

The following concurrent resolutions and Senate resolutions were read, and referred (or acted upon), as indicated:

By Mr. BYRD:

S. Res. 304. An original resolution encouraging the Senate Committee on Appropriations to report thirteen, fiscally responsible, bipartisan appropriations bills to the Senate not later than July 31, 2002; from the Committee on Appropriations; placed on the calendar.

ADDITIONAL COSPONSORS

S. 486

At the request of Mr. LEAHY, the name of the Senator from Washington (Mrs. MURRAY) was added as a cosponsor of S. 486, a bill to reduce the risk that innocent persons may be executed, and for other purposes.

S. 668

At the request of Mr. AKAKA, the name of the Senator from New Jersey (Mr. TORRICELLI) was added as a cosponsor of S. 668, a bill to amend the Animal Welfare Act to ensure that all dogs and cats used by research facilities are obtained legally.

S. 2047

At the request of Mr. BREAUX, the names of the Senator from North Dakota (Mr. DORGAN) and the Senator from Nebraska (Mr. NELSON) were added as cosponsors of S. 2047, a bill to amend the Internal Revenue Code of 1986 to allow distilled spirits wholesalers a credit against income tax for their cost of carrying Federal excise taxes prior to the sale of the product bearing the tax.

S. 2076

At the request of Mr. JOHNSON, his name was withdrawn as a cosponsor of S. 2076, a bill to prohibit the cloning of humans.

S. 2194

At the request of Mrs. FEINSTEIN, the name of the Senator from Arkansas (Mrs. LINCOLN) was added as a cosponsor of S. 2194, a bill to hold accountable the Palestine Liberation Organization and the Palestinian Authority, and for other purposes.

S. 2268

At the request of Mr. MILLER, the names of the Senator from New Mexico (Mr. DOMENICI) and the Senator from Oklahoma (Mr. INHOFE) were added as cosponsors of S. 2268, a bill to amend the Act establishing the Department of Commerce to protect manufacturers and sellers in the firearms and ammunition industry from restrictions on interstate or foreign commerce.

S. 2667

At the request of Mr. DODD, the name of the Senator from Vermont (Mr. LEAHY) was added as a cosponsor of S. 2667, a bill to amend the Peace Corps Act to promote global acceptance of the principles of international peace and nonviolent coexistence among peoples of diverse cultures and systems of government, and for other purposes.

S. 2684

At the request of Mrs. CLINTON, the name of the Senator from New Hampshire (Mr. GREGG) was added as a cosponsor of S. 2684, a bill to amend the Atomic Energy Act of 1954 to establish a task force to identify legislative and administrative action that can be taken to ensure the security of sealed sources of radioactive material, and for other purposes.

S. 2727

At the request of Mr. AKAKA, the name of the Senator from Hawaii (Mr. INOUE) was added as a cosponsor of S. 2727, a bill to provide for the protection of paleontological resources on Federal lands, and for other purposes.

S. 2736

At the request of Mr. HAGEL, the name of the Senator from Pennsylvania (Mr. SANTORUM) was added as a cosponsor of S. 2736, a bill to amend title XVIII of the Social Security Act to provide medicare beneficiaries with a drug discount card that ensures access to affordable outpatient prescription drugs.

S. CON. RES. 128

At the request of Mr. DODD, the name of the Senator from New York (Mrs. CLINTON) was added as a cosponsor of S. Con. Res. 128, a concurrent resolution honoring the invention of modern air conditioning by Dr. Willis H. Carrier on the occasion of its 100th anniversary.

AMENDMENT NO. 4305

At the request of Ms. STABENOW, the name of the Senator from California (Mrs. BOXER) was added as a cosponsor of amendment No. 4305 proposed to S. 812, a bill to amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals.

STATEMENTS ON INTRODUCED BILLS AND JOINT RESOLUTIONS

By Mr. ENZI (for himself, Mr. LIEBERMAN, Mr. ALLEN, Mrs.

BOXER, Mr. BURNS, Mr. FRIST, and Mr. ENSIGN):

S. 2760. A bill to direct the Securities and Exchange Commission to conduct a study and make recommendations regarding the accounting treatment of stock options for purposes of the Federal securities laws; to the Committee on Banking, Housing, and Urban Affairs.

Mr. ENZI. Mr. President, I rise today to introduce the Enzi-Lieberman-Allen-Boxer amendment on stock options. Our bipartisan amendment helps solve many of the perceived problems with the issuance of stock options by giving the SEC a broad mandate to look into and analyze numerous issues concerning stock options, including disclosure, corporate governance, and the benefits and detriments of expensing stock options.

After its analysis, the SEC will be required to furnish recommendations, if any, for changes in corporate America's uses of stock options, and we envision that being done through FASB. We are not trying to tell FASB, the Federal Accounting Standards Board, how to do their work; we are trying to provide them with more information so they can make a consideration of that issue again.

I and the other original cosponsors of this bill have sent a letter to Chairman Harvey Pitt and the other Commissioners on the SEC asking them to initiate on their own the action items outlined in our bill and to make recommendations on these issues in the next 60 days. I hope they take such initiative.

Mr. President, I ask unanimous consent the letter be printed in the RECORD.

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

U.S. SENATE,

Washington, DC, July 19, 2002.

Hon. HARVEY L. PITT, Chairman,
Hon. ISAAC C. HUNT, Jr., Commissioner,
Hon. CYNTHIA A. GLASSMAN, Commissioner,
Mr. ROBERT K. HERDMAN, Chief Accountant,
Securities and Exchange Commission, Washington, DC.

DEAR CHAIRMAN PITT, COMMISSIONERS HUNT AND GLASSMAN, AND MR. HERDMAN: We are writing to request that the Securities and Exchange Commission (SEC) analyze and propose recommendations, if needed, on issues regarding stock options. We have introduced legislation mandating such action by the Commission, but ask that you proceed before this legislation is enacted.

The legislation is the Stock Option Fairness and Accountability Act. This legislation focuses on key issues regarding stock options, which include stock option pricing models; disclosure to investors and shareholders; shareholder approval of stock option plans; and restrictions on senior management sale of stock. The bill also mandates a review of the benefits and detriments of any new options expensing rules on the productivity and performance of companies and start-up enterprises, the recruitment retention of skilled workers, and employees at various income levels, with particular focus

on the effect on rank-and-file employees and the income of women.

It is our view the debate on stock options has focused narrowly on the accounting of stock options, and failed to focus on other critical stock option policy issues. We seek to broaden the debate to ensure that Congress, the Commission, and other relevant agencies take action to eliminate any problems which might exist with stock options, while ensuring their benefits are retained.

We believe options should be preserved and protected because, when they are properly structured, they are incentives for productivity and growth. In most instances, they reflect America's best business values—the willingness to take business risks, the vision to develop new entrepreneurial companies and technologies, a way to broaden ownership and participation among employees, and a strong performance incentive for both management and employees. We should focus on strengthening stock option incentives and enabling them to yield even greater economic growth dividends for our economy.

In general, we believe the Senate should not be legislating detailed accounting or regulatory standards regarding stock options or other accounting issues. These are issues best left to the SEC and its expert staff. The Financial Accounting Standards Board (FASB) has independent authority to set accounting standards, and should continue to do so. That is why our legislation and this letter request that the Commission address all of these issues and make recommendations.

Regarding shareholder approval of stock option plans, a Special Committee of New York Stock Exchange recommended shareholder approval of all stock option plans, while the NASDAQ has recommended shareholder approval of any plan that includes officers and directors. We want the SEC to examine whether these measures are adequate, and whether any additional accountability to shareholders is needed.

Current disclosure requirements for stock options exist which focus on the potential cost of stock options when they are exercised, the potential dilution of earnings per share, and other issues. We believe the SEC should look at whether these disclosure rules should be strengthened in order to provide investors and shareholders more accurate and complete information.

We understand that restricting the sale of stock acquired through stock option plans is a complex and controversial issue. We ask you to review whether a need exists for imposition of a holding period for senior executives and whether the benefits of such a rule would outweigh the costs. Should you recommend such a rule, we suggest you also review whether any exemptions are necessary, given individuals may have a legitimate need to sell stock to raise cash to pay taxes on their options or for personal emergencies. We urge you to also consider whether a holding period might impose a special burden on small companies and start-up enterprises, where stock options form a greater proportion of employee compensation.

We appreciate the assistance of the Commission addressing these vital issues and promptly making recommendations. We believe we have presented you with a comprehensive agenda of stock option policy issues, which will ensure positive action is taken to restore investor and shareholder confidence, calm and markets, and prevent perceived problems associated with stock options. We look forward to receiving a response with your recommendations and plan for action within 60 days.

Sincerely,

Senator Mike Enzi, Senator Joseph Lieberman, Senator Barbara Boxer,

Senator Conrad Burns, Senator John Ensign, Senator George Allen, Senator Bill Frist.

Mr. ENZI. How did we get here, to this point of perhaps possibly legislating on stock options? The debate on stock options became heated over the last few months, following the accounting debacles of Enron, WorldCom, and Global Crossing. I think we can all agree that the use of stock options did not cause the demise of these companies, but nevertheless their use by these and other companies has become increasingly scrutinized during the current accounting debate and evidence of top executive abuse.

What initially raised everyone's attention to stock options was Enron. As we all know, Enron's executives and employees were issued numerous stock options. It is now clear that months before Enron filed for bankruptcy, executives who were aware of the true condition of the company, exercised millions of dollars of their options. Now, Enron employees—kept in the dark on company finances—are left with worthless Enron stock and retirement savings. While these Enron executives absconded with money from the sell of stock options, we all know the financial collapse of Enron had little to do with its accounting procedures on stock options. Enron went bankrupt. Nevertheless, concerns about stock option use by corporations have become magnified.

We all know that when properly used, stock options can be a marvelous opportunity for all employees. In addition, small businesses and startup companies use stock options as an incentive and sometimes the only means to attract qualified employees.

There have been many suggestions on what will stop future Enrons, and included in that debate has been a discussion on improving the accounting practices and other issues concerning stock options. Some members have come up with some creative and not so creative ideas on how to improve their use.

Some have not considered how their ideas will affect rank-and-file employees, while others have kept that as their primary consideration. Some members have proposed setting a new expensing standard or directing the Federal Accounting Standards Board to take some specific action in setting new expensing rules. But, these amendments have pre-ordained what the solution to stock options will be.

Members promoting these amendments are furnishing their own conclusions. They mandate either codification of new expensing rules, or direct the Federal Accounting Standards Board, known as FASB, to require stock option expensing at the time of grant or exercise. This is a conclusion some of us do not believe should be made by non-experts in Congress, without careful analysis.

Our bipartisan amendment is different. It doesn't preordain what the solution to stock options will be. In-

stead, it directs the SEC to analyze the treatment of stock options in several categories, not just stock option expensing, and lend its superior expertise in furnishing a report and making useful recommendations.

This is a smart amendment because 99 non-accountant Senators, and one accountant Senator, all without expertise in securities accounting and law, have no business making a definitive decision on what the answer to stock option problems should be. Instead, the SEC should analyze the problem and make recommendations on what is needed.

Let me get to the specifics of our amendment. First, it requires an analysis of the accounting treatment of employee stock options, including the accuracy of available stock option pricing models. What are these models?

Currently, companies estimate the value of granted stock options using something called the Black-Scholes model. This is because they do not know what the future value of their stock will be when the options are actually exercised and sold. So they make an educated guess with the Black-Scholes model.

However, many believe the current practice of using the Black-Scholes method to value stock options, as currently used on footnotes, is fatally flawed. This method will be just as flawed if it must be used for expensing stock options at the time of grant. This amendment directs the SEC to look at the accuracy of this and other pricing models.

Second, our amendment directs the SEC to analyze the adequacy of current disclosure requirements to investors and shareholders on stock options. The SEC needs to determine whether better disclosure provisions would solve the current, perceived problem with stock option reporting. The SEC can study what further disclosure and transparency provisions, if any, would be useful.

We do not know what the SEC's recommendations might be. They might include a recommendation for user-friendly disclosure in clear, plain English with graphs and charts, which are comparable with other company disclosures. They might recommend increased quarterly reporting on certain information.

Even high profile financial celebrities have differing view on expensing and disclosure. Like me, Secretary O'Neill has advocated fuller disclosure as a means to cure the present perceived problems with the information provided to investors and shareholders in footnotes on company financial statements, rather than expensing. Others, like Warren Buffet, have said fuller disclosure and transparency will not cure these problems, and Congress should do something about expensing. Alan Greenspan believes expensing of stock options at the time of grant is needed, but that Congress should not be the one deciding this or setting accounting standards.

Given these differing views by financial heavy weights like Secretary O'Neill, Greenspan and Buffett, it makes sense to let the SEC analyze this issue and make the determination of what, if any, disclosure improvements are necessary, taking into account the effect on all affected parties—companies, shareholders, investors, and rank-and-file employees.

Next, our amendment would direct the SEC to analyze the adequacy of corporate governance requirements on stock options, including the usefulness of having shareholders approve stock option plans.

Previously, I advocated shareholder approval of stock option issuance to top corporate executives to prevent them from abusing stock options. Now, I and others of us are leaving it to the SEC to determine whether this will prevent stock option abuse.

Our bipartisan amendment also requires an analysis of the need, if any, for stock holding period requirements for senior executives. Some Senators have advocated a holding period during which top executives cannot sell their stock options. One suggestion was that a 90-day cooling off period occur before a top executive can sell his stock. Another suggestion was that these executives could not sell their stock until they left the company and a two-year period expired.

These suggestions pose a dramatic solution which needs more study by the SEC. These are not provisions to be taken lightly, nor drafted hurriedly by Senators. This type of amendment could possibly help prevent abuses, or have the opposite effect of chilling the future use of stock options entirely. Because I do not know what the effect of this will be and whether it will prevent executive fraud and abuse, I am at least willing to let the SEC study it to see if there is any merit to it.

And finally, our amendment directs the SEC to look at the benefit and detriment of any new options expensing rules. So, instead of Senators, who have little knowledge of securities accounting, making an accounting decision on stock option expensing, we are leaving it in the hands of the SEC to see how expensing will affect all segments related to stock options.

Our bipartisan amendment directs the SEC to look at the benefit and detriment of stock option expensing on companies and start-up enterprises. Specifically, it requires the SEC to look at what stock options expensing would do to the productivity and performance of all sizes of companies, and start-up enterprises.

I am particularly concerned about the effect of expensing stock options on small companies and start-up enterprises. Many small businesses and start-up companies cannot afford to offer the salaries larger companies give, so they offer stock options as an incentive to attract highly-skilled employees. In addition, our amendment would require the SEC to look at the

benefits and detriments of stock option expensing on the recruitment and retention of skilled workers.

Currently, employees who risk working for start-up companies have the ability to make much more money than through traditional methods of payment by salaries or wages. Those who stay with the company tend to have a vested interest in the company through the issuance of stock options. Stock options may be the very reason that some employees start with a company and stay with it. We are asking the SEC to look at the issue of what effect stock option expensing will have on future recruitment and retention of employees.

Finally, and most importantly, our amendment asks the SEC to look at the benefits and detriments of stock options on employees at all income levels, with particular emphasis on rank-and-file employees.

These are some of the questions the SEC needs to look at and make a recommendation on.

Whatever we do, we need to make sure the cure is not worse than the disease. We should not rush to pass something just for the sake of legislating on stock options. Let us step back and see what recommendations the SEC makes. Then, with cooler heads, perhaps we can prevail in getting rules and regulations on stock options which are truly needed, and not merely an overreaction to the current atmosphere of Enron.

I would hate to see any hastily decision chill the ability of companies to issue stock options to millions of rank-and-file employees. Or chill new start-up companies' use of stock options to attract employees. At the same time, we have to stop future abuses by corporate executives who thumb their noses while plundering companies resources.

For these reasons, I ask you to vote in favor of the Enzi-Lieberman-Allen-Boxer Amendment.

By Mr. FEINGOLD:

S. 2761. A bill to amend the Internal Revenue Code of 1986 to provide that reimbursements for costs of using passenger automobiles for charitable and other organizations are excluded from gross income, and for other purposes; to the Committee on Finance.

Mr. FEINGOLD. Mr. President, I am pleased to offer legislation today that will increase the mileage reimbursement rate for volunteers.

Under current law, when volunteers use their cars for charitable purposes, the volunteers may be reimbursed up to 14 cents per mile for their donated services without triggering a tax consequence for either the organizations or the volunteers. If the charitable organization reimburses any more than that, they are required to file an information return indicating the amount, and the volunteers must include the amount over 14 cents per mile in their taxable income. By contrast, the mile-

age reimbursement level currently permitted for businesses is 36.5 cents per mile.

At a time when government is asking volunteers and volunteer organizations to bear a greater burden of delivering essential services, the 14 cents per mile limit is posing a very real hardship.

I have heard from a number of groups in Wisconsin in recent weeks on the need to increase this reimbursement limit. One organization, the Portage County Department on Aging, explained just how important volunteer drivers are to their ability to provide services to seniors in that county. The Department on Aging reported that last year 54 volunteer drivers delivered meals to homes and transported people to medical appointments, meal sites, and other essential services. The Department noted that their volunteer drivers provided 4,676 rides, and drove nearly 126,000 miles. They also delivered 9,385 home-delivered meals, and nearly two-thirds of the drivers logged more than 100 miles per month in providing these needed services. Altogether, volunteers donated over 5,200 hours last year, and as the Department notes, at the rate of minimum wage, that amounts to over \$27,000, not including other benefits.

The senior meals program is one of the most vital services provided under the Older Americans Act, and ensuring that meals can be delivered to seniors or that seniors can be taken to meal sites is an essential part of that program. Unfortunately, Federal support for the senior nutrition programs has stagnated in recent years. This has increased pressure on local programs to leverage more volunteer services to make up for lagging federal support. The 14 cent per mile reimbursement limit, though, increasingly poses a barrier to obtaining those contributions. Portage County reports that the many of their volunteers cannot afford to offer their services under such a restriction. And if volunteers cannot be found, their services will have to be replaced by contracting with a provider, greatly increasing costs to the Department, costs that come directly out of the pot of funds available to pay for meals and other services.

By contrast, businesses do not face this restrictive mileage reimbursement limit. The comparable mileage rate for someone who works for a business is currently 36.5 cents per mile. This disparity means that a business hired to deliver the same meals delivered by volunteers for Portage County may reimburse their employees over double the amount permitted the volunteer without a tax consequence.

This doesn't make sense.

Moreover, the 14 cent per mile volunteer reimbursement limit is outdated. According to the Congressional Research Service, Congress first set a reimbursement rate of 12 cents per mile as part of the Deficit Reduction Act of 1984, and did not increase it until 1997, when the level was raised slightly, to

14 cents per mile, as part of the Taxpayer Relief Act of 1997.

The bill I am introducing today raises the limit on volunteer mileage reimbursement to the level permitted to businesses. It is essentially the same provision passed by the Senate as part of a tax bill passed in 1999 that was vetoed by President Clinton. At the time of the 1999 measure, the Joint Committee on Taxation, JCT, estimated that the mileage reimbursement provision would result in the loss of \$1 million over the five year fiscal period from 1999 to 2004. The revenue loss was so small that the JCT did not make the estimate on a year by year basis.

Though the revenue loss is small, I have also included an offset to make the measure deficit neutral by including a provision that would impose a civil penalty of up to \$5,000 on failure to report interest in foreign financial transactions. That provision was recently included in the CARE Act legislation by the Senate Finance Committee.

I urge my colleagues to support this measure. It will help ensure charitable organizations can continue to attract the volunteers that play such a critical role in helping to deliver services and it will simplify the tax code both for non-profit groups and the volunteers themselves.

I ask unanimous consent that the text of the legislation be printed in the RECORD.

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

S. 2761

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. MILEAGE REIMBURSEMENTS TO CHARITABLE VOLUNTEERS EXCLUDED FROM GROSS INCOME.

(a) IN GENERAL.—Part III of subchapter B of chapter 1 of the Internal Revenue Code of 1986 is amended by inserting after section 139 the following new section:

“SEC. 139A. MILEAGE REIMBURSEMENTS TO CHARITABLE VOLUNTEERS.

“(a) IN GENERAL.—Gross income of an individual does not include amounts received, from an organization described in section 170(c), as reimbursement of operating expenses with respect to use of a passenger automobile for the benefit of such organization. The preceding sentence shall apply only to the extent that such reimbursement would be deductible under this chapter if section 274(d) were applied—

“(1) by using the standard business mileage rate established under such section, and

“(2) as if the individual were an employee of an organization not described in section 170(c).

“(b) NO DOUBLE BENEFIT.—Subsection (a) shall not apply with respect to any expenses if the individual claims a deduction or credit for such expenses under any other provision of this title.

“(c) EXEMPTION FROM REPORTING REQUIREMENTS.—Section 6041 shall not apply with respect to reimbursements excluded from income under subsection (a).”

(b) CLERICAL AMENDMENT.—The table of sections for part III of subchapter B of chapter 1 of such Code is amended by inserting after the item relating to section 139 and inserting the following new item:

“Sec. 139A. Reimbursement for use of passenger automobile for charity.”.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after the date of the enactment of this Act.

SEC. 2. PENALTY ON FAILURE TO REPORT INTERESTS IN FOREIGN FINANCIAL ACCOUNTS.

(a) IN GENERAL.—Section 5321(a)(5) of title 31, United States Code, is amended to read as follows:

“(5) FOREIGN FINANCIAL AGENCY TRANSACTION VIOLATION.—

“(A) PENALTY AUTHORIZED.—The Secretary of the Treasury may impose a civil money penalty on any person who violates, or causes any violation of, any provision of section 5314.

“(B) AMOUNT OF PENALTY.—

“(i) IN GENERAL.—Except as provided in subparagraph (C), the amount of any civil penalty imposed under subparagraph (A) shall not exceed \$5,000.

“(ii) REASONABLE CAUSE EXCEPTION.—No penalty shall be imposed under subparagraph (A) with respect to any violation if—

“(I) such violation was due to reasonable cause, and

“(II) the amount of the transaction or the balance in the account at the time of the transaction was properly reported.

“(C) WILLFUL VIOLATIONS.—In the case of any person willfully violating, or willfully causing any violation of, any provision of section 5314—

“(i) the maximum penalty under subparagraph (B)(i) shall be increased to the greater of—

“(I) \$25,000, or

“(II) the amount (not exceeding \$100,000) determined under subparagraph (D), and

“(ii) subparagraph (B)(ii) shall not apply.

“(D) AMOUNT.—The amount determined under this subparagraph is—

“(i) in the case of a violation involving a transaction, the amount of the transaction, or

“(ii) in the case of a violation involving a failure to report the existence of an account or any identifying information required to be provided with respect to an account, the balance in the account at the time of the violation.”

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to violations occurring after the date of the enactment of this Act.

By Mrs. FEINSTEIN (for herself,
Mr. HUTCHINSON, and Mr. KOHL):

S. 2763. A bill to respond to the illegal production distribution, and use of methamphetamines in the United States, and for other purposes; to the Committee on the Judiciary.

Mrs. FEINSTEIN. Mr. President, I rise today to introduce the “CLEAN-UP Meth Act,” a bill to address illegal and environmentally disastrous methamphetamine production.

I am pleased to submit this bill on behalf of myself, Senator HUTCHINSON of Arkansas, and Senator KOHL.

Essentially, this bill would help our Federal, State and local governments combat methamphetamine on a number of levels, from production to clean-up, prosecution to prevention.

The legislation would accomplish this with two key components: First, the bill would allocate \$125 million for important training and cleanup efforts,

including training local law enforcement to effectively clean up meth lab and dump sites. And second, we would make it much harder for meth dealers to get the precursor pseudoephedrine products necessary to make this illegal drug.

Once predominantly found in the American Southwest, methamphetamine's presence now stretches from coast to coast. Once predominantly found in rural areas, its harmful effects now extend from our smallest towns to our biggest cities.

For instance, the number of clandestine meth labs discovered in North Carolina has doubled every year for the past four years.

In New Orleans, police in the Jefferson district seized a total of 828 grams of methamphetamine in all of the year 2000. Last year, they seized more than ten times that amount, 9,003 grams, with a street value of more than \$1 million.

I'm sorry to say that my home State of California has been referred to as the “Colombia of meth production.” In fact, our State is known as the “source country” for the drug, producing roughly 80 percent of the Nation's methamphetamine supply. According to the DEA, 1,847 clandestine meth labs were found last year in California alone.

Each of these 1,847 labs in California, and each of the labs scattered around this Nation near schools, on farms, in trailer parks and in quiet suburban neighborhoods, creates a whole host of dangers and toxic waste.

The actual production of methamphetamine is harmful in a number of ways. First, the hazardous chemicals used in meth production are toxic, and long-term exposure is damaging. Furthermore, the materials can also be explosive and dangerous. Production using these volatile materials has resulted in countless accidents, houses and even apartment buildings burned to the ground, explosions that scatter chemicals and flames, and chemical reactions that cause untold damage to the individuals involved in meth production or simply living in the same household, individuals that, too often, include children.

Meth production also poses risks to the health of the surrounding public and environment. According to the National Drug Intelligence Center, NDIC, for every pound of meth produced, five to seven pounds of hazardous waste results from the production as well. Meth producers dump this waste anywhere and everywhere, from nearby ditches to public lands, from pits dug in the middle of a farm to rivers and lakes.

One private contractor hired to clean up meth-related hazardous dump sites in California responded to more than 500 calls in 2000 alone. And one of those dump sites was located along the banks of the California Aqueduct, which is a direct source of water for Los Angeles.

NDIC investigators have found also found toxic chemicals discarded into

household drains and storm drains. And the precursors used to make meth, and the toxic byproducts, may last for years in the soil. Decontaminating these sites is what makes clean-up so expensive, with costs ranging from \$5,000 to \$150,000 per site. State police in Baltimore, MD claim that its costs taxpayers nearly \$75,000 each time a meth lab must be cleaned up. According to the DEA, that agency spent more than \$22 million cleaning up 6,609 labs nationwide.

These extraordinary costs simply cannot be maintained on the local level without Federal support. These costs are proof of why Federal funding for such valuable efforts is necessary.

So the first thing this legislation would do is help law enforcement as well as the public pay these important costs, by providing millions to help clean-up labs and train law enforcement authorities to properly and safely do this important work.

Specifically, the CLEAN-UP Meth bill would provide: \$15 million for clean-up and remediation of meth contaminated lands managed by the Departments of Agriculture or Interior; \$15 million for Department of Agriculture grants to State and local governments and to private persons to clean up meth contaminated lands; \$20 million for OSHA grants to local law enforcement agencies for training and equipment for the safe identification, handling, clean-up and disposal of meth labs; and \$10 million for Department of Labor grants to local law enforcement agencies to help them comply with Federal laws regarding cleanup and disposal of meth labs.

Second, this legislation includes resources to help State and local officials prosecute meth offenses, educate the public, and study the effects of meth use.

Methamphetamine is so prevalent partly because it is simple to make and is profitable. Producers of meth range from people with advanced chemistry degrees to those who are self-taught. Recipes are easily available in books as well as over the Internet.

The drug does not have to be smuggled in across secured international borders. Fifty percent of the Nation's consumed methamphetamine is produced right here in our country. In fact, the basic ingredients can be found in your local pharmacy. These relatively inexpensive materials can be used to create a drug that fetches much higher prices. For example, ounce quantities are worth between \$1,500 and \$2,000 and can be sold to individual users for about \$100 a gram in crystallized powder form that can be smoked, snorted, swallowed or turned into liquid and injected. According to the Office of National Drug Control Policy, ONDCP, methamphetamine users spent nearly \$6 billion on the drug in 1999.

Methamphetamine is also highly addictive. Known on the street as crank, speed, ice and zip, methamphetamine is

cheaper than cocaine, more addictive than crack and causes more brain damage than heroin or alcohol. A single dose of this "poor man's cocaine" can keep a person awake for three to four days at a time and has been associated with paranoia and often violence. In California's Central Valley, methamphetamine has become the drug of choice and a principal cause of crime.

I firmly believe that law enforcement officials cannot effectively fight this drug and its harmful effects unless we provide them with the proper resources. Already this year, police in Oklahoma City have seized 115 meth labs. Law enforcement officials there have attributed these seizures to the support from Federal grants.

Keith Cain, a sheriff in Daviess County, KY also claims that Federal funding has proved to be crucial to the war against meth. According to Cain, "Without that money, we would not have been able to be as proactive as we've been."

Last year, the federally funded Central Valley High-Intensity Drug Trafficking project to restrict the supply of the chemical agents used in making the deadly drug was showing impressive results. A team of specialists from local drug units, the California Highway Patrol, DEA and FBI averaged one bust a week of the clandestine "super labs" that had made the Central Valley the national center for the production of methamphetamine. These triumphs were the direct result of federal funding and proof that allocating Federal resources is imperative to progress.

However, since September 11, agents have been removed from the project and transferred to anti-terrorism work. The lack of drug enforcement resources has created a strain on the project and threatens the progress it has had combating methamphetamine.

It would be a tragedy to California and the country if we lost all of the progress this program and others like it have made in the war on meth simply due to a lack of resources. Programs like this one have proven to be effective and need our continued support.

Our bill would provide: \$20 million for training of State and local prosecutors and law enforcement agents for prosecution of meth offenses, \$5 million of which will be dedicated for rural communities and \$2 million to reimburse the DEA for existing training programs; \$10 million additional for training at the DEA's Clandestine Laboratory Training Facility in Quantico, VA; \$2 million for the Department of Justice for the collection, aggregation and dissemination of meth lab seizure stats by the El Paso Intelligence Center, EPIC.

Third, we address the problems of our children. Raids and seizures of clandestine meth labs have been instrumental to the war on meth and have uncovered a number of alarming issues, but none more troubling than the effect meth production has on the children of meth dealers and their friends.

Drug rings and meth trafficking organizations found throughout the American West have been linked to Mexican drug traffickers as well as white supremacist groups. Last year, for instance, law enforcement authorities in Los Angeles County uncovered a sophisticated meth trafficking ring that includes suspects with tattoos of Nazi swastikas and belong to a local gang called the "Untouchables." During police raids of their meth labs and headquarters, agents seized nearly \$500,000 in cash and more than 100 high-powered weapons, including assault rifles and a grenade launcher.

Earlier this year, Central Valley investigators raided a methamphetamine super-lab in a farmhouse on the outskirts on Merced, CA. Inside, investigators found vats of toxic chemicals, large supplies of pseudoephedrine used in producing meth and three illegal firearms.

Yet, the most disturbing part of this story is that while the manufacturers were engaged in the potentially explosive process of extracting pure methamphetamine, four small children watched television in the next room. The children were taken to a local hospital and tested positive for methamphetamine contamination.

I would like to say that this is a rare case. However, this story is no exception. In 2001, 1,989 children were found in clandestine meth labs, materials storage sites and dump sites across the country.

The CLEAN-UP Meth Act would provide \$2.5 million for grants to states for treatment of children suffering adverse health impacts from meth-related exposure.

The bill also includes \$20 million for the development of anti-methamphetamine education programs in our nation's schools. Informing and educating our children on the dangers of this drug is the first step in reducing the number of new users of methamphetamine.

In addition to the funding provisions of the bill, which were introduced by Representative OSE in the House, this legislation also contains language to close the "Blister Pack Loophole" in current law, which currently allows meth dealers to purchase unlimited quantities of pseudoephedrine products, generally cold and sinus medication, as long as it is packaged in blister packs, those tin foil and plastic packages most of us buy these days, which require that each pill be separate rather than simply poured into a bottle.

Our current law limits retail sales of bottled pseudoephedrine to just 9 grams, because we found several years ago that meth dealers would go into a pharmacy, a Costco or other large store, sweep the shelves clean of cold medicine, bring the bottles back to the lab, cut off the tops of the bottles without even bothering to unscrew the caps instead, and pour the pills out as the first step to making meth.

When we passed the 9 gram threshold, and before that the 24-gram

threshold, for bottled pills, I made the case that if limits were placed on bottles only, meth dealers would simply start buying blister-packed pills instead. At the time, some argued that blister packs were simply too unwieldy for meth manufacturers to bother with, the process of popping individual pills out of each blister would be too time consuming. But we had evidence from California that dealers were already using these blister packs, so as a compromise we asked the DEA to conduct a nationwide study of whether blister packs posed a problem. Well, guess what, they do.

According to the report we requested from the DEA, which was finalized late last year, blister packaged pseudoephedrine products seized at clandestine methamphetamine laboratories and other locations, such as dumpsites, have involved seizures of over a million tablets. The seizure of so many blister packaged pseudoephedrine products shows convincingly that blister packaging is not a deterrent to ordinary, over-the-counter pseudoephedrine use in clandestine methamphetamine laboratories.

Indeed, the report even includes information about automated machines whose sole purpose is to remove pills from blister packs on a massive scale. These machines have been found in meth labs, along with hundreds, even thousands, of empty blister packs.

So clearly, what we argued in 1999, and in 1996, is true. Meth manufacturers are using blister packs, and something must be done to stop them as best we can.

In order to address this problem, DEA recommended in the report it released late last year that the blister pack loophole be closed, and that the current retail sales limit of 9 grams for bottled pseudoephedrine be extended to blister packed products as well. And that is what this bill would do.

The meth problem is not just a California problem, or a New York problem, or even an Iowa problem. The meth problem is a national problem, with tragic consequences across this great country. Without a continuing, nationwide, relentless effort on the part of the Federal Government, this problem will continue to grow and to infect our children and our communities with the scourge of methamphetamine production and use.

I believe DEA Director Hutchinson put it best this spring when he argued in support of Federal efforts to crack down on meth. "It clearly impacts every one of our districts, every segment of our society and every age group."

I urge my colleagues to support this legislation and join the latest step towards progress in our war against methamphetamine.

Mr. KOHL. Mr. President, I rise in support of the CLEAN-UP Meth Act of 2002. I am pleased to join my fellow cosponsors, Senators FEINSTEIN and

HUTCHINSON in introducing this legislation.

Methamphetamine is a plague in Wisconsin that affects not only the people who purchase and use it, their families and friends, but also the law enforcement officials who are involved in cleaning up the abandoned meth laboratories. These home grown meth labs inflict significant damage to the environment unlike other illicit drugs. The labs contaminate the environment and threaten those who discover and break down the labs, are exposed to the precursor chemicals and clean up the polluted environment.

The meth scourge is growing every day. In 1998, Wisconsin State authorities seized only two methamphetamine labs. By 2001, that number had increased to 52 and shows no signs of abating. Its appearance in the last few years in the western part of Wisconsin, trafficked from Minnesota and Iowa, has created a dramatic new problem for law enforcement. And, production in the State has grown dramatically in the last four years.

The amount of methamphetamine produced in Wisconsin is also growing by leaps and bounds. In 1999, State drug task forces seized 1.6 kilograms of methamphetamine. In 2000, the number increased to 2.5 kilograms. Finally, in 2001, the amount of methamphetamine seized in Wisconsin skyrocketed to 20.9 kilograms, an increase of 13 fold in only two years.

The existence of a significant and growing meth problem comes as no surprise to us. In fact, with the assistance of Wisconsin's Department of Narcotics Enforcement, we have attempted to fight the spread of meth for the past several years. We have augmented DEA's representation in Wisconsin, specifically adding new agents in the western part of the state to work in conjunction with state drug officials. We have secured DEA mobile drug teams to traverse the northwestern part of the State where much of the meth can be found. We have also secured millions of dollars in the appropriations process to aid in prevention and clean up efforts in western Wisconsin.

Unfortunately, this has not stemmed the spread of meth. We fear to consider how much worse the problem would be if it were not for the efforts of our state and local law enforcement officials.

We must do more. The legislation we introduced today is another weapon in the battle against the spread of meth. The bill authorizes more funding for the education, prevention and clean up of methamphetamine.

Educating more people about the dangers of meth and assisting in safe environmental cleanup are important, long-term approaches to the meth problem. There is, however, something that can be done immediately to make it more difficult for meth producers to manufacture the drugs.

We need to make it more difficult for meth producers to get access to the

precursor chemicals they use to produce methamphetamine. That means closing a loophole in the law that currently makes it too easy for meth producers to get pseudoephedrine. Pseudoephedrine is the central ingredient in both methamphetamine and most major cold medicines sold over the counter.

To combat the sale of pseudoephedrine to meth producers, Congress passed the Comprehensive Methamphetamine Control Act of 1996. This limited the amount of pseudoephedrine or ephedrine that any one person could purchase at one time. Yet, Congress did not proscribe the purchase of pseudoephedrine in so-called "blister packs." The pharmaceutical industry argued that it is sufficiently difficult to remove each pill from a blister pack, that the sale of pseudoephedrine in that form need not be limited. Only the sale of pseudoephedrine in bottles where it would be easy for meth producers to access large quantities needed to be restricted.

As it turns out, the meth producers adapted their behavior to take advantage of the loophole in the law by finding a way to make the blister packaged pseudoephedrine economical to purchase. They did so with the advent of presses that simply punctured all of the blister packs—therefore removing the type of packaging as an impediment to their access to the pseudoephedrine.

The DEA conducted a study on the use of blister packs and found that among the refuse left at meth labs are more and more blister packs. This demonstrates, in the DEA's view, that the blister pack loophole needs to be closed. We agree with their recommendation and therefore recommend limiting the amount of pseudoephedrine that can be purchased by any one person at any one time.

Closing this loophole in the law governing the manufacture of meth is one more weapon in the battle against the drug. Combined with education, prevention and greater resources for law enforcement throughout Wisconsin, we can stem the tide of this scourge before it does even more damage.

By Mr. MILLER:

S. 2764. A bill to eliminate the Federal quota and price support for tobacco, to compensate quota holders and active producers for the loss of tobacco quota asset value, to establish a permanent advisory board to determine and describe the physical characteristics of domestic and imported tobacco, and for other purposes; to the Committee on Finance.

Mr. MILLER. Mr. President, I ask unanimous consent that the text of the bill be printed in the RECORD.

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

S. 2764

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) **SHORT TITLE.**—This Act may be cited as the “Tobacco Livelihood and Economic Assistance for Our Farmers Act of 2002”.

(b) **TABLE OF CONTENTS.**—The table of contents for this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—TERMINATION OF CURRENT TOBACCO PROGRAMS

Sec. 101. Termination of tobacco production adjustment programs.

Sec. 102. Termination of tobacco price support program.

Sec. 103. Geographical restrictions on expansion of tobacco production.

Sec. 104. Continued availability of Federal crop insurance.

TITLE II—PAYMENTS TO TOBACCO QUOTA HOLDERS AND PRODUCERS

Sec. 201. Definitions.

Sec. 202. Payments to tobacco quota holders.

Sec. 203. Transition payments for active producers of quota tobacco.

TITLE III—TOBACCO QUALITY BOARD

Sec. 301. Definitions.

Sec. 302. Establishment of Board.

Sec. 303. Duties.

Sec. 304. Administration.

TITLE IV—TOBACCO PRODUCT MANUFACTURER AND IMPORTER USER FEES

Sec. 401. User fee.

Sec. 402. Allocation of user fees.

TITLE V—FDA REGULATION OF TOBACCO PRODUCTS

Sec. 501. Findings.

Subtitle A—FDA Jurisdiction Over Tobacco Products

Sec. 511. Definition of tobacco product.

Sec. 512. Tobacco products.

Sec. 513. Conforming and technical amendments.

Subtitle B—Cigarette Labeling and Advertising

Sec. 521. Definition of cigarette.

Sec. 522. Cigarette label and advertising warnings.

Subtitle C—Smokeless Tobacco Labels and Advertising Warnings

Sec. 531. Smokeless tobacco labels and advertising warnings.

Subtitle D—Administration

Sec. 541. FTC jurisdiction not affected.

TITLE I—TERMINATION OF CURRENT TOBACCO PROGRAMS**SEC. 101. TERMINATION OF TOBACCO PRODUCTION ADJUSTMENT PROGRAMS.**

(a) **TOBACCO CONTROL.**—The Act of April 25, 1936 (commonly known as the Tobacco Control Act; 7 U.S.C. 515 et seq.), is repealed.

(b) **COMMODITY HANDLING ORDERS.**—Section 8c(2)(A) of the Agricultural Adjustment Act (7 U.S.C. 608c(2)(A)), reenacted with amendments by the Agricultural Marketing Agreement Act of 1937, is amended by striking “tobacco.”

(c) **PROCESSING TAX.**—Section 9(b) of the Agricultural Adjustment Act (7 U.S.C. 609(b)), reenacted with amendments by the Agricultural Marketing Agreement Act of 1937, is amended—

(1) in paragraph (2), by striking “tobacco,”; and

(2) in paragraph (6)(B)(i), by striking “, or, in the case of tobacco, is less than the fair exchange value by not more than 10 per centum.”

(d) **BURLEY TOBACCO IMPORT REVIEW.**—Section 3 of Public Law 98-59 (7 U.S.C. 625) is repealed.

(e) **DECLARATION OF POLICY.**—Section 2 of the Agricultural Adjustment Act of 1938 (7

U.S.C. 1282) is amended by striking “tobacco.”

(f) **DEFINITIONS.**—Section 301(b) of the Agricultural Adjustment Act of 1938 (7 U.S.C. 1301(b)) is amended—

(1) in paragraph (3)—

(A) by striking subparagraph (C); and

(B) by redesignating subparagraph (D) as subparagraph (C);

(2) in paragraph (6)(A), by striking “tobacco,”;

(3) in paragraph (7), by striking the following:

“Tobacco (Flue-cured), July 1—June 30;

“Tobacco (other than Flue-cured), October 1–September 30;”;

(4) in paragraph (10)—

(A) by striking subparagraph (B); and

(B) by redesignating subparagraph (C) as subparagraph (B);

(5) in paragraph (11)(B), by striking “and tobacco”;

(6) in paragraph (12), by striking “tobacco,”;

(7) in paragraph (14)—

(A) in subparagraph (A), by striking “(A)”;

and

(B) by striking subparagraphs (B), (C), and (D);

(8) by striking paragraph (15);

(9) in paragraph (16)—

(A) by striking subparagraph (B); and

(B) by redesignating subparagraph (C) as subparagraph (B);

(10) by striking paragraph (17); and

(11) by redesignating paragraph (16) as paragraph (15).

(g) **PARITY PAYMENTS.**—Section 303 of the Agricultural Adjustment Act of 1938 (7 U.S.C. 1303) is amended in the first sentence by striking “rice, or tobacco,” and inserting “or rice.”

(h) **MARKETING QUOTAS.**—Part I of subtitle B of title III of the Agricultural Adjustment Act of 1938 (7 U.S.C. 1311 et seq.) is repealed.

(i) **ADMINISTRATIVE PROVISIONS.**—Section 361 of the Agricultural Adjustment Act of 1938 (7 U.S.C. 1361) is amended by striking “tobacco.”

(j) **ADJUSTMENT OF QUOTAS.**—Section 371 of the Agricultural Adjustment Act of 1938 (7 U.S.C. 1371) is amended—

(1) in the first sentence of subsection (a), by striking “rice, or tobacco” and inserting “or rice”; and

(2) in the first sentence of subsection (b), by striking “rice, or tobacco” and inserting “or rice”.

(k) **REPORTS AND RECORDS.**—Section 373 of the Agricultural Adjustment Act of 1938 (7 U.S.C. 1373) is amended—

(1) by striking “rice, or tobacco” each place it appears in subsections (a) and (b) and inserting “or rice”; and

(2) in subsection (a)—

(A) in the first sentence, by striking “all persons engaged in the business of redrying, prizing, or stemming tobacco for producers,”; and

(B) in the last sentence, by striking “\$500;” and all that follows through the period at the end of the sentence and inserting “\$500.”

(l) **REGULATIONS.**—Section 375(a) of the Agricultural Adjustment Act of 1938 (7 U.S.C. 1375(a)) is amended by striking “peanuts, or tobacco” and inserting “or peanuts”.

(m) **EMINENT DOMAIN.**—Section 378 of the Agricultural Adjustment Act of 1938 (7 U.S.C. 1378) is amended—

(1) in the first sentence of subsection (c), by striking “cotton, and tobacco” and inserting “and cotton”; and

(2) by striking subsections (d), (e), and (f).

(n) **BURLEY TOBACCO FARM RECONSTITUTION.**—Section 379 of the Agricultural Adjustment Act of 1938 (7 U.S.C. 1379) is amended—

(1) in subsection (a)—

(A) by striking “(a)”;

(B) in paragraph (6), by striking “, but this clause (6) shall not be applicable in the case of burley tobacco”; and

(C) by striking subsections (b) and (c).

(A) by striking “(a)”;

(B) in paragraph (6), by striking “, but this clause (6) shall not be applicable in the case of burley tobacco”; and

(C) by striking subsections (b) and (c).

(o) **ACREAGE-POUNDAGE QUOTAS.**—Section 4 of the Act of April 16, 1955 (Public Law 89-12; 7 U.S.C. 1314c note), is repealed.

(p) **BURLEY TOBACCO ACREAGE ALLOTMENTS.**—The Act of July 12, 1952 (7 U.S.C. 1315), is repealed.

(q) **TRANSFER OF ALLOTMENTS.**—Section 703 of the Food and Agriculture Act of 1965 (7 U.S.C. 1316) is repealed.

(r) **ADVANCE RECOURSE LOANS.**—Section 13(a)(2)(B) of the Food Security Improvements Act of 1986 (7 U.S.C. 1433c-1(a)(2)(B)) is amended by striking “tobacco and”.

(s) **TOBACCO FIELD MEASUREMENT.**—Section 1112 of the Omnibus Budget Reconciliation Act of 1987 (Public Law 100-203) is amended by striking subsection (c).

(t) **LIABILITY.**—The amendments made by this section shall not affect the liability of any person under any provision of law as in effect before the effective date under subsection (u).

(u) **CROPS.**—This section and the amendments made by this section shall apply with respect to the 2003 and subsequent crops of the kind of tobacco involved.

SEC. 102. TERMINATION OF TOBACCO PRICE SUPPORT PROGRAM.

(a) **PARITY PRICE SUPPORT.**—Section 101 of the Agricultural Act of 1949 (7 U.S.C. 1441) is amended—

(1) in the first sentence of subsection (a), by striking “tobacco (except as otherwise provided herein), corn,” and inserting “corn”;

(2) by striking subsections (c), (g), (h), and (i);

(3) in subsection (d)(3)—

(A) by striking “, except tobacco,”; and

(B) by striking “and no price support shall be made available for any crop of tobacco for which marketing quotas have been disapproved by producers,”; and

(4) by redesignating subsections (d) and (e) as subsections (c) and (d), respectively.

(b) **TERMINATION OF TOBACCO PRICE SUPPORT AND NO NET COST PROVISIONS.**—Sections 106, 106A, and 106B of the Agricultural Act of 1949 (7 U.S.C. 1445, 1445-1, 1445-2) are repealed.

(c) **DEFINITION OF BASIC AGRICULTURAL COMMODITY.**—Section 408(c) of the Agricultural Act of 1949 (7 U.S.C. 1428(c)) is amended by striking “tobacco.”

(d) **REVIEW OF BURLEY TOBACCO IMPORTS.**—Section 3 of Public Law 98-59 (7 U.S.C. 625) is repealed.

(e) **POWERS OF COMMODITY CREDIT CORPORATION.**—Section 5 of the Commodity Credit Corporation Charter Act (15 U.S.C. 714c) is amended by inserting “(other than tobacco)” after “agricultural commodities” each place it appears.

(f) **TRANSITION PROVISIONS.**—

(1) **LIABILITY.**—The amendments made by this section shall not affect the liability of any person under any provision of law as in effect before the date of enactment of this Act.

(2) **TOBACCO STOCKS AND LOANS.**—The Secretary of Agriculture shall promulgate regulations that require—

(A) the orderly disposition of quota tobacco held by any producer-owned cooperative marketing association that has entered into a loan agreement with the Commodity Credit Corporation to make price support available to producers of quota tobacco; and

(B) the repayment of all tobacco price support loans or surrender of collateral by the associations not later than 1 year after the date of enactment of this Act.

(3) SPECIAL RULES FOR TERMINATION OF NO NET COST FUNDS AND ACCOUNTS.—Notwithstanding any other provision of law, on the repeal by subsection (b) of the authority under section 106A and 106B of the Agricultural Act of 1949 (7 U.S.C. 1445-1, 1445-2) for the establishment of the No Net Cost Tobacco Funds and Accounts, respectively—

(A) any obligation of a tobacco producer, purchaser, or importer to make payments into the Fund or Account shall terminate; and

(B) any amounts in the Fund or Account shall be disposed of in the manner prescribed by the Secretary of Agriculture, except that—

(i) to the extent necessary, the amounts shall be applied or used for the purposes prescribed by that section; and

(ii) if any funds remain, the Secretary shall transfer the funds to the Secretary of Health and Human Services for use in accordance with section 402.

(g) CROPS.—This section and the amendments made by this section shall apply with respect to the 2003 and subsequent crops of the kind of tobacco involved.

SEC. 103. GEOGRAPHICAL RESTRICTIONS ON EXPANSION OF TOBACCO PRODUCTION.

(a) PURPOSES.—The purposes of this section are—

(1) to provide an orderly economic transition from the marketing of tobacco based on quotas and price support; and

(2) to address the economic dislocation, and the resulting impact on interstate commerce, that the termination of the tobacco program might cause for producers of certain agricultural communities.

(b) DEFINITIONS.—In this section:

(1) **MARKETING QUOTA.**—The term “marketing quota in the 2002 marketing year” means a quota established for the 2002 marketing year pursuant to part I of subtitle B of title III of the Agricultural Adjustment Act of 1938 (7 U.S.C. 1311 et seq.) (as in effect before the amendment made by section 101(h)) and related provisions of law, as in effect for that marketing year.

(2) **MARKETING YEAR.**—The term “marketing year” means—

(A) in the case of Flue-cured tobacco, July 1 through June 30; and

(B) in the case of each other kind of tobacco, October 1 through September 30.

(c) **PENALTY APPLICABLE TO TOBACCO GROWN IN NONQUOTA COUNTIES AND STATES.**—The marketing in the 2003 or subsequent marketing years of a kind of tobacco that was subject to a marketing quota in the 2002 marketing year shall be subject to a penalty equal to 100 percent of the total amount received for the marketing of the tobacco, unless the Secretary of Agriculture determines that the tobacco was grown in a county in which the kind of tobacco was grown pursuant to a marketing quota in the 2002 marketing year.

SEC. 104. CONTINUED AVAILABILITY OF FEDERAL CROP INSURANCE.

Nothing in this title affects the eligibility of a tobacco producer to obtain crop insurance for a crop of the producer under the Federal Crop Insurance Act (7 U.S.C. 1501 et seq.).

TITLE II—PAYMENTS TO TOBACCO QUOTA HOLDERS AND PRODUCERS

SEC. 201. DEFINITIONS.

In this title:

(1) **ACTIVE PRODUCER OF QUOTA TOBACCO.**—The term “active producer of quota tobacco” means a person that was the actual producer of tobacco marketed under a marketing quota for the 2001 tobacco marketing year, as determined by the Secretary.

(2) **QUOTA TOBACCO.**—The term “quota tobacco” means a kind of tobacco that is sub-

ject to a farm marketing quota or farm acreage allotment for the 1999, 2000, 2001, and 2002 tobacco marketing years under a marketing quota or allotment program established under part I of subtitle B of title III of the Agricultural Adjustment Act of 1938 (7 U.S.C. 1281 et seq.) (as in effect before the amendment made by section 101(h)).

(3) **SECRETARY.**—The term “Secretary” means the Secretary of Agriculture.

(4) **TOBACCO QUOTA HOLDER.**—The term “tobacco quota holder” means an owner of a farm on January 1, 2002, for which a tobacco farm marketing quota or farm acreage allotment for quota tobacco was established with respect to the 2002 tobacco marketing year under a marketing quota program established under part I of subtitle B of title III of the Agricultural Adjustment Act of 1938 (7 U.S.C. 1281 et seq.) (as in effect before the amendment made by section 101(h)).

SEC. 202. PAYMENTS TO TOBACCO QUOTA HOLDERS.

(a) **PAYMENT REQUIRED.**—The Secretary shall make payments to each eligible tobacco quota holder for the termination of tobacco marketing quotas and related price support under the amendments made by title I, which shall constitute full and fair compensation for any losses relating to the termination of the quotas and support.

(b) **ELIGIBILITY.**—

(1) **IN GENERAL.**—To be eligible to receive a payment under this section, a person shall submit to the Secretary an application containing such information as the Secretary may require to demonstrate to the satisfaction of the Secretary that the person is a tobacco quota holder.

(2) **ADMINISTRATION.**—The application shall be submitted within such time, in such form, and in such manner as the Secretary may require.

(c) **BASE QUOTA LEVEL.**—

(1) **IN GENERAL.**—The Secretary shall establish a base quota level applicable to each eligible tobacco quota holder, as determined under subsection (b).

(2) **POUNDAGE QUOTAS.**—For each kind of tobacco for which a marketing quota is expressed in pounds, the base quota level for each tobacco quota holder shall be equal to the basic tobacco marketing quota under part I of subtitle B of title III of the Agricultural Adjustment Act of 1938 (7 U.S.C. 1281 et seq.) (as in effect before the amendment made by section 101(h)) for the 1998 marketing year for quota tobacco on the farm owned by the tobacco quota holder.

(3) **MARKETING QUOTAS OTHER THAN POUNDAGE QUOTAS.**—For each kind of tobacco for which there is a marketing quota or allotment on an acreage basis, the base quota level for each tobacco quota holder shall be the quantity obtained by multiplying—

(A) the basic tobacco farm marketing quota or allotment for the 1998 marketing year established by the Secretary for quota tobacco on the farm owned by the tobacco quota holder; by

(B) the average county production yield per acre for the county in which the farm is located for the kind of tobacco for the 1998 marketing year.

(d) **PAYMENT.**—The Secretary shall make payments to each eligible tobacco quota holder under subsection (b) in an amount obtained by multiplying—

(1) \$8 per pound; by

(2) the base quota level established for the quota holder under subsection (c).

(e) **TIME FOR PAYMENT.**—The payments to eligible tobacco quota holders required under this section shall be made in 5 equal installments during fiscal years 2003, 2004, 2005, 2006, and 2007.

(f) **RESOLUTION OF DISPUTES.**—Any dispute regarding the eligibility of a person to re-

ceive a payment under this section, or the amount of the payment, shall be resolved by the county committee established under section 8(b)(5) of the Soil Conservation and Domestic Allotment Act (16 U.S.C. 590h(b)(5)) for the county or other area in which the farm owned by the person is located.

(g) **COMMODITY CREDIT CORPORATION.**—The Secretary shall use the funds, facilities, and authorities of the Commodity Credit Corporation to carry out this section.

SEC. 203. TRANSITION PAYMENTS FOR ACTIVE PRODUCERS OF QUOTA TOBACCO.

(a) **TRANSITION PAYMENTS REQUIRED.**—The Secretary shall make transition payments under this section to eligible active producers of quota tobacco.

(b) **ELIGIBILITY.**—

(1) **IN GENERAL.**—To be eligible to receive a transition payment under this section, a person shall submit to the Secretary an application containing such information as the Secretary may require to demonstrate to the satisfaction of the Secretary that the person is an active producer of quota tobacco.

(2) **ADMINISTRATION.**—The application shall be submitted within such time, in such form, and in such manner as the Secretary may require.

(c) **PRODUCTION BASE.**—

(1) **IN GENERAL.**—The Secretary shall establish a production base applicable to each eligible active producer of quota tobacco, as determined under subsection (b).

(2) **QUANTITY.**—The production base of a producer shall be equal to the quantity, in pounds, of quota tobacco subject to the basic marketing quota produced and marketed by the producer under part I of subtitle B of title III of the Agricultural Adjustment Act of 1938 (7 U.S.C. 1281 et seq.) (as in effect before the amendment made by section 101(h)) for the 2001 marketing year.

(d) **PAYMENT.**—The Secretary shall make payments to each eligible active producer of quota tobacco, as determined under subsection (b), in an amount obtained by multiplying—

(1) \$4 per pound; by

(2) the production base established for the active producer under subsection (c).

(e) **TIME FOR PAYMENT.**—The payments to eligible active producers of quota tobacco required under this section shall be made in 5 equal installments during fiscal years 2003, 2004, 2005, 2006, and 2007.

(f) **RESOLUTION OF DISPUTES.**—Any dispute regarding the eligibility of a person to receive a payment under this section, or the amount of the payment, shall be resolved by the county committee established under section 8(b)(5) of the Soil Conservation and Domestic Allotment Act (16 U.S.C. 590h(b)(5)) for the county or other area in which the farming operation of the person is located.

(g) **COMMODITY CREDIT CORPORATION.**—The Secretary shall use the funds, facilities, and authorities of the Commodity Credit Corporation to carry out this section.

TITLE III—TOBACCO QUALITY BOARD

SEC. 301. DEFINITIONS.

In this title:

(1) **BOARD.**—The term “Board” means the Tobacco Quality Board established under section 302.

(2) **SECRETARY.**—The term “Secretary” means the Secretary of Agriculture.

SEC. 302. ESTABLISHMENT OF BOARD.

(a) **IN GENERAL.**—The Secretary shall establish a permanent advisory board within the Department of Agriculture to be known as the Tobacco Quality Board.

(b) **NOMINATION AND APPOINTMENT.**—The Board shall consist of 11 members, of which—

(1) 5 members shall be appointed by the Secretary from nominations submitted by representatives of tobacco producers in the United States;

(2) 5 members shall be appointed by the Secretary from nominations submitted by representatives of tobacco product manufacturers in the United States; and

(3) 1 member shall be an officer or employee of the Department of Agriculture appointed by the Secretary, who shall serve as Chairperson of the Board.

(c) TERMS.—

(1) CHAIRPERSON.—The Chairperson of the Board shall serve at the pleasure of the Secretary.

(2) OTHER MEMBERS.—Other members of the Board shall serve for 2-year terms, except that of the members first appointed to the Board, 2 producer representatives and 2 manufacturer representatives shall have initial terms of 1 year, as determined by the Secretary.

SEC. 303. DUTIES.

The Board shall—

(1) determine and describe the physical characteristics of tobacco produced in the United States and unmanufactured tobacco imported into the United States;

(2) assemble and evaluate, in a systematic manner, concerns and problems with the quality of tobacco produced in the United States, expressed by domestic and foreign buyers and manufacturers of tobacco products;

(3) review data collected by Federal agencies on the physical and chemical integrity of tobacco produced in the United States and unmanufactured tobacco imported into the United States, to ensure that tobacco being used in domestically-manufactured tobacco products is of the highest quality and is free from prohibited physical and chemical agents;

(4) investigate and communicate to the Secretary—

(A) conditions with respect to the production of tobacco that discourage improvements in the quality of tobacco produced in the United States; and

(B) recommendations for regulatory changes that would address tobacco quality issues; and

(5) carry out such other related activities as are assigned to the Board by the Secretary.

SEC. 304. ADMINISTRATION.

(a) IN GENERAL.—The Secretary shall provide the Board with (as determined by the Secretary)—

(1) a staff that is—

(A) experienced in the sampling and analysis of unmanufactured tobacco; and

(B) capable of collecting data and monitoring tobacco production information; and

(2) other resources necessary for the Board to perform the duties of the Board under this title.

(b) COMMODITY CREDIT CORPORATION.—The Secretary shall use the funds, facilities, and authorities of the Commodity Credit Corporation to carry out this title.

TITLE IV—TOBACCO PRODUCT MANUFACTURER AND IMPORTER USER FEES

SEC. 401. USER FEE.

(a) IN GENERAL.—

(1) ASSESSMENT.—The Secretary of Health and Human Services shall assess an annual user fee, calculated in accordance with this section, on each tobacco product manufacturer and tobacco product importer that sells tobacco products in domestic commerce in the United States.

(2) COMMENCEMENT.—The assessments shall commence during calendar year 2003, based on domestic sales of tobacco products during fiscal year 2003.

(b) BASE AMOUNT OF USER FEE FOR EACH CLASS OF TOBACCO PRODUCT.—The base amount of the user fee shall be—

(1) for cigarette manufacturers and importers, \$2,116,252,000;

(2) for small cigar manufacturers and importers, \$1,051,000;

(3) for large cigar manufacturers and importers, \$164,274,000;

(4) for snuff manufacturers and importers, \$9,920,000;

(5) for chewing tobacco manufacturers and importers, \$2,275,000;

(6) for pipe tobacco manufacturers and importers, \$1,505,000; and

(7) for roll-your-own tobacco manufacturers and importers, \$3,231,000.

(c) DETERMINATION OF ANNUAL USER FEE FOR EACH CLASS OF TOBACCO PRODUCT.—The total user fee to be assessed on, and paid by, the manufacturers and importers of each class of tobacco product in each calendar year, as allocated pursuant to subsection (d), shall be the amount obtained by multiplying—

(1) the base amount for that class of tobacco product provided under subsection (b); by

(2) a fraction—

(A) the numerator of which is the total volume of domestic sales of that class of tobacco product during the fiscal year ending on September 30 of that calendar year; and

(B) the denominator of which is the total volume of domestic sales of that class of tobacco product during fiscal year 2003.

(d) ALLOCATION OF TOTAL USER FEE AMOUNTS BY MARKET SHARE—

(1) DEFINITION OF MARKET SHARE.—In this subsection, the term “market share” means the share of each manufacturer or importer of a class of tobacco product (expressed as a decimal to the fourth place) of the total volume of domestic sales of the class of tobacco product during the calendar year immediately preceding the calendar year of an assessment under this section.

(2) ALLOCATION.—The amount of the user fee for each class of tobacco product to be paid by each manufacturer or importer of the class of tobacco product under subsection (a) shall be determined for each calendar year by multiplying—

(A) the market share of the manufacturer or importer, as calculated with respect to the calendar year, of the class of tobacco product; by

(B) the total user fee amount for the calendar year, as determined under subsection (c), for the class of tobacco product.

(e) DETERMINATION OF VOLUME OF DOMESTIC SALES.—

(1) IN GENERAL.—The calculation of the volume of domestic sales of a class of tobacco product by a manufacturer or importer, and by all manufacturers and importers as a group, shall be made by the Secretary of Health and Human Services based on certified reports submitted by the manufacturers and importers pursuant to subsection (f).

(2) MEASUREMENT.—For purposes of the calculations under this subsection and the certifications under subsection (f) by the Secretary of Health and Human Services, the volumes of domestic sales shall be measured by—

(A) in the case of cigarettes, the numbers of cigarettes sold; and

(B) in the case of each other class of tobacco products, such unit as is specified by regulation by the Secretary.

(f) CERTIFICATION OF VOLUME OF DOMESTIC SALES.—

(1) IN GENERAL.—Each manufacturer and importer of tobacco products shall submit for each year a certified report to the Secretary of Health and Human Services setting forth for each class of tobacco products marketed or imported the total, for the preceding year, of domestic sales of the tobacco products by the manufacturer and importer,

respectively, to wholesalers and retailers and directly to consumers.

(2) DEADLINE.—The certified report shall be submitted to the Secretary of Health and Human Services not later than March 1 of the year after the year for which the certified report is made.

SEC. 402. ALLOCATION OF USER FEES.

(a) IN GENERAL.—The user fees collected pursuant to section 401 and any funds transferred to the Secretary of Health and Human Services by the Secretary of Agriculture pursuant to section 102(f)(3)(B)(ii) shall be available, without further appropriation, in accordance with, and for the purposes described in, this section, to remain available until expended.

(b) FUNDING FOR FDA REGULATION OF TOBACCO PRODUCTS.—The Secretary of Health and Human Services shall make 15 percent of the user fee amounts collected pursuant to section 401 for each year available to the Secretary, acting through the Commissioner of Food and Drugs, for the regulation of tobacco products under chapter IX of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 391 et seq.).

(c) FUNDING FOR OTHER TOBACCO-RELATED PROGRAMS.—The Secretary of Health and Human Services shall use the remaining 85 percent of the user fee amounts collected each year pursuant to section 401 and any amounts transferred to the Secretary of Health and Human Services by the Secretary of Agriculture pursuant to section 102(f)(3)(B)(ii)—

(1) to reimburse the Commodity Credit Corporation for the expenditures made by the Commodity Credit Corporation under title II; and

(2) if any funds remain after carrying out paragraph (1), to fund any other program that relates to tobacco products.

TITLE V—FDA REGULATION OF TOBACCO PRODUCTS

SEC. 501. FINDINGS.

Congress finds that—

(1) the use of tobacco products by the children of the United States is a pediatric disease of epic 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 addictive;

(4) virtually all new users of tobacco products are under the minimum legal age to purchase tobacco products;

(5) tobacco advertising and marketing contribute significantly to the use of nicotine-containing tobacco products by adolescents;

(6) since 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 tobacco products are needed;

(7) Federal and State governments have lacked the legal and regulatory authority and resources 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, 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 affect interstate

commerce because tobacco products are sold, marketed, advertised, and distributed in interstate commerce on a nationwide basis;

(11) the sale, distribution, marketing, advertising, and use of tobacco 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 adopt comprehensive public health legislation because of—

(A) the unique position of tobacco in the history and economy of the United States; and

(B) the need to prevent the sale, distribution, marketing and advertising of tobacco products to persons under the minimum legal age to purchase tobacco products;

(13) the public interest requires a timely, fair, equitable, and consistent result that will serve the public interest by restricting throughout the United States the sale, distribution, marketing, and advertising of tobacco products only to persons of legal age to purchase tobacco products;

(14) public health authorities estimate that the benefits to the United States of enacting Federal legislation to accomplish the goals described in this section would be significant in human and economic terms;

(15) reducing the use of tobacco by minors by 50 percent would prevent well over 60,000 early deaths each year and save up to \$43,000,000,000 each year in reduced medical costs, improved productivity, and the avoidance of premature deaths;

(16)(A) advertising, marketing, and promotion of tobacco products have been especially directed to attract young persons to use tobacco products, resulting in increased use of tobacco products by youth; and

(B) past efforts to oversee those activities have not been successful in adequately preventing the increased use;

(17) tobacco advertising increases the size of the market consumption of tobacco products and the use of tobacco by young people;

(18) children—

(A) are more influenced by tobacco advertising than adults; and

(B) smoke the most advertised brands;

(19) tobacco company documents indicate that young people are an important and often crucial segment of the tobacco market;

(20) advertising restrictions will have a positive effect on the smoking rates of young people;

(21) restrictions on advertising are necessary to prevent unrestricted tobacco advertising from undermining legislation prohibiting access to young people; and

(22) it is in the public interest for Congress to adopt legislation to address the public health crisis created by actions of the tobacco industry.

Subtitle A—FDA Jurisdiction Over Tobacco Products

SEC. 511. DEFINITION OF TOBACCO PRODUCT.

Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following:

“(11) TOBACCO PRODUCT.—

“(A) IN GENERAL.—The term ‘tobacco product’ means any product made or derived from tobacco that is intended for human consumption.

“(B) INCLUSIONS.—The term ‘tobacco product’ includes any component, part, or accessory of a tobacco product.

“(C) EXCLUSIONS.—The term ‘tobacco product’ does not include any raw material, other than tobacco, used in manufacturing a component, part, or accessory of a tobacco product.”.

SEC. 512. TOBACCO PRODUCTS.

The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is amended—

(1) by redesignating chapter IX (21 U.S.C. 391 et seq.) as chapter X;

(2) by redesignating sections 901 through 907 (21 U.S.C. 391 through 397) as sections 1001 through 1007, respectively; and

(3) by inserting after chapter VIII (21 U.S.C. 381 et seq.) the following:

“CHAPTER IX—TOBACCO PRODUCTS

“SEC. 901. DEFINITIONS.

“In this title:

“(1) BRAND.—The term ‘brand’ means a variety of tobacco product distinguished by the tobacco used, tar content, nicotine content, flavoring used, size, filtration, or packaging, logo, registered trademark or brand name, identifiable pattern of colors, or any combination of those attributes.

“(2) CIGARETTE.—The term ‘cigarette’ has the meaning given the term in section 3 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1332).

“(3) COMMERCE.—The term ‘commerce’ has the meaning given the term in section 3 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1332).

“(4) CONSTITUENT.—The term ‘constituent’ means, with respect to cigarettes, any element of mainstream or sidestream smoke.

“(5) DISTRIBUTOR.—

“(A) IN GENERAL.—The term ‘distributor’ means, with respect to a tobacco product, any person that furthers the distribution of cigarette or smokeless tobacco, whether domestic or imported, at any point from the original place of manufacture to the place of business of a person that sells or distributes the product to individuals for personal consumption.

“(B) EXCLUSION.—The term ‘distributor’ does not include a common carrier.

“(6) INGREDIENT.—

“(A) IN GENERAL.—The term ‘ingredient’ means, with respect to cigarettes or smokeless tobacco products, any substance, chemical, or compound (other than tobacco, water, or reconstituted tobacco sheet made wholly from tobacco) added, or specified for addition, by a manufacturer to the tobacco, paper, or filter of a cigarette, or to the tobacco of a smokeless tobacco product.

“(B) INCLUSIONS.—The term ‘ingredient’ includes, with respect to cigarettes or smokeless tobacco products, flavorants, processing aids, casing sauces, preservatives, and combustion modifiers.

“(7) MANUFACTURER.—

“(A) IN GENERAL.—The term ‘manufacturer’ means any person that manufactures a tobacco product intended to be sold in the United States.

“(B) INCLUSIONS.—The term ‘manufacturer’ includes an importer, or other first purchaser for resale in the United States, of—

“(i) a tobacco product manufactured outside of the United States; or

“(ii) a tobacco product manufactured in the United States but not intended for sale in the United States.

“(8) 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.

“(9) PACKAGE.—The term ‘package’ means—

“(A) a pack, box, carton, or container of any kind; or

“(B) if no other container is used, any wrapping (including cellophane) in which cigarettes or smokeless tobacco is offered for sale, sold, or otherwise distributed to consumers.

“(10) RETAILER.—The term ‘retailer’ means any person that—

“(A) sells cigarettes or smokeless tobacco to individuals for personal consumption; or

“(B) operates a facility at which self-service displays of tobacco products are permitted.

“(11) SMOKELESS TOBACCO.—The term ‘smokeless tobacco’ means any product that—

“(A) consists of cut, ground, powdered, or leaf tobacco; and

“(B) is intended to be placed in the oral or nasal cavity.

“SEC. 902. FDA JURISDICTION OVER TOBACCO PRODUCTS.

“(a) IN GENERAL.—A tobacco product shall be regulated by the Secretary under this chapter and shall not be subject to the provisions of chapter V, except to the extent that—

“(1) the tobacco product is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease (within the meaning of section 201(g)(1)(B) or 201(h)(2)); or

“(2) a health claim is made for the tobacco product under section 201(g)(1)(C) or 201(h)(3), except that this paragraph shall not apply to a reduced exposure tobacco product or a reduced risk tobacco product covered by section 913.

“(b) APPLICABILITY.—This chapter shall apply to—

“(1) all tobacco products subject to part 897 of title 21, Code of Federal Regulations and any successor regulations; and

“(2) any other tobacco product that the Secretary by regulation determines to be subject to this chapter.

“(c) SCOPE.—

“(1) OTHER PRODUCTS.—Nothing in this chapter affects the authority of the Secretary over, or the regulation of, products under this Act that are not tobacco products under chapter V or any other chapter of this Act.

“(2) LEAF TOBACCO.—

“(A) DEFINITION OF CONTROLLED BY.—In this paragraph, the term ‘controlled by’ means, when used with respect to a tobacco product manufacturer, that the tobacco product manufacturer—

“(i) is a member of the same controlled group of corporations (as that term is used in section 52(a) of the Internal Revenue Code of 1986); or

“(ii) is under common control (within the meaning of the regulations promulgated under section 52(b) of that Code).

“(B) NONAPPLICABILITY.—This chapter shall not apply to—

“(i) leaf tobacco that is not in the possession of a manufacturer; or

“(ii) a producer of leaf tobacco, including a tobacco grower, tobacco warehouse, and tobacco grower cooperative.

“(C) ENTRY ONTO FARMS.—An officer or employee of the Food and Drug Administration shall not have any authority to enter onto a farm owned by a producer of leaf tobacco without the written consent of the producer.

“(D) DUAL CAPACITY AS LEAF TOBACCO PRODUCER AND MANUFACTURER.—Notwithstanding any other provision of this subparagraph, if a producer of leaf tobacco is also a tobacco product manufacturer or is controlled by a tobacco product manufacturer, the producer shall be subject to this chapter in the producer’s capacity as a manufacturer.

“(E) REGULATIONS ON LEAF TOBACCO PRODUCTION.—Nothing in this chapter grants the Secretary authority to promulgate regulations on any matter that involves the production of leaf tobacco or a producer of leaf tobacco, other than activities by a manufacturer affecting production.

“SEC. 903. ADULTERATED TOBACCO PRODUCTS.

“(a) CONTAMINATED SUBSTANCES.—A tobacco product shall be deemed adulterated if the tobacco product—

“(1) consists in whole or in part of any filthy, putrid, or decomposed substance; or

“(2) is otherwise contaminated by any poisonous or deleterious substance that may render the tobacco product more injurious to health.

“(b) UNSANITARY CONDITIONS.—A tobacco product shall be deemed adulterated if the tobacco product has been prepared, packed, or held under unsanitary conditions under which the tobacco product may have been contaminated with filth, or under which the tobacco product may have been rendered more injurious to health.

“(c) CONTAINERS.—A tobacco product shall be deemed adulterated if the container of the tobacco product is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents more injurious to health.

“(d) PERFORMANCE STANDARDS.—A tobacco product shall be deemed adulterated if the tobacco product is, purports to be, or is represented as a tobacco product that is subject to a performance standard established under section 908 unless the tobacco product is in all respects in conformity with the standard.

“(e) PREMARKET APPROVAL.—A tobacco product shall be deemed adulterated if the tobacco product—

“(1) is required by section 911(b) to have premarket approval;

“(2) is not exempt under section 907(f); and

“(3) does not have an approved application in effect.

“(f) MANUFACTURING PRACTICES.—A tobacco product shall be deemed adulterated if the methods used in, or the facilities or controls used for, the manufacture, packing, or storage of the tobacco product are not in conformity with applicable requirements under section 907(e)(1) or an applicable condition prescribed by an order under section 907(e)(2).

“(g) INVESTIGATIONAL USE.—A tobacco product shall be deemed adulterated if—

“(1) the tobacco product is a tobacco product for which an exemption has been granted under section 907(f) for investigational use; and

“(2) the person that is granted the exemption or any investigator that uses the tobacco product under the exemption fails to comply with a requirement prescribed by or under section 907(f).

“(h) IMPORTED CIGARETTES.—A tobacco product shall be deemed adulterated if the tobacco product is imported, or offered for import, into the United States in violation of section 5754 of the Internal Revenue Code of 1986 or title VIII of the Tariff Act of 1930 (19 U.S.C. 1681 et seq.).

“SEC. 904. MISBRANDED TOBACCO PRODUCTS.

“(a) FALSE LABELING.—A tobacco product shall be deemed misbranded if the labeling of the tobacco product is false or misleading.

“(b) MISLABELED PACKAGES.—

“(1) IN GENERAL.—Subject to paragraph (2), a tobacco product in package form shall be deemed misbranded unless the tobacco product bears a label containing—

“(A) the name and place of business of the tobacco product manufacturer, packer, or distributor; and

“(B) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

“(2) ADMINISTRATION.—In carrying out paragraph (1)(B), the Secretary shall (by regulation)—

“(A) permit reasonable variations; and

“(B) establish exemptions for small packages.

“(c) INFORMATION.—A tobacco product shall be deemed misbranded 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 on the label or labeling with such conspicuousness (as compared with other words, statements, or designs in the labeling) and in such terms as to render the information likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

“(d) ESTABLISHED NAME.—A tobacco product shall be deemed misbranded if—

“(1) the tobacco product has an established name; and

“(2) the label of the tobacco product does not bear, to the exclusion of any other non-proprietary name, the established name of the tobacco product prominently printed in type, as required by the Secretary by regulation.

“(e) DIRECTIONS.—A tobacco product shall be deemed misbranded if the Secretary has promulgated regulations requiring that the labeling of the tobacco product bear adequate directions for use, or adequate warnings against use by children, that are necessary for the protection of users unless the labeling of the tobacco product conforms in all respects to the regulations.

“(f) PROCESSING.—A tobacco product shall be deemed misbranded if—

“(1) the tobacco product was manufactured, prepared, propagated, compounded, or processed in any State in an establishment not duly registered under section 906(b);

“(2) the tobacco product was not included in a list required by section 906(i);

“(3) a notice or other information with respect to the tobacco product was not provided as required by section 906(i) or 906(j); or

“(4) the tobacco product does not bear such symbols from the uniform system for identification of tobacco products prescribed under section 906(e) as the Secretary by regulation requires.

“(g) FALSE ADVERTISING.—In the case of any tobacco product distributed or offered for sale in any State, a tobacco product shall be deemed misbranded if—

“(1) the advertising of the tobacco product is false or misleading; or

“(2) the tobacco product is sold, distributed, advertised, or promoted in violation of section 916 or regulations prescribed under section 907(d).

“(h) REQUIRED STATEMENTS.—In the case of any tobacco product distributed or offered for sale in any State, a tobacco product shall be deemed misbranded unless the manufacturer, packer, or distributor of the tobacco product includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to the tobacco product—

“(1) a true statement of the established name of the tobacco product (as required under subsection (d)), printed prominently; and

“(2) a brief description of—

“(A) the uses of the tobacco product and relevant warnings, precautions, side effects, and contraindications; and

“(B) in the case of specific tobacco products made subject to a finding by the Secretary after notice and opportunity for comment that the action is necessary to protect the public health, a full description of the components of the tobacco product or the formula showing quantitatively each ingredient of the tobacco product, to the extent required in regulations which shall be promulgated by the Secretary after an opportunity for a hearing.

“(i) MANDATORY DISCLAIMERS.—In the case of any tobacco product distributed or offered for sale in any State, a tobacco product shall be deemed misbranded unless the manufacturer, packer, or distributor of the tobacco product includes in all advertisements the information required by section 917(c).

“(j) PERFORMANCE STANDARDS.—A tobacco product shall be deemed misbranded if the tobacco product is a tobacco product subject to a performance standard established under section 908, unless the tobacco product bears such labeling as may be prescribed in the performance standard.

“(k) NOTICE.—A tobacco product shall be deemed misbranded if there is a failure or refusal—

“(1) to comply with any requirement prescribed under section 905 or 909; or

“(2) to furnish any material or information required by or under section 910.

“(l) LABELING.—A tobacco product shall be deemed misbranded if the tobacco product is not in compliance with—

“(1) the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1331 et seq.); or

“(2) the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4401 et seq.).

“(m) PRIOR APPROVAL OF STATEMENTS ON LABEL.—

“(1) IN GENERAL.—Subject to paragraphs (2) and (3), the Secretary may, by regulation, require prior approval of statements made on the label of a tobacco product.

“(2) ADVERTISEMENT CONTENT.—In the case of matters specified in this section or covered by regulations promulgated under this section—

“(A) no regulation promulgated under this subsection may require prior approval by the Secretary of the content of any advertisement; and

“(B) no advertisement of a tobacco product, published after the date of enactment of the Tobacco Livelihood and Economic Assistance for Our Farmers Act of 2002, shall be subject to sections 12 through 15 of the Federal Trade Commission Act (15 U.S.C. 52 through 55).

“(3) LABELING.—This subsection does not apply to any printed matter that the Secretary determines to be labeling (as defined in section 201).

“SEC. 905. SUBMISSION OF HEALTH INFORMATION TO THE SECRETARY.

“(a) REQUIREMENT.—Not later than 180 days after the date of enactment of the Tobacco Livelihood and Economic Assistance for Our Farmers Act of 2002, each tobacco product manufacturer or importer of tobacco products, or their agents, shall submit to the Secretary the following information:

“(1) A listing of all tobacco ingredients, substances, and compounds that are, as of that date, added by the manufacturer to the tobacco, paper, filter, or other component 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.

“(3) All documents (including underlying scientific information) relating to research activities and research findings conducted, supported, or possessed by the manufacturer (or agents) on the health, behavioral, or physiological effects of tobacco products, their constituents, ingredients, and components, and tobacco additives described in paragraph (1).

“(4) All documents (including underlying scientific information) relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer (or agents) that relate to the issue of whether a reduction in risk to health from tobacco products can occur on the employment of technology available or known to the manufacturer.

“(5) All documents (including underlying scientific information) relating to marketing research involving the use of tobacco products.

“(b) ANNUAL SUBMISSION OF INFORMATION.—A tobacco product manufacturer or importer that is required to submit information under subsection (a) shall update the information on an annual basis in accordance with a schedule determined by the Secretary.

“(c) TIME FOR SUBMISSION.—

“(1) NEW PRODUCTS.—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 Tobacco Livelihood and Economic Assistance for Our Farmers Act of 2002—

“(A) the manufacturer of the tobacco product shall provide the information required under subsection (a); and

“(B) the tobacco product shall be subject to the annual submission requirement under subsection (b).

“(2) MODIFICATION OF EXISTING PRODUCTS.—Not later than 60 days after the date of an action described in this paragraph, a tobacco product manufacturer shall advise the Secretary of the action in writing, and reference the action in submissions made under subsection (b), if the manufacturer—

“(A) adds to the tobacco product a new tobacco additive;

“(B) increases or decreases the quantity of an existing tobacco additive or the nicotine content, delivery, or form; or

“(C) eliminates a tobacco additive from the tobacco product.

“SEC. 906. ANNUAL REGISTRATION.

“(a) DEFINITIONS.—In this section:

“(1) MANUFACTURE, PREPARATION, COMPOUNDING, OR PROCESSING.—The term ‘manufacture, preparation, compounding, or processing’ includes (consistent with section 902(c)(2)) 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 of the tobacco product to the place of business of the person that makes final delivery or sale to the ultimate consumer or user.

“(2) NAME.—The term ‘name’ includes—

“(A) in the case of a partnership, the name of each partner; and

“(B) in the case of a corporation—

“(i) the name of each corporate officer and director; and

“(ii) the State of incorporation.

“(b) REGISTRATION BY OWNERS AND OPERATORS.—On or before December 31 of each year, each person that owns or operates any establishment in any State engaged in the manufacture, preparation, compounding, or processing of 1 or more tobacco products shall register with the Secretary the name, places of business, and all such establishments of the person.

“(c) REGISTRATION OF NEW OWNERS AND OPERATORS.—On first engaging in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products in an establishment owned or operated in any State by a person, the person shall immediately register with the Secretary the person’s name, place of business, and the establishment.

“(d) REGISTRATION OF ADDED ESTABLISHMENTS.—Each person required to register under subsection (b) or (c) shall immediately register with the Secretary any additional establishment that person owns or operates in any State and at which the person begins the manufacture, preparation, compounding, or processing of 1 or more tobacco products.

“(e) UNIFORM PRODUCT IDENTIFICATION SYSTEM.—The Secretary may by regulation—

“(1) prescribe a uniform system for the identification of tobacco products; and

“(2) require that persons that are required to list the tobacco products under subsection (i) shall list the tobacco products in accordance with the system.

“(f) PUBLIC ACCESS TO REGISTRATION INFORMATION.—On request, the Secretary shall make available for inspection any registration filed under this section.

“(g) BIENNIAL INSPECTION OF REGISTERED ESTABLISHMENTS.—

“(1) IN GENERAL.—Each establishment in any State registered with the Secretary under this section shall be subject to inspection under section 704.

“(2) ADMINISTRATION.—Each 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—

“(A) at least once during the 2-year period beginning with the date of registration of the establishment under this section; and

“(B) at least once in every successive 2-year period thereafter.

“(h) FOREIGN ESTABLISHMENTS.—

“(1) REGISTRATION.—Any establishment within any foreign country engaged in the manufacture of a tobacco product that is imported, or offered for import, into the United States shall register with the Secretary the name and place of business of the establishment and the name of the United States agent for the establishment.

“(2) REGISTRATION INFORMATION.—Any establishment required to be registered under paragraph (1) shall—

“(A) provide to the Secretary the information required by subsection (i); and

“(B) comply with any other requirement of this section that is applicable to domestic manufacturers.

“(3) INSPECTIONS.—Any establishment required to be registered under paragraph (1) shall—

“(A) be subject to inspection under section 704; and

“(B) be inspected under that section by 1 or more officers or employees designated by the Secretary at least once during—

“(i) the 2-year period beginning on the date of the registration of the establishment under paragraph (1); and

“(ii) each 2-year period thereafter.

“(4) COOPERATIVE AGREEMENTS.—The Secretary may enter into cooperative agreements with officials of foreign countries to ensure that adequate and effective means are available for purposes of determining, from time to time, whether tobacco products manufactured by an establishment required to be registered under paragraph (1), if imported or offered for import into the United States, shall be refused admission under section 801(a).

“(i) REGISTRATION INFORMATION.—

“(1) PRODUCT LIST.—Each person that registers with the Secretary under subsection (b), (c), or (d) shall, at the time of registration under any of those subsections, file with the Secretary a list of all tobacco products that—

“(A) are being manufactured, prepared, compounded, or processed by the person for commercial distribution; and

“(B) have not been included in any list of tobacco products filed by that person with the Secretary under this paragraph or paragraph (2) before the time of registration.

“(2) CONTENTS OF LIST.—The 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 performance standard has been established under section 908 or that is subject to section 911—

“(i) a reference to the authority for the marketing of the tobacco product; and

“(ii) a copy of all labeling for the tobacco product;

“(B) in the case of any other tobacco product contained in an applicable list—

“(i) a copy of all consumer information and other labeling for the tobacco product;

“(ii) a representative sampling of advertisements for the tobacco product; and

“(iii) on 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 the list is not subject to a performance standard established under section 908, a brief statement of the basis on which the registrant made the determination, if the Secretary requests such a statement with respect to the particular tobacco product.

“(3) SEMIANNUAL REPORT OF ANY CHANGE IN PRODUCT LIST.—Each person that registers with the Secretary under this subsection 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)(i) A list of each tobacco product introduced by the registrant for commercial distribution that has not been included in any list previously filed by the person with the Secretary under this subparagraph or paragraph (1).

“(ii) A list under this subparagraph shall list a tobacco product by the established name of the tobacco product and shall be accompanied by the other information required by paragraphs (1) and (2).

“(B) If, since the date the registrant last made a report under this paragraph, the 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)—

“(i) notice of the discontinuance;

“(ii) the date of the discontinuance; and

“(iii) the identity of the established name of the tobacco product.

“(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 a notice of discontinuance was reported, notice of the resumption, the date of the resumption, the identity of the tobacco product by established name, and other information required by paragraphs (1) and (2), unless the registrant has previously reported the 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.—Each person that is required to register under this section and that 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 in the United States as of the date of enactment of the Tobacco Livelihood and Economic Assistance for Our Farmers Act of 2002 (as defined by the Secretary by regulation) shall, at least 90 days before making the introduction or delivery, report to the Secretary (in such form and manner as the Secretary shall by regulation prescribe)—

“(1) the basis for the person’s determination that the tobacco product is substantially equivalent (as defined in section 911) to a tobacco product commercially marketed in the United States as of the date of enactment of the Tobacco Livelihood and Economic Assistance for Our Farmers Act of

2002 that is in compliance with the requirements of this Act; and

“(2) action taken by the person to comply with the requirements under section 908 that are applicable to the tobacco product.

“SEC. 907. GENERAL PROVISIONS CONCERNING CONTROL OF TOBACCO PRODUCTS.

“(a) IN GENERAL.—

“(1) APPLICABLE REQUIREMENTS.—Any requirement established by or under section 903, 904, 906, or 910 that is applicable to a tobacco product shall apply to the tobacco product until the applicability of the requirement to the tobacco product has been changed by action taken under section 908, section 911, or subsection (d).

“(2) INAPPLICABLE REQUIREMENTS.—Any requirement established by or under section 903, 904, 906, or 910 that is inconsistent with a requirement imposed on the tobacco product under section 908, section 911, or subsection (d) shall not apply to the tobacco product.

“(b) INFORMATION ON PUBLIC ACCESS AND COMMENT.—

“(1) APPLICATION.—This subsection applies to—

“(A) each notice of proposed rulemaking under this section or section 908, 909, 910, or 911;

“(B) any other notice that is published in the Federal Register with respect to any other action taken under any such section and that states the reasons for the action; and

“(C) each publication of findings required to be made in connection with rulemaking under any such section.

“(2) INFORMATION.—Each notice and publication described in paragraph (1) shall set forth—

“(A) the manner in which interested persons may examine data and other information on which the notice or findings are based; and

“(B) the period within which interested persons may present their comments on the notice or findings (including the need for the notice or findings) orally or in writing, which period shall be not less than 60 days, and not more than 90 days, unless the period is extended by the Secretary by a notice published in the Federal Register stating good cause for the extension.

“(c) LIMITED CONFIDENTIALITY OF INFORMATION.—

“(1) IN GENERAL.—Except as provided in paragraph (2), any information reported to or otherwise obtained by the Secretary or the Secretary's representative under section 704, 905, 906, 908, 909, 910, 911, or 913, or under subsection (e) or (f), that is exempt from disclosure under section 552(a) of title 5, United States Code, by reason of section 552(b)(4) of that title shall be considered confidential and shall not be disclosed.

“(2) EXCEPTIONS.—Information described in paragraph (1) may be disclosed—

“(A) to other officers or employees that are carrying out this chapter; or

“(B) when relevant in any proceeding under this chapter.

“(d) RESTRICTIONS.—

“(1) IN GENERAL.—The Secretary may by regulation require that a tobacco product be restricted to sale or distribution on such conditions (including restrictions on the access to, and the advertising and promotion of, the tobacco product) as the Secretary may prescribe in the regulation if the Secretary determines that the regulation would be appropriate for the prevention of, or decrease in, the use of tobacco products by children under the age at which tobacco products may be legally purchased.

“(2) PRESCRIPTIONS.—No condition under paragraph (1) 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.

“(3) LABELS.—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 by regulation prescribe.

“(4) FACE-TO-FACE TRANSACTIONS.—No restriction under paragraph (1) may prohibit the sale of any tobacco product in face-to-face transactions by a specific category of retail outlets.

“(e) GOOD MANUFACTURING PRACTICES.—

“(1) METHODS, FACILITIES, AND CONTROLS.—

“(A) IN GENERAL.—The Secretary may, in accordance with subparagraph (B), prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation (including a process to assess the performance of a tobacco product), and packing, and storage of a tobacco product conform to current good manufacturing practice for an agricultural product, as prescribed in the regulations, to ensure that the public health is protected and that the tobacco product is in compliance with this chapter.

“(B) ADMINISTRATION.—The Secretary shall—

“(i) before promulgating any regulation under subparagraph (A), afford an 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 advisory committee a reasonable time to make the recommendation of the advisory committee with respect to a proposed regulation under subparagraph (A); and

“(iv) in establishing the effective date of a regulation promulgated under this subsection—

“(I) take into account the differences in—

“(aa) the manner in which the different types of tobacco products have historically been produced;

“(bb) the financial resources of the different tobacco product manufacturers; and

“(cc) the state of their existing manufacturing facilities; and

“(II) provide for a reasonable period of time for the manufacturers to conform to good manufacturing practices.

“(2) EXEMPTIONS; VARIANCES.—

“(A) IN GENERAL.—Any person subject to any requirement prescribed under paragraph (1) may petition the Secretary for a permanent or temporary exemption or variance from the requirement.

“(B) CONTENT.—The 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 ensure 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.

“(C) ADVISORY COMMITTEE.—

“(i) REFERRAL.—The Secretary may refer to an advisory committee any petition submitted under subparagraph (A).

“(ii) RECOMMENDATIONS.—The advisory committee shall report the recommenda-

tions of the advisory committee to the Secretary with respect to a petition referred to the advisory committee within 60 days after the date of the petition's referral.

“(iii) DEADLINE FOR APPROVAL OR DENIAL.—The Secretary shall by order either approve or deny the petition not later than 60 days after the later of—

“(I) the date on which the petition was submitted to the Secretary under subparagraph (A); or

“(II) the day after the date on which the petition was referred to an advisory committee.

“(D) GROUNDS FOR 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 the requirement is not required to ensure 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, controls, and facilities prescribed by the requirement are sufficient to ensure that the tobacco product will be in compliance with this chapter.

“(E) 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 ensure that the tobacco product will be in compliance with this chapter.

“(F) HEARING.—After the issuance of an order under subparagraph (C) with respect to a petition, the petitioner shall have an opportunity for an informal hearing on the order.

“(f) EXEMPTION FOR INVESTIGATIONAL USE.—The Secretary may exempt tobacco products intended for investigational use from this chapter under such conditions as the Secretary may prescribe by regulation.

“(g) RESEARCH AND DEVELOPMENT.—The Secretary may enter into contracts for research, testing, and demonstrations with respect to tobacco products, and may obtain tobacco products for research, testing, and demonstration purposes, without regard to section 3324(a) and (b) of title 31, United States Code, and section 5 of title 41, United States Code.

“SEC. 908. PERFORMANCE STANDARDS.

“(a) IN GENERAL.—

“(1) FINDING.—

“(A) REQUIREMENT.—The Secretary may adopt a performance standard for a tobacco product if the Secretary finds that the performance standard is appropriate for the protection of the public health.

“(B) BASIS.—The finding shall be determined with respect to the risks and benefits to the population as a whole, including users and non-users of the tobacco product, and taking into account—

“(i) the increased or decreased likelihood that existing users of tobacco products will stop using tobacco products; and

“(ii) the increased or decreased likelihood that those individuals who do not use tobacco products will start using tobacco products.

“(2) CONTENT OF PERFORMANCE STANDARDS.—A performance standard established under this section for a tobacco product—

“(A) shall include provisions to provide performance that is appropriate for the protection of the public health, including provisions, where appropriate—

“(i) for the reduction of nicotine yields of the tobacco product;

“(ii) for the reduction or elimination of other harmful constituents or harmful components of the tobacco product; or

“(iii) relating to any other requirement under subparagraph (B);

“(B) shall, if necessary for the protection of public health, include—

“(i) provisions respecting the construction, components, ingredients, 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 performance characteristics of the tobacco product; and

“(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) demonstrate that the tobacco product is in conformity with the portions of the standard for which the test or tests were required; and

“(C) shall not render the tobacco product unacceptable for adult consumption.

“(3) PERIODIC REEVALUATION OF PERFORMANCE STANDARDS.—

“(A) IN GENERAL.—The Secretary shall provide for periodic evaluation of performance standards established under this section to determine whether the standards should be changed to reflect new medical, scientific, or other technological data.

“(B) TESTER.—The Secretary may provide for testing under paragraph (2) by any person.

“(4) INVOLVEMENT OF OTHER AGENCIES; INFORMED PERSONS.—In carrying out duties under this section, the Secretary shall, to the maximum extent practicable—

“(A) use available personnel, facilities, and other technical support of 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, or consumer organizations who, in the Secretary’s judgment, can make a significant contribution.

“(b) ESTABLISHMENT, AMENDMENT, OR REVOCATION OF STANDARDS.—

“(1) NOTICE.—

“(A) IN GENERAL.—The Secretary shall publish in the Federal Register a notice of proposed rulemaking for the establishment, amendment, or revocation of any performance standard for a tobacco product.

“(B) ESTABLISHMENT OR AMENDMENT.—A notice of proposed rulemaking for the establishment or amendment of a performance standard for a tobacco product shall—

“(i) set forth a finding with supporting justification that the performance standard is appropriate for the protection of the public health;

“(ii) set forth proposed findings with respect to the risk of illness or injury that the performance standard is intended to reduce or eliminate; and

“(iii) invite interested persons to submit an existing performance standard for the tobacco product, including a draft or proposed performance standard, for consideration by the Secretary.

“(C) REVOCATION.—A notice of proposed rulemaking for the revocation of a performance standard shall set forth a finding with supporting justification that the performance standard is no longer necessary for the protection of the public health.

“(D) ADMINISTRATION.—The Secretary shall—

“(i) consider all information submitted in connection with a proposed standard, including information concerning the countervailing effects of the performance standard on the health of adolescent tobacco users, adult tobacco users, or non-tobacco 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 the demand; and

“(ii) issue the standard, if the Secretary determines that the standard would be appropriate for the protection of the public health.

“(E) COMMENT PERIOD.—In issuing a standard under this subsection, the Secretary shall provide for a comment period of not less than 60 days.

“(2) PROMULGATION.—

“(A) IN GENERAL.—After the expiration of the period for comment on a notice of proposed rulemaking published under paragraph (1) with respect to a performance standard and after consideration of the comments and any report from an advisory committee, the Secretary shall—

“(i) promulgate a regulation establishing a performance standard and publish in the Federal Register findings on the matters referred to in paragraph (1); or

“(ii) publish a notice terminating the proceeding for the development of the standard, together with the reasons for the termination.

“(B) EFFECTIVE DATE.—

“(i) IN GENERAL.—Subject to clauses (ii) and (iii), a regulation establishing a performance standard shall set forth the 1 or more dates on which the standard takes effect.

“(ii) EARLIEST EFFECTIVE DATE.—No such regulation may take effect before the date that is 1 year after the date of the publication of the regulation unless the Secretary determines that an earlier effective date is necessary for the protection of the public health.

“(iii) BASIS.—The 1 or more effective 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.

“(3) POWERS RESERVED TO CONGRESS.—Congress expressly reserves the power to make a decision establishing a performance standard—

“(A) eliminating all cigarettes, all smokeless tobacco products, or any similar class of tobacco products; or

“(B) requiring the reduction of nicotine yields of a tobacco product to zero.

“(4) AMENDMENT; REVOCATION.—

“(A) IN GENERAL.—On the Secretary’s own initiative or on petition of an interested person, the Secretary may, by regulation promulgated in accordance with paragraphs (1) and (2)(B), amend or revoke a performance standard.

“(B) INTERIM EFFECTIVENESS.—The Secretary may declare a proposed amendment of a performance standard to be effective on and after the publication of the amendment in the Federal Register and until the effective date of any final action taken on the amendment, if the Secretary determines that making it so effective is in the public interest.

“(5) REFERENCE TO ADVISORY COMMITTEE.—

“(A) IN GENERAL.—In the case of a proposed regulation for the establishment, amendment, or revocation of a performance standard, the Secretary—

“(i) on the Secretary’s own initiative, may refer to an advisory committee, for a report and recommendation, any matter involved in

the proposed regulation that requires the exercise of scientific judgment; and

“(ii) on the request of an interested person that demonstrates good cause for referral and that is made before the expiration of the period for submission of comments on a proposed regulation, shall refer to an advisory committee, for a report and recommendation, any matter described in clause (i).

“(B) INFORMATION.—If a proposed regulation is referred to the advisory committee under this paragraph, the Secretary shall provide the advisory committee with the data and information on which the proposed regulation is based.

“(C) REPORT AND RECOMMENDATION.—Not later than 60 days after the referral of a proposed regulation, the advisory committee shall—

“(i) conduct an independent study of the data and information furnished to the advisory committee by the Secretary and other data and information before the advisory committee; and

“(ii) submit to the Secretary a report and recommendation with respect to the proposed regulation, together with all underlying data and information and a statement of the reason or basis for the recommendation.

“(D) COPY.—A copy of the report and recommendation shall be made public by the Secretary.

“SEC. 909. NOTIFICATION AND OTHER REMEDIES.

“(a) NOTIFICATION.—

“(1) CONDITIONS.—The Secretary may issue an order described in paragraph (2) if the Secretary determines that—

“(A) a tobacco product that is introduced or delivered for introduction into interstate commerce for commercial distribution presents a risk of substantial harm to the public health that exceeds the risks posed by similar tobacco products marketed before the date of enactment of the Tobacco Livelihood and Economic Assistance for Our Farmers Act of 2002; and

“(B)(i) notification under this subsection is necessary to eliminate the unreasonable risk of the harm; and

“(ii) no more practicable means is available under the provisions of this chapter (other than this section) to eliminate the risk.

“(2) ORDER.—If the Secretary makes a determination described in paragraph (2), the Secretary may issue such order as may be necessary to ensure that adequate notification is provided in an appropriate form, by the persons and means best suited under the circumstances involved, to all persons that should properly receive the notification in order to eliminate the risk.

“(3) MEANS.—The Secretary may order notification by any appropriate means, including public service announcements.

“(4) CONSULTATION.—Before issuing an order under this subsection, the Secretary shall consult with the persons that 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.

“(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 the tobacco product.

“(2) HEARING.—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 the tobacco product.

“(3) VACATION OF ORDER.—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.

“(4) AMENDMENT OF ORDER TO REQUIRE RECALL.—

“(A) IN GENERAL.—Except as provided in subparagraph (C), 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 amend the order to require a recall.

“(B) TIMETABLE.—The Secretary shall specify a timetable during which the tobacco product recall will occur and shall require periodic reports to the Secretary describing the progress of the recall.

“(C) CONTENTS.—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 the tobacco product.

“(D) NOTIFICATION BY RETAILERS.—In providing the notice required by subparagraph (C)(ii), the Secretary may use the assistance of retailers and other persons that distribute the tobacco product.

“(E) NOTIFICATION BY SECRETARY.—If a significant number of persons described in subparagraph (D) cannot be identified, the Secretary shall notify the 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. 910. RECORDS AND REPORTS ON TOBACCO PRODUCTS.

“(a) IN GENERAL.—Each person that 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 ensure that the tobacco product is not adulterated or misbranded and to otherwise protect public health.

“(b) ADMINISTRATION.—Regulations promulgated under subsection (a)—

“(1) may require a tobacco product manufacturer or importer to report to the Secretary in any case in which the manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that 1 of the marketed tobacco products of the manufacturer or importer 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 that are unduly burdensome to a tobacco product manufacturer or importer, taking into account the cost of complying with the 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

the regulations for submission of a report or information to the Secretary state the reason or purpose for the request and identify, to the maximum extent practicable, the 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 the report or information and identify to the maximum extent practicable the 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 disclosure is necessary—

“(A) to protect the medical welfare of an individual;

“(B) to determine risks to public health of a tobacco product; or

“(C) to verify a record, report, or information submitted under this chapter.

“(c) MEDICAL ETHICS AND PATIENT INTERESTS.—

“(1) IN GENERAL.—In promulgating regulations under this section, the Secretary shall have due regard for the professional ethics of the medical profession and the interests of patients.

“(2) CONFIDENTIALITY.—The prohibitions of subsection (b)(6) shall continue to apply to records, reports, and information concerning any individual that has been a patient, irrespective of whether or when the individual ceases to be a patient.

“(d) REPORTS OF REMOVALS AND CORRECTIONS.—

“(1) IN GENERAL.—Except as provided in paragraph (3), 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 the 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 that may present a risk to health.

“(2) RECORD.—A tobacco product manufacturer or importer of a tobacco product that undertakes a corrective action or removal from the market of a tobacco product that is not required to be reported under this subsection shall keep a record of the correction or removal.

“(3) PREVIOUS REPORT.—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. 911. PREMARKET REVIEW OF CERTAIN TOBACCO PRODUCTS.

“(a) DEFINITION OF SUBSTANTIALLY EQUIVALENT.—

“(1) IN GENERAL.—In this section and section 906(j), the term ‘substantially equivalent’ or ‘substantial equivalence’ mean, with respect to the tobacco product being compared to the predicate tobacco product, that the Secretary by order has determined that—

“(A) the tobacco product has the same characteristics as the predicate tobacco product; or

“(B) the tobacco product has different characteristics, and the information for the tobacco product submitted contains information, including clinical data if considered necessary by the Secretary, that demonstrates that it is not appropriate to regulate the product under the applicable section because the product could not reasonably be expected to increase the health risks to consumers compared to a conventional tobacco product that is commercially marketed in

the United States and that is in compliance with the requirements of this Act.

“(2) DEFINITION OF CHARACTERISTICS.—In subparagraph (A), the term ‘characteristics’ means the materials, ingredients, design, composition, heating source, or other features of a tobacco product.

“(3) INAPPLICABLE TOBACCO PRODUCTS.—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.

“(b) REQUIREMENT FOR PREMARKET APPROVAL.—

“(1) IN GENERAL.—Approval under this section of an application for premarket approval for any tobacco product, other than a reduced exposure tobacco product or a reduced risk tobacco product under section 913, that is not commercially marketed in the United States as of the date of enactment of the Tobacco Livelihood and Economic Assistance for Our Farmers Act of 2002 shall be required unless—

“(A) the manufacturer has submitted a report under section 906(j); and

“(B) the Secretary has not suspended the distribution of the product under this paragraph.

“(2) SUSPENSION OF DISTRIBUTION.—Not later than 90 days after the submission of a report under section 906(j), the Secretary may by order suspend the distribution of the tobacco product that is the subject of the report if the Secretary determines that there is a reasonable likelihood that the tobacco product is not substantially equivalent to a tobacco product that is—

“(A) commercially marketed in the United States as of the date of the Tobacco Livelihood and Economic Assistance for Our Farmers Act of 2002; and

“(B) in compliance with the requirements of this Act.

“(3) FAILURE TO ISSUE ORDER.—If the Secretary fails to issue an order within the 90-day period described in paragraph (2), the tobacco product that is the subject of the report shall be deemed to be substantially equivalent to a predicate tobacco product.

“(4) FINAL AGENCY ACTION.—

“(A) IN GENERAL.—Subject to subparagraph (B), the issuance of an order under this paragraph shall constitute final agency action for purposes of section 702 of title 5, United States Code.

“(B) RESCISSION OR MODIFICATION.—The Secretary may rescind or modify an order issued under this subsection at any time.

“(c) HEALTH INFORMATION.—

“(1) IN GENERAL.—As part of a submission under section 906(j) with respect to a tobacco product, the person required to file a premarket notification under section 906(j) shall provide an adequate summary of any health information relating to the tobacco product or state that the information will be made available on request by any person.

“(2) ADMINISTRATION.—Any summary under paragraph (1) respecting a tobacco product shall—

“(A) contain detailed information regarding data concerning adverse health effects; and

“(B) be made available to the public by the Secretary not later than 30 days after the date of issuance of a determination that the tobacco product is substantially equivalent to another tobacco product.

“(3) REQUIREMENTS.—The communication that the product is a reduced exposure tobacco product or a reduced risk tobacco product shall comply with requirements prescribed by the Secretary relating to the communication.

“(4) PRIOR APPROVAL.—The Secretary may require prior approval of the communication in each case in accordance with section 913.

“(d) APPLICATION.—

“(1) CONTENTS.—An application for premarket approval shall contain—

“(A) full reports of all information, published or known to, or that should reasonably be known to, the applicant, concerning investigations that have been made to show the health risks of the tobacco product and whether the tobacco product presents greater risk than other tobacco products;

“(B) a full statement of the components, ingredients, and properties, and of the principle or principles of operation, of the 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, the tobacco product;

“(D) an identifying reference to any performance standard under section 908 that would be applicable to any aspect of the tobacco product, and either adequate information to show that the aspect of the tobacco product fully meets the performance standard or adequate information to justify any deviation from the standard;

“(E) such samples of the tobacco product and of components of the tobacco product as the Secretary may reasonably require;

“(F) specimens of the labeling proposed to be used for the tobacco product; and

“(G) such other information relevant to the subject matter of the application as the Secretary may require.

“(2) REFERENCE TO ADVISORY COMMITTEE.—On receipt of an application meeting the requirements set forth in paragraph (1), the Secretary—

“(A) on the Secretary's own initiative, may refer the application to an advisory committee for submission (within such period as the Secretary may establish) of a report and recommendation respecting approval of the application, together with all underlying data and the reasons or basis for the recommendation; or

“(B) on the request of an applicant, shall refer the application to an advisory committee in accordance with subparagraph (A).

“(e) ACTION ON APPLICATION.—

“(1) DEADLINE.—

“(A) IN GENERAL.—As promptly as practicable, but not later than 180 days, after the date of receipt of an application under subsection (d), the Secretary, after considering the report and recommendation submitted under subsection (d)(2), shall—

“(i) issue an order approving the application, if the Secretary finds that none of the grounds for denying approval specified in paragraph (2) applies; or

“(ii) deny approval of the application, if the Secretary finds (and sets forth the basis for the finding as part of or accompanying the denial) that 1 or more grounds for denial specified in paragraph (2) apply.

“(B) SALES RESTRICTIONS.—An order approving an application for a tobacco product may require as a condition to the approval 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 promulgated under section 907(d).

“(2) DENIAL OF APPROVAL.—The Secretary shall deny approval of an application for a tobacco product if, on the basis of the information submitted to the Secretary as part of the application and any other information before the Secretary with respect to the tobacco product, the Secretary finds that—

“(A) there is a lack of a showing that permitting the tobacco product to be marketed would pose no greater risk to the public

health than currently marketed tobacco products;

“(B) the methods used in, or the facilities or controls used for, the manufacture, processing, or packing of the tobacco product do not conform to the requirements of section 907(e);

“(C) based on a fair evaluation of all material facts, the proposed labeling is false or misleading; or

“(D)(i) the tobacco product is not shown to conform in all respects to a performance standard in effect under section 908, compliance with which is a condition to approval of the application; and

“(ii) there is a lack of adequate information to justify the deviation from the standard.

“(3) DENIAL INFORMATION.—Any denial of an application shall, to the extent that the Secretary determines to be practicable, be accompanied by a statement informing the applicant of the measures required to make the application approvable (which measures may include further research by the applicant in accordance with 1 or more protocols prescribed by the Secretary).

“(4) BASIS FOR ACTION.—

“(A) IN GENERAL.—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) EVIDENCE.—If the Secretary determines that there exists valid scientific evidence (other than evidence derived from investigations described in subparagraph (A)) that is sufficient to evaluate the tobacco product, the Secretary may authorize that the determination under paragraph (2)(A) be made on the basis of the evidence.

“(f) WITHDRAWAL AND TEMPORARY SUSPENSION.—

“(1) IN GENERAL.—The Secretary shall, on obtaining, where appropriate, advice on scientific matters from an advisory committee, and after due notice and opportunity for informal hearing to the holder of an approved application for a tobacco product, issue an order withdrawing approval of the application if the Secretary finds that—

“(A) the continued marketing of the tobacco product poses greater risks to the public health than other available products;

“(B) the application contained or was accompanied by a false or misleading statement of a material fact;

“(C) 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 910;

“(ii) has refused to permit access to, or copying or verification of, the records as required by section 704; or

“(iii) has not complied with the requirements of section 906;

“(D) on the basis of new information before the Secretary with respect to the tobacco product, evaluated, together with the evidence before the Secretary when the application was approved, whether the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or installation of the tobacco product do not conform with the requirements of section 907(e) and were not brought into conformity with the 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 ap-

plication was approved, whether the labeling of the tobacco product, based on a fair evaluation of all material facts, is false or misleading and was not corrected within a reasonable time after receipt of written notice from the Secretary of the fact; or

“(F) on the basis of new information before the Secretary, evaluated, together with the evidence before the Secretary when the application was approved, whether the tobacco product is shown to conform in all respects to a performance standard that is in effect under section 908, compliance with which was a condition to approval of the application, and whether there is a lack of adequate information to justify the deviation from the standard.

“(2) APPEAL.—The holder of an application subject to an order issued under paragraph (1) withdrawing approval of the application may, by petition filed on or before the 30th day after the date on which the holder receives notice of the withdrawal, obtain review of the order in accordance with subsection (e).

“(3) TEMPORARY SUSPENSION.—

“(A) IN GENERAL.—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 approved application 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 approval of the application approved under this section.

“(B) WITHDRAWAL OF APPLICATION.—If the Secretary issues such an order, the Secretary shall proceed expeditiously under paragraph (1) to withdraw the application.

“(g) 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.

“SEC. 912. JUDICIAL REVIEW.

“(a) DEFINITION OF RECORD.—In this section, the term ‘record’ means—

“(1) all notices and other matter published in the Federal Register with respect to a regulation or order reviewed;

“(2) all information submitted to the Secretary with respect to—

“(A) a regulation or order;

“(B) proceedings of any panel or advisory committee with respect to the regulation or order; and

“(C) any hearing held with respect to the regulation or order; and

“(3) any other information identified by the Secretary, in the administrative proceeding held with respect to the regulation or order, as being relevant to the regulation or order.

“(b) PETITION.—

“(1) IN GENERAL.—Not later than 30 days after the date of promulgation of a regulation under section 908 establishing, amending, or revoking a performance standard for a tobacco product, or a denial of an application for approval under section 911(c), any person adversely affected by the regulation or order may file a petition with the United States Court of Appeals for the District of Columbia, or for the circuit in which the person resides or has the person's principal place of business, for judicial review of the regulation or order.

“(2) COPY OF PETITION.—A copy of the petition shall be transmitted by the clerk of the court to the Secretary or other officer designated by the Secretary for that purpose.

“(3) RECORD OF PROCEEDINGS.—

“(A) FILING.—The Secretary shall file in the court the record of the proceedings on which the Secretary based the Secretary's regulation or order.

“(B) RATIONALE.—Each record or order shall contain a statement of the reasons for the issuance of the order and the basis, on the record, for the issuance of the order.

“(C) ADDITIONAL FINDINGS BY SECRETARY.—

“(1) IN GENERAL.—The court may order the Secretary to provide additional opportunity for the oral presentation of data, views, or arguments and for written submissions if the petitioner—

“(A) applies to the court for leave to adduce additional data, views, or arguments respecting the regulation or order being reviewed; and

“(B) demonstrates to the satisfaction of the court that—

“(i) the additional data, views, or arguments are material; and

“(ii) there were reasonable grounds for the petitioner's failure to adduce the data, views, or arguments in the proceedings before the Secretary.

“(2) MODIFICATION.—The Secretary—

“(A) may modify the Secretary's findings, or make new findings by reason of the additional data, views, or arguments so taken; and

“(B) shall file with the court—

“(i) the modified or new findings;

“(ii) the Secretary's recommendation, if any, for the modification or setting aside of the regulation or order being reviewed; and

“(iii) the return of the additional data, views, or arguments.

“(d) STANDARD OF REVIEW.—

“(1) IN GENERAL.—On the filing of the petition under subsection (a) for judicial review of a regulation or order, the court shall have jurisdiction—

“(A) to review the regulation or order in accordance with chapter 7 of title 5, United States Code; and

“(B) to grant appropriate relief, including interim relief, as provided in that chapter.

“(2) STANDARD.—A regulation or order described in paragraph (1) or (2) of subsection (a) shall not be affirmed if the regulation or order is found to be unsupported by substantial evidence on the record taken as a whole.

“(e) 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 on certiorari or certification, as provided in section 1254 of title 28, United States Code.

“(f) OTHER REMEDIES.—The remedies provided for in this section shall be in addition to and not in lieu of any other remedy provided by law.

“(g) REGULATIONS AND ORDERS MUST RECITE BASIS IN RECORD.—To facilitate judicial review under this section or under any other provision of law or a regulation or order issued under section 907, 908, 909, 910, 911, or 914, each such regulation or order shall contain a statement of—

“(1) the reasons for the issuance of the regulation or order; and

“(2) the basis, in the record of the proceedings held in connection with the issuance of the regulation or order, for the issuance of the regulation or order.

“SEC. 913. REDUCED EXPOSURE AND REDUCED RISK TOBACCO PRODUCTS.

“(a) DEFINITIONS OF REDUCED EXPOSURE AND REDUCED RISK TOBACCO PRODUCTS.—In this section, the terms ‘reduced exposure tobacco product’ and ‘reduced risk tobacco product’ mean a tobacco product designated by the Secretary as a reduced exposure tobacco product or a reduced risk tobacco product, respectively, under subsection (b).

“(b) DESIGNATION.—

“(1) IN GENERAL.—A product may be designated by the Secretary as a reduced exposure tobacco product or a reduced risk tobacco product if the Secretary finds that the product is demonstrated to significantly reduce harm to individuals caused by a tobacco product in accordance with the standards provided under subparagraph (B), based on an application submitted by the manufacturer of the product (or other responsible person) that—

“(A)(i) demonstrates, through appropriate chemical and biological testing (including testing on animals and short-term human testing), that use of the product results in ingestion or inhalation of a substantially lower yield of toxic substances than use of another tobacco product in the same or different category as the subject tobacco product; or

“(ii) contains scientific evidence showing that use of the product results in a substantially lower potential risk to health in 1 or more specific respects than use of another tobacco product in the same or different category as the proposed reduced exposure tobacco product or the reduced risk product; and

“(B) if required by the Secretary, includes studies of the long-term health effects of the product.

“(2) CONSULTATION ON PROTOCOLS.—If studies are required under paragraph (1), the manufacturer may consult with the Secretary regarding protocols for conducting the studies.

“(3) BASIS FOR FINDING.—

“(A) REDUCED EXPOSURE TOBACCO PRODUCTS.—The Secretary shall designate a tobacco product as a reduced exposure tobacco product if the Secretary determines, based on such information as may be submitted by the applicant and other available information, that—

“(i) the product substantially reduces exposure to 1 or more tobacco toxicants; and

“(ii) independent scientific experts have found or predict, through clinical or epidemiological studies, a measurable reduction in the morbidity or mortality associated with the use of the product compared with the use of other tobacco products (whether in the same or a different category) commercially marketed in the United States.

“(B) REDUCED RISK TOBACCO PRODUCTS.—The Secretary shall designate a tobacco product as a reduced risk tobacco product only if the Secretary determines, based on such information as may be submitted by the applicant and other available information, that—

“(i) the product meets the criteria established under subparagraph (A); and

“(ii) there is sufficient evidence that the product can reasonably be expected to reduce the risk of 1 or more specific diseases or other adverse health effects, as compared with the use of other tobacco products (whether in the same or a different category) commercially marketed in the United States.

“(4) MARKETING REQUIREMENTS.—A tobacco product may be marketed and labeled as a reduced exposure tobacco product or a reduced risk tobacco product if the tobacco product—

“(A) has been designated by the Secretary under paragraph (1);

“(B) bears a label statement prescribed by the Secretary concerning the product's contribution to reducing harm to health; and

“(C) complies with—

“(i) requirements prescribed by the Secretary relating to marketing and advertising of the product to ensure that neither the marketing nor the labeling is false or misleading; and

“(ii) other provisions of this chapter, as prescribed by the Secretary.

“(c) REVOCATION OF DESIGNATION.—At any time after the date on which a tobacco product is designated as a reduced exposure tobacco product or a reduced risk tobacco product under this section, the Secretary may, after providing an opportunity for an informal hearing, revoke the designation if the Secretary determines, based on information not available at the time of the designation, that—

“(1) the finding made under subsection (b)(1) is no longer valid; or

“(2) the product is being marketed in violation of subsection (b)(3).

“(d) LIMITATION.—A tobacco product that is designated as a reduced exposure tobacco product or a reduced risk tobacco product that is in compliance with subsection (b) shall not be regulated as a drug or device.

“(e) DEVELOPMENT OF REDUCED EXPOSURE AND RISK TOBACCO PRODUCT TECHNOLOGY.—A tobacco product manufacturer shall provide written notice to the Secretary on the development or acquisition by the manufacturer of any technology that would reduce exposure to 1 or more tobacco toxicants, or the risk of a tobacco product to the health of the user, for which the manufacturer is not seeking designation as a reduced exposure tobacco product or a reduced risk tobacco product under this section.

“(f) POSTMARKET SURVEILLANCE.—

“(1) DISCRETIONARY SURVEILLANCE.—The Secretary may require a tobacco product manufacturer to conduct postmarket surveillance for a reduced exposure tobacco product or a reduced risk tobacco product of the manufacturer if the Secretary determines that postmarket surveillance of the tobacco product is necessary to protect the public health or is necessary to provide information regarding the health risks and other safety issues involving the tobacco product.

“(2) SURVEILLANCE APPROVAL.—

“(A) IN GENERAL.—Each tobacco product manufacturer required to conduct a surveillance of a reduced exposure tobacco product or a reduced risk tobacco product under paragraph (1) shall, not later than 30 days after receiving notice that the manufacturer is required to conduct the surveillance, submit, for the approval of the Secretary, a protocol for the required surveillance.

“(B) BASIS.—The Secretary, not later than 60 days after the receipt of the protocol, shall determine if—

“(i) the principal investigator proposed to be used in the surveillance has sufficient qualifications and experience to conduct the surveillance; and

“(ii) the protocol will result in collection of useful data or other information necessary to protect the public health.

“(C) REVIEW.—The Secretary may not approve such a protocol until the protocol has been reviewed by an appropriately qualified scientific and technical review committee established by the Secretary.

“SEC. 914. PRESERVATION OF STATE AND LOCAL AUTHORITY.**“(a) ADDITIONAL REQUIREMENTS.—**

“(1) IN GENERAL.—Except as provided in paragraph (2), nothing in this Act prohibits a State or political subdivision of a State from adopting or enforcing a requirement applicable to a tobacco product that is in addition to, or more stringent than, requirements established under this chapter.

“(2) PREEMPTION OF CERTAIN STATE AND LOCAL REQUIREMENTS.—

“(A) IN GENERAL.—Except as provided in subparagraph (B), no State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement that is different from, or in

addition to, any requirement applicable under the provisions of this chapter relating to performance standards, premarket approval, adulteration, misbranding, registration, labeling, good manufacturing standards, or reduced exposure tobacco products or reduced risk tobacco products.

“(B) SALE, DISTRIBUTION, OR USE.—Subparagraph (A) does not apply to requirements relating to the sale, use, or distribution of a tobacco product, including requirements relating to the access to, and the advertising and promotion of, a tobacco product.

“(b) PRODUCT LIABILITY.—No provision of this chapter relating to a tobacco product modifies or otherwise affects any action or the liability of any person under the product liability law of any State.

“SEC. 915. EQUAL TREATMENT OF RETAIL OUTLETS.

“The Secretary shall promulgate regulations that require that retail establishments for which the predominant business is the sale of tobacco products to comply with any advertising restrictions applicable to retail establishments accessible to individuals under the age of 18.

“SEC. 916. ACCESS AND MARKETING RESTRICTIONS.

“(a) DEFINITIONS.—In this section:

“(1) ADULT.—The term ‘adult’ means any person who is older than the minimum age at which it is legal to purchase or possess (whichever minimum age is older) tobacco products.

“(2) ADULT-ONLY FACILITY.—

“(A) IN GENERAL.—The term ‘adult-only facility’ means a facility or restricted area (whether open-air or enclosed) where the operator ensures or has a reasonable basis to believe (such as by checking identification as required under State law, or by checking the identification of any person appearing to be under the age of 27) that only adults are present.

“(B) TEMPORARY ADULT-ONLY FACILITY.—A facility or restricted area need not be permanently restricted to adults in order to constitute an adult-only facility, if the operator ensures or has a reasonable basis to believe that only adults are present during the event or time period in question.

“(3) BRAND NAME.—

“(A) IN GENERAL.—The term ‘brand name’ means a brand name (alone or in conjunction with any other word), trademark, logo, symbol, motto, selling message, recognizable pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any domestic brand of tobacco products.

“(B) EXCLUSION.—The term ‘brand name’ shall not include the corporate name of any tobacco product manufacturer that does not, after the date of enactment of the Tobacco Livelihood and Economic Assistance for Our Farmers Act of 2002, sell a brand of tobacco products in the United States that includes the corporate name.

“(b) CIGARETTE AND SMOKELESS TOBACCO PRODUCT REQUIREMENTS.—

“(1) MINIMUM SALES AGE.—No retailer may sell a tobacco product to any person younger than 18 years of age.

“(2) PROOF OF AGE.—

“(A) IN GENERAL.—Except as provided in subparagraph (B), each retailer shall verify by means of photographic identification containing the bearer’s date of birth that no person purchasing the product is younger than 18 years of age.

“(B) MAXIMUM AGE.—No such verification is required for any person over the age of 26.

“(3) ENFORCEMENT BY STATES.—

“(A) IN GENERAL.—The Secretary may enter into an agreement with a State if—

“(i) the State has in effect a State law that is at least as restrictive as this subsection

under which the State agrees to enforce the State law in a manner reasonably designed to prevent the violation of the State law; and

“(ii) the Secretary provides a grant to the State for the purpose of enforcing the State law.

“(B) AUTHORITY OF SECRETARY.—No action taken by the Secretary under subparagraph (A) limits the authority of the Secretary under this subsection.

“(4) MAIL ORDER SALES.—Not later than 2 years after the date of enactment of the Tobacco Livelihood and Economic Assistance for Our Farmers Act of 2002, the Secretary shall submit to Congress a report describing the extent, if any, to which individuals younger than 18 years of age are obtaining tobacco products through the mail.

“(c) MINIMUM PACKAGE SIZE REQUIREMENTS.—

“(1) MINIMUM NUMBER OF CIGARETTES.—No manufacturer, distributor, or retailer may sell or cause to be sold, or distribute or cause to be distributed, any cigarette package that contains fewer than 20 cigarettes.

“(2) OPENING TOBACCO PRODUCT PACKAGES.—No retailer may break or otherwise open any tobacco product package to sell or distribute individual cigarettes or a number of unpackaged cigarettes that is smaller than—

“(A) the quantity in the minimum cigarette package size provided under paragraph (1); or

“(B) any quantity of another tobacco product that is smaller than the smallest package distributed by the manufacturer for individual consumer use.

“(d) PROHIBITION ON YOUTH ACCESS TO FREE SAMPLES.—

“(1) DEFINITION OF FREE SAMPLE.—In this subsection, the term ‘free sample’ does not include a tobacco product that is provided to an adult in connection with—

“(A) the purchase, exchange or redemption for proof of purchase of any tobacco product (including a free offer in connection with the purchase of a tobacco product, such as a 2-for-1 offer); or

“(B) the conducting of consumer testing or evaluation of a tobacco product with persons who certify that they are adults.

“(2) PROHIBITION.—No manufacturer, distributor, or retailer may distribute or cause to be distributed any free sample of a tobacco product, except in an adult-only facility.

“(e) VENDING MACHINES, SELF-SERVICE DISPLAYS, MAIL-ORDER SALES, AND OTHER IMPERSONAL MODES OF SALE.—

“(1) DEFINITION OF SELF-SERVICE DISPLAY.—In this subsection, the term ‘self-service display’ means any display located in an area in which the customer has access to the tobacco products without the aid of a sales clerk.

“(2) REQUIREMENT.—Except as provided in paragraph (3), a retailer may sell a tobacco product—

“(A) only in a direct, face-to-face exchange between the retailer and the consumer; and

“(B) not through a method of sale such as a vending machine or self-service display.

“(3) PERMITTED METHODS.—The following methods of sale of tobacco products shall be permitted under this subsection:

“(A) Mail-order sales, excluding mail-order redemption of coupons and distribution of free samples through the mail.

“(B) Vending machines that are located in an adult-only facility.

“(f) PROHIBITION ON YOUTH TARGETING.—

“(1) DEFINITION OF YOUTH.—In this subsection, the term ‘youth’ means any person or persons under 18 years of age.

“(2) PROHIBITION.—No manufacturer, distributor, or retailer may take—

“(A) any action, directly or indirectly, to target youth in the advertising, promotion, or marketing of tobacco products; or

“(B) any action the primary purpose of which is to initiate, maintain, or increase the incidence of youth smoking.

“(g) PROHIBITION ON USE OF CARTOONS.—

“(1) DEFINITION OF CARTOON.—In this subsection:

“(A) IN GENERAL.—The term ‘cartoon’ means any drawing or other depiction of an object, person, animal, or creature, or any similar caricature, that satisfies any of the following criteria:

“(i) The use of comically exaggerated features.

“(ii) The attribution of human characteristics to animals, plants, or other objects, or the similar use of anthropomorphic techniques.

“(iii) The attribution of unnatural or extrahuman abilities, such as imperviousness to pain or injury, X-ray vision, tunneling at very high speeds, or transformation.

“(B) INCLUSION.—The term ‘cartoon’ includes a drawing or other depiction of the character popularly known as ‘Joe Camel’.

“(C) EXCLUSIONS.—The term ‘cartoon’ does not include any drawing or other depiction that, on July 1, 1998, was in use in the United States in any manufacturer’s corporate logo or in any manufacturer’s tobacco product packaging.

“(2) PROHIBITION.—No manufacturer, distributor, or retailer may use or cause to be used any cartoon in the advertising, promoting, packaging, or labeling of tobacco products.

“(h) PROHIBITION ON OUTDOOR ADVERTISING.—

“(1) DEFINITIONS.—In this subsection:

“(A) OUTDOOR ADVERTISING.—

“(i) IN GENERAL.—The term ‘outdoor advertising’ means advertising through—

“(I) billboards;

“(II) signs and placards in arenas, stadiums, shopping malls, and video game arcades (regardless of whether located in the open air or enclosed); and

“(III) any other advertisements placed—

“(aa) outdoors; or

“(bb) on the inside surface of a window facing outward.

“(ii) EXCLUSIONS.—The term ‘outdoor advertising’ does not include—

“(I) an advertisement on the outside of a tobacco product manufacturing facility;

“(II) an individual advertisement that—

“(aa) does not occupy an area larger than 14 square feet;

“(bb) is not placed in such proximity to any other such advertisement so as to create a single mosaic-type advertisement larger than 14 square feet;

“(cc) does not function solely as a segment of a larger advertising unit or series; and

“(dd) is placed on the outside of any retail establishment that sells tobacco products (other than solely through a vending machine), on the outside (but on the property of) any such establishment, or on the inside surface of a window facing outward in any such establishment; or

“(III) an advertisement inside a retail establishment that sells tobacco products (other than solely through a vending machine) that is not placed on the inside surface of a window facing outward.

“(B) VIDEO GAME ARCADE.—The term ‘video game arcade’ means an entertainment establishment primarily consisting of video games (other than video games intended primarily for use by persons 18 years of age or older) or pinball machines.

“(2) PROHIBITION.—No manufacturer, distributor, or retailer may place or cause to be

placed any outdoor advertisement for tobacco products.

“(i) PROHIBITION ON TRANSIT ADVERTISEMENTS.—

“(1) DEFINITION OF TRANSIT ADVERTISEMENT.—In this subsection:

“(A) IN GENERAL.—The term ‘transit advertisement’ means—

“(i) advertising on or within a private or public vehicle; and

“(ii) an advertisement placed at, on, or within any bus stop, taxi stand, transportation waiting area, train station, airport, or any similar location.

“(B) EXCLUSION.—The term ‘transit advertisement’ does not include any advertisement placed in, on, or outside the premises of any retail establishment that sells tobacco products (other than solely through a vending machine), unless the individual advertisement—

“(i) occupies an area larger than 14 square feet;

“(ii) is placed in such proximity to any other such advertisement so as to create a single mosaic-type advertisement larger than 14 square feet; or

“(iii) functions solely as a segment of a larger advertising unit or series.

“(2) PROHIBITION.—No manufacturer, distributor, or retailer may place or cause to be placed any transit advertisement advertising tobacco products.

“(j) PROHIBITION ON ADVERTISING IN YOUTH-ORIENTED PUBLICATIONS.—

“(1) DEFINITION OF YOUTH-ORIENTED PUBLICATION.—In this subsection, the term ‘youth-oriented publication’ means a newspaper, magazine, periodical, or other publication—

“(A) at least 15 percent of the total readership of which is comprised of readers younger than 18 years of age, as measured by competent and reliable survey evidence; or

“(B) that is read by 2,000,000 or more persons younger than 18 years of age, as measured by competent and reliable survey evidence.

“(2) PROHIBITION.—No manufacturer, distributor, or retailer shall advertise a tobacco product in any youth-oriented publication, regardless of whether the publication has periodic or limited distribution.

“(k) PROHIBITION ON TOBACCO PRODUCT BRAND NAME SPONSORSHIPS.—

“(1) IN GENERAL.—No manufacturer, distributor, or retailer may sponsor or cause to be sponsored any athletic, musical, artistic, or other social or cultural event, or any entry or team in any event, using the brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, that used for any brand of cigarettes or smokeless tobacco.

“(2) EXCEPTIONS.—Nothing in this subsection prevents a manufacturer, distributor, or retailer from sponsoring or causing to be sponsored any athletic, musical, artistic, or other social or cultural event, or team or entry, in the name of the corporation that manufactures the tobacco product, if—

“(A) both the corporate name and the corporation were registered and in use in the United States before January 1, 2001; and

“(B) the corporate name does not include any brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, that used for any brand of cigarettes or smokeless tobacco.

“(3) ADULT-ONLY FACILITIES.—This subsection shall not apply to any event sponsored in an adult-only facility.

“(1) PROHIBITION ON TOBACCO BRAND NAME MERCHANDISE.—

“(1) IN GENERAL.—No manufacturer may market, distribute, offer, sell, license or cause to be marketed, distributed, offered, sold, or licensed (including by catalog or direct mail), any apparel or other merchandise that bears the brand name of a tobacco product, other than items the sole function of which is to advertise tobacco products or written or electronic publications.

“(2) EXCEPTIONS.—Nothing in this subsection shall—

“(A) prohibit the distribution to any manufacturer’s employee who is an adult of any item described in paragraph (1) that is intended for the personal use of the employee;

“(B) require any manufacturer to retrieve, collect, or otherwise recover any item that, before the date of enactment of the Tobacco Livelihood and Economic Assistance for Our Farmers Act of 2002, was marketed, distributed, offered, sold, licensed, or caused to be marketed, distributed, offered, sold, or licensed by the manufacturer;

“(C) apply to coupons or other items used by adults solely in connection with the purchase of tobacco products; or

“(D) apply to apparel or other merchandise used within an adult-only facility that is not distributed (by sale or otherwise) to any member of the general public.

“(m) PROHIBITION ON GIFTS TO UNDERAGE PERSONS BASED ON PROOFS OF PURCHASE.—

“(1) IN GENERAL.—No manufacturer, distributor, or retailer may provide or cause to be provided to any person, without sufficient proof that the person is an adult, any item in exchange for the purchase of tobacco products, or the furnishing of credits, proofs-of-purchase, or coupons with respect to such a purchase.

“(2) PROOF OF AGE.—

“(A) IN GENERAL.—For purposes of paragraph (1), a driver’s license or other government-issued identification (or legible photocopy of the license or identification), the validity of which is certified by the person to whom the item is provided, shall by itself be deemed to be a sufficient form of proof of age.

“(B) RETAILERS.—In the case of items provided (or to be redeemed) at retail establishments, a manufacturer shall be entitled to rely on verification of proof of age by the retailer, if the retailer is required to obtain verification under applicable Federal, State, or local law.

“(n) PROHIBITION ON NON-TOBACCO PRODUCT BRAND NAMES.—

“(1) DEFINITION OF OTHER VALUABLE CONSIDERATION.—In this subsection, the term ‘other valuable consideration’ does not include an agreement between 2 entities that enter into an agreement for the sole purpose of avoiding infringement claims.

“(2) PROHIBITION.—Except as provided in paragraph (3), no manufacturer may, pursuant to any agreement requiring the payment of money or other valuable consideration, use or cause to be used as a brand name of any tobacco product—

“(A) any nationally recognized or nationally established brand name or trade name of any non-tobacco item or service; or

“(B) any nationally recognized or nationally established sports team, entertainment group, or individual celebrity.

“(3) NONAPPLICABILITY.—Paragraph (2) shall not apply to any tobacco product brand name in existence as of July 1, 1998.

“(o) LIMITATION ON THIRD PARTY USE OF TOBACCO BRAND NAMES.—

“(1) IN GENERAL.—No manufacturer may license or otherwise expressly authorize any third party to use or advertise any brand name of a tobacco product in a manner pro-

hibited by this chapter if used or advertised by the manufacturer itself.

“(2) EXCEPTIONS.—Nothing in this subsection requires any manufacturer to retrieve, collect, or otherwise recover any item that, before the date of enactment of the Tobacco Livelihood and Economic Assistance for Our Farmers Act of 2002, was marketed, distributed, offered, sold, licensed, or caused to be marketed, distributed, offered, sold, or licensed by the manufacturer.

“(p) PROHIBITION ON PRODUCT PLACEMENT IN CERTAIN MEDIA.—

“(1) IN GENERAL.—Except as provided in paragraph (2), no manufacturer may make, or cause to be made, any payment or other consideration to any other person or entity to use, display, make reference to, or use as a prop any tobacco product, tobacco product package, advertisement for a tobacco product, or any other item bearing a brand name in any motion picture, television show, theatrical production or other live performance, live or recorded performance of music, commercial film or video, or video game (collectively referred to in this subsection as ‘media’).

“(2) EXCEPTIONS.—Paragraph (1) shall not apply to—

“(A) media the audience or viewers of which are within an adult-only facility, if the media are not visible to persons outside the adult-only facility;

“(B) media not intended for distribution or display to the public; or

“(C) instructional media concerning non-conventional tobacco products or tobacco products designated as reduced exposure tobacco products or reduced risk tobacco products viewed only by or provided only to consumers who are adults.

“(q) EFFECTIVE DATES.—

“(1) IN GENERAL.—Except as provided in paragraph (2), this section shall apply beginning on the date that is 180 days after the date of enactment of the Tobacco Livelihood and Economic Assistance for Our Farmers Act of 2002.

“(2) VENDING MACHINES; SPONSORSHIPS.—Subsections (e) and (k) shall apply beginning on the date that is 1 year after the date of enactment of that Act.

“SEC. 917. MANDATORY DISCLOSURES.

“(a) DISCLOSURE OF INGREDIENTS TO THE PUBLIC.—

“(1) IN GENERAL.—Not later than 1 year after the date of enactment of the Tobacco Livelihood and Economic Assistance for Our Farmers Act of 2002, except as otherwise provided in this subsection, the Secretary shall promulgate regulations requiring the disclosure to the public on a brand-by-brand basis of the common or usual name of each ingredient of a tobacco product in descending order of predominance by weight.

“(2) SPICES, FLAVORINGS, AND COLORINGS.—A manufacturer may elect to designate spices, flavorings, and colorings under paragraph (1) without naming each spice, flavoring, or coloring.

“(3) OTHER LAWS.—Any ingredient that has been disclosed to the public pursuant to any other law (including regulations) with respect to a particular brand may be required to be disclosed for the brand pursuant to this subsection.

“(4) INCIDENTAL ADDITIVES.—The regulations required by this subsection shall provide that incidental additives that are present in a tobacco product at insignificant levels and that do not have any technical or functional effect in the finished tobacco product shall be exempt from disclosure.

“(5) SMALL QUANTITIES.—The requirement of this subsection to disclose ingredients in descending order of predominance shall not

apply to ingredients in quantities of 2 percent or less by weight if a listing of the ingredients is placed at the end of the ingredients statement following an appropriate quantifying statement, such as 'contains ___ percent or less of ___', or 'less than ___ percent of ___'.

“(6) MEANS OF DISCLOSURE.—

“(A) IN GENERAL.—Except as provided in subparagraph (B), any disclosure required pursuant to this subsection may be required by appropriate means.

“(B) LISTING OF INGREDIENTS.—Notwithstanding any other provision of this Act, the Secretary shall not require the listing of any ingredient of a tobacco product on any package or in any advertisement.

“(b) DISCLOSURE OF PERCENTAGE OF DOMESTIC AND FOREIGN TOBACCO.—Not later than 1 year after the date of enactment of the Tobacco Livelihood and Economic Assistance for Our Farmers Act of 2002, the Secretary shall promulgate regulations that require that each package of a tobacco product disclose, with respect to the tobacco contained in that brand—

“(1) the percentage of tobacco that is domestic tobacco; and

“(2) the percentage of tobacco that is foreign tobacco.

“(c) MANDATORY DISCLAIMER.—

“(1) IN GENERAL.—Except as otherwise provided in this subsection, any tobacco product advertising that includes a term classifying a brand of tobacco product according to the tar yield or the yield of the brand to consumers of any substance, including terms such as ‘light’ or ‘low tar’, shall also include the following disclaimer: ‘[Brand] not shown to be less hazardous than other [type of tobacco product]’.

“(2) FILTERED.—This section shall apply to the use of the terms ‘filtered’ or ‘filter’.

“(3) TOBACCO PRODUCT PACKAGES.—A disclaimer described in paragraph (1) shall not be required on any tobacco product package.

“(4) USE OF TERMS.—Not later than 1 year after the date of enactment of the Tobacco Livelihood and Economic Assistance for Our Farmers Act of 2002, the Secretary shall promulgate regulations relating to the use of the terms described in paragraph (1) to ensure that the terms are not false or misleading.

“(5) REDUCED EXPOSURE AND REDUCED RISK TOBACCO PRODUCTS.—The Secretary may modify or waive any requirement under this subsection with respect to any product that has been designated by the Secretary as a reduced exposure tobacco product or a reduced risk tobacco product under section 913.

“SEC. 918. REGULATORY RECORD.

“(a) IN GENERAL.—Notwithstanding subchapter II of chapter 5 of title 5, United States Code, in promulgating regulations under this chapter, the record developed and used by the Secretary for the purposes of promulgating subparts (B) and (D) of the regulations relating to the sale, distribution, and use of tobacco products on or about August 28, 1996, as reflected in articles IV and VI of the preamble to the 1996 Food and Drug Administration Tobacco Rule (including public comments, Food and Drug Administration documents, and any other information generated or compiled for purposes of promulgating the regulations), shall be deemed to have the same legal status as if the record had been developed under a rule-making proceeding conducted pursuant to section 907(d)(1).

“(b) OTHER RESPECTS.—In all other respects (including the issue of whether the regulations conform to section 907(d)(1)), the procedural requirements of this chapter and subchapter II of chapter 5, and chapter 7, of title 5, United States Code (commonly

known as the ‘Administrative Procedure Act’) shall apply to this chapter.

“SEC. 919. REGULATION REQUIREMENT.

“(a) TESTING, REPORTING, AND DISCLOSURE.—Not later than 2 years after the date of enactment of the Tobacco Livelihood and Economic Assistance for Our Farmers Act of 2002, the Secretary, acting through the Commissioner of Food and Drugs, shall promulgate regulations under this Act that meet the requirements of subsection (b).

“(b) CONTENTS OF RULES.—

“(1) IN GENERAL.—The rules promulgated under subsection (a) shall require the testing, reporting, and disclosure of tobacco product smoke constituents and ingredients that the Secretary determines should be disclosed to the public in order to protect the public health.

“(2) CONSTITUENTS.—The constituents shall include tar, nicotine, carbon monoxide, and such other smoke constituents or ingredients as the Secretary may determine to be appropriate.

“(3) ADMINISTRATION.—The rules may require that tobacco product manufacturers, packagers, or importers make—

“(A) the disclosures relating to tar and nicotine through labels or advertising; and

“(B) the disclosures regarding other smoke constituents or ingredients that the Secretary determines are necessary to protect the public health.

“(c) AUTHORITY.—The Secretary, acting through the Commissioner of Food and Drugs, shall have authority to conduct or to require the testing, reporting, or disclosure of tobacco product smoke constituents.”

SEC. 513. CONFORMING AND TECHNICAL AMENDMENTS.

(a) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended—

(1) in subsections (a), (b), (c), (g), (h), and (k), by inserting “tobacco product,” after “device,” each place it appears;

(2) in subsection (e), by striking “515(f), or 519” and inserting “515(f), 519, or 910”;

(3) in subsection (j), by striking “708, or 721” and inserting “708, 721, 904, 905, 906, 907, 908, 909, 910, 911, or 913”;

(4) by striking subsection (p) and inserting the following:

“(p) The failure—

“(1) to register in accordance with section 510 or 906;

“(2) to provide any information required by section 510(j), 510(k), 906(i), or 906(j); or

“(3) to provide a notice required by section 510(j)(2) or 906(j)(2).”;

(5) in subsection (q)—

(A) by striking paragraph (1) and inserting the following:

“(1) The failure or refusal—

“(A) to comply with any requirement prescribed under section 518, 520(g), 907(f), or 909;

“(B) to furnish any notification or other material or information required by or under section 519, 520(g), 905, 907(f), or 910; or

“(C) to comply with a requirement under section 522.”; and

(B) in paragraph (2), by striking “device,” and inserting “device or tobacco product.”;

(6) in subsection (r), by inserting “or tobacco product” after “device” each place it appears; and

(7) by adding at the end the following:

“(bb) The sale of a tobacco product in violation of a no-tobacco-sale order issued under section 303(g)(3).”

(b) PENALTIES.—Section 303(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(g)) is amended—

(1) by striking “(g)(1)(A) Except” and inserting the following:

“(g) CIVIL PENALTIES.—

“(1) IN GENERAL.—

“(A) PENALTY.—Except”;

(2) in paragraph (1)(A), by inserting “or tobacco products” after “devices”;

(3) by redesignating paragraphs (3), (4), and (5) as paragraphs (4), (5), and (6), respectively;

(4) by inserting after paragraph (2) the following:

“(3) NO-TOBACCO-SALE ORDERS.—

“(A) IN GENERAL.—If the Secretary finds that a person has committed repeated violations of restrictions promulgated under section 906(d) at a particular retail outlet, the Secretary may impose a no-tobacco-sale order on the person prohibiting the sale of tobacco products in the outlet.

“(B) CIVIL PENALTIES.—A no-tobacco-sale order may be imposed with a civil penalty under paragraph (1).”;

(5) in paragraph (4) (as redesignated by paragraph (3))—

(A) in subparagraph (A)—

(i) in the first sentence, by striking “assessed” the first place it appears and inserting “assessed, or a no-tobacco-sale order may be imposed,”; and

(ii) in the second sentence, by striking “penalty” and inserting “penalty, or on whom a no-tobacco-order is to be imposed,”;

(B) in subparagraph (B)—

(i) by striking “(B) In” and inserting the following:

“(B) ADMINISTRATION.—

“(i) FACTORS.—In”

(ii) by inserting after “penalty” the following: “or the period to be covered by a no-tobacco-sale order.”; and

(iii) by adding at the end the following:

“(ii) NO-TOBACCO-SALE ORDERS.—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

(C) by adding at the end the following:

“(D) COMPROMISE, MODIFICATION, OR TERMINATION OF NO-TOBACCO-SALE ORDERS.—The Secretary may compromise, modify, or terminate, with or without conditions, any no-tobacco-sale order.”;

(6) in paragraph (5) (as redesignated by paragraph (3))—

(A) in the first sentence—

(i) by striking “(3)(A)” and inserting “(4)(A)”;

(ii) by inserting “or the imposition of a no-tobacco-sale order” after “penalty” the first 2 places it appears; and

(B) in the second sentence, by inserting before the period at the end the following: “, or on which the no-tobacco-sale order was imposed, as the case may be”; and

(7) in paragraph (6) (as redesignated by paragraph (3)), by striking “paragraph (4)” each place it appears and inserting “paragraph (5)”.

(c) SEIZURE.—Section 304 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334) is amended—

(1) in subsection (a)(2)—

(A) by striking “and” before “(D)”;

(B) by inserting before the period at the end the following: “, and (E) Any adulterated or misbranded tobacco product”;

(2) in the first sentence of subsection (d)(1), by inserting “tobacco product,” after “device,”; and

(3) in subsection (g), by inserting “or tobacco product” after “device” each place it appears.

(d) EXAMINATIONS AND INVESTIGATIONS.—Section 702(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 372(a)) is amended—

(1) by striking the section heading through

“(a) The Secretary” and inserting the following:

“SEC. 702. EXAMINATIONS AND INVESTIGATIONS.

“(a) IN GENERAL.—

“(1) AUTHORITY.—The Secretary”; and
(2) by adding at the end the following:

“(2) TOBACCO PRODUCTS.—In the case of a tobacco product, to the maximum extent practicable, the Secretary shall contract with States in accordance with paragraph (1) to carry out inspections of retailers in connection with the enforcement of this Act.”.

(e) RECORDS OF INTERSTATE SHIPMENT.—Section 703 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 373) is amended—

(1) by inserting “tobacco products,” after “devices,” each place it appears; and

(2) by inserting “tobacco product,” after “device,” each place it appears.

(f) FACTORY INSPECTION.—Section 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374) is amended—

(1) in subsection (a)(1), by inserting “tobacco products,” after “devices,” each place it appears; and

(2) in subsection (b), by inserting “tobacco product,” after “device.”.

(g) PUBLICITY.—Section 705(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 375(b)) is amended in the first sentence by inserting “tobacco products,” after “devices.”.

(h) PRESUMPTION.—Section 709 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379) is amended by inserting “tobacco product,” after “device.”.

(i) IMPORTS AND EXPORTS.—Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) is amended—

(1) in subsection (a)—

(A) in the first sentence, by inserting “tobacco products,” after “devices.”;

(B) in the second sentence, by striking “subsection (i) of section 510” and inserting “section 510(i) or 906(j)”;

(C) by striking “drugs or devices” each place it appears and inserting “drugs, devices, or tobacco products”;

(2) in subsection (e)(1), by inserting “tobacco product,” after “device.”.

(j) FOOD AND DRUG ADMINISTRATION.—Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (as redesignated by section 512(2)) is amended by striking “and devices” and inserting “devices, and tobacco products”.

(k) EFFECTIVE DATE FOR NO-TOBACCO-SALE ORDER AMENDMENTS.—The amendments made by subsection (a), other than the amendment to section 301(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(b)) made by subsection (a)(1), shall take effect only on the promulgation of final regulations by the Secretary of Health and Human Services—

(1) defining the term “repeated violation”, as used in section 303(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(g)) (as amended by subsection (b)), by identifying the number of violations of particular requirements over a specified period of time that constitute a repeated violation;

(2) providing for notice to the retailer of each violation at a particular retail outlet;

(3) providing that a person may not be charged with repeated violations at a particular retail outlet unless the Secretary has provided notice of previous violations at the outlet;

(4) establishing a period of time during which, if there are no violations by a particular retail outlet, the outlet will not be considered to have been the site of repeated violations when the next violation occurs; and

(5) providing that good faith reliance on false identification does not constitute a violation of any minimum age requirement for the sale of tobacco products.

Subtitle B—Cigarette Labeling and Advertising**SEC. 521. DEFINITION OF CIGARETTE.**

Section 3(1) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1332) is amended—

(1) in subparagraph (A), by striking “and” at the end;

(2) in subparagraph (B), by striking the period at the end and inserting “; and”; and

(3) by adding at the end the following:

“(C) any tobacco product, in any form (including Bidi and Kretek cigarettes), if—

“(i) the tobacco in the product—

“(I) is heated or burned; and

“(II) is functional in the product; and

“(ii) the product, because of the appearance of the product, the type of tobacco used in the filler, or the packaging and labeling of the product, is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco.”.

SEC. 522. CIGARETTE LABEL AND ADVERTISING WARNINGS.

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, 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, 1 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 non-smokers.

“WARNING: Quitting smoking now greatly reduces serious risks to your health.

“(2) FORMAT.—

“(A) LOCATION.—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.

“(B) PERCENTAGE OF PANELS.—Except as provided in subparagraph (C), each label statement shall comprise at least the top 25 percent of the front and rear panels of the package.

“(C) TEXT.—

“(i) IN GENERAL.—Except as provided in clause (ii), the word ‘WARNING’ shall appear in capital letters and all text shall be in conspicuous and legible 17-point type.

“(ii) SMALLER TYPE SIZE.—If the text of the label statement would occupy more than 70 percent of the area of a panel, the text may be in a smaller conspicuous and legible type size, if at least 60 percent of the area of the panel is occupied by required text.

“(iii) CONTRAST.—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 (b)(4).

“(D) FLIP-TOP BOXES.—

“(i) IN GENERAL.—For any cigarette brand package manufactured or distributed before January 1, 2000, that employs a flip-top style (if the packaging was used for that brand in commerce before June 21, 1997), the label

statement required by paragraph (1) shall be located on the flip-top area of the package, even if the area is less than 25 percent of the area of the front panel.

“(ii) PACKAGES.—Except as provided in clause (i), the provisions of this subsection shall apply to the package.

“(3) FOREIGN DISTRIBUTION.—This subsection does not apply to a tobacco product manufacturer or distributor of cigarettes that does not manufacture, package, or import cigarettes for sale or distribution within the United States.

“(4) TAR, NICOTINE, AND OTHER SMOKE CONSTITUENT DISCLOSURE TO THE PUBLIC.—

“(A) 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), or on the package label, or both, the tar and nicotine yields of the advertised or packaged brand.

“(B) METHOD.—Any such disclosure shall—

“(i) be in accordance with the methodology established under the regulations;

“(ii) conform to the type size requirements of subsection (b); and

“(iii) appear within the area specified in subsection (b).

“(C) CONSISTENCY WITH FTC REPORTING REQUIREMENTS.—Any differences between the requirements established by the Secretary under subparagraph (A) 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.

“(D) SMOKE CONSTITUENTS.—

“(i) IN GENERAL.—In addition to the disclosures required by subparagraph (A), 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 smoke constituent.

“(ii) CONDITIONS.—Any disclosure under this subparagraph may be required if the Secretary determines that disclosure would—

“(I) be of benefit to the public health; or

“(II) otherwise increase consumer awareness of the health consequences of the use of tobacco products.

“(iii) FACE OF CIGARETTE PACKAGE OR ADVERTISEMENT.—No disclosure shall be required under this subparagraph on the face of any cigarette package or advertisement.

“(iv) OTHER MEANS.—Nothing in this section prohibits the Secretary from requiring disclosure under this subparagraph through a cigarette or other tobacco product package or advertisement insert, or by any other means, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

“(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 the advertising for the cigarette bears, in accordance with this section, 1 of the labels specified in subsection (a)(1).

“(2) FORMAT.—

“(A) IN GENERAL.—Each label statement required by subsection (a) in cigarette advertising shall comply with the standards set forth in this paragraph.

“(B) PRESS AND POSTER ADVERTISEMENTS.—In the case of a press or poster advertisement, each such statement and (if applicable) any required statement relating to tar, nicotine, or other constituent yield shall—

“(i) comprise at least 20 percent of the area of the advertisement; and

“(ii) appear in a conspicuous and prominent format and location at the top of each advertisement within the border area.

“(C) REVISION OF TYPE SIZES.—The Secretary may revise the required type sizes in the border area in such manner as the Secretary determines appropriate.

“(D) TEXT.—

“(i) IN GENERAL.—The word ‘WARNING’ shall appear in capital letters, and each label statement shall appear in conspicuous and legible type.

“(ii) CONTRAST.—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 paragraph (4).

“(E) BORDER.—The label statement shall be enclosed by a rectangular border that is—

“(i) the same color as the letters of the statement; and

“(ii) the width of the first downstroke of the capital ‘W’ of the word ‘WARNING’ in the label statement.

“(F) TYPEFACE.—The text of the label statement shall be in a typeface pro rata to the following requirements:

“(i) 45-point type for a whole-page broadsheet newspaper advertisement.

“(ii) 39-point type for a half-page broadsheet newspaper advertisement.

“(iii) 39-point type for a whole-page tabloid newspaper advertisement.

“(iv) 27-point type for a half-page tabloid newspaper advertisement.

“(v) 31.5-point type for a double page spread magazine or whole-page magazine advertisement.

“(vi) 22.5-point type for a 28-centimeter-by-3-column advertisement.

“(vii) 15-point type for a 20-centimeter-by-2-column advertisement.

“(G) LANGUAGE.—

“(i) IN GENERAL.—Except as provided in clauses (ii) and (iii), the label statements shall be in English.

“(ii) NON-ENGLISH PUBLICATIONS.—In the case of an advertisement that appears in a newspaper, magazine, periodical, or other publication that is not in English, the statement shall appear in the predominant language of the publication.

“(iii) NON-ENGLISH ADVERTISEMENTS.—In the case of any other advertisement that is not in English, the statement shall appear in the same language as that principally used in the advertisement.

“(3) ADJUSTMENTS BY SECRETARY.—

“(A) IN GENERAL.—The Secretary may, through a rulemaking under section 553 of title 5, United States Code—

“(i) adjust the format and type sizes for the label statements required by this subsection;

“(ii) adjust the text, format, and type sizes of any required tar, nicotine yield, or other constituent disclosures; or

“(iii) establish the text, format, and type sizes for any other disclosures required under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

“(B) LOCATION.—

“(i) IN GENERAL.—The text of any such label statements or disclosures adjusted under this paragraph shall be required to appear only within the 20 percent area of cigarette advertisements required under paragraph (2).

“(ii) REGULATIONS.—The Secretary shall promulgate regulations that provide for adjustments in the format and type sizes of any text required to appear in the 20 percent area to ensure that the total text required to appear by law will fit within the area.

“(4) MARKETING REQUIREMENTS.—

“(A) IN GENERAL.—The label statements specified in subsection (a)(1) shall be randomly displayed—

“(i) in each 12-month period, in as equal a number of times as is practicable on each brand of the product; and

“(ii) 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) QUARTERLY 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.

“(C) APPROVAL OF PLAN.—The Secretary shall review each plan submitted under subparagraph (B) and approve the plan 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) ensures 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.

“(c) CHANGE IN REQUIRED 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 warning label statements required by this section (subject to the limitation on proportional size of the warning contained in subsections (a)(2) and (b)(2)), or establish the format, type size, and text of any other disclosures required under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), if the Secretary finds that such a change would promote greater public understanding of the risks associated with the use of cigarettes or smokeless tobacco products.”

Subtitle C—Smokeless Tobacco Labels and Advertising Warnings

SEC. 531. SMOKELESS TOBACCO LABELS AND ADVERTISING WARNINGS.

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) LABELS.—It shall be unlawful for any person to manufacture, package, 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, 1 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) FORMAT.—

“(A) LOCATION.—Each label statement required by paragraph (1) shall be located on the 2 principal display panels of the package.

“(B) PERCENT OF PANEL.—Each label statement shall comprise at least 25 percent of each display panel.

“(C) TEXT.—

“(i) IN GENERAL.—Except as provided in clause (ii), under the plan submitted under subsection (b)(3), each label statement shall be—

“(I) in 17-point conspicuous and legible type; and

“(II) in black text on a white background, or white text on a black background, in a manner that contrasts by typography, lay-

out, or color, with all other printed material on the package, in an alternating fashion.

“(ii) SMALLER TYPE.—If the text of a label statement would occupy more than 70 percent of the warning area of a package, the text may appear in a smaller type size, if least 60 percent of the warning area is occupied by the label statement.

“(3) CONCURRENT INTRODUCTION.—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 the products.

“(4) FOREIGN DISTRIBUTION.—This subsection does 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.

“(b) REQUIRED LABELS.—

“(1) IN GENERAL.—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 the advertising for the product bears, in accordance with this section, 1 of the labels specified in subsection (a)(1).

“(2) STANDARDS.—

“(A) IN GENERAL.—Each label statement required by subsection (a) in smokeless tobacco advertising shall comply with the standards set forth in this paragraph.

“(B) PRESS AND POSTER ADVERTISEMENTS.—For press and poster advertisements, each such statement and (where applicable) any required statement relating to tar, nicotine, or other constituent yield shall—

“(i) comprise at least 20 percent of the area of the advertisement, and the warning area shall be delineated by a dividing line of contrasting color from the advertisement; and

“(ii) the word ‘WARNING’ shall appear in capital letters and each label statement shall appear in conspicuous and legible type.

“(C) TEXT.—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).

“(3) MARKETING REQUIREMENTS.—

“(A) IN GENERAL.—The label statements specified in paragraph (1) shall be randomly displayed—

“(i) in each 12-month period, in as equal a number of times as is practicable on each brand of the product; and

“(ii) 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) QUARTERLY ROTATION.—The label statements specified in paragraph (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) APPROVAL OF PLAN.—The Secretary shall review each plan submitted under subparagraph (B) and approve the plan if the plan, as determined by the Secretary—

“(i) will provide for the equal distribution and display on packaging and the rotation required in advertising under this subsection; and

“(ii) ensures 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.

“(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.

“(d) AUTHORITY TO REVISE WARNING LABEL STATEMENTS.—The Secretary may, by a rule-making conducted under section 553 of title 5, United States Code, adjust the format, type size, and text of any of the warning label statements required by this section (subject to the limitations on proportional size of the warning required under this section), or establish the format, type size, and text of any other disclosures required under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), if the Secretary finds that such a change would promote greater public understanding of the risks associated with the use of smokeless tobacco products.”

Subtitle D—Administration

SEC. 541. FTC JURISDICTION NOT AFFECTED.

(a) IN GENERAL.—Except as otherwise expressly provided in this Act or an amendment made by this Act, nothing in this Act or an amendment made by this Act limits or diminishes the authority of the Federal Trade Commission to enforce the laws under the jurisdiction of the Commission with respect to the advertising, sale, or distribution of tobacco products.

(b) ENFORCEMENT BY FTC.—Any advertising that violates this Act or an amendment made by this Act shall be considered—

(1) an unfair or deceptive act or practice under section 5(a) of the Federal Trade Commission Act (15 U.S.C. 45(a)); and

(2) a violation of a rule promulgated under section 18 of that Act (15 U.S.C. 57a).

SUBMITTED RESOLUTIONS

SENATE RESOLUTION 304—ENCOURAGING THE SENATE COMMITTEE ON APPROPRIATIONS TO REPORT THIRTEEN, FISCALLY RESPONSIBLE, BIPARTISAN APPROPRIATIONS BILLS TO THE SENATE NOT LATER THAN JULY 31, 2002

Mr. BYRD submitted the following resolution; from the Committee on Appropriations; which was placed on the calendar.

S. RES. 304

Resolved, That the Senate encourages the Senate Committee on Appropriations to report thirteen, fiscally responsible, bipartisan appropriations bills to the Senate not later than July 31, 2002.

HONORING INVENTION OF MODERN AIR CONDITIONING

Mrs. LINCOLN. Mr. President, I ask unanimous consent that the Judiciary Committee be discharged from further consideration of H. Con. Res. 413 and that the Senate then proceed to its consideration.

The PRESIDING OFFICER. Without objection, it is so ordered. The clerk will report the concurrent resolution by title.

The assistant legislative clerk read as follows:

A concurrent resolution (H. Con. Res. 413) honoring the invention of modern air-conditioning by Dr. Willis H. Carrier on the occasion of its 100th anniversary.

There being no objection, the Senate proceeded to consider the concurrent resolution.

Mrs. LINCOLN. Mr. President, I ask unanimous consent that the concurrent resolution and preamble be agreed to en bloc, the motion to reconsider be laid upon the table en bloc, and that any statements relating thereto be printed in the RECORD, without further intervening action or debate.

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

The concurrent resolution (H. Con. Res. 413) was agreed to.

The preamble was agreed to.

HONORING THE INVENTION OF MODERN AIR CONDITIONING

Mrs. LINCOLN. Mr. President, I ask unanimous consent that the Judiciary Committee be discharged from further consideration of S. Con. Res. 128 and that the Senate then proceed to its immediate consideration.

The PRESIDING OFFICER. Without objection, it is so ordered. The clerk will report the concurrent resolution.

The assistant legislative clerk read as follows:

A concurrent resolution (S. Con. Res. 128) honoring the invention of modern air conditioning by Dr. Willis H. Carrier on the occasion of its 100th anniversary.

There being no objection, the Senate proceeded to the consideration of the concurrent resolution.

Mrs. LINCOLN. I ask unanimous consent that the concurrent resolution be agreed to en bloc, the motion to reconsider be laid upon the table en bloc, that any statements relating thereto be printed in the RECORD, without further intervening action or debate.

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

The concurrent resolution (S. Con. Res. 128) was agreed to.

The preamble was agreed to.

The concurrent resolution, with its preamble, reads as follows:

S. CON. RES. 128

Whereas on July 17, 1902, Dr. Willis H. Carrier submitted designs to a printing plant in Brooklyn, New York, for equipment to control temperature, humidity, ventilation, and air quality, marking the birth of modern air conditioning;

Whereas air conditioning has become an integral technology enabling the advancement of society through improvements to the Nation's health and well-being, manufacturing processes, building capacities, re-

search, medical capabilities, food preservation, art and historical conservation, and general productivity and indoor comfort;

Whereas Dr. Carrier debuted air conditioning technology for legislative activity in the House of Representatives Chamber in 1928, and the Senate Chamber in 1929;

Whereas the air conditioning industry now totals \$36,000,000,000 on a global basis and employs more than 700,000 people in the United States; and

Whereas the year 2002 marks the 100th anniversary of modern air conditioning: Now, therefore, be it

Resolved by the Senate (the House of Representatives concurring), That Congress honors the invention of modern air conditioning by Dr. Willis H. Carrier on the occasion of its 100th anniversary.

ORDER FOR RECORD TO REMAIN OPEN UNTIL 1:30 P.M.

Mrs. LINCOLN. Mr. President, I ask unanimous consent that the RECORD remain open until 1:30 p.m. for the submission of statements and introduction of legislation.

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

ORDERS FOR MONDAY, JULY 22, 2002

Mrs. LINCOLN. Mr. President, I ask unanimous consent that when the Senate completes its business today, it stand in adjournment until 2 p.m., Monday, July 22; that following the prayer and the pledge, the morning hour be deemed expired, the Journal of proceedings be approved to date, the time for the two leaders be reserved for their use later in the day, and the Senate resume consideration of S. 812, with the time until 6 p.m. equally divided between the two managers or their designees.

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

PROGRAM

Mrs. LINCOLN. Mr. President, no rollcall votes will occur on Monday. The next rollcall vote will occur on Tuesday morning at approximately 10:45 a.m.

ADJOURNMENT UNTIL MONDAY, JULY 22, 2002, AT 2 P.M.

Mrs. LINCOLN. If there is no further business to come before the Senate, I ask unanimous consent that the Senate stand in adjournment under the previous order.

There being no objection, the Senate, at 12:12 p.m., adjourned until Monday, July 22, 2002, at 2 p.m.