Wildlife Society, and Award of Merit from the ASCS for helping write and pass the Farm Bill. Mr. Evans has also received the American Motors Conservation Award for his many contributions to the success of the Missouri Conservation Department's coordinated forest habitat management program, and the E. Sydney Stephens Award for his career contributions to Missouri's wildlife resources. I wish to honor and thank him for his hard work and dedication to the preservation of wildlife and the environment.

To people in Missouri, Mr. Evans has always been known as ''Ray''. His trademark ribbon tie, warm smile and commitment to his neighbors and the land they live on will remain his legacy. On the national scene, Ray has been a tireless advocate of Federal assistance to promote local initiatives. Ray has always understood that conservation is a ''public good'' and, consequently, the public should help landowners provide that public good. As a practicing farmer, Ray also understands and helps our urban friends understand that farmers are the most committed practitioners of conservation because it is good business and because they want to leave more value to their children and future generations. In other words, they want to leave it better than they found it. It is that understanding that won him the trust of landowners which is a key element to the success with which Ray is associated.

Ray's advocacy has been tireless, both for him and those of us he pursued constantly. With Ray, the ''to-do'' list is never complete and every success is followed by a new initiative. Recently, after Ray witnessed President Bush signing the 4th consecutive Farm Bill Ray worked on, Ray innocently succeeded in lifting the President's speech and convincing the President to sign it for him. While Ray was a good enough salesman to pull that off, he couldn't get past the staff who have obligations to the National Archives but if anyone deserves a high-level souvenir for his work in conservation, it would be Ray. Nevertheless, I am pleased that Ray got some face time with the Commander-in-Chief out of the deal.

On behalf of many citizens who benefited from his friendship, work, and guidance, I thank Ray and I thank his wife Carole for lending him to us. While I trust he will continue sharing his presence at many conservation-related events, I am pleased that he and Carole will have more time to enjoy time together. I recommend that he take her for long walks in the countryside so they can both appreciate what they have done for the landscape.●

MESSAGES FROM THE PRESIDENT

Messages from the President of the United States were communicated to the Senate by Ms. Evans, one of his secretaries.

EXECUTIVE MESSAGES REFERRED

As in executive session the Presiding Officer laid before the Senate messages from the President of the United States submitting sundry nominations which were referred to the appropriate committees.

(The nominations received today are printed at the end of the Senate proceedings.)

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. BINGAMAN:

S. 2624. A bill to amend part A of title IV of the Social Security Act to require a comprehensive strategic plan for the State temporary assistance to needy families program; to the Committee on Finance.

By Mr. GRAHAM (for himself, Mr. MILLER, Mr. KENNEDY, Mr. ROCKEFELLER, Mr. DASCHLE, Mr. CLELAND, Mr. INOUYE, Mr. REID, Ms. MIKULSKI, Mr. JOHNSON, Mr. LEAHY, Mrs. CLINTON, Mr. NELSON of Florida, Mr. SARBANES, Mr. BINGAMAN, Ms. STABENOW, Mr. WELLSTONE, Mr. HOLLINGS, Mrs. MURRAY, Mr. SCHUMER, Mr. AKAKA, Mrs. BOXER, Mr. REED, Mr. DODD, Mr. LEVIN, Mrs. CARNAHAN, Ms. CANTWELL, Mr. DURBIN, and Mr. DAYTON):

S. 2625. A bill to amend title XVIII of the Social Security Act to provide coverage of outpatient prescription drugs under the medicare program; to the Committee on Finance.

By Mr. KENNEDY (for himself, Mr. DEWINE, Mr. HARKIN, Mr. MCCAIN, Mr. DURBIN, Mr. GRAHAM, Mr. WELLSTONE, Ms. COLLINS, Mrs. FEINSTEIN, and Mr. REED):

S. 2626. A bill to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products; to the Committee on Health, Education, Labor, and Pensions.

By Mr. CLELAND:

S. 2627. A bill to protect marine species off the coast of Georgia; to the Committee on Commerce, Science, and Transportation.

ADDITIONAL COSPONSORS

S. 839

At the request of Mr. NELSON of Florida, his name was added as a cosponsor of S. 839, a bill to amend title XVIII of the Social Security Act to increase the amount of payment for inpatient hospital services under the medicare program and to freeze the reduction in payments to hospitals for indirect costs of medical education.

S. 1339

At the request of Mr. CAMPBELL, the names of the Senator from Virginia (Mr. ALLEN) and the Senator from Alabama (Mr. SESSIONS) were added as cosponsors of S. 1339, a bill to amend the Bring Them Home Alive Act of 2000 to provide an asylum program with regard to American Persian Gulf War POW/MIAs, and for other purposes.

S. 1678

At the request of Mr. MCCAIN, the name of the Senator from Arkansas (Mr. HUTCHINSON) was added as a cosponsor of S. 1678, a bill to amend the Internal Revenue Code of 1986 to provide that a member of the uniformed services or the Foreign Service shall be treated as using a principal residence while away from home on qualified official extended duty in determining the exclusion of gain from the sale of such residence.

S. 1785

At the request of Mr. CLELAND, the name of the Senator from New Mexico (Mr. DOMENICI) was added as a cosponsor of S. 1785, a bill to urge the President to establish the White House Commission on National Military Appreciation Month, and for other purposes.

S. 2051

At the request of Mr. REID, the name of the Senator from North Carolina (Mr. EDWARDS) was added as a cosponsor of S. 2051, a bill to remove a condition preventing authority for concurrent receipt of military retired pay and veterans' disability compensation from taking affect, and for other purposes.

S. 2059

At the request of Ms. MIKULSKI, the name of the Senator from Mississippi (Mr. COCHRAN) was added as a cosponsor of S. 2059, a bill to amend the Pubic Health Service Act to provide for Alzheimer's disease research and demonstration grants.

S. 2194

At the request of Mr. MCCONNELL, the name of the Senator from Alabama (Mr. SHELBY) 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. RES. 283

At the request of Mr. GRAHAM, the names of the Senator from Massachusetts (Mr. KENNEDY) and the Senator from Connecticut (Mr. LIEBERMAN) were added as cosponsors of S. Res. 283, a resolution recognizing the successful completion of democratic elections in the Republic of Colombia.

AMENDMENT NO. 3838

At the request of Mr. ALLEN, the name of the Senator from Maine (Ms. COLLINS) was added as a cosponsor of amendment No. 3838 proposed to S. 2600, a bill to ensure the continued financial capacity of insurers to provide coverage for risks from terrorism.

At the request of Mr. TORRICELLI, his name was added as a cosponsor of amendment No. 3838 proposed to S. 2600, supra.

STATEMENTS ON INTRODUCED BILLS AND JOINT RESOLUTIONS

By Mr. GRAHAM (for himself, Mr. MILLER, Mr. KENNEDY, Mr. ROCKEFELLER, Mr. DASCHLE, Mr. CLELAND, Mr. INOUYE, Mr. REID, Ms. MIKULSKI, Mr. JOHNSON, Mr. LEAHY, Mrs. CLINTON, Mr. NELSON of Florida, Mr. SARBANES, Mr. BINGAMAN, Ms.

STABENOW, Mr. WELLSTONE, Mr. HOLLINGS, Mrs. MURRAY, Mr. SCHUMER, Mr. AKAKA, Mrs. BOXER, Mr. REED, Mr. DODD, Mr. LEVIN, Mrs. CARNAHAN, Ms. CANTWELL, Mr. DURBIN, and Mr. DAYTON):

S. 2625. A bill to amend title XVIII of the Social Security Act to provide coverage of outpatient prescription drugs under the Medicare Program; to the Committee on Finance.

Mr. GRAHAM. Madam President, along with my colleagues, Senators, MILLER and KENNEDY, I am very pleased to announce the introduction of the Medicare Outpatient Prescription Drug Act of 2002.

A prescription drug benefit is the most fundamental shift we can make in the health care of older Americans. Adding a prescription drug benefit to Medicare will represent a 180 degree turn, a change in the focus of how we deliver health care to our Nation's seniors.

Quite simply, including prescription drugs will transform Medicare from a sickness program to a wellness program. Failure to provide a prescription drug benefit will continue to confine millions of elderly Americans to a system that is antiquated, one that only looks backward, not forward.

The sponsors of this legislation do not buy the conventional wisdom that nothing significant can be enacted in an election year. We are committed to meeting our goal this year: passage of a universal, comprehensive, and affordable prescription drug benefit.

To be sure, there are questions in this debate which still remain. But, the most important question, ''will our drug benefit meet seniors' needs?'', can be answered with a resounding ''YES.''

The voluntary benefit we are offering to all seniors is very simple, no gimmicks, gotchas or ''gaps'' to fall into. With our benefit, ''what you see is what you get.'' Seniors will know exactly what they will pay, and exactly what they will get: the monthly premium is $25, no matter where a person lives; all beneficiaries get assistance from the very first prescription of the year.

For the first two years, seniors will pay $10 for each generic prescription, and no more than $40 for all medically-necessary brand-name medicines. All other drugs would cost no more than $60. After two years, the co-pay will be indexed to the increase in prescription drug prices.

Seniors who either pay $4,000 out of their own pocket or have a third party contribute towards this $4,000 spending level would pay no more.

Seniors with very low incomes, below 135 percent of poverty, would pay no premiums. Seniors with incomes between 135 and 150 percent of the poverty level would pay reduced premiums.

And no senior will be faced with a burdensome ''asset test'' that could deny them the very drugs they need.

This kind of certainty, and this kind of help, is what beneficiaries need. Take, for example a 68-year-old man with two conditions very common among the elderly, congestive heart failure and diabetes, and no drug coverage. He would have to spend over $5,100 annually for a typical medication regimen. Under our plan, this gentleman would get the medicines he needs to stay healthy, and would save nearly $3,300.

In addition to being affordable, comprehensive, and universally available to all of America's seniors, we need a drug benefit that will be attractive to beneficiaries. Why? Because voluntary participation of all seniors will ensure that we will have a program that is sustainable for the long run. A program that attracts only the sickest beneficiaries is doomed to fail.

The Congressional Budget Office has evaluated our plan and has stated that it does not leave a single Medicare beneficiary without access to drug coverage.

How does this bill achieve this goal? By following the principle that the drug benefit should track the prescription drug benefits that seniors have been accustomed to in their working years. We have an attractive benefit with an affordable premium and a catastrophic provision that is an insurance policy for all elderly, in particular, for those seniors who are healthy right now, but who may face health problems later in life. We have modeled our bill after what works for most Americans right now. Our benefit includes tiered copayments, and we use as our delivery system the private sector model in place today in every part of the country.

Addition of a prescription drug benefit will be the largest expansion of the Medicare program since it was initiated in 1965. This fact challenges Congress to be sure that we get it right. In light of the scope of the changes we are making, we are suggesting that, after seven years, Congress should examine how well the benefit is working and to make whatever modifications are necessary and appropriate. Not only will we learn about how our delivery system has worked, but we can discover that access to prescription drugs will save Medicare money. How? By doctors prescribing medications instead of performing costly medical procedures. A physician on my staff recently told me that his students had never seen an ulcer operation. Why? Because prescription drugs have ended the need for this surgery.

Improving Medicare by including a prescription drug benefit is a serious and critical undertaking, and deserves our most serious efforts. We all know that our seniors cannot afford to wait out another election cycle.

I am pleased to announce that the American Association of Retired Persons, America Federation of State and County Municipal Employees, the National Council on the Aging, Families USA, the AFL–CIO, the Alliance for Retired Americans, the National Committee to Preserve Social Security and Medicare, and the Generic Pharmaceutical Association support our legislation. I ask unanimous consent that their letters of support be printed in the RECORD. With their help, we can get this done this year.

There being no objection, the letters were ordered to be printed in the RECORD, as follows:

AARP,
Washington, DC, June 12, 2002.

Hon. BOB GRAHAM and Hon. ZELL MILLER,
U.S. Senate,
Washington, DC.

DEAR SENATORS: We are pleased to restate our position on your revised Medicare prescription drug proposal. Action on a bipartisan prescription drug benefit is a top priority for AARP, our members and the nation.

Medicare beneficiaries have waited long enough for access to meaningful, affordable prescription drug coverage. We know from our membership that in order for a Medicare prescription drug benefit to provide comprehensive coverage it must include:

An affordable premium and coinsurance;

Meaningful catastrophic stop-loss that limits out-of-pocket costs;

A benefit that does not expose beneficiaries to a gap in insurance coverage;

Additional assistance for low-income beneficiaries; and

Quality and safety features to curb unnecessary costs and prevent dangerous drug interactions.

AARP supports your initiative in incorporate these goals. We commend you for including key elements in your proposal that Medicare beneficiaries and our members have indicated they find valuable. For instance, your proposal includes a premium that many Medicare beneficiaries view as affordable and a benefit design that does not include a gap in insurance coverage. Your proposal also now includes co-payments specified as dollar amounts, an approach that our research shows our members prefer to coinsurance. In our view, this plan could provide real value to beneficiaries in protecting them against the high costs of prescription drugs.

It is important that any prescription drug benefit be made a permanent and stable part of Medicare, and we want to work with you to achieve this before enactment.

Thank you for your leadership on this issue. We look forward to working with you and your colleagues as the legislation moves forward. AARP will continue to urge Congress to work in a bipartisan manner to enact affordable, meaningful Medicare prescription drug coverage.

Sincerely,

WILLIAM D. NOVELLI,
Executive Director and CEO.

THE NATIONAL COUNCIL ON THE AGING,
Washington, DC, June 11, 2002.

Hon. BOB GRAHAM,
Hart Senate Office Building,
Washington, DC.

DEAR SENATOR GRAHAM: On behalf of the National Council on the Aging (NCOA)—the nation's first organization formed to represent America's seniors and those who serve them—I write to commend and thank you for your proposal to provide meaningful Medicare prescription drug coverage to America's seniors. The Medicare Outpatient Prescription Drug Act of 2002 is consistent with the principles supported by the vast majority of

organizations representing Medicare beneficiaries. It provides the foundation for a vehicle that we hope can achieve bipartisan consensus on this issue this year.

NCOA is particularly pleased that your legislation would provide prescription drug coverage that is universal, voluntary, reliable, and continuous. Other proposals being offered include significant coverage gaps and would fail to solve the problem. Under such bills, a significant number of beneficiaries would not want to participate in the program, and many of those who do participate would continue to be forced to choose between buying food and essential medicines.

We commend many of the modifications you have made to your Medicare bill from last year. These improvements include a significantly lower premium, the option to provide a flat copayment, an earlier effective date, and assistance with the very first prescription. We believe these changes will make the coverage affordable and attractive to the vast majority of beneficiaries, which is so critical to making a voluntary prescription drug program work. While we have concerns about the need to reauthorize the program after 2010, we understand the budget trade-offs needed to provide meaningful and attractive coverage, and fully expect that the Congress would reauthorize the program.

NCOA is also pleased that your proposal does not include price controls and that the program would promote stability and efficiency through administration by multiple, competing Pharmacy Benefit Managers (PBMs), using management tools available in the private sector in which PBMs would be at risk of their performance, including effective cost containment.

NCOA deeply appreciates your efforts to move this critical debate in a direction that guarantees access to meaningful coverage—even in rural and frontier areas of the country—and responds in a constructive manner to many of the specific concerns that have been raised regarding other Medicare prescription drug proposals.

It is impossible to have real health security without coverage for prescription drugs. Prescription drug coverage is the number one legislative priority for America's seniors. Virtually every member of Congress has made campaign promises to try to pass a good prescription drug bill. The time has come to get serious and to work together to achieve consensus on the issues in controversy. Your proposal provides us with an excellent starting point.

NCOA looks forward to working on a bipartisan basis with you and other members of Congress to pass legislation this year that provides meaningful, continuous, affordable prescription drug coverage to all Medicare beneficiaries.

Sincerely,

JAMES FIRMAN,
President and CEO.

NATIONAL COMMITTEE TO PRESERVE SOCIAL SECURITY AND MEDICARE,
Washington, DC, June 12, 2002.

Sen. BOB GRAHAM,
Senate Hart Office Building,
Washington, DC.

DEAR SENATOR GRAHAM: On behalf of the millions of members and supporters of the National Committee to Preserve Social Security and Medicare, I write in support of your Medicare prescription drug legislation that will provide much needed relief to seniors. Your bill contains all of the elements that seniors need in a comprehensive drug benefit under Medicare, such as universal, voluntary, affordable, not means tested and most importantly, with a defined benefit, so that seniors can plan accordingly. Prescription drug prices are increasing over 17% per year (faster than inflation) and seniors are spending more on out-of-pocket drug expenditures than ever. The time is now to enact a drug benefit that will provide the Medicare beneficiary with some assistance.

We are pleased that your plan would be available for seniors, no matter where they live. Our members have expressed to us that a prescription drug benefit must be affordable. We believe that a plan such as yours, with no annual deductible and a $4,000 cap on out of pocket expenditures, is reasonable and one that most seniors would be able to afford.

We applaud you for your leadership in this area. Please let me know how we can further support your efforts.

Sincerely,

BARBARA KENNELLY,
President.

FAMILIES USA,
Washington, DC, June 13, 2002.

Sen. BOB GRAHAM,
Hart Senate Office Building,
Washington, DC.

DEAR SENATOR GRAHAM: We congratulate you and Senators Miller, Kennedy and Rockefeller on the introduction of your bill, ''The Medicare Outpatient Prescription Drug Act,'' which provides a prescription drug benefit for Medicare beneficiaries.

This is an issue of utmost importance to all Americans who need prescription drugs, especially to seniors and people with disabilities. As you well know, seniors' ability to afford prescription drugs is a particularly difficult problem today. In our 2001 report entitled, ''Enough to Make You Sick: Prescription Drug Prices for the Elderly,'' we concluded that the 50 top drugs used by seniors rose 2.3 times the rate of inflation between 2000 and 2001. We are in the process of updating this report for last year, and our preliminary data shows that this devastating rate of price increases continues. Millions of seniors have limited income and no, or limited, drug coverage and will find themselves deciding whether to buy drugs or to pay for other essentials.

Your bill addresses many important design issues that we care about in a Medicare prescription drug benefit. The benefit is universal, comprehensive, and is delivered through the Medicare program, ensuring that seniors know it will be available to them when it is needed. Low-income people get extra assistance. Also, there are provisions to assure that costs will be contained and quality maintained.

Please let us know how we can assist you to move this bill toward enactment so that all Medicare beneficiaries can have access to the prescription drugs they need.

Sincerely,

RONALD F. POLLACK,
Executive Director.

AMERICAN FEDERATION OF STATE, COUNTY AND MUNICIPAL EMPLOYEES, AFL–CIO,
Washington, DC, June 12, 2002.

Senators EDWARD KENNEDY, BOB GRAHAM, and ZELL MILLER,
U.S. Senate,
Washington, DC.

DEAR SENATORS: On behalf of the 1.3 million members of the American Federation of State, County and Municipal Employees (AFSCME), I am writing to express our support for the Medicare prescription drug benefit proposal you unveiled today.

AFSCME has long supported the creation of a Medicare prescription drug benefit that is comprehensive in coverage, affordable and voluntary for all Medicare beneficiaries. We believe that your proposal is a solid step forward in meeting these standards.

In particular, we applaud your proposal's provisions for continuous coverage. We believe that it is one of the most critical components of a meaningful prescription drug benefit. Beneficiaries must have coverage they can count on, with no gaps in coverage. Doing anything less would force our seniors to pay all prescription costs out of their own pocket when they will need the coverage the most.

Since Medicare was started over 35 years ago, many illnesses that were once only treatable in a hospital can now be effectively treated with prescription drugs. Adding a drug benefit to the program is the most urgently needed Medicare reform. We applaud you for not holding the prescription drug benefit hostage to force radical privatization proposals that would cut benefits and increase costs for retirees.

We look forward to working with you and the other sponsors of this important legislation. A Medicare prescription drug benefit is long overdue, and our nation's seniors deserve no less.

Sincerely,

CHARLES M. LOVELESS,
Director of Legislation.

AMERICAN FEDERATION OF LABOR AND CONGRESS OF INDUSTRIAL ORGANIZATIONS,
Washington, DC, June 12, 2002.

Hon. BOB GRAHAM,
U.S. Senate, Hart Senate Office Building, Washington, DC.

DEAR SENATOR GRAHAM: On behalf of the 13 million members of the AFL–CIO, I am writing to commend you for your efforts to provide much-needed relief to Medicare beneficiaries. Your proposal to create a voluntary drug benefit within the Medicare program represents an encouraging and solid step toward enacting the one reform most urgently needed for Medicare.

Seniors need a real benefit that provides comprehensive, continuous and certain coverage. The Graham-Miller-Kennedy bill provides that benefit, giving seniors coverage they can count on. A Medicare drug benefit must also be affordable for beneficiaries. The $25 monthly premium and zero deductible in your proposal means seniors need only pay an affordable premium to begin getting coverage immediately. And no senior will have to pay more than $40 for the drugs they need and often will pay less.

In addition, your proposal would not put at risk those retirees who currently have some prescription drug coverage through an employer. Retiree health care is the primary source of prescription drug coverage for seniors, and your proposal rightly provides some relief for employers that choose to continue that coverage.

A proposal widely reported under consideration by House Republican leaders offers only unreliable, expensive and unworkable coverage through private plans, with an enormous gap in coverage that leaves seniors without any coverage at all for drug costs between $2000 and $4500. And the only relief for employers is if they drop the coverage they now offer. Such a proposal will not move us any closer to a real benefit.

As this debate moves forward, we want to work with you and your co-sponsors to enact the best possible Medicare drug benefit. We appreciate your role in advancing that process.

Sincerely,

WILLIAM SAMUEL,
Director of Legislation.

ALLIANCE FOR RETIRED AMERICANS,
Washington, DC, June 12, 2002.

Sen. EDWARD M. KENNEDY,
U.S. Senate,
Washington, DC.

DEAR SENATOR KENNEDY: On behalf of the over 2.7 million members of the Alliance for Retired Americans, I want to thank you for your tireless work on behalf of older and disabled Americans to create a Medicare prescription drug benefit program. I also want to express our views on the Medicare prescription drug legislation proposed by you and Senators Graham and Miller. The Alliance supports this proposal as a positive step forward in the effort to create a Medicare prescription drug benefit program.

The Alliance for Retired Americans believes that all older and disabled Americans need an affordable, comprehensive, and voluntary Medicare prescription drug benefit now. Such a benefit program should have low monthly premiums, annual deductibles, and be administered as part of the Medicare program. Your proposed legislation meets these Alliance principles. Unlike other proposals that would begin in 2005, your plan would start in 2004, which gives beneficiaries the coverage they need a full year earlier.

The Alliance will work to enact your legislation. During legislative deliberations, the Alliance will seek to improve benefits because we believe that an 80/20 co-insurance payment system, like the rest of Medicare, will provide the best benefits for older and disabled Americans. The Alliance also supports a $2,000 annual catastrophic cap. We will continue to work to improve any legislation that moves through Congress in order to reach these goals.

Older Americans will spend $1.8 trillion on prescription drugs during the next decade. The inflation rate for prescription drugs will continue at an annual double digit pace as well. Our members and indeed all Americans simply cannot afford these costs. We look forward to working with you and Senators Graham and Miller to enact a comprehensive Medicare prescription drug benefit as soon as possible.

Sincerely yours,

EDWARD F. COYLE,
Executive Director.

GENERIC PHARMACEUTICAL ASSOCIATION,
Washington, DC, June 12, 2002.

Hon. BOB GRAHAM,
Hart Senate Office Building,
Washington, DC.

DEAR SENATOR GRAHAM: On behalf of the Generic Pharmaceutical Association (GPhA), we would like to commend you and Senators Miller and Kennedy for your leadership introducing legislation to create a Medicare prescription drug benefit for our nation's seniors. We agree with you that the passage and enactment of a voluntary Medicare prescription drug benefit is long overdue. We are strongly supportive of your innovative tiered co-pay structure, as well as the other provisions advocated by you and your colleagues, that are designed to increase the utilization of high-quality, affordable generic medicines.

Generic pharmaceuticals have a proven track record of substantially lowering drug costs. Studies have shown that for every 1 percent increase in generic drug utilization, consumer, business, and health plan purchasers save over $1 billion. The increased use of generics can play an invaluable role in helping Medicare, Medicaid, the Federal Employees Health Benefit Plan (FEHBP) and other Federal and private plans assure that beneficiaries have access to quality, affordable medications. A tiered co-pay system with a significant differential between brand and generic pharmaceuticals will ensure an appropriate incentive is in place for seniors to consider more cost-effective options when making choices about pharmaceutical therapies. We believe an explicit dollar co-pay will also provide seniors with the comfort of knowing they will pay a fixed cost to have their prescriptions filled.

With your leadership, the Graham/Miller/Kennedy bill employs a number of private sector best practices that are now widely used to assure access to cost-effective, quality affordable medications. These provisions not only encourage the appropriate and beneficial use of these products, but provide unbiased and greatly needed educational information to the public about the benefits of these medicines.

The Graham/Miller/Kennedy bill adheres to GPhA's principles for creating a Medicare prescription drug benefit and steers the Medicare reform debate down a prudent public policy path. We look forward to working with you, your cosponsors and with other Members of the House and Senate of both parties to further our common objective of providing our nation's nearly 40 million Medicare beneficiaries and the taxpayers who help support them with the most affordable and highest quality prescription drug benefit possible. If the rest of the Congress and the Administration follow your lead in recognizing the role generics must play in reaching this objective, we are confident we will achieve this goal.

Thank you again for your efforts. If we can be of any assistance to you, please do not hesitate to call.

Sincerely,

KATHLEEN JAEGER,
President and CEO.

Mr. GRAHAM. I want to thank Senators MILLER and KENNEDY for their leadership and commitment to this issue, and urge all of our colleagues to join us in ensuring passage of this critical legislation this year.

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. 2625

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 ''Medicare Outpatient Prescription Drug Act of 2002''.

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

SEC. 2. MEDICARE OUTPATIENT PRESCRIPTION DRUG BENEFIT PROGRAM.

(a) ESTABLISHMENT.—Title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) is amended by redesignating part D as part E and by inserting after part C the following new part:

''PART D—OUTPATIENT PRESCRIPTION DRUG BENEFIT PROGRAM

''DEFINITIONS

''SEC. 1860. In this part:

''(1) COVERED OUTPATIENT DRUG.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), the term 'covered outpatient drug' means any of the following products:

''(i) A drug which may be dispensed only upon prescription, and—

''(I) which is approved for safety and effectiveness as a prescription drug under section 505 of the Federal Food, Drug, and Cosmetic Act;

''(II)(aa) which was commercially used or sold in the United States before the date of enactment of the Drug Amendments of 1962 or which is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (bb) which has not been the subject of a final determination by the Secretary that it is a 'new drug' (within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act) or an action brought by the Secretary under section 301, 302(a), or 304(a) of such Act to enforce section 502(f) or 505(a) of such Act; or

''(III)(aa) which is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need, or is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (bb) for which the Secretary has not issued a notice of an opportunity for a hearing under section 505(e) of the Federal Food, Drug, and Cosmetic Act on a proposed order of the Secretary to withdraw approval of an application for such drug under such section because the Secretary has determined that the drug is less than effective for all conditions of use prescribed, recommended, or suggested in its labeling.

''(ii) A biological product which—

''(I) may only be dispensed upon prescription;

''(II) is licensed under section 351 of the Public Health Service Act; and

''(III) is produced at an establishment licensed under such section to produce such product.

''(iii) Insulin approved under appropriate Federal law, including needles, syringes, and disposable pumps for the administration of such insulin.

''(iv) A prescribed drug or biological product that would meet the requirements of

clause (i) or (ii) except that it is available over-the-counter in addition to being available upon prescription.

''(B) EXCLUSION.—The term 'covered outpatient drug' does not include any product—

''(i) except as provided in subparagraph (A)(iv), which may be distributed to individuals without a prescription;

''(ii) for which payment is available under part A or B or would be available under part B but for the application of a deductible under such part (unless payment for such product is not available because benefits under part A or B have been exhausted), determined, except as provided in subparagraph (C), without regard to whether the beneficiary involved is entitled to benefits under part A or enrolled under part B; or

''(iii) except for agents used to promote smoking cessation and agents used for the treatment of obesity, for which coverage may be excluded or restricted under section 1927(d)(2).

''(C) CLARIFICATION REGARDING IMMUNOSUPPRESSIVE DRUGS.—In the case of a beneficiary who is not eligible for any coverage under part B of drugs described in section 1861(s)(2)(J) because of the requirements under such section (and would not be so eligible if the individual were enrolled under such part), the term 'covered outpatient drug' shall include such drugs if the drugs would otherwise be described in subparagraph (A).

''(2) ELIGIBLE BENEFICIARY.—The term 'eligible beneficiary' means an individual that is entitled to benefits under part A or enrolled under part B.

''(3) ELIGIBLE ENTITY.—The term 'eligible entity' means any entity that the Secretary determines to be appropriate to provide eligible beneficiaries with covered outpatient drugs under a plan under this part, including—

''(A) a pharmacy benefit management company;

''(B) a retail pharmacy delivery system;

''(C) a health plan or insurer;

''(D) a State (through mechanisms established under a State plan under title XIX);

''(E) any other entity approved by the Secretary; or

''(F) any combination of the entities described in subparagraphs (A) through (E) if the Secretary determines that such combination—

''(i) increases the scope or efficiency of the provision of benefits under this part; and

''(ii) is not anticompetitive.

''(4) MEDICARE+CHOICE ORGANIZATION; MEDICARE+CHOICE PLAN.—The terms 'Medicare+Choice organization' and 'Medicare+Choice plan' have the meanings given such terms in subsections (a)(1) and (b)(1), respectively, of section 1859 (relating to definitions relating to Medicare+Choice organizations).

''(5) PRESCRIPTION DRUG ACCOUNT.—The term 'Prescription Drug Account' means the Prescription Drug Account (as established under section 1860K) in the Federal Supplementary Medical Insurance Trust Fund under section 1841.

''ESTABLISHMENT OF OUTPATIENT PRESCRIPTION DRUG BENEFIT PROGRAM

''SEC. 1860A. (a) PROVISION OF BENEFIT.—

''(1) IN GENERAL.—Beginning in 2004, the Secretary shall provide for and administer an outpatient prescription drug benefit program under which each eligible beneficiary enrolled under this part shall be provided with coverage of covered outpatient drugs as follows:

''(A) MEDICARE+CHOICE PLAN.—If the eligible beneficiary is eligible to enroll in a Medicare+Choice plan, the beneficiary—

''(i) may enroll in such a plan; and

''(ii) if so enrolled, shall obtain coverage of covered outpatient drugs through such plan.

''(B) MEDICARE PRESCRIPTION DRUG PLAN.—If the eligible beneficiary is not enrolled in a Medicare+Choice plan, the beneficiary shall obtain coverage of covered outpatient drugs through enrollment in a plan offered by an eligible entity with a contract under this part.

''(2) VOLUNTARY NATURE OF PROGRAM.—Nothing in this part shall be construed as requiring an eligible beneficiary to enroll in the program established under this part.

''(3) SCOPE OF BENEFITS.—The program established under this part shall provide for coverage of all therapeutic classes of covered outpatient drugs.

''(b) ACCESS TO ALTERNATIVE PRESCRIPTION DRUG COVERAGE.—In the case of an eligible beneficiary who has creditable prescription drug coverage (as defined in section 1860B(b)(1)(F)), such beneficiary—

''(1) may continue to receive such coverage and not enroll under this part; and

''(2) pursuant to section 1860B(b)(1)(C), is permitted to subsequently enroll under this part without any penalty and obtain coverage of covered outpatient drugs in the manner described in subsection (a) if the beneficiary involuntarily loses such coverage.

''(c) FINANCING.—The costs of providing benefits under this part shall be payable from the Prescription Drug Account.

''ENROLLMENT UNDER PROGRAM

''SEC. 1860B. (a) ESTABLISHMENT OF PROCESS.—

''(1) PROCESS SIMILAR TO ENROLLMENT UNDER PART B.—The Secretary shall establish a process through which an eligible beneficiary (including an eligible beneficiary enrolled in a Medicare+Choice plan offered by a Medicare+Choice organization) may make an election to enroll under this part. Such process shall be similar to the process for enrollment in part B under section 1837, including the deeming provisions of such section.

''(2) REQUIREMENT OF ENROLLMENT.—An eligible beneficiary must enroll under this part in order to be eligible to receive covered outpatient drugs under this title.

''(b) SPECIAL ENROLLMENT PROCEDURES.—

''(1) LATE ENROLLMENT PENALTY.—

''(A) INCREASE IN PREMIUM.—Subject to the succeeding provisions of this paragraph, in the case of an eligible beneficiary whose coverage period under this part began pursuant to an enrollment after the beneficiary's initial enrollment period under part B (determined pursuant to section 1837(d)) and not pursuant to the open enrollment period described in paragraph (2), the Secretary shall establish procedures for increasing the amount of the monthly part D premium under section 1860E(a) applicable to such beneficiary—

''(i) by an amount that is equal to 10 percent of such premium for each full 12-month period (in the same continuous period of eligibility) in which the eligible beneficiary could have been enrolled under this part but was not so enrolled; or

''(ii) if determined appropriate by the Secretary, by an amount that the Secretary determines is actuarily sound for each such period.

''(B) PERIODS TAKEN INTO ACCOUNT.—For purposes of calculating any 12-month period under subparagraph (A), there shall be taken into account—

''(i) the months which elapsed between the close of the eligible beneficiary's initial enrollment period and the close of the enrollment period in which the beneficiary enrolled; and

''(ii) in the case of an eligible beneficiary who reenrolls under this part, the months which elapsed between the date of termination of a previous coverage period and the close of the enrollment period in which the beneficiary reenrolled.

''(C) PERIODS NOT TAKEN INTO ACCOUNT.—

''(i) IN GENERAL.—For purposes of calculating any 12-month period under subparagraph (A), subject to clause (ii), there shall not be taken into account months for which the eligible beneficiary can demonstrate that the beneficiary had creditable prescription drug coverage (as defined in subparagraph (F)).

''(ii) APPLICATION.—This subparagraph shall only apply with respect to a coverage period the enrollment for which occurs before the end of the 60-day period that begins on the first day of the month which includes—

''(I) in the case of a beneficiary with coverage described in clause (ii) of subparagraph (F), the date on which the plan terminates, ceases to provide, or reduces the value of the prescription drug coverage under such plan to below the actuarial value of the coverage provided under the program under this part; or

''(II) in the case of a beneficiary with coverage described in clause (i), (iii), or (iv) of subparagraph (F), the date on which the beneficiary loses eligibility for such coverage.

''(D) PERIODS TREATED SEPARATELY.—Any increase in an eligible beneficiary's monthly part D premium under subparagraph (A) with respect to a particular continuous period of eligibility shall not be applicable with respect to any other continuous period of eligibility which the beneficiary may have.

''(E) CONTINUOUS PERIOD OF ELIGIBILITY.—

''(i) IN GENERAL.—Subject to clause (ii), for purposes of this paragraph, an eligible beneficiary's 'continuous period of eligibility' is the period that begins with the first day on which the beneficiary is eligible to enroll under section 1836 and ends with the beneficiary's death.

''(ii) SEPARATE PERIOD.—Any period during all of which an eligible beneficiary satisfied paragraph (1) of section 1836 and which terminated in or before the month preceding the month in which the beneficiary attained age 65 shall be a separate 'continuous period of eligibility' with respect to the beneficiary (and each such period which terminates shall be deemed not to have existed for purposes of subsequently applying this paragraph).

''(F) CREDITABLE PRESCRIPTION DRUG COVERAGE DEFINED.—For purposes of this part, the term 'creditable prescription drug coverage' means any of the following:

''(i) MEDICAID PRESCRIPTION DRUG COVERAGE.—Prescription drug coverage under a medicaid plan under title XIX, including through the Program of All-inclusive Care for the Elderly (PACE) under section 1934 and through a social health maintenance organization (referred to in section 4104(c) of the Balanced Budget Act of 1997).

''(ii) PRESCRIPTION DRUG COVERAGE UNDER A GROUP HEALTH PLAN.—Prescription drug coverage under a group health plan, including a health benefits plan under the Federal Employees Health Benefit Program under chapter 89 of title 5, United States Code, and a qualified retiree prescription drug plan (as defined in section 1860J(e)(3)), that provides coverage of the cost of prescription drugs the actuarial value of which (as defined by the Secretary) to the beneficiary equals or exceeds the actuarial value of the benefits provided to an individual enrolled in the outpatient prescription drug benefit program under this part.

''(iii) STATE PHARMACEUTICAL ASSISTANCE PROGRAM.—Coverage of prescription drugs under a State pharmaceutical assistance program.

''(iv) VETERANS' COVERAGE OF PRESCRIPTION DRUGS.—Coverage of prescription drugs for veterans, and survivors and dependents of veterans, under chapter 17 of title 38, United States Code.

''(2) OPEN ENROLLMENT PERIOD FOR CURRENT BENEFICIARIES IN WHICH LATE ENROLLMENT PROCEDURES DO NOT APPLY.—

''(A) IN GENERAL.—The Secretary shall establish an applicable period, which shall begin on the date on which the Secretary first begins to accept elections for enrollment under this part, during which any eligible beneficiary may enroll under this part without the application of the late enrollment procedures established under paragraph (1)(A).

''(B) OPEN ENROLLMENT PERIOD TO BEGIN PRIOR TO JANUARY 1, 2004.—The Secretary shall ensure that eligible beneficiaries are permitted to enroll under this part prior to January 1, 2004, in order to ensure that coverage under this part is effective as of such date.

''(3) SPECIAL ENROLLMENT PERIOD FOR BENEFICIARIES WHO INVOLUNTARILY LOSE CREDITABLE PRESCRIPTION DRUG COVERAGE.—The Secretary shall establish a special open enrollment period for an eligible beneficiary that loses creditable prescription drug coverage.

''(c) PERIOD OF COVERAGE.—

''(1) IN GENERAL.—Except as provided in paragraph (2) and subject to paragraph (3), an eligible beneficiary's coverage under the program under this part shall be effective for the period provided in section 1838, as if that section applied to the program under this part.

''(2) OPEN AND SPECIAL ENROLLMENT.—Subject to paragraph (3), an eligible beneficiary who enrolls under the program under this part pursuant to paragraph (2) or (3) of subsection (b) shall be entitled to the benefits under this part beginning on the first day of the month following the month in which such enrollment occurs.

''(3) LIMITATION.—Coverage under this part shall not begin prior to January 1, 2004.

''(d) TERMINATION.—

''(1) IN GENERAL.—The causes of termination specified in section 1838 shall apply to this part in the same manner as such causes apply to part B.

''(2) COVERAGE TERMINATED BY TERMINATION OF COVERAGE UNDER PARTS A AND B.—

''(A) IN GENERAL.—In addition to the causes of termination specified in paragraph (1), the Secretary shall terminate an individual's coverage under this part if the individual is no longer enrolled in either part A or B.

''(B) EFFECTIVE DATE.—The termination described in subparagraph (A) shall be effective on the effective date of termination of coverage under part A or (if later) under part B.

''(3) PROCEDURES REGARDING TERMINATION OF A BENEFICIARY UNDER A PLAN.—The Secretary shall establish procedures for determining the status of an eligible beneficiary's enrollment under this part if the beneficiary's enrollment in a plan offered by an eligible entity under this part is terminated by the entity for cause (pursuant to procedures established by the Secretary under section 1860C(a)(1)).

''ENROLLMENT IN A PLAN

''SEC. 1860C. (a) PROCESS.—

''(1) ESTABLISHMENT.—

''(A) IN GENERAL.—The Secretary shall establish a process through which an eligible beneficiary who is enrolled under this part but not enrolled in a Medicare+Choice plan offered by a Medicare+Choice organization shall make an annual election to enroll in any plan offered by an eligible entity that has been awarded a contract under this part and serves the geographic area in which the beneficiary resides. Such process shall include for the default enrollment in such a plan in the case of an eligible beneficiary who is enrolled under this part but who has failed to make an election of such a plan.

''(B) RULES.—In establishing the process under subparagraph (A), the Secretary shall—

''(i) use rules similar to the rules for enrollment, disenrollment, and termination of enrollment with a Medicare+Choice plan under section 1851, including—

''(I) the establishment of special election periods under subsection (e)(4) of such section; and

''(II) the application of the guaranteed issue and renewal provisions of subsection (g) of such section (other than paragraph (3)(C)(i), relating to default enrollment); and

''(ii) coordinate enrollments, disenrollments, and terminations of enrollment under part C with enrollments, disenrollments, and terminations of enrollment under this part.

''(2) FIRST ENROLLMENT PERIOD FOR PLAN ENROLLMENT.—The process developed under paragraph (1) shall—

''(A) ensure that eligible beneficiaries who choose to enroll under this part are permitted to enroll with an eligible entity prior to January 1, 2004, in order to ensure that coverage under this part is effective as of such date; and

''(B) be coordinated with the open enrollment period under section 1860B(b)(2)(A).

''(b) MEDICARE+CHOICE ENROLLEES.—

''(1) IN GENERAL.—An eligible beneficiary who is enrolled under this part and enrolled in a Medicare+Choice plan offered by a Medicare+Choice organization shall receive coverage of covered outpatient drugs under this part through such plan.

''(2) RULES.—Enrollment in a Medicare+Choice plan is subject to the rules for enrollment in such a plan under section 1851.

''PROVIDING INFORMATION TO BENEFICIARIES

''SEC. 1860D. (a) ACTIVITIES.—

''(1) IN GENERAL.—The Secretary shall conduct activities that are designed to broadly disseminate information to eligible beneficiaries (and prospective eligible beneficiaries) regarding the coverage provided under this part.

''(2) SPECIAL RULE FOR FIRST ENROLLMENT UNDER THE PROGRAM.—To the extent practicable, the activities described in paragraph (1) shall ensure that eligible beneficiaries are provided with such information at least 30 days prior to the open enrollment period described in section 1860B(b)(2)(A).

''(b) REQUIREMENTS.—

''(1) IN GENERAL.—The activities described in subsection (a) shall—

''(A) be similar to the activities performed by the Secretary under section 1851(d);

''(B) be coordinated with the activities performed by the Secretary under such section and under section 1804; and

''(C) provide for the dissemination of information comparing the plans offered by eligible entities under this part that are available to eligible beneficiaries residing in an area.

''(2) COMPARATIVE INFORMATION.—The comparative information described in paragraph (1)(C) shall include a comparison of the following:

''(A) BENEFITS.—The benefits provided under the plan, including the prices beneficiaries will be charged for covered outpatient drugs, any preferred pharmacy networks used by the eligible entity under the plan, and the formularies and appeals processes under the plan.

''(B) QUALITY AND PERFORMANCE.—To the extent available, the quality and performance of the eligible entity offering the plan.

''(C) BENEFICIARY COST-SHARING.—The cost-sharing required of eligible beneficiaries under the plan.

''(D) CONSUMER SATISFACTION SURVEYS.—To the extent available, the results of consumer satisfaction surveys regarding the plan and the eligible entity offering such plan.

''(E) ADDITIONAL INFORMATION.—Such additional information as the Secretary may prescribe.

''(3) INFORMATION STANDARDS.—The Secretary shall develop standards to ensure that the information provided to eligible beneficiaries under this part is complete, accurate, and uniform.

''(c) USE OF MEDICARE CONSUMER COALITIONS TO PROVIDE INFORMATION.—

''(1) IN GENERAL.—The Secretary may contract with Medicare Consumer Coalitions to conduct the informational activities under—

''(A) this section;

''(B) section 1851(d); and

''(C) section 1804.

''(2) SELECTION OF COALITIONS.—If the Secretary determines the use of Medicare Consumer Coalitions to be appropriate, the Secretary shall—

''(A) develop and disseminate, in such areas as the Secretary determines appropriate, a request for proposals for Medicare Consumer Coalitions to contract with the Secretary in order to conduct any of the informational activities described in paragraph (1); and

''(B) select a proposal of a Medicare Consumer Coalition to conduct the informational activities in each such area, with a preference for broad participation by organizations with experience in providing information to beneficiaries under this title.

''(3) PAYMENT TO MEDICARE CONSUMER COALITIONS.—The Secretary shall make payments to Medicare Consumer Coalitions contracting under this subsection in such amounts and in such manner as the Secretary determines appropriate.

''(4) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Secretary such sums as may be necessary to contract with Medicare Consumer Coalitions under this section.

''(5) MEDICARE CONSUMER COALITION DEFINED.—In this subsection, the term 'Medicare Consumer Coalition' means an entity that is a nonprofit organization operated under the direction of a board of directors that is primarily composed of beneficiaries under this title.

''PREMIUMS

''SEC. 1860E. (a) ANNUAL ESTABLISHMENT OF MONTHLY PART D PREMIUM RATES.—

''(1) IN GENERAL.—The Secretary shall, during September of each year (beginning in 2003), determine and promulgate a monthly part D premium rate for the succeeding year.

''(2) AMOUNT.—The Secretary shall determine the monthly part D premium rate for the succeeding year as follows:

''(A) PREMIUM FOR 2004.—The monthly part D premium rate for 2004 shall be $25.

''(B) INFLATION ADJUSTMENT OF PREMIUM FOR 2005 AND SUBSEQUENT YEARS.—

''(i) IN GENERAL.—Subject to clause (ii), in the case of any calendar year beginning after 2004, the monthly part D premium rate for the year shall be the amount described in subparagraph (A) increased by an amount equal to—

''(I) such dollar amount, multiplied by

''(II) the percentage (if any) by which the amount of the average annual per capita aggregate expenditures payable from the Prescription Drug Account for the year (as estimated under section 1860J(c)(2)(C)) exceeds the amount of such expenditures in 2004.

''(ii) ROUNDING.—If the monthly part D premium rate determined under clause (i) is not a multiple of $1, such rate shall be rounded to the nearest multiple of $1.

''(b) COLLECTION OF PART D PREMIUM.—The monthly part D premium applicable to an eligible beneficiary under this part (after application of any increase under section 1860B(b)(1)) shall be collected and credited to the Prescription Drug Account in the same manner as the monthly premium determined under section 1839 is collected and credited to the Federal Supplementary Medical Insurance Trust Fund under section 1840.

''OUTPATIENT PRESCRIPTION DRUG BENEFITS

''SEC. 1860F. (a) REQUIREMENT.—A plan offered by an eligible entity under this part shall provide eligible beneficiaries enrolled in such plan with—

''(1) coverage of covered outpatient drugs—

''(A) without the application of any deductible; and

''(B) with the cost-sharing described in subsection (b); and

''(2) access to negotiated prices for such drugs under subsection (c).

''(b) COST-SHARING.—

''(1) THREE-TIERED COPAYMENT STRUCTURE FOR DRUGS INCLUDED IN THE FORMULARY.—

''(A) IN GENERAL.—Subject to the succeeding provisions of this subsection, in the case of a covered outpatient drug that is dispensed in a year to an eligible beneficiary and that is included in the formulary established by the eligible entity (pursuant to section 1860H(c)) for the plan, the beneficiary shall be responsible for a copayment for the drug in an amount equal to the following:

''(i) GENERIC DRUGS.—In the case of a generic covered outpatient drug, $10 for each prescription (as defined by the Secretary in consultation with the Medicare Prescription Drug Advisory Committee established under section 1860L) of such drug.

''(ii) PREFERRED BRAND NAME DRUGS.—In the case of a preferred brand name covered outpatient drug (including a drug treated as a preferred brand name drug under subparagraph (C)), $40 for each prescription (as so defined) of such drug.

''(iii) NONPREFERRED BRAND NAME DRUG.—In the case of a nonpreferred brand name covered outpatient drug (that is not treated as a preferred brand name drug under subparagraph (C)), $60 for each prescription (as so defined) of such drug.

''(B) REDUCTION BY ELIGIBLE ENTITY.—An eligible entity offering a plan under this part may reduce the applicable copayment amount that an eligible beneficiary enrolled in the plan is subject to under subparagraph (A) if the Secretary determines that such reduction—

''(i) is tied to the performance requirements described in section 1860I(b)(1)(C); and

''(ii) will not result in an increase in the expenditures made from the Prescription Drug Account.

''(C) TREATMENT OF MEDICALLY NECESSARY NONPREFERRED AND NONFORMULARY DRUGS.—The eligible entity shall treat a nonpreferred brand name drug and a nonformulary drug as a preferred brand name drug under subparagraph (A)(ii) if such nonpreferred or nonformulary drug, as the case may be, is determined (pursuant to subparagraph (D) or (E) of section 1860H(a)(3)) to be medically necessary.

''(2) AUTHORITY FOR INCREASED COST-SHARING FOR NONFORMULARY DRUGS.—Pursuant to section 1860H(c)(3)(A), an eligible entity offering a plan under this part may require cost-sharing for a nonformulary drug that is higher than the copayment amount described in paragraph (1)(A)(iii).

''(3) COST-SHARING MAY NOT EXCEED NEGOTIATED PRICE.—

''(A) IN GENERAL.—If the amount of cost-sharing for a covered outpatient drug that would otherwise be required under this subsection (but for this paragraph) is greater than the applicable amount, then the amount of such cost-sharing shall be reduced to an amount equal to such applicable amount.

''(B) APPLICABLE AMOUNT DEFINED.—For purposes of subparagraph (A), the term 'applicable amount' means an amount equal to—

''(i) in the case of generic drugs and preferred brand name drugs, the negotiated price for the drug (as reported to the Secretary pursuant to section 1860H(a)(5)(A)) less $5; and

''(ii) in the case of nonpreferred brand name drugs and nonformulary drugs, the negotiated price for the drug (as so reported).

''(4) NO COST-SHARING ONCE EXPENSES EQUAL ANNUAL OUT-OF-POCKET LIMIT.—

''(A) IN GENERAL.—An eligible entity offering a plan under this part shall provide coverage of covered outpatient drugs without any cost-sharing if the individual has incurred costs (as described in subparagraph (C)) for covered outpatient drugs in a year equal to the annual out-of-pocket limit specified in subparagraph (B).

''(B) ANNUAL OUT-OF-POCKET LIMIT.—Subject to paragraph (5), for purposes of this part, the 'annual out-of-pocket limit' specified in this subparagraph is equal to $4,000.

''(C) APPLICATION.—In applying subparagraph (A)—

''(i) incurred costs shall only include costs incurred for the cost-sharing described in this subsection; but

''(ii) such costs shall be treated as incurred without regard to whether the individual or another person, including a State program or other third-party coverage, has paid for such costs.

''(5) INFLATION ADJUSTMENT FOR COPAYMENT AMOUNTS AND ANNUAL OUT-OF-POCKET LIMIT.—

''(A) IN GENERAL.—For any year after 2005—

''(i) the copayment amounts described in clauses (i), (ii), and (iii) of paragraph (1)(A) are equal to the copayment amounts determined under such paragraph (or this paragraph) for the previous year increased by the annual percentage increase described in subparagraph (B); and

''(ii) the annual out-of-pocket limit specified in paragraph (4)(B) is equal to the annual out-of-pocket limit determined under such paragraph (or this paragraph) for the previous year increased by the annual percentage increase described in subparagraph (B).

''(B) ANNUAL PERCENTAGE INCREASE.—The annual percentage increase specified in this subparagraph for a year is equal to the annual percentage increase in the prices of covered outpatient drugs (including both price inflation and price changes due to changes in therapeutic mix), as determined by the Secretary for the 12-month period ending in July of the previous year.

''(C) ROUNDING.—If any amount determined under subparagraph (A) is not a multiple of $1, such amount shall be rounded to the nearest multiple of $1.

''(c) ACCESS TO NEGOTIATED PRICES.—Under a plan offered by an eligible entity with a contract under this part, the eligible entity offering such plan shall provide eligible beneficiaries enrolled in such plan with access to negotiated prices (including applicable discounts) used for payment for covered outpatient drugs, regardless of the fact that only partial benefits may be payable under the coverage with respect to such drugs because of the application of the cost-sharing under subsection (b).

''ENTITIES ELIGIBLE TO PROVIDE OUTPATIENT DRUG BENEFIT

''SEC. 1860G. (a) ESTABLISHMENT OF PANELS OF PLANS AVAILABLE IN AN AREA.—

''(1) IN GENERAL.—The Secretary shall establish procedures under which the Secretary—

''(A) accepts bids submitted by eligible entities for the plans which such entities intend to offer in an area established under subsection (b); and

''(B) awards contracts to such entities to provide such plans to eligible beneficiaries in the area.

''(2) COMPETITIVE PROCEDURES.—Competitive procedures (as defined in section 4(5) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(5))) shall be used to enter into contracts under this part.

''(b) AREA FOR CONTRACTS.—

''(1) REGIONAL BASIS.—

''(A) IN GENERAL.—Except as provided in subparagraph (B) and subject to paragraph (2), the contract entered into between the Secretary and an eligible entity with respect to a plan shall require the eligible entity to provide coverage of covered outpatient drugs under the plan in a region determined by the Secretary under paragraph (2).

''(B) PARTIAL REGIONAL BASIS.—

''(i) IN GENERAL.—If determined appropriate by the Secretary, the Secretary may permit the coverage described in subparagraph (A) to be provided in a partial region determined appropriate by the Secretary.

''(ii) REQUIREMENTS.—If the Secretary permits coverage pursuant to clause (i), the Secretary shall ensure that the partial region in which coverage is provided is—

''(I) at least the size of the commercial service area of the eligible entity for that area; and

''(II) not smaller than a State.

''(2) DETERMINATION.—

''(A) IN GENERAL.—In determining regions for contracts under this part, the Secretary shall—

''(i) take into account the number of eligible beneficiaries in an area in order to encourage participation by eligible entities; and

''(ii) ensure that there are at least 10 different regions in the United States.

''(B) NO ADMINISTRATIVE OR JUDICIAL REVIEW.—The determination of coverage areas under this part shall not be subject to administrative or judicial review.

''(c) SUBMISSION OF BIDS.—

''(1) SUBMISSION.—

''(A) IN GENERAL.—Subject to subparagraph (B), each eligible entity desiring to offer a plan under this part in an area shall submit a bid with respect to such plan to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may reasonably require.

''(B) BID THAT COVERS MULTIPLE AREAS.—The Secretary shall permit an eligible entity to submit a single bid for multiple areas if the bid is applicable to all such areas.

''(2) REQUIRED INFORMATION.—The bids described in paragraph (1) shall include—

''(A) a proposal for the estimated prices of covered outpatient drugs and the projected annual increases in such prices, including differentials between formulary and nonformulary prices, if applicable;

''(B) a statement regarding the amount that the entity will charge the Secretary for managing, administering, and delivering the benefits under the contract;

''(C) a statement regarding whether the entity will reduce the applicable cost-sharing amount pursuant to section 1860F(b)(1)(B) and if so, the amount of such reduction and how such reduction is tied to the performance requirements described in section 1860I(b)(1)(C);

''(D) a detailed description of the performance requirements for which the payments to the entity will be subject to risk pursuant to section 1860I(b)(1)(C);

''(E) a detailed description of access to pharmacy services provided under the plan, including information regarding—

''(i) whether the entity will use a preferred pharmacy network under the plan; and

''(ii) if a preferred pharmacy network is used, whether the entity will offer access to pharmacies that are outside such network and if such access is provided, rules for accessing such pharmacies;

''(F) with respect to the formulary used by the entity, a detailed description of the procedures and standards the entity will use for—

''(i) adding new drugs to a therapeutic class within the formulary; and

''(ii) determining when and how often the formulary should be modified;

''(G) a detailed description of any ownership or shared financial interests with other entities involved in the delivery of the benefit as proposed under the plan;

''(H) a detailed description of the entity's estimated marketing and advertising expenditures related to enrolling eligible beneficiaries under the plan and retaining such enrollment; and

''(I) such other information that the Secretary determines is necessary in order to carry out this part, including information relating to the bidding process under this part.

''(d) ACCESS TO BENEFITS IN CERTAIN AREAS.—

''(1) AREAS NOT COVERED BY CONTRACTS.—The Secretary shall develop procedures for the provision of covered outpatient drugs under this part to each eligible beneficiary enrolled under this part that resides in an area that is not covered by any contract under this part.

''(2) BENEFICIARIES RESIDING IN DIFFERENT LOCATIONS.—The Secretary shall develop procedures to ensure that each eligible beneficiary enrolled under this part that resides in different areas in a year is provided the benefits under this part throughout the entire year.

''(e) AWARDING OF CONTRACTS.—

''(1) NUMBER OF CONTRACTS.—The Secretary shall, consistent with the requirements of this part and the goal of containing costs under this title, award in a competitive manner at least 2 contracts to offer a plan in an area, unless only 1 bidding entity (and the plan offered by the entity) meets the minimum standards specified under this part and by the Secretary.

''(2) DETERMINATION.—In determining which of the eligible entities that submitted bids that meet the minimum standards specified under this part and by the Secretary to award a contract, the Secretary shall consider the comparative merits of each bid, as determined on the basis of the past performance of the entity and other relevant factors, with respect to—

''(A) how well the entity (and the plan offered by the entity) meet such minimum standards;

''(B) the amount that the entity will charge the Secretary for managing, administering, and delivering the benefits under the contract;

''(C) the performance requirements for which the payments to the entity will be subject to risk pursuant to section 1860I(b)(1)(C);

''(D) the proposed negotiated prices of covered outpatient drugs and annual increases in such prices;

''(E) the factors described in section 1860D(b)(2);

''(F) prior experience of the entity in managing, administering, and delivering a prescription drug benefit program;

''(G) effectiveness of the entity and plan in containing costs through pricing incentives and utilization management; and

''(H) such other factors as the Secretary deems necessary to evaluate the merits of each bid.

''(3) EXCEPTION TO CONFLICT OF INTEREST RULES.—In awarding contracts under this part, the Secretary may waive conflict of interest laws generally applicable to Federal acquisitions (subject to such safeguards as the Secretary may find necessary to impose) in circumstances where the Secretary finds that such waiver—

''(A) is not inconsistent with the—

''(i) purposes of the programs under this title; or

''(ii) best interests of beneficiaries enrolled under this part; and

''(B) permits a sufficient level of competition for such contracts, promotes efficiency of benefits administration, or otherwise serves the objectives of the program under this part.

''(4) NO ADMINISTRATIVE OR JUDICIAL REVIEW.—The determination of the Secretary to award or not award a contract to an eligible entity with respect to a plan under this part shall not be subject to administrative or judicial review.

''(f) APPROVAL OF MARKETING MATERIAL AND APPLICATION FORMS.—The provisions of section 1851(h) shall apply to marketing material and application forms under this part in the same manner as such provisions apply to marketing material and application forms under part C.

''(g) DURATION OF CONTRACTS.—Each contract awarded under this part shall be for a term of at least 2 years but not more than 5 years, as determined by the Secretary.

''MINIMUM STANDARDS FOR ELIGIBLE ENTITIES

''SEC. 1860H. (a) IN GENERAL.—The Secretary shall not award a contract to an eligible entity under this part unless the Secretary finds that the eligible entity agrees to comply with such terms and conditions as the Secretary shall specify, including the following:

''(1) QUALITY AND FINANCIAL STANDARDS.—The eligible entity meets the quality and financial standards specified by the Secretary.

''(2) PROCEDURES TO ENSURE PROPER UTILIZATION, COMPLIANCE, AND AVOIDANCE OF ADVERSE DRUG REACTIONS.—

''(A) IN GENERAL.—The eligible entity has in place drug utilization review procedures to ensure—

''(i) the appropriate utilization by eligible beneficiaries enrolled in the plan covered by the contract of the benefits to be provided under the plan;

''(ii) the avoidance of adverse drug reactions among such beneficiaries, including problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions (including serious interactions with nonprescription or over-the-counter drugs), incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse and misuse; and

''(iii) the reasonable application of peer-reviewed medical literature pertaining to improvements in pharmaceutical safety and appropriate use of drugs.

''(B) AUTHORITY TO USE CERTAIN COMPENDIA AND LITERATURE.—The eligible entity may use the compendia and literature referred to in clauses (i) and (ii), respectively, of section 1927(g)(1)(B) as a source for the utilization review under subparagraph (A).

''(3) PATIENT PROTECTIONS.—

''(A) ACCESS.—

''(i) IN GENERAL.—The eligible entity ensures that the covered outpatient drugs are accessible and convenient to eligible beneficiaries enrolled in the plan covered by the contract, including by offering the services 24 hours a day and 7 days a week for emergencies.

''(ii) AGREEMENTS WITH PHARMACIES.—The eligible entity shall enter into a participation agreement with any pharmacy that meets the requirements of subsection (d) to furnish covered prescription drugs to eligible beneficiaries under this part. Such agreements shall include the payment of a reasonable dispensing fee for covered outpatient drugs dispensed to a beneficiary under the agreement.

''(iii) PREFERRED PHARMACY NETWORKS.—If the eligible entity utilizes a preferred pharmacy network, the network complies with the standards under subsection (e).

''(B) ENSURING THAT BENEFICIARIES ARE NOT OVERCHARGED.—The eligible entity has procedures in place to ensure that each pharmacy with a participation agreement under this part with the entity complies with the requirements under subsection (d)(1)(C) (relating to adherence to negotiated prices).

''(C) CONTINUITY OF CARE.—

''(i) IN GENERAL.—The eligible entity ensures that, in the case of an eligible beneficiary who loses coverage under this part with such entity under circumstances that would permit a special election period (as established by the Secretary under section 1860C(a)(1)), the entity will continue to provide coverage under this part to such beneficiary until the beneficiary enrolls and receives such coverage with another eligible entity under this part or, if eligible, with a Medicare+Choice organization.

''(ii) LIMITED PERIOD.—In no event shall an eligible entity be required to provide the extended coverage required under clause (i) beyond the date which is 30 days after the coverage with such entity would have terminated but for this subparagraph.

''(D) PROCEDURES REGARDING THE DETERMINATION OF DRUGS THAT ARE MEDICALLY NECESSARY.—

''(i) IN GENERAL.—The eligible entity has in place procedures on a case-by-case basis to treat a nonpreferred brand name drug as a preferred brand name drug and a nonformulary drug as a preferred brand name drug under this part if the nonpreferred brand name drug or the nonformulary drug, as the case may be, is determined—

''(I) to be not as effective for the enrollee in preventing or slowing the deterioration of, or improving or maintaining, the health of the enrollee; or

''(II) to have a significant adverse effect on the enrollee.

''(ii) REQUIREMENT.—The procedures under clause (i) shall require that determinations under such clause are based on professional medical judgment, the medical condition of the enrollee, and other medical evidence.

''(E) PROCEDURES REGARDING APPEAL RIGHTS WITH RESPECT TO DENIALS OF CARE.—The eligible entity has in place procedures to ensure—

''(i) a timely internal review for resolution of denials of coverage (in whole or in part and including those regarding the coverage of nonpreferred brand name drugs and nonformulary drugs as preferred brand name drugs) in accordance with the medical exigencies of the case and a timely resolution of complaints, by enrollees in the plan, or by providers, pharmacists, and other individuals acting on behalf of each such enrollee (with the enrollee's consent) in accordance with requirements (as established by the Secretary) that are comparable to such requirements for Medicare+Choice organizations under part C (and are not less favorable to the enrollee than such requirements under

such part as in effect on the date of enactment of the Medicare Outpatient Prescription Drug Act of 2002);

''(ii) that the entity complies in a timely manner with requirements established by the Secretary that (I) provide for an external review by an independent entity selected by the Secretary of denials of coverage described in clause (i) not resolved in the favor of the beneficiary (or other complainant) under the process described in such clause, and (II) are comparable to the external review requirements established for Medicare+Choice organizations under part C (and are not less favorable to the enrollee than such requirements under such part as in effect on the date of enactment of the Medicare Outpatient Prescription Drug Act of 2002); and

''(iii) that enrollees are provided with information regarding the appeals procedures under this part at the time of enrollment with the entity and upon request thereafter.

''(F) PROCEDURES REGARDING PATIENT CONFIDENTIALITY.—Insofar as an eligible entity maintains individually identifiable medical records or other health information regarding eligible beneficiaries enrolled in the plan that is covered by the contract, the entity has in place procedures to—

''(i) safeguard the privacy of any individually identifiable beneficiary information;

''(ii) maintain such records and information in a manner that is accurate and timely;

''(iii) ensure timely access by such beneficiaries to such records and information; and

''(iv) otherwise comply with applicable laws relating to patient confidentiality.

''(G) PROCEDURES REGARDING TRANSFER OF MEDICAL RECORDS.—

''(i) IN GENERAL.—The eligible entity has in place procedures for the timely transfer of records and information described in subparagraph (F) (with respect to a beneficiary who loses coverage under this part with the entity and enrolls with another entity (including a Medicare+Choice organization) under this part) to such other entity.

''(ii) PATIENT CONFIDENTIALITY.—The procedures described in clause (i) shall comply with the patient confidentiality procedures described in subparagraph (F).

''(H) PROCEDURES REGARDING MEDICAL ERRORS.—The eligible entity has in place procedures for—

''(i) working with the Secretary to deter medical errors related to the provision of covered outpatient drugs; and

''(ii) ensuring that pharmacies with a contract with the entity have in place procedures to deter medical errors related to the provision of covered outpatient drugs.

''(4) PROCEDURES TO CONTROL FRAUD, ABUSE, AND WASTE.—The eligible entity has in place procedures to control fraud, abuse, and waste.

''(5) REPORTING REQUIREMENTS.—

''(A) IN GENERAL.—The eligible entity provides the Secretary with reports containing information regarding the following:

''(i) The negotiated prices that the eligible entity is paying for covered outpatient drugs.

''(ii) The prices that eligible beneficiaries enrolled in the plan that is covered by the contract will be charged for covered outpatient drugs.

''(iii) The management costs of providing such benefits.

''(iv) Utilization of such benefits.

''(v) Marketing and advertising expenditures related to enrolling and retaining eligible beneficiaries.

''(B) TIMEFRAME FOR SUBMITTING REPORTS.—

''(i) IN GENERAL.—The eligible entity shall submit a report described in subparagraph (A) to the Secretary within 3 months after the end of each 12-month period in which the eligible entity has a contract under this part. Such report shall contain information concerning the benefits provided during such 12-month period.

''(ii) LAST YEAR OF CONTRACT.—In the case of the last year of a contract under this part, the Secretary may require that a report described in subparagraph (A) be submitted 3 months prior to the end of the contract. Such report shall contain information concerning the benefits provided between the period covered by the most recent report under this subparagraph and the date that a report is submitted under this clause.

''(C) CONFIDENTIALITY OF INFORMATION.—

''(i) IN GENERAL.—Notwithstanding any other provision of law and subject to clause (ii), information disclosed by an eligible entity pursuant to subparagraph (A) (except for information described in clause (ii) of such subparagraph) is confidential and shall only be used by the Secretary for the purposes of, and to the extent necessary, to carry out this part.

''(ii) UTILIZATION DATA.—Subject to patient confidentiality laws, the Secretary shall make information disclosed by an eligible entity pursuant to subparagraph (A)(iv) (regarding utilization data) available for research purposes. The Secretary may charge a reasonable fee for making such information available.

''(6) APPROVAL OF MARKETING MATERIAL AND APPLICATION FORMS.—The eligible entity complies with the requirements described in section 1860G(f).

''(7) RECORDS AND AUDITS.—The eligible entity maintains adequate records related to the administration of the benefits under this part and affords the Secretary access to such records for auditing purposes.

''(b) SPECIAL RULES REGARDING COST-EFFECTIVE PROVISION OF BENEFITS.—In providing the benefits under a contract under this part, an eligible entity shall—

''(1) employ mechanisms to provide the benefits economically, such as through the use of—

''(A) alternative methods of distribution;

''(B) preferred pharmacy networks (pursuant to subsection (e)); and

''(C) generic drug substitution;

''(2) use mechanisms to encourage eligible beneficiaries to select cost-effective drugs or less costly means of receiving drugs, such as through the use of—

''(A) pharmacy incentive programs;

''(B) therapeutic interchange programs; and

''(C) disease management programs;

''(3) encourage pharmacy providers to—

''(A) inform beneficiaries of the differentials in price between generic and brand name drug equivalents; and

''(B) provide medication therapy management programs in order to enhance beneficiaries' understanding of the appropriate use of medications and to reduce the risk of potential adverse events associated with medications; and

''(4) develop and implement a formulary in accordance with subsection (c).

''(c) REQUIREMENTS FOR FORMULARIES.—

''(1) IN GENERAL.—The formulary developed and implemented by the eligible entity shall comply with standards established by the Secretary in consultation with the Medicare Prescription Drug Advisory Committee established under section 1860L.

''(2) REQUIREMENTS FOR STANDARDS.—The standards established under paragraph (1) shall require that the eligible entity—

''(A) use a pharmacy and therapeutic committee (that meets the standards for a pharmacy and therapeutic committee established by the Secretary in consultation with such Medicare Prescription Drug Advisory Committee) to develop and implement the formulary;

''(B) assign all brand name drugs included in the formulary to either the preferred category or nonpreferred category of drugs;

''(C) include—

''(i) all generic covered outpatient drugs in the formulary;

''(ii) at least 1 brand name covered outpatient drug from each therapeutic class (as defined by the Secretary in consultation with such Medicare Prescription Drug Advisory Committee) as a preferred brand name drug in the formulary; and

''(iii) if there is more than 1 brand name covered outpatient drug available in a therapeutic class, at least 1 such drug as a preferred brand name drug in the formulary and at least 1 such drug as a nonpreferred brand name drug in the formulary;

''(D) develop procedures for the modification of the formulary, including for the addition of new drugs to an existing therapeutic class;

''(E) pursuant to section 1860F(b)(1)(C), provide for coverage of nonpreferred brand name drugs and nonformulary drugs at the preferred rate when determined under subparagraph (D) or (E) of subsection (a)(3) to be medically necessary;

''(F) disclose to current and prospective beneficiaries and to providers in the service area the nature of the formulary restrictions, including information regarding the drugs included in the formulary and any difference in the cost-sharing for—

''(i) drugs included in the formulary; and

''(ii) for drugs not included in the formulary; and

''(G) provide a reasonable amount of notice to beneficiaries enrolled in the plan that is covered by the contract under this part of any change in the formulary.

''(3) CONSTRUCTION.—Nothing in this part shall be construed as precluding an eligible entity from—

''(A) except as provided in section 1860F(b)(1)(C) (relating to the coverage of medically necessary drugs at the preferred rate), requiring cost-sharing for nonformulary drugs that is higher than the copayment amount established in section 1860F(b)(1)(A)(iii);

''(B) educating prescribing providers, pharmacists, and beneficiaries about the medical and cost benefits of drugs included in the formulary (including generic drugs); or

''(C) requesting prescribing providers to consider a drug included in the formulary prior to dispensing of a drug not so included or a preferred brand name drug prior to dispensing of a nonpreferred brand name drug, as long as such a request does not unduly delay the provision of the drug.

''(d) TERMS OF PARTICIPATION AGREEMENT WITH PHARMACIES.—

''(1) IN GENERAL.—A participation agreement between an eligible entity and a pharmacy under this part (pursuant to subsection (a)(3)(A)(ii)) shall include the following terms and conditions:

''(A) APPLICABLE REQUIREMENTS.—The pharmacy shall meet (and throughout the contract period continue to meet) all applicable Federal requirements and State and local licensing requirements.

''(B) ACCESS AND QUALITY STANDARDS.—The pharmacy shall comply with such standards as the Secretary (and the eligible entity) shall establish concerning the quality of, and enrolled beneficiaries' access to, pharmacy services under this part. Such standards shall require the pharmacy—

''(i) not to refuse to dispense covered outpatient drugs to any eligible beneficiary enrolled under this part;

''(ii) to keep patient records (including records on expenses) for all covered outpatient drugs dispensed to such enrolled beneficiaries;

''(iii) to submit information (in a manner specified by the Secretary to be necessary to administer this part) on all purchases of such drugs dispensed to such enrolled beneficiaries; and

''(iv) to comply with periodic audits to assure compliance with the requirements of this part and the accuracy of information submitted.

''(C) ENSURING THAT BENEFICIARIES ARE NOT OVERCHARGED.—

''(i) ADHERENCE TO NEGOTIATED PRICES.—The total charge for each covered outpatient drug dispensed by the pharmacy to a beneficiary enrolled in the plan, without regard to whether the individual is financially responsible for any or all of such charge, shall not exceed the negotiated price for the drug (as reported to the Secretary pursuant to subsection (a)(5)(A)).

''(ii) ADHERENCE TO BENEFICIARY OBLIGATION.—The pharmacy may not charge (or collect from) such beneficiary an amount that exceed's the cost-sharing that the beneficiary is responsible for under this part (as determined under section 1860F(b) using the negotiated price of the drug).

''(D) ADDITIONAL REQUIREMENTS.—The pharmacy shall meet such additional contract requirements as the eligible entity specifies under this section.

''(2) APPLICABILITY OF FRAUD AND ABUSE PROVISIONS.—The provisions of section 1128 through 1128C (relating to fraud and abuse) apply to pharmacies participating in the program under this part.

''(e) PREFERRED PHARMACY NETWORKS.—

''(1) IN GENERAL.—If an eligible entity uses a preferred pharmacy network to deliver benefits under this part, such network shall meet minimum access standards established by the Secretary.

''(2) STANDARDS.—In establishing standards under paragraph (1), the Secretary shall take into account reasonable distances to pharmacy services in both urban and rural areas.

''PAYMENTS

''SEC. 1860I. (a) PROCEDURES FOR PAYMENTS TO ELIGIBLE ENTITIES.—The Secretary shall establish procedures for making payments to each eligible entity with a contract under this part for the management, administration, and delivery of the benefits under this part.

''(b) REQUIREMENTS FOR PROCEDURES.—

''(1) IN GENERAL.—The procedures established under subsection (a) shall provide for the following:

''(A) MANAGEMENT PAYMENT.—Payment for the management, administration, and delivery of the benefits under this part.

''(B) REIMBURSEMENT FOR NEGOTIATED COSTS OF DRUGS PROVIDED.—Payments for the negotiated costs of covered outpatient drugs provided to eligible beneficiaries enrolled under this part and in a plan offered by the eligible entity, reduced by any applicable cost-sharing under section 1860F(b).

''(C) RISK REQUIREMENT TO ENSURE PURSUIT OF PERFORMANCE REQUIREMENTS.—An adjustment of a percentage (as determined under paragraph (2)) of the payments made to an entity under subparagraph (A) to ensure that the entity, in managing, administering, and delivering the benefits under this part, pursues performance requirements established by the Secretary, including the following:

''(i) CONTROL OF MEDICARE AND BENEFICIARY COSTS.—The entity contains costs to the Prescription Drug Account and to eligible beneficiaries enrolled under this part and in the plan offered by the entity, as measured by generic substitution rates, price discounts, and other factors determined appropriate by the Secretary that do not reduce the access of such beneficiaries to medically necessary covered outpatient drugs.

''(ii) QUALITY CLINICAL CARE.—The entity provides such beneficiaries with quality clinical care, as measured by such factors as—

''(I) the level of adverse drug reactions and medical errors among such beneficiaries; and

''(II) providing specific clinical suggestions to improve health and patient and prescriber education as appropriate.

''(iii) QUALITY SERVICE.—The entity provides such beneficiaries with quality services, as measured by such factors as sustained pharmacy network access, timeliness and accuracy of service delivery in claims processing and card production, pharmacy and member service support access, response time in mail delivery service, and timely action with regard to appeals and current beneficiary service surveys.

''(2) PERCENTAGE OF PAYMENT TIED TO RISK.—

''(A) IN GENERAL.—Subject to subparagraph (B), the Secretary shall determine the percentage (which may be up to 100 percent) of the payments made to an entity under subparagraph (A) that will be tied to the performance requirements described in paragraph (1)(C).

''(B) LIMITATION ON RISK TO ENSURE PROGRAM STABILITY.—In order to provide for program stability, the Secretary may not establish a percentage to be adjusted under this subsection at a level that jeopardizes the ability of an eligible entity to administer and deliver the benefits under this part or administer and deliver such benefits in a quality manner.

''(3) RISK ADJUSTMENT OF PAYMENTS BASED ON ENROLLEES IN PLAN.—To the extent that an eligible entity is at risk under this subsection, the procedures established under subsection (a) may include a methodology for risk adjusting the payments made to such entity based on the differences in actuarial risk of different enrollees being served if the Secretary determines such adjustments to be necessary and appropriate.

''(4) PASS-THROUGH OF REBATES AND PRICE CONCESSIONS OBTAINED BY THE ELIGIBLE ENTITY.—The Secretary, if determined by the Secretary to be in the best interests of the medicare program or eligible beneficiaries, may establish procedures for reducing the amount of payments to an eligible entity under subsection (a) to take into account any rebates or price concessions obtained by the entity from manufacturers of covered outpatient drugs.

''(c) PAYMENTS TO MEDICARE+CHOICE ORGANIZATIONS.—For provisions related to payments to Medicare+Choice organizations for the administration and delivery of benefits under this part to eligible beneficiaries enrolled in a Medicare+Choice plan offered by the organization, see section 1853(c)(8).

''(d) SECONDARY PAYER PROVISIONS.—The provisions of section 1862(b) shall apply to the benefits provided under this part.

''EMPLOYER INCENTIVE PROGRAM FOR EMPLOYMENT-BASED RETIREE DRUG COVERAGE

''SEC. 1860J. (a) PROGRAM AUTHORITY.—The Secretary is authorized to develop and implement a program under this section to be known as the 'Employer Incentive Program' that encourages employers and other sponsors of employment-based health care coverage to provide adequate prescription drug benefits to retired individuals by subsidizing, in part, the sponsor's cost of providing coverage under qualifying plans.

''(b) SPONSOR REQUIREMENTS.—In order to be eligible to receive an incentive payment under this section with respect to coverage of an individual under a qualified retiree prescription drug plan (as defined in subsection (e)(3)), a sponsor shall meet the following requirements:

''(1) ASSURANCES.—The sponsor shall—

''(A) annually attest, and provide such assurances as the Secretary may require, that the coverage offered by the sponsor is a qualified retiree prescription drug plan, and will remain such a plan for the duration of the sponsor's participation in the program under this section; and

''(B) guarantee that it will give notice to the Secretary and covered retirees—

''(i) at least 120 days before terminating its plan; and

''(ii) immediately upon determining that the actuarial value of the prescription drug benefit under the plan falls below the actuarial value of the outpatient prescription drug benefit under this part.

''(2) BENEFICIARY INFORMATION.—The sponsor shall report to the Secretary, for each calendar quarter for which it seeks an incentive payment under this section, the names and social security numbers of all retirees (and their spouses and dependents) covered under such plan during such quarter and the dates (if less than the full quarter) during which each such individual was covered.

''(3) AUDITS.—The sponsor and the employment-based retiree health coverage plan seeking incentive payments under this section shall agree to maintain, and to afford the Secretary access to, such records as the Secretary may require for purposes of audits and other oversight activities necessary to ensure the adequacy of prescription drug coverage, the accuracy of incentive payments made, and such other matters as may be appropriate.

''(4) OTHER REQUIREMENTS.—The sponsor shall provide such other information, and comply with such other requirements, as the Secretary may find necessary to administer the program under this section.

''(c) INCENTIVE PAYMENTS.—

''(1) IN GENERAL.—A sponsor that meets the requirements of subsection (b) with respect to a quarter in a calendar year shall be entitled to have payment made by the Secretary on a quarterly basis (to the sponsor or, at the sponsor's direction, to the appropriate employment-based health plan) of an incentive payment, in the amount determined in paragraph (2), for each retired individual (or spouse or dependent) who—

''(A) was covered under the sponsor's qualified retiree prescription drug plan during such quarter; and

''(B) was eligible for, but was not enrolled in, the outpatient prescription drug benefit program under this part.

''(2) AMOUNT OF PAYMENT.—

''(A) IN GENERAL.—The amount of the payment for a quarter shall be, for each individual described in paragraph (1), ⅔ of the sum of the monthly Government contribution amounts (computed under subparagraph (B)) for each of the 3 months in the quarter.

''(B) COMPUTATION OF MONTHLY GOVERNMENT CONTRIBUTION AMOUNT.—For purposes of subparagraph (A), the monthly Government contribution amount for a month in a year is equal to the amount by which—

''(i) 1/12 of the amount estimated under subparagraph (C) for the year involved; exceeds

''(ii) the monthly Part D premium under section 1860E(a) (determined without regard to any increase under section 1860B(b)(1)) for the month involved.

''(C) ESTIMATE OF AVERAGE ANNUAL PER CAPITA AGGREGATE EXPENDITURES.—

''(i) IN GENERAL.—The Secretary shall for each year after 2003 estimate for that year

an amount equal to average annual per capita aggregate expenditures payable from the Prescription Drug Account for that year.

''(ii) TIMEFRAME FOR ESTIMATION.—The Secretary shall make the estimate described in clause (i) for a year before the beginning of that year.

''(3) PAYMENT DATE.—The payment under this section with respect to a calendar quarter shall be payable as of the end of the next succeeding calendar quarter.

''(d) CIVIL MONEY PENALTIES.—A sponsor, health plan, or other entity that the Secretary determines has, directly or through its agent, provided information in connection with a request for an incentive payment under this section that the entity knew or should have known to be false shall be subject to a civil monetary penalty in an amount up to 3 times the total incentive amounts under subsection (c) that were paid (or would have been payable) on the basis of such information.

''(e) DEFINITIONS.—In this section:

''(1) EMPLOYMENT-BASED RETIREE HEALTH COVERAGE.—The term 'employment-based retiree health coverage' means health insurance or other coverage, whether provided by voluntary insurance coverage or pursuant to statutory or contractual obligation, of health care costs for retired individuals (or for such individuals and their spouses and dependents) based on their status as former employees or labor union members.

''(2) EMPLOYER.—The term 'employer' has the meaning given the term in section 3(5) of the Employee Retirement Income Security Act of 1974 (except that such term shall include only employers of 2 or more employees).

''(3) QUALIFIED RETIREE PRESCRIPTION DRUG PLAN.—The term 'qualified retiree prescription drug plan' means health insurance coverage included in employment-based retiree health coverage that—

''(A) provides coverage of the cost of prescription drugs with an actuarial value (as defined by the Secretary) to each retired beneficiary that equals or exceeds the actuarial value of the benefits provided to an individual enrolled in the outpatient prescription drug benefit program under this part; and

''(B) does not deny, limit, or condition the coverage or provision of prescription drug benefits for retired individuals based on age or any health status-related factor described in section 2702(a)(1) of the Public Health Service Act.

''(4) SPONSOR.—The term 'sponsor' has the meaning given the term 'plan sponsor' in section 3(16)(B) of the Employer Retirement Income Security Act of 1974.

''(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated from time to time, out of any moneys in the Treasury not otherwise appropriated, such sums as may be necessary to carry out the program under this section.

''PRESCRIPTION DRUG ACCOUNT IN THE FEDERAL SUPPLEMENTARY MEDICAL INSURANCE TRUST FUND

''SEC. 1860K. (a) ESTABLISHMENT.—

''(1) IN GENERAL.—There is created within the Federal Supplementary Medical Insurance Trust Fund established by section 1841 an account to be known as the 'Prescription Drug Account' (in this section referred to as the 'Account').

''(2) FUNDS.—The Account shall consist of such gifts and bequests as may be made as provided in section 201(i)(1), and such amounts as may be deposited in, or appropriated to, the account as provided in this part.

''(3) SEPARATE FROM REST OF TRUST FUND.—Funds provided under this part to the Account shall be kept separate from all other funds within the Federal Supplementary Medical Insurance Trust Fund.

''(b) PAYMENTS FROM ACCOUNT.—

''(1) IN GENERAL.—The Managing Trustee shall pay from time to time from the Account such amounts as the Secretary certifies are necessary to make payments to operate the program under this part, including payments to eligible entities under section 1860I, payments to Medicare+Choice organizations under section 1853(c)(8), and payments with respect to administrative expenses under this part in accordance with section 201(g).

''(2) TREATMENT IN RELATION TO PART B PREMIUM.—Amounts payable from the Account shall not be taken into account in computing actuarial rates or premium amounts under section 1839.

''(c) APPROPRIATIONS TO COVER BENEFITS AND ADMINISTRATIVE COSTS.—

''(1) IN GENERAL.—Subject to paragraph (2), there are appropriated to the Account in a fiscal year, out of any moneys in the Treasury not otherwise appropriated, an amount equal to the amount by which the benefits and administrative costs of providing the benefits under this part in the year exceed the premiums collected under section 1860E(b) for the year.

''(2) LIMITATION.—No amounts shall be appropriated, and no amounts expended, for expenses incurred for providing coverage of covered outpatient drugs after January 1, 2011. The Secretary may make payments on or after such date for expenses incurred to the extent such expenses were incurred for providing coverage of covered outpatient drugs prior to such date.

''MEDICARE PRESCRIPTION DRUG ADVISORY COMMITTEE

''SEC. 1860L. (a) ESTABLISHMENT OF COMMITTEE.—There is established a Medicare Prescription Drug Advisory Committee (in this section referred to as the 'Committee').

''(b) FUNCTIONS OF COMMITTEE.—On and after March 1, 2003, the Committee shall advise the Secretary on policies related to—

''(1) the development of guidelines for the implementation and administration of the outpatient prescription drug benefit program under this part; and

''(2) the development of—

''(A) standards for a pharmacy and therapeutics committee required of eligible entities under section 1860H(c)(2)(A);

''(B) standards required under subparagraphs (D) and (E) of section 1860H(a)(3) for determining if a drug is medically necessary;

''(C) standards for—

''(i) establishing therapeutic classes;

''(ii) adding new therapeutic classes to a formulary; and

''(iii) defining a prescription of covered outpatient drugs for purposes of applying cost-sharing under section 1860F(b);

''(D) procedures to evaluate the bids submitted by eligible entities under this part; and

''(E) procedures to ensure that eligible entities with a contract under this part are in compliance with the requirements under this part.

''(c) STRUCTURE AND MEMBERSHIP OF THE COMMITTEE.—

''(1) STRUCTURE.—The Committee shall be composed of 19 members who shall be appointed by the Secretary.

''(2) MEMBERSHIP.—

''(A) IN GENERAL.—The members of the Committee shall be chosen on the basis of their integrity, impartiality, and good judgment, and shall be individuals who are, by reason of their education, experience, attainments, and understanding of pharmaceutical cost control and quality enhancement, exceptionally qualified to perform the duties of members of the Committee.

''(B) SPECIFIC MEMBERS.—Of the members appointed under paragraph (1)—

''(i) five shall be chosen to represent physicians, 2 of whom shall be geriatricians;

''(ii) two shall be chosen to represent nurse practitioners;

''(iii) four shall be chosen to represent pharmacists;

''(iv) one shall be chosen to represent the Centers for Medicare & Medicaid Services;

''(v) four shall be chosen to represent actuaries, pharmacoeconomists, researchers, and other appropriate experts;

''(vi) one shall be chosen to represent emerging drug technologies;

''(vii) one shall be closed to represent the Food and Drug Administration; and

''(viii) one shall be chosen to represent individuals enrolled under this part.

''(d) TERMS OF APPOINTMENT.—Each member of the Committee shall serve for a term determined appropriate by the Secretary. The terms of service of the members initially appointed shall begin on January 1, 2003.

''(e) CHAIRPERSON.—The Secretary shall designate a member of the Committee as Chairperson. The term as Chairperson shall be for a 1-year period.

''(f) COMMITTEE PERSONNEL MATTERS.—

''(1) MEMBERS.—

''(A) COMPENSATION.—Each member of the Committee who is not an officer or employee of the Federal Government shall be compensated at a rate equal to the daily equivalent of the annual rate of basic pay prescribed for level IV of the Executive Schedule under section 5315 of title 5, United States Code, for each day (including travel time) during which such member is engaged in the performance of the duties of the Committee. All members of the Committee who are officers or employees of the United States shall serve without compensation in addition to that received for their services as officers or employees of the United States.

''(B) TRAVEL EXPENSES.—The members of the Committee shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for employees of agencies under subchapter I of chapter 57 of title 5, United States Code, while away from their homes or regular places of business in the performance of services for the Committee.

''(2) STAFF.—The Committee may appoint such personnel as the Committee considers appropriate.

''(g) OPERATION OF THE COMMITTEE.—

''(1) MEETINGS.—The Committee shall meet at the call of the Chairperson (after consultation with the other members of the Committee) not less often than quarterly to consider a specific agenda of issues, as determined by the Chairperson after such consultation.

''(2) QUORUM.—Ten members of the Committee shall constitute a quorum for purposes of conducting business.

''(h) FEDERAL ADVISORY COMMITTEE ACT.—Section 14 of the Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to the Committee.

''(i) TRANSFER OF PERSONNEL, RESOURCES, AND ASSETS.—For purposes of carrying out its duties, the Secretary and the Committee may provide for the transfer to the Committee of such civil service personnel in the employ of the Department of Health and Human Services (including the Centers for Medicare & Medicaid Services), and such resources and assets of the Department used in carrying out this title, as the Committee requires.

''(j) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such

sums as may be necessary to carry out the purposes of this section.''.

(b) EXCLUSIONS FROM COVERAGE.—

(1) APPLICATION TO PART D.—Section 1862(a) of the Social Security Act (42 U.S.C. 1395y(a)) is amended in the matter preceding paragraph (1) by striking ''part A or part B'' and inserting ''part A, B, or D''.

(2) PRESCRIPTION DRUGS NOT EXCLUDED FROM COVERAGE IF REASONABLE AND NECESSARY.—Section 1862(a)(1) of the Social Security Act (42 U.S.C. 1395y(a)(1)) is amended—

(A) in subparagraph (H), by striking ''and'' at the end;

(B) in subparagraph (I), by striking the semicolon at the end and inserting '', and''; and

(C) by adding at the end the following new subparagraph:

''(J) in the case of prescription drugs covered under part D, which are not reasonable and necessary to prevent or slow the deterioration of, or improve or maintain, the health of eligible beneficiaries;''.

(c) CONFORMING AMENDMENTS TO FEDERAL SUPPLEMENTARY MEDICAL INSURANCE TRUST FUND.—Section 1841 of the Social Security Act (42 U.S.C. 1395t) is amended—

(1) in the last sentence of subsection (a)—

(A) by striking ''and'' before ''such amounts''; and

(B) by inserting before the period the following: '', and such amounts as may be deposited in, or appropriated to, the Prescription Drug Account established by section 1860K'';

(2) in subsection (g), by inserting after ''by this part,'' the following: ''the payments provided for under part D (in which case the payments shall be made from the Prescription Drug Account in the Trust Fund),'';

(3) in subsection (h), by inserting after ''1840(d)'' the following: ''and section 1860E(b) (in which case the payments shall be made from the Prescription Drug Account in the Trust Fund)''; and

(4) in subsection (i), by inserting after ''section 1840(b)(1)'' the following: '', section 1860E(b) (in which case the payments shall be made from the Prescription Drug Account in the Trust Fund),''.

(d) CONFORMING REFERENCES TO PREVIOUS PART D.—

(1) IN GENERAL.—Any reference in law (in effect before the date of enactment of this Act) to part D of title XVIII of the Social Security Act is deemed a reference to part E of such title (as in effect after such date).

(2) SECRETARIAL SUBMISSION OF LEGISLATIVE PROPOSAL.—Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to Congress a legislative proposal providing for such technical and conforming amendments in the law as are required by the provisions of this Act.

SEC. 3. PART D BENEFITS UNDER MEDICARE+CHOICE PLANS.

(a) ELIGIBILITY, ELECTION, AND ENROLLMENT.—Section 1851 of the Social Security Act (42 U.S.C. 1395w–21) is amended—

(1) in subsection (a)(1)(A), by striking ''parts A and B'' and inserting ''parts A, B, and D''; and

(2) in subsection (i)(1), by striking ''parts A and B'' and inserting ''parts A, B, and D''.

(b) VOLUNTARY BENEFICIARY ENROLLMENT FOR DRUG COVERAGE.—Section 1852(a)(1)(A) of the Social Security Act (42 U.S.C. 1395w–22(a)(1)(A)) is amended by inserting ''(and under part D to individuals also enrolled under that part)'' after ''parts A and B''.

(c) ACCESS TO SERVICES.—Section 1852(d)(1) of the Social Security Act (42 U.S.C. 1395w–22(d)(1)) is amended—

(1) in subparagraph (D), by striking ''and'' at the end;

(2) in subparagraph (E), by striking the period at the end and inserting ''; and''; and

(3) by adding at the end the following new subparagraph:

''(F) in the case of covered outpatient drugs (as defined in section 1860(1)) provided to individuals enrolled under part D, the organization complies with the access requirements applicable under part D.''.

(d) PAYMENTS TO ORGANIZATIONS FOR PART D BENEFITS.—

(1) IN GENERAL.—Section 1853(a)(1)(A) of the Social Security Act (42 U.S.C. 1395w–23(a)(1)(A)) is amended—

(A) by inserting ''determined separately for the benefits under parts A and B and under part D (for individuals enrolled under that part)'' after ''as calculated under subsection (c)'';

(B) by striking ''that area, adjusted for such risk factors'' and inserting ''that area. In the case of payment for the benefits under parts A and B, such payment shall be adjusted for such risk factors as''; and

(C) by inserting before the last sentence the following: ''In the case of the payments under subsection (c)(8) for the provision of coverage of covered outpatient drugs to individuals enrolled under part D, such payment shall be adjusted for the risk factors of each enrollee as the Secretary determines to be feasible and appropriate to ensure actuarial equivalence.''.

(2) AMOUNT.—Section 1853(c) of the Social Security Act (42 U.S.C. 1395w–23(c)) is amended—

(A) in paragraph (1), in the matter preceding subparagraph (A), by inserting ''for benefits under parts A and B'' after ''capitation rate''; and

(B) by adding at the end the following new paragraph:

''(8) CAPITATION RATE FOR PART D BENEFITS.—

''(A) IN GENERAL.—In the case of a Medicare+Choice plan that provides coverage of covered outpatient drugs to an individual enrolled under part D, the capitation rate for such coverage shall be the amount described in subparagraph (B). Such payments shall be made in the same manner and at the same time as the payments to the Medicare+Choice organization offering the plan for benefits under parts A and B are otherwise made, but such payments shall be payable from the Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund under section 1841.

''(B) AMOUNT.—The amount described in this paragraph is an amount equal to 1/12 of the average annual per capita aggregate expenditures payable from the Prescription Drug Account for the year (as estimated under section 1860J(c)(2)(C)).''.

(e) LIMITATION ON ENROLLEE LIABILITY.—Section 1854(e) of the Social Security Act (42 U.S.C. 1395w–24(e)) is amended by adding at the end the following new paragraph:

''(5) SPECIAL RULE FOR PART D BENEFITS.—With respect to outpatient prescription drug benefits under part D, a Medicare+Choice organization may not require that an enrollee pay any deductible or pay a cost-sharing amount that exceeds the amount of cost-sharing applicable for such benefits for an eligible beneficiary under part D.''.

(f) REQUIREMENT FOR ADDITIONAL BENEFITS.—Section 1854(f)(1) of the Social Security Act (42 U.S.C. 1395w–24(f)(1)) is amended by adding at the end the following new sentence: ''Such determination shall be made separately for the benefits under parts A and B and for prescription drug benefits under part D.''.

(g) EFFECTIVE DATE.—The amendments made by this section shall apply to items and services provided under a Medicare+Choice plan on or after January 1, 2004.

SEC. 4. ADDITIONAL ASSISTANCE FOR LOW-INCOME BENEFICIARIES.

(a) INCLUSION IN MEDICARE COST-SHARING.—Section 1905(p)(3) of the Social Security Act (42 U.S.C. 1396d(p)(3)) is amended—

(1) in subparagraph (A)—

(A) in clause (i), by striking ''and'' at the end;

(B) in clause (ii), by inserting ''and'' at the end; and

(C) by adding at the end the following new clause:

''(iii) premiums under section 1860E(a).''; and

(2) in subparagraph (B), by inserting ''and cost-sharing described in section 1860F(b)'' after ''section 1813''.

(b) EXPANSION OF MEDICAL ASSISTANCE.—Section 1902(a)(10)(E) of the Social Security Act (42 U.S.C. 1396a(a)(10)(E)) is amended—

(1) in clause (iii)—

(A) by striking ''section 1905(p)(3)(A)(ii)'' and inserting ''clauses (ii) and (iii) of section 1905(p)(3)(A) and for medicare cost-sharing described in section 1905(p)(3)(B) (but only insofar as it relates to benefits provided under part D of title XVIII),''; and

(B) by striking ''and'' at the end;

(2) by redesignating clause (iv) as clause (vi); and

(3) by inserting after clause (iii) the following new clauses:

''(iv) for making medical assistance available for medicare cost-sharing described in section 1905(p)(3)(A)(iii) and for medicare cost-sharing described in section 1905(p)(3)(B) (but only insofar as it relates to benefits provided under part D of title XVIII) for individuals who would be qualified medicare beneficiaries described in section 1905(p)(1) but for the fact that their income exceeds 120 percent but does not exceed 135 percent of such official poverty line for a family of the size involved;

''(v) for making medical assistance available for medicare cost-sharing described in section 1905(p)(3)(A)(iii) on a linear sliding scale based on the income of such individuals for individuals who would be qualified medicare beneficiaries described in section 1905(p)(1) but for the fact that their income exceeds 135 percent but does not exceed 150 percent of such official poverty line for a family of the size involved; and''.

(c) NONAPPLICABILITY OF RESOURCE REQUIREMENTS TO MEDICARE PART D COST-SHARING.—Section 1905(p)(1) of the Social Security Act (42 U.S.C. 1396d(p)(1)) is amended by adding at the end the following flush sentence:

''In determining if an individual is a qualified medicare beneficiary under this paragraph, subparagraph (C) shall not be applied for purposes of providing the individual with medicare cost-sharing described in section 1905(p)(3)(A)(iii) or for medicare cost-sharing described in section 1905(p)(3)(B) (but only insofar as it relates to benefits provided under part D of title XVIII).''.

(d) NONAPPLICABILITY OF PAYMENT DIFFERENTIAL REQUIREMENTS TO MEDICARE PART D COST-SHARING.—Section 1902(n)(2) of the Social Security Act (42 U.S.C. 1396a(n)(2)) is amended by adding at the end the following new sentence: ''The preceding sentence shall not apply to the cost-sharing described in section 1860F(b).''.

(e) 100 PERCENT FEDERAL MEDICAL ASSISTANCE PERCENTAGE.—The first sentence of section 1905(b) of the Social Security Act (42 U.S.C. 1396d(b)) is amended—

(1) by striking ''and'' before ''(4)''; and

(2) by inserting before the period at the end the following: '', and (5) the Federal medical assistance percentage shall be 100 percent

with respect to medical assistance provided under clauses (iv) and (v) of section 1902(a)(10)(E)''.

(f) TREATMENT OF TERRITORIES.—Section 1108(g) of the Social Security Act (42 U.S.C. 1308(g)) is amended by adding at the end the following new paragraph:

''(3) Notwithstanding the preceding provisions of this subsection, with respect to fiscal year 2004 and any fiscal year thereafter, the amount otherwise determined under this subsection (and subsection (f)) for the fiscal year for a Commonwealth or territory shall be increased by the ratio (as estimated by the Secretary) of—

''(A) the aggregate amount of payments made to the 50 States and the District of Columbia for the fiscal year under title XIX that are attributable to making medical assistance available for individuals described in clauses (i), (iii), (iv), and (v) of section 1902(a)(10)(E) for payment of medicare cost-sharing described in section 1905(p)(3)(A)(iii) and for medicare cost-sharing described in section 1905(p)(3)(B) (but only insofar as it relates to benefits provided under part D of title XVIII); to

''(B) the aggregate amount of total payments made to such States and District for the fiscal year under such title.''.

(g) CONFORMING AMENDMENTS.—Section 1933 of the Social Security Act (42 U.S.C. 1396u–3) is amended—

(1) in subsection (a), by striking ''section 1902(a)(10)(E)(iv)'' and inserting ''section 1902(a)(10)(E)(vi)'';

(2) in subsection (c)(2)(A)—

(A) in clause (i), by striking ''section 1902(a)(10)(E)(iv)(I)'' and inserting ''section 1902(a)(10)(E)(vi)(I)''; and

(B) in clause (ii), by striking ''section 1902(a)(10)(E)(iv)(II)'' and inserting ''section 1902(a)(10)(E)(vi)(II)'';

(3) in subsection (d), by striking ''section 1902(a)(10)(E)(iv)'' and inserting ''section 1902(a)(10)(E)(vi)''; and

(4) in subsection (e), by striking ''section 1902(a)(10)(E)(iv)'' and inserting ''section 1902(a)(10)(E)(vi)''.

(h) EFFECTIVE DATE.—The amendments made by this section shall apply for medical assistance provided under section 1902(a)(10)(E) of the Social Security Act (42 U.S.C. 1396a(a)(10)(E)) on and after January 1, 2004.

SEC. 5. MEDIGAP REVISIONS.

Section 1882 of the Social Security Act (42 U.S.C. 1395ss) is amended by adding at the end the following new subsection:

''(v) MODERNIZED BENEFIT PACKAGES FOR MEDICARE SUPPLEMENTAL POLICIES.—

''(1) REVISION OF BENEFIT PACKAGES.—

''(A) IN GENERAL.—Notwithstanding subsection (p), the benefit packages classified as 'H', 'I', and 'J' under the standards established by subsection (p)(2) (including the benefit package classified as 'J' with a high deductible feature, as described in subsection (p)(11)) shall be revised so that—

''(i) the coverage of outpatient prescription drugs available under such benefit packages is replaced with coverage of outpatient prescription drugs that complements but does not duplicate the coverage of outpatient prescription drugs that is otherwise available under this title;

''(ii) the revised benefit packages provide a range of coverage options for outpatient prescription drugs for beneficiaries, but do not provide coverage for more than 90 percent of the cost-sharing amount applicable to an individual under section 1860F(b);

''(iii) uniform language and definitions are used with respect to such revised benefits;

''(iv) uniform format is used in the policy with respect to such revised benefits;

''(v) such revised standards meet any additional requirements imposed by the amendments made by the Medicare Outpatient Prescription Drug Act of 2002; and

''(vi) except as revised under the preceding clauses or as provided under subsection (p)(1)(E), the benefit packages are identical to the benefit packages that were available on the date of enactment of the Medicare Outpatient Prescription Drug Act of 2002.

''(B) MANNER OF REVISION.—The benefit packages revised under this section shall be revised in the manner described in subparagraph (E) of subsection (p)(1), except that for purposes of subparagraph (C) of such subsection, the standards established under this subsection shall take effect not later than January 1, 2004.

''(2) CONSTRUCTION OF BENEFITS IN OTHER MEDICARE SUPPLEMENTAL POLICIES.—Nothing in the benefit packages classified as 'A' through 'G' under the standards established by subsection (p)(2) (including the benefit package classified as 'F' with a high deductible feature, as described in subsection (p)(11)) shall be construed as providing coverage for benefits for which payment may be made under part D.

''(3) GUARANTEED ISSUANCE AND RENEWAL OF REVISED POLICIES.—The provisions of subsections (q) and (s), including provisions of subsection (s)(3) (relating to special enrollment periods in cases of termination or disenrollment), shall apply to medicare supplemental policies revised under this subsection in the same manner as such provisions apply to medicare supplemental policies issued under the standards established under subsection (p).

''(4) OPPORTUNITY OF CURRENT POLICYHOLDERS TO PURCHASE REVISED POLICIES.—

''(A) IN GENERAL.—No medicare supplemental policy of an issuer with a benefit package that is revised under paragraph (1) shall be deemed to meet the standards in subsection (c) unless the issuer—

''(i) provides written notice during the 60-day period immediately preceding the period established for the open enrollment period established under section 1860B(b)(2)(A), to each individual who is a policyholder or certificate holder of a medicare supplemental policy issued by that issuer (at the most recent available address of that individual) of the offer described in clause (ii) and of the fact that such individual will no longer be covered under such policy as of January 1, 2004; and

''(ii) offers the policyholder or certificate holder under the terms described in subparagraph (B), during at least the period established under section 1860B(b)(2)(A), a medicare supplemental policy with the benefit package that the Secretary determines is most comparable to the policy in which the individual is enrolled with coverage effective as of the date on which the individual is first entitled to benefits under part D.

''(B) TERMS OF OFFER DESCRIBED.—The terms described in this subparagraph are terms which do not—

''(i) deny or condition the issuance or effectiveness of a medicare supplemental policy described in subparagraph (A)(ii) that is offered and is available for issuance to new enrollees by such issuer;

''(ii) discriminate in the pricing of such policy because of health status, claims experience, receipt of health care, or medical condition; or

''(iii) impose an exclusion of benefits based on a preexisting condition under such policy.

''(5) ELIMINATION OF OBSOLETE POLICIES WITH NO GRANDFATHERING.—No person may sell, issue, or renew a medicare supplemental policy with a benefit package that is classified as 'H', 'I', or 'J' (or with a benefit package classified as 'J' with a high deductible feature) that has not been revised under this subsection on or after January 1, 2004.

''(6) PENALTIES.—Each penalty under this section shall apply with respect to policies revised under this subsection as if such policies were issued under the standards established under subsection (p), including the penalties under subsections (a), (d), (p)(8), (p)(9), (q)(5), (r)(6)(A), (s)(4), and (t)(2)(D).''.

SEC. 6. HHS STUDIES AND REPORT ON UNIFORM PHARMACY BENEFIT CARDS AND SYSTEMS FOR TRANSFERRING PRESCRIPTIONS ELECTRONICALLY.

(a) STUDIES.—The Secretary of Health and Human Services shall conduct a study to determine the feasibility and advisability of—

(1) establishing a uniform format for pharmacy benefit cards provided to beneficiaries by eligible entities under the outpatient prescription drug benefit program under part D of title XVIII of the Social Security Act (as added by section 2); and

(2) developing systems to electronically transfer prescriptions under such program from the prescriber to the pharmacist.

(b) REPORT.—Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to Congress a report on the results of the studies conducted under subsection (a) together with any recommendations for legislation that the Secretary determines to be appropriate as a result of such studies.

SEC. 7. GAO STUDY AND BIENNIAL REPORTS ON COMPETITION AND SAVINGS.

(a) ONGOING STUDY.—The Comptroller General of the United States shall conduct an ongoing study and analysis of the outpatient prescription drug benefit program under part D of title XVIII of the Social Security Act (as added by section 2), including an analysis of—

(1) the extent to which the competitive bidding process under such program fosters maximum competition and efficiency; and

(2) the savings to the medicare program resulting from such outpatient prescription drug benefit program, including the reduction in the number or length of hospital visits.

(b) INITIAL REPORT ON COMPETITIVE BIDDING PROCESS.—Not later than 9 months after the date of enactment of this Act, the Comptroller General of the United States shall submit to Congress a report on the results of the portion of the study conducted pursuant to subsection (a)(1).

(c) BIENNIAL REPORTS.—Not later than January 1, 2005, and biennially thereafter, the Comptroller General of the United States shall submit to Congress a report on the results of the study conducted under subsection (a) together with such recommendations for legislation and administrative action as the Comptroller General determines appropriate.

SEC. 8. EXPANSION OF MEMBERSHIP AND DUTIES OF MEDICARE PAYMENT ADVISORY COMMISSION (MEDPAC).

(a) EXPANSION OF MEMBERSHIP.—

(1) IN GENERAL.—Section 1805(c) of the Social Security Act (42 U.S.C. 1395b–6(c)) is amended—

(A) in paragraph (1), by striking ''17'' and inserting ''19''; and

(B) in paragraph (2)(B), by inserting ''experts in the area of pharmacology and prescription drug benefit programs,'' after ''other health professionals,''.

(2) INITIAL TERMS OF ADDITIONAL MEMBERS.—

(A) IN GENERAL.—For purposes of staggering the initial terms of members of the Medicare Payment Advisory Commission under section 1805(c)(3) of the Social Security Act (42 U.S.C. 1395b–6(c)(3)), the initial terms of the 2 additional members of the Commission provided for by the amendment under paragraph (1)(A) are as follows:

(i) One member shall be appointed for 1 year.

(ii) One member shall be appointed for 2 years.

(B) COMMENCEMENT OF TERMS.—Such terms shall begin on January 1, 2003.

(b) EXPANSION OF DUTIES.—Section 1805(b)(2) of the Social Security Act (42 U.S.C. 1395b–6(b)(2)) is amended by adding at the end the following new subparagraph:

''(D) PRESCRIPTION MEDICINE BENEFIT PROGRAM.—Specifically, the Commission shall review, with respect to the outpatient prescription drug benefit program under part D, the impact of such program on—

''(i) the pharmaceutical market, including costs and pricing of pharmaceuticals, beneficiary access to such pharmaceuticals, and trends in research and development;

''(ii) franchise, independent, and rural pharmacies; and

''(iii) beneficiary access to outpatient prescription drugs, including an assessment of out-of-pocket spending, generic and brand name drug utilization, and pharmacists' services.''.

Mr. MILLER. Madam President, I am proud to tell America's seniors who have been waiting in line for a long time that, finally, they have reached the front of the line. Their time has come. This Senate is ready to take action on prescription drugs.

Our action cannot come soon enough. Most of our elderly in this country are not wealthy. Many live on fixed incomes. They are the ones who are hurt first and hurt most by rising health care costs.

Our elderly have been waiting a long time. Waiting for Congress to do something. Waiting for Congress to help them with the skyrocketing costs of their prescription drugs.

Our bill provides an affordable prescription drug benefit under Medicare for all seniors for the first time. Coverage begins with the first prescription filled because there is no deductible.

For the roughly 12 million seniors in this country who earn less than $11,900 a year, there is no premium and no copayment. For our neediest seniors, our bill gives them their medicine for free.

For those who earn more, our plan has an affordable a $25 monthly premium and a copayment of $10 for generic drugs and $40 for brand-name drugs. Also, our bill has no gap in coverage and an out-of-pocket maximum of $4,000 a year.

We realize it is a huge, complex and complicated undertaking. And that is why this bill provides that in 2011, we will come back and re-evaluate this program, just like we do with other complicated legislation.

We believe that is the wise and judicious thing to do. In fact, if the original Medicare program had required such a reauthorization, we probably would have had a prescription drug benefit added to it long ago.

But since Medicare was permanently authorized from the beginning, there was no requirement for Congress to re-evaluate and therefore modernize the program as circumstances changed over the years.

And, reauthorization is not anything new or different. We re-evaluate many programs on a regular basis: We just did it with the Farm Bill. Welfare Reform, the Elementary and Secondary Education program, Head Start, all of them are re-evaluated at regular intervals.

I hope that all members of the Senate will come together and pass this bill in the next few weeks so that our elderly across this land of plenty, those folks who have played by the rules and worked hard, can have some hope and some dignity in the last few years they are on this earth.

Mr. KENNEDY. Madam President, Medicare is a solemn promise between government and its citizens and between the generations. It says, ''Contribute to the system during your working years and we will assure you health security in your retirement years.'' But that promise is broken every day, because Medicare does not cover prescription drugs. The Graham-Miller-Kennedy Medicare Prescription Drug Act of 2002 sends the message loud and clear: it is time to mend Medicare's broken promise.

There is no domestic issue that is more important to the American people than assuring that senior citizens can afford the prescription drugs they need. Senior citizens have an average income of $15,000, and they spend an average of $2,000 of that limited income on prescription drugs. Too many of our elderly citizens must choose between food on the table and the medicine their doctors prescribe. Too many of the elderly are taking half the drugs their doctor prescribes, or none at all, because they simply can't afford them.

Every day we delay, the problem becomes worse. Prescription drugs costs are escalating at double-digit rates. One-third of all senior citizens don't have a dime of prescription drug coverage, and those who do have coverage are in danger of losing it. The sad fact is that the only senior citizens who have reliable, affordable, adequate coverage are the very poor on Medicaid. That is not good enough, and we are here today to say that America owes it to its senior citizens to do better.

Every politician understands that senior citizens, and their children, and their grandchildren want action. Every politician understands that opposition to a prescription drug benefit is not a sustainable position. The question is not whether Congress will pass a bill; the question is whether we will pass a bill that truly provides the protection senior citizens need. The elderly do not need a prescription drug benefit that cannot pass the truth in advertising test. They don't need a benefit that pays pennies on the dollar for the medicines the elderly need to survive. They do not need a benefit that offers the pretence of relief but not the performance.

The bill we are offering today mends the broken promise of Medicare. It offers real benefits at a price the elderly can afford. It is a lifeline for every senior citizen who needs prescription drugs. It is a priority for the American people.

It is time to pass a Medicare prescription drug benefit. It is time for Congress to listen to the American people instead of the powerful special interests.

By Mr. CLELAND:

S. 2627. A bill to protect marine species off the coast of Georgia; to the Committee on Commerce, Science, and Transportation.

Mr. CLELAND. Madam President, I rise today to introduce legislation to help protect marine species in the exclusive economic zone off the coast of Georgia. Shark gillnetting causes bycatch of many marine species, including valuable gamefish such as tarpon, red drum, king mackerel, and cobia and leatherback sea turtles, a protected species. Gillnets are already prohibited in Georgia's State waters, and my legislation would also prohibit this gear from being used in the Federal waters off the coast of Georgia. This legislation is supported by the Georgia Department of Natural Resources, which has jurisdiction over the State's coastal resources.

My proposal does not prohibit shark fishing but rather affects the means of fishing. Shark fishers can use other methods for fishing such as long-lines or hook and line as alternatives. Additionally, this bill only affects the waters off the coast of Georgia. The neighboring States are still allowed to handle the bycatch, enforcement, and other issues as they believe is appropriate.

The waters affected by the legislation are home to many types of marine life that are vitally important to Georgia's traditional and expanding charter fishery, as well as the state's coastal communities and tourism industry. These businesses are negatively impacted by the shark gillnetting bycatch rates and its impacts on gamefish populations, including some already overfished stocks. In August 2000, I was contacted by some of these Georgia business people who are concerned over what they see as a dramatic decrease in the fish population and about the future viability of their businesses. These citizens work to create a delicate balance between the environment and their livelihood by limiting their catches and releasing fish to help insure the sustained health of local fish stocks and their habitats. Shark gillnetting has disrupted this balance. My legislation is the first step to bringing this balance back in line.

As the Commerce Committee, of which I am a member, begins the reauthorization of the Magnuson-Stevens Fishery Conservation Management Act, I will work with Chairman HOLLINGS to address this issue. It is at once an environmental issue, a small business issue, a state sovereignty issue, and it is the right thing to do.

By Mr. KENNEDY (for himself, Mr. DEWINE, Mr. HARKIN, Mr. MCCAIN, Mr. DURBIN, Mr.

GRAHAM, Mr. WELLSTONE, Ms. COLLINS, Mrs. FEINSTEIN, and Mr. REED):

S. 2626. A bill to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products; to the Committee on Health, Education, Labor, and Pensions.

Mr. DEWINE. Madam President, today Senator KENNEDY, my colleague from Massachusetts, and I, Senator DURBIN, and others are introducing a bill designed to help protect children from the dangers of tobacco. Quite simply, our bill would finally give the Food and Drug Administration the authority it needs to effectively regulate both the manufacture and the sale of tobacco products.

My colleagues will all remember that we visited this issue a few years ago, in 1998, when our colleague from Arizona, Senator MCCAIN, and others introduced the Universal Tobacco Settlement Act, which included a major section that provided the FDA with the authority to regulate tobacco products. Also, of course, during 1998, 46 States entered into an agreement known as the Master Settlement Agreement, MSA. They entered into that agreement with the major tobacco companies to settle all State lawsuits seeking to recover the Medicaid costs of treating smokers.

Fast forward from 1998 until today. Tobacco proponents would have you believe this master settlement resolved the issue of tobacco use by imposing all these restrictions. But the truth is, it did not. Smoking among young people remains a huge national problem.

Every day in this country, nearly 5,000 young people under the age of 18 try their first cigarette. In my own home State of Ohio, 33 percent—one-third—of children 18 and under smoke. These kids in Ohio, by themselves, go through 45 million packs of cigarettes each year.

If that is not bad enough, look at it another way: 90 percent of smokers start smoking before the age of 19. More than 6.4 million children across this country will die prematurely because of a decision they will make as children, as adolescents—a decision to start smoking cigarettes.

In my home State of Ohio, as I indicated, one-third of the children smoke. We know the statistics are that one-third of people who smoke in this country will die prematurely because of an alcohol-related illness. One-third of the one-third, therefore, in the State of Ohio will die prematurely.

While States have limited options available for tobacco advertising under this 1998 Master Settlement Agreement, the reality is that the tobacco companies still are able to choose the contents of their advertisements. They are still able to get around this settlement. They are still able to run ads like this: ''Skol, A Pinch Better.'' Guess where that ad ran? In Sports Illustrated.

How many young people in this country every week wait for that Sports Illustrated to come in the mail, or buy it when it comes to the store?

The companies are savvy. They have really changed their marketing strategies. They have concentrated more money into different advertising markets. As a result, more than 3 years after the major tobacco companies agreed to stop marketing to children as part of this tobacco settlement, children are still twice as likely as adults to be exposed to tobacco advertising.

Let me repeat that. Children are still twice as likely as adults to be exposed to tobacco advertising.

This chart shows and represents a poll which was done. The question asked was: Have you seen any advertising for cigarettes or tobacco in the last 2 weeks? Among teens, 64 percent said yes; adults, only 27 percent.

In spite of the claim that tobacco companies are not targeting children, for whatever reason that is the market that is hearing it; that is who is seeing the message; that is who is hearing the message; that is whom the message is affecting.

According to the Federal Trade Commission's annual report on cigarette sales and advertising, the year 2000 represented the largest increase ever in tobacco companies' spending on ''promotional allowances''; that is, the money tobacco companies pay retailers to promote their products in prominent locations in stores, or for high visible shelf space. We know that is one of the greatest marketing techniques—put it somewhere I can see it when I walk in the store. It is right at eye level for kids near the cash register, in an aisle where the customer must walk by to pay the cashier.

That same year—the year 2000—cigarette manufacturers spent a record $9.5 billion on advertising and promotion. That is an increase of 16 percent from the year 1999.

Tobacco companies also spend billions of dollars advertising through enticing promotional items—lighters, hats, and other products—they give away for free at the ''point of sale,'' or, in other words, at the cash register or the place of checkout in the grocery store or the convenience store.

In fact, spending on such promotional or value-added items increased by 37 percent between 1999 and the year 2000.

Let us not fool ourselves. These promotional strategies and advertisements reach our children. Statistics show that 75 percent of our children visit a convenience store at least once a week.

I ask my colleagues. The next time you walk into a convenience store, look at how many different times you see an advertisement for tobacco products. They are everywhere. You walk in the store, and it may be on the clock—a little promotional clock that says when the store is open and when the store is closed. They will be at eye level. They will be by the cashier when you check out. They will be everywhere—image after image after image. It is calculated, and it works. Convenience stores are a place—right or wrong—where kids go. Seventy-five percent of kids visit convenience stores, as I said, at least once a week. That is a target area.

This isn't just about advertising and marketing schemes. It is also about to be manufacturers' failure to disclose the specific ingredients in their products.

I realize full well that tobacco users and nonusers alike recognize and understand that tobacco products are hazardous to their health. Everybody knows that. That is not what I am talking about. I am talking about requiring the tobacco companies to list the ingredients in their products. They do not have to do that today. Tobacco is an unregulated product. I believe it makes common sense that tobacco companies should be required to list when they put arsenic—and they do—or put formaldehyde or ammonia in the cigarettes. They should have to at least list it. It just makes common sense. Yet the law today does not require them to do that.

While simply listing the ingredients, toxic as they may be, might not seem like much, think about it this way. Current law makes sure that we know what is in products designed to help people quit smoking—products such as the patch or the Nicorette gum, which are regulated, but not the very product that gets people addicted in the first place, the cigarettes. Doesn't that seem absurd?

Think about it this way: Right now, the Food and Drug Administration requires Philip Morris to print the ingredients in its Kraft Macaroni and Cheese. They have to print all of the ingredients. Pick up a box. Every single ingredient that is in there they have to print but not the ingredients in cigarettes, a product, by the way, that contributes to the deaths of more than 440,000 people a year.

Right now the FDA requires Philip Morris, which owns Nabisco, to print the ingredients contained in Oreo cookies and Ritz crackers but not the ingredients in Camel or Winston cigarettes, even though cigarettes cause one-third of all cancer deaths and 90 percent of lung cancer deaths. It is unfathomable to me—and I think it is unfathomable to everybody—that we would require the listing of ingredients on these products. We even require the listing of the ingredients on bottled water. Yet we do not require the listing of ingredients for one of the leading causes of death and disease in this country.

Right now, the FDA requires printed ingredients for chewing gum, lipstick, bottled water, and ice cream, but not for cigarettes—a product that causes 20 percent of all heart disease deaths, 90 percent of lung cancer, which is the leading cause of cancer deaths among women, and the leading cause of preventable death in the United States.

Another way to look at it is if a company wants to market a food product

as ''fat-free'' or ''reduced-fat'' or ''lite,'' that company is required to meet certain standards regarding the number of calories or the amount of fat grams in that product. You can look right on that package and find it. Yet cigarette companies can call a cigarette a ''Camel Light'' or a ''Marlboro Light'' and not reveal a thing about the amount of tar or nicotine or arsenic in that supposedly ''light'' cigarette.

Not having access to all of the information about this deadly product just makes no sense. It is something we need to change. With the bill we are introducing, we can change it.

It is time we finally give the FDA the authority it needs to fix these problems. The legislation that Senator KENNEDY and Senator DURBIN and I are introducing will do just that.

First, the bill would make changes regarding tobacco advertising. It would give the FDA authority to restrict tobacco industry marketing—consistent with the first amendment—that targets our children.

Additionally, our bill would require advertisements to be in black and white text only, unless they are in adult publications, and would define adult publications in terms of readership.

Next, our legislation would give consumers more information about the ingredients in tobacco products. Specifically, the bill would provide the FDA with the ability to publish the ingredients of tobacco products.

It would require a listing of all ingredients, substances, and compounds added by the manufacturer to the tobacco, to the paper, or to the filter.

It would require a description of the content, delivery, and form of nicotine in each tobacco product.

It would require information on the health, behavioral, or physiologic effects of the tobacco products.

Further, it would require tobacco companies to provide information on the reduction of risk to health available through technology.

And finally, it would establish an approval process for all new tobacco products entering the market—new products such as advance with its ''trionic filter'', which claims to have—and I quote—''all of the taste . . . less of the toxins'' of other cigarettes.

Obviously, we already know that smoking is a health risk. We all know that. But, what we don't know about is the harm caused by or what adverse health effects are created by the other ingredients in tobacco products or by how the tobacco is burned. We do not know all the details about that. Tobacco companies should share that. There are tobacco products on the market that are not conventional cigarettes. They have carbon filters running down the center of them. They are sophisticated products that burn tobacco differently, that affect the body differently, and that may cause people to smoke them differently. These are all things that should be examined, they should be reviewed, and they should be commented on by the Food and Drug Administration, so the public knows what they are choosing to consume.

Here we have a pack of Eclipse cigarettes, which claims it will—and I quote—''Change the way you smoke.'' It also claims that it—and again I quote—''may present less risk of cancer, bronchitis, and possibly emphysema.'' This is what they say in the bold print. I don't know who ''they'' are, and I don't know where they got their information, but the public should know.

Below the bold print in this same pack is the following, smaller print:

Evidence suggests that smokers who already have cardiovascular disease and who switch to Eclipse may further increase their health risk.

So in the bold print we have a statement that is not cited and not supported, and then in the fine print we have a statement that is supported by numerous studies. Which claim are you more likely to believe? And which statement should be broadcast in bold lettering to the consumer?

By introducing this bill, we are finally saying we are not going to let tobacco manufacturers have free rein over markets and consumers anymore.

Today, we are taking a step towards making sure the public gets adequate information about whether to continue to smoke or even to start smoking in the first place. We all know it is dangerous. But the tobacco companies no longer should be able to hide all the facts.

With this bill, we are not just saying, ''Buyer beware''—we all know there are dangers—but what we are saying is, ''Tobacco companies, be honest.'' We are saying, ''Tobacco companies, stop marketing to our kids.'' We are saying, ''Tobacco companies, tell consumers about what they are really buying.''

Madam President, it is time we hold these companies to the same standards we expect from other producers. It is time to give kids a fighting chance when it comes to resisting cigarettes. It is time to finally just do the right thing.

I thank the Chair and yield the floor.

The PRESIDING OFFICER. The Senator from Massachusetts is recognized.

Mr. KENNEDY. Madam President, I join my friend and colleague from Ohio, Senator DEWINE, in expressing our appreciation to all of our cosponsors for this legislation that we have introduced. And I commend him for the excellent presentation and description of the legislation that he has just given to the Senate this morning.

We indicate to our friends and colleagues that this legislation is very similar to the legislation that was included in the larger tobacco legislation the Senate considered several years ago. It was not really subject to any amendments that I remember during that period of time. That overall legislation, I believe, gained 58 votes on the floor of the Senate. So we had broad support for the legislation. In many respects, I think there is even broader support for this particular legislation.

So we are very hopeful we will be able to make progress in considering this legislation favorably in the Senate, and in the House, and have it become law. We have every intention of holding hearings and, hopefully a markup in July. I believe we will have very broad support from our colleagues for the reasons Senator DEWINE has outlined.

This legislation is focused on children and what we can do to discourage children from becoming addicted to tobacco in this country. I will just take a very few moments to review the highlights.

Just very quickly, every day, 5,000 children try their first cigarette. More than 2,000 become new daily smokers. A third will die prematurely.

If the current trend continues, 6.4 million children, who are under 18 years of age, will die prematurely from smoking related illness. 400,000 people a year die from smoke related illness. We are telling the youth of America their lives are going to be greatly shortened as a result of this kind of addiction.

As I mentioned, 400,000 Americans die each year from smoke-caused disease, and tobacco costs $75 billion in annual health care costs. These are costs that are spent by Medicare, Medicaid, veterans hospitals, and expended privately.

Again, to give the focus of where the advertising is going, this chart shows the number of teens between 12 and 17 who were reached five or more times by tobacco advertising in the year 1999.

A March 2002 study asked teenagers and adults, ''have you seen any advertising for cigarettes or spit tobacco in the last 2 weeks?'' For the teenagers, 64 percent had seen advertising; while for adults, just 27 percent.

What we are maintaining is that the industry is targeting children. These are commercial surveys, and they substantiate our point.

The money that is being expended for these extraordinary advertising budgets is targeted to teenagers, to effectively hook them and addict them.

This chart shows the very substantial increase in promotional expenditures from 1997 to the year 2000. As the chart showed, expenditures totaled $5.660 billion in 1997 and increased to $9.5 billion in the year 2000.

Over the last 5 years, it has virtually doubled. Where is it being targeted? The children. Are the children seeing it? Yes. Are they becoming more addicted? Yes. Is this really a national problem? Yes. Can we do something about it? Yes. Will this legislation do something about it? Yes, because it incorporates many of the recommendations made by former heads of the FDA as well as from the many experts we have heard from at a range of hearings we have held.

The bottom line: If smoking rates do not decline, over 6 million children who are alive today under the age of 18 will suffer premature death.

This is a matter of enormous importance. It is of importance to families, to parents, to children, and to our country. We have targeted, responsible legislation to deal with this issue. We are serious about presenting it to the Senate, which we will do. We are looking for broad support from the American people.

We are grateful for all of the public health agencies that support it: cancer, heart, lung, all of the various health-related agencies that support this legislation. They are going to be strong allies.

Mr. Myers, who is with Tobacco Free Children, has done such an extraordinary job and has made this a high priority. We are serious about it, and we hope to be able to help the families in this country by doing something about children being addicted to cigarettes.

This bill will give the Food and Drug Administration broad authority to regulate tobacco products for the protection of the public health. We cannot in good conscience allow the federal agency most responsible for protecting the public health to remain powerless to deal with the enormous risks of tobacco, the most deadly of all consumer products.

The provisions in this bill closely track those in the bipartisan compromise reached during Senate consideration of comprehensive tobacco control legislation in 1998. Fifty-eight Senators supported it at that time. That legislation was never enacted because of disputes over tobacco taxation and litigation, not over FDA authority.

This FDA provision is a fair and balanced approach to FDA regulation. It creates a new section in FDA jurisdiction for the regulation of tobacco products, with standards that allow for consideration of the unique issues raised by tobacco use. It is sensitive to the concerns of tobacco farmers, small businesses, and nicotine-dependent smokers. But, it clearly gives FDA the authority it needs in order to prevent youth smoking and to reduce addiction to this highly lethal product.

I believe that any attempt to weaken the 1998 language would undermine the FDA's ability to deal effectively with the enormous health risks posed by smoking. This concern is shared by a number of independent public health experts. The bipartisan compromise agreed to in 1998 is still the best opportunity for Senators to come together and grant FDA the regulatory authority it needs to substantially reduce the number of children who start smoking and to help addicted smokers quit. Nothing less will do the job.

The stakes are vast. Five thousand children have their first cigarette every day, and two thousand of them become daily smokers. Nearly a thousand of them will die prematurely from tobacco-induced diseases. Smoking is the number one preventable cause of death in the nation today. Cigarettes kill well over four hundred thousand Americans each year. That is more lives lost than from automobile accidents, alcohol abuse, illegal drugs, AIDS, murder, suicide, and fires combined. Our response to a public health problem of this magnitude must consist of more than half-way measures.

We must deal firmly with tobacco company marketing practices that target children and mislead the public. The Food and Drug Administration needs broad authority to regulate the sale, distribution, and advertising of cigarettes and smokeless tobacco.

The tobacco industry currently spends over nine billion dollars a year to promote its products. Much of that money is spent in ways designed to tempt children to start smoking, before they are mature enough to appreciate the enormity of the health risk. The industry knows that more than 90 percent of smokers begin as children and are addicted by the time they reach adulthood.

Documents obtained from tobacco companies prove, in the companies' own words, the magnitude of the industry's efforts to trap children into dependency on their deadly product. Recent studies by the Institute of Medicine and the Centers for Disease Control show the substantial role of industry advertising in decisions by young people to use tobacco products. If we are serious about reducing youth smoking, FDA must have the power to prevent industry advertising designed to appeal to children wherever it will be seen by children. This legislation will give FDA the ability to stop tobacco advertising which glamorizes smoking from appearing where it will be seen by significant numbers of children.

FDA authority must also extend to the sale of tobacco products. Nearly every state makes it illegal to sell cigarettes to children under 18, but surveys show that those laws are rarely enforced and frequently violated. FDA must have the power to limit the sale of cigarettes to face-to-face transactions in which the age of the purchaser can be verified by identification. This means an end to self-service displays and vending machine sales. There must also be serious enforcement efforts with real penalties for those caught selling tobacco products to children. This is the only way to ensure that children under 18 are not able to buy cigarettes.

The FDA conducted the longest rulemaking proceeding in its history, studying which regulations would most effectively reduce the number of children who smoke. Seven hundred thousand public comments were received in the course of that rulemaking. At the conclusion of its proceeding, the Agency promulgated rules on the manner in which cigarettes are advertised and sold. Due to litigation, most of those regulations were never implemented. If we are serious about curbing youth smoking as much as possible, as soon as possible; it makes no sense to require FDA to reinvent the wheel by conducting a new multi-year rulemaking process on the same issues. This legislation will give the youth access and advertising restrictions already developed by FDA the immediate force of law, as if they had been issued under the new statute.

The legislation also provides for stronger warnings on all cigarette and smokeless tobacco packages, and in all print advertisements. These warnings will be more explicit in their description of the medical problems which can result from tobacco use. The FDA is given the authority to change the text of these warning labels periodically, to keep their impact strong.

Nicotine in cigarettes is highly addictive. Medical experts say that it is as addictive as heroin or cocaine. Yet for decades, tobacco companies have vehemently denied the addictiveness of their products. No one can forget the parade of tobacco executives who testified under oath before Congress as recently as 1994 that smoking cigarettes is not addictive. Overwhelming evidence in industry documents obtained through the discovery process proves that the companies not only knew of this addictiveness for decades, but actually relied on it as the basis for their marketing strategy. As we now know, cigarette manufacturers chemically manipulated the nicotine in their products to make it even more addictive.

The tobacco industry has a long, dishonorable history of providing misleading information about the health consequences of smoking. These companies have repeatedly sought to characterize their products as far less hazardous than they are. They made minor innovations in product design seem far more significant for the health of the user than they actually were. It is essential that FDA have clear and unambiguous authority to prevent such misrepresentations in the future. The largest disinformation campaign in the history of the corporate world must end.

Given the addictiveness of tobacco products, it is essential that the FDA regulate them for the protection of the public health. Over forty million Americans are currently addicted to cigarettes. No responsible public health official believes that cigarettes should be banned. A ban would leave forty million people without a way to satisfy their drug dependency. FDA should be able to take the necessary steps to help addicted smokers overcome their addiction, and to make the product less toxic for smokers who are unable or unwilling to stop. To do so, FDA must have the authority to reduce or remove hazardous ingredients from cigarettes, to the extent that it becomes scientifically feasible. The inherent risk in smoking should not be unnecessarily compounded.

Recent statements by several tobacco companies make clear that they plan to develop what they characterize as ''reduced risk'' cigarettes. This legislation will require manufacturers to submit such ''reduced risk'' products to the FDA for analysis before they can be marketed. No health-related claims will be permitted until they have been verified to the FDA's satisfaction. These safeguards are essential to prevent deceptive industry marketing campaigns, which could lull the public into a false sense of health safety.

Smoking is the number one preventable cause of death in America. Congress must vest FDA not only with the responsibility for regulating tobacco products, but with full authority to do the job effectively.

This legislation will give the FDA the legal authority it needs: To reduce youth smoking by preventing tobacco advertising which targets children; to prevent the sale of tobacco products to minors; to help smokers overcome their addiction; to make tobacco products less toxic for those who continue to use them; and to prevent the tobacco industry from misleading the public about the dangers of smoking.

We cannot allow the tobacco industry to stop us from doing what we know is right for America's children. I intend to do all I can to see that Congress enacts this legislation this year. The public health demands it.

Mrs. FEINSTEIN. Mr. President, I rise today with Senators KENNEDY and DEWINE in support of legislation to empower the Food and Drug Administration, FDA, to regulate tobacco products.

During my time in the Senate, I have become very involved with cancer. I am the Co-Chair of the Senate Cancer Caucus and the Vice-Chair of the National Dialogue on Cancer, which is Chaired by former President and Barbara Bush.

The cancer community is united in the belief that the single most important preventive measure is to place tobacco products under the regulatory control of the FDA. I stand behind the cancer community and express the same belief.

Smoking causes one-third of all cancers, and is the cause of approximately 165,000 deaths annually.

I firmly believe that cancer cannot be conquered without addressing smoking and the use of tobacco products.

Smoking results in death or disability for over half of tobacco users, according to the Centers for Disease Control, CDC. Smoking costs the health care system over $70 billion annually.

Over the past two decades, we have learned that tobacco companies have manipulated the level of nicotine in cigarettes to increase the number of people addicted to their product.

There are more than 40 chemicals in tobacco smoke that cause cancer in humans and animals, according to the CDC. Tobacco smoke has toxic components, as well as tar, carbon monoxide and other dangerous additives.

It is long past time to reduce the addictive nature of cigarettes and curtail the marketing of these products to young people. I believe that empowering the FDA to regulate tobacco will help do that.

The U.S. Surgeon General and the Centers for Disease Control and Prevention have unequivocally demonstrated that, for example, anti-smoking campaigns can reduce smoking, a major cause of cancer.

California is a good example: My state started an aggressive tobacco control program in 1989 and throughout the 1990s, tobacco use dropped at two to three times faster than the rest of the country.

Ninety percent of adult smokers begin before age 18 and every day, 3,000 young people become smokers.

This bill will provide meaningful regulation by the Food and Drug Administration of the content and marketing of tobacco products, especially the addicting and carcinogenic components.

Dr. C. Everett Koop, former US Surgeon General, and Dr. David Kessler, former Commissioner of the Food and Drug Administration, in 1997 report, cited FDA and other studies and said:

> Nicotine in cigarettes and smokeless tobacco has the same pharmacological effects as other drugs that FDA has traditionally regulated . . . nicotine is extremely addictive . . . and the vast majority of people who use nicotine-containing cigarettes and smokeless tobacco do so to satisfy their craving for the pharmacological effects of nicotine; that is, to satisfy their drug-dependence or addiction.

They go to recommend that the ''FDA should continue to have authority to regulate all areas of nicotine, as well as other constituents and ingredients, and that authority should be made completely explicit.''

I am pleased that to note that even the Philip Morris Companies has acknowledged the need for FDA to regulate tobacco. On their website, they say:

> We believe federal legislation that includes granting FDA authority to regulate tobacco products could effectively address many of the complex tobacco issues that concern the public, the public health community and us.

It is long past time to reduce the addictive nature of cigarettes and curtail the marketing of these products to young people. This bill gives FDA the power to regulate tobacco products' content, design, sale, and marketing.

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. 2626

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 ''Youth Smoking Prevention and Public Health Protection Act''.

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

SEC. 2. FINDINGS.

The Congress finds the following:

(1) The use of tobacco products by the Nation's children is a pediatric disease of epic and worsening proportions that results in new generations of tobacco-dependent children and adults.

(2) A consensus exists within the scientific and medical communities that tobacco products are inherently dangerous and cause cancer, heart disease, and other serious adverse health effects.

(3) Nicotine is an addictive drug.

(4) Virtually all new users of tobacco products are under the minimum legal age to purchase such products.

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

(6) Because past efforts to restrict advertising and marketing of tobacco products have failed adequately to curb tobacco use

by adolescents, comprehensive restrictions on the sale, promotion, and distribution of such products are needed.

(7) Federal and State governments have lacked the legal and regulatory authority and resources they need to address comprehensively the public health and societal problems caused by the use of tobacco products.

(8) Federal and State public health officials, the public health community, and the public at large recognize that the tobacco industry should be subject to ongoing oversight.

(9) Under Article I, Section 8 of the Constitution, the Congress is vested with the responsibility for regulating interstate commerce and commerce with Indian tribes.

(10) The sale, distribution, marketing, advertising, and use of tobacco products are activities in and substantially affecting interstate commerce because they are sold, marketed, advertised, and distributed in interstate commerce on a nationwide basis, and have a substantial effect on the Nation's economy.

(11) The sale, distribution, marketing, advertising, and use of such products substantially affect interstate commerce through the health care and other costs attributable to the use of tobacco products.

(12) It is in the public interest for Congress to enact legislation that provides the Food and Drug Administration with the authority to regulate tobacco products. The benefits to the American people from enacting such legislation would be significant in human and economic terms.

(13) Tobacco use is the foremost preventable cause of premature death in America. It causes over 400,000 deaths in the United States each year.

(14) Reducing the use of tobacco by minors by 50 percent would prevent well over 10,000,000 of today's children from becoming regular, daily smokers, saving over 3,000,000 of them from premature death due to tobacco induced disease. Such a reduction in youth smoking would also result in approximately $110,000,000,000 in savings attributable to reduced health care costs.

(15) Advertising, marketing, and promotion of tobacco products have been especially directed to attract young persons to use tobacco products and these efforts have resulted in increased use of such products by youth. Past efforts to oversee these activities have not been successful in adequately preventing such increased use.

(16) In 1999, the tobacco industry spent close to $8,240,000,000 to attract new users, retain current users, increase current consumption, and generate favorable long-term attitudes toward smoking and tobacco use.

(17) Tobacco product advertising often misleadingly portrays the use of tobacco as socially acceptable and healthful to minors.

(18) Tobacco product advertising is regularly seen by persons under the age of 18, and persons under the age of 18 are regularly exposed to tobacco product promotional efforts.

(19) Through advertisements during and sponsorship of sporting events, tobacco has become strongly associated with sports and has become portrayed as an integral part of sports and the healthy lifestyle associated with rigorous sporting activity.

(20) Children are exposed to substantial and unavoidable tobacco advertising that leads to favorable beliefs about tobacco use, plays a role in leading young people to overestimate the prevalence of tobacco use, and increases the number of young people who begin to use tobacco.

(21) The use of tobacco products in motion pictures and other mass media glamorizes its use for young people and encourages them to use tobacco products.

(22) Tobacco advertising expands the size of the tobacco market by increasing consumption of tobacco products including tobacco use by young people.

(23) Children are more influenced by tobacco advertising than adults, they smoke the most advertised brands, and children as young as 3 to 6 years old can recognize a character associated with smoking at the same rate as they recognize cartoons and fast food characters.

(24) Tobacco company documents indicate that young people are an important and often crucial segment of the tobacco market.

(25) Comprehensive advertising restrictions will have a positive effect on the smoking rates of young people.

(26) Restrictions on advertising are necessary to prevent unrestricted tobacco advertising from undermining legislation prohibiting access to young people and providing for education about tobacco use.

(27) International experience shows that advertising regulations that are stringent and comprehensive have a greater impact on overall tobacco use and young people's use than weaker or less comprehensive ones.

(28) Text-only requirements, while not as stringent as a ban, will help reduce underage use of tobacco products while preserving the informational function of advertising.

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

(30) The final regulations promulgated by the Secretary of Health and Human Services in the August 28, 1996, issue of the Federal Register (62 Fed. Reg. 44615-44618) for inclusion as part 897 of title 21, Code of Federal Regulations, are consistent with the standards set forth in the amendments made by this Act for the regulation of tobacco products by the Food and Drug Administration and the restriction on the sale and distribution, including access to and the advertising and promotion of, tobacco products contained in such regulations are substantially related to accomplishing the public health goals of this Act.

(31) The regulations described in paragraph (30) will directly and materially advance the Federal Government's substantial interest in reducing the number of children and adolescents who use cigarettes and smokeless tobacco and in preventing the life-threatening health consequences associated with tobacco use. An overwhelming majority of Americans who use tobacco products begin using such products while they are minors and become addicted to the nicotine in those product before reaching the age of 18. Tobacco advertising and promotion plays a crucial role in the decision of these minors to begin using tobacco products. Less restrictive and less comprehensive approaches have not and will not be effective in reducing the problems addressed by such regulations. The reasonable restrictions on the advertising and promotion of tobacco products contained in such regulations will lead to a significant decrease in the number of minors using and becoming addicted to those products.

(32) The regulations described in paragraph (30) impose no more extensive restrictions on communication by tobacco manufacturers and sellers than are necessary to reduce the number of children and adolescents who use cigarettes and smokeless tobacco and to prevent the life-threatening health consequences associated with tobacco use. Such regulations are narrowly tailored to restrict those advertising and promotional practices which are most likely to be seen or heard by youth and most likely to entice them into tobacco use, while affording tobacco manufacturers and sellers ample opportunity to convey information about their products to adult consumers.

SEC. 3. PURPOSE.

The purposes of this Act are—

(1) to provide authority to the Food and Drug Administration to regulate tobacco products under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), by recognizing it as the primary Federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products;

(2) to ensure that the Food and Drug Administration has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco;

(3) to authorize the Food and Drug Administration to set national standards controlling the manufacture of tobacco products and the identity, public disclosure, and amount of ingredients used in such products;

(4) to provide new and flexible enforcement authority to ensure that there is effective oversight of the tobacco industry's efforts to develop and introduce less harmful tobacco products;

(5) to vest the Food and Drug Administration with the authority to regulate the levels of tar, nicotine, and other harmful components of tobacco products;

(6) in order to ensure that adults are better informed, to require tobacco product manufacturers to disclose research which has not previously been made available, as well as research generated in the future, relating to the health and dependency effects or safety of tobacco products;

(7) to continue to permit the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage purchasers; and

(8) to impose appropriate regulatory controls on the tobacco industry

SEC. 4. SCOPE AND EFFECT.

(a) INTENDED EFFECT.—Nothing in this Act (or an amendment made by this Act) shall be construed to—

(1) establish a precedent with regard to any other industry, situation, circumstance, or legal action; or

(2) affect any action pending in State, Tribal, or Federal court, or any agreement, consent decree, or contract of any kind.

(b) AGRICULTURAL ACTIVITIES.—The provisions of this Act (or an amendment made by this Act) which authorize the Secretary to take certain actions with regard to tobacco and tobacco products shall not be construed to affect any authority of the Secretary of Agriculture under existing law regarding the growing, cultivation, or curing of raw tobacco.

TITLE I—AUTHORITY OF THE FOOD AND DRUG ADMINISTRATION

SEC. 101. AMENDMENT OF FEDERAL FOOD, DRUG, AND COSMETIC ACT.

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

''(kk) The term 'tobacco product' means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).''.

(b) FDA AUTHORITY OVER TOBACCO PRODUCTS.—The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is amended—

(1) by redesignating chapter IX as chapter X;

(2) by redesignating sections 901 through 907 as sections 1001 through 1007; and

(3) by inserting after section 803 the following:

"CHAPTER IX—TOBACCO PRODUCTS

"SEC. 900. DEFINITIONS.

''In this chapter:

''(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 such attributes.

''(2) CIGARETTE.—The term 'cigarette' has the meaning given that term by section 3(1) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1332(1)), but also includes tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco.

''(3) CIGARETTE TOBACCO.—The term 'cigarette tobacco' means any product that consists of loose tobacco that is intended for use by consumers in a cigarette. Unless otherwise stated, the requirements for cigarettes shall also apply to cigarette tobacco.

''(4) COMMERCE.—The term 'commerce' has the meaning given that term by section 3(2) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1332(2)).

''(5) DISTRIBUTOR.—The term 'distributor' as regards a tobacco product means any person who furthers the distribution of cigarette or smokeless tobacco, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Common carriers are not considered distributors for purposes of this chapter.

''(6) INDIAN TRIBE.—The term 'Indian tribe' has the meaning given such term in section 4(e) of the Indian Self Determination and Education Assistance Act (25 U.S.C. 450b(e)).

''(7) LITTLE CIGAR.—The term 'little cigar' has the meaning given that term by section 3(7) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1332(7)).

''(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 pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which cigarettes or smokeless tobacco are offered for sale, sold, or otherwise distributed to consumers.

''(10) RETAILER.—The term 'retailer' means any person who sells cigarettes or smokeless tobacco to individuals for personal consumption, or who operates a facility where self-service displays of tobacco products are permitted.

''(11) ROLL-YOUR-OWN TOBACCO.—The term 'roll-your-own tobacco' means any tobacco which, because of its appearance, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco for making cigarettes.

''(12) SMOKELESS TOBACCO.—The term 'smokeless tobacco' means any product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity.

''(13) STATE.—The term 'State' means any State of the United States and, for purposes of this chapter, includes the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, Johnston Atoll, the Northern Mariana Islands, and any other trust territory or possession of the United States.

''(14) TOBACCO PRODUCT MANUFACTURER.—Term 'tobacco product manufacturer' means any person, including any repacker or relabeler, who—

''(A) manufactures, fabricates, assembles, processes, or labels a finished cigarette or smokeless tobacco product; or

''(B) imports a finished cigarette or smokeless tobacco product for sale or distribution in the United States.

''(15) UNITED STATES.—The term 'United States' means the 50 States of the United States of America and the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, Johnston Atoll, the Northern Mariana Islands, and any other trust territory or possession of the United States.

"SEC. 901. FDA AUTHORITY OVER TOBACCO PRODUCTS.

''(a) IN GENERAL.—Tobacco products shall be regulated by the Secretary under this chapter and shall not be subject to the provisions of chapter V, unless—

''(1) such products are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease (within the meaning of section 201(g)(1)(B) or section 201(h)(2)); or

''(2) a health claim is made for such products under section 201(g)(1)(C) or 201(h)(3).

''(b) APPLICABILITY.—This chapter shall apply to all tobacco products subject to the regulations referred to in section 102 of the Youth Smoking Prevention and Public Health Protection Act, and to any other tobacco products that the Secretary by regulation deems to be subject to this chapter.

''(c) SCOPE.—

''(1) IN GENERAL.—Nothing in this chapter, or any policy issued or regulation promulgated thereunder, or the Youth Smoking Prevention and Public Health Protection Act, shall be construed to affect the Secretary's authority over, or the regulation of, products under this Act that are not tobacco products under chapter V or any other chapter.

''(2) TOBACCO LEAF.—

''(A) IN GENERAL.—The provisions of this chapter shall not apply to tobacco leaf that is not in the possession of the manufacturer, or to the producers of tobacco leaf, including tobacco growers, tobacco warehouses, and tobacco grower cooperatives, nor shall any employee of the Food and Drug Administration have any authority to enter onto a farm owned by a producer of tobacco leaf without the written consent of such producer.

''(B) EXCEPTION.—Notwithstanding any other provision of this subparagraph, if a producer of tobacco leaf is also a tobacco product manufacturer or controlled by a tobacco product manufacturer, the producer shall be subject to this chapter in the producer's capacity as a manufacturer.

''(C) RULE OF CONSTRUCTION.—Nothing in this chapter shall be construed to grant the Secretary authority to promulgate regulations on any matter that involves the production of tobacco leaf or a producer thereof, other than activities by a manufacturer affecting production. For purposes of the preceding sentence, the term 'controlled by' means 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 under common control within the meaning of the regulations promulgated under section 52(b) of such Code.

"SEC. 902. ADULTERATED TOBACCO PRODUCTS.

''A tobacco product shall be deemed to be adulterated if—

''(1) it consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise contaminated by any poisonous or deleterious substance that may render the product injurious to health;

''(2) it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health;

''(3) its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

''(4) it is, or purports to be or is represented as, a tobacco product which is subject to a performance standard established under section 907 unless such tobacco product is in all respects in conformity with such standard;

''(5) it is required by section 910(a) to have premarket approval, is not exempt under section 906(f), and does not have an approved application in effect;

''(6) the methods used in, or the facilities or controls used for, its manufacture, packing or storage are not in conformity with applicable requirements under section 906(e)(1) or an applicable condition prescribed by an order under section 906(e)(2); or

''(7) it is a tobacco product for which an exemption has been granted under section 906(f) for investigational use and the person who was granted such exemption or any investigator who uses such tobacco product under such exemption fails to comply with a requirement prescribed by or under such section.

"SEC. 903. MISBRANDED TOBACCO PRODUCTS.

''(a) IN GENERAL.—A tobacco product shall be deemed to be misbranded—

''(1) if its labeling is false or misleading in any particular;

''(2) if in package form unless it bears a label containing—

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

''(B) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; and

''(C) an accurate statement of the percentage of the tobacco used in the product that is domestically grown tobacco and the percentage that is foreign grown tobacco,

except that under subparagraph (B) reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary;

''(3) if any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements or designs in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

''(4) if it has an established name, unless its label bears, to the exclusion of any other nonproprietary name, its established name prominently printed in type as required by the Secretary by regulation;

''(5) if the Secretary has issued regulations requiring that its labeling bear adequate directions for use, or adequate warnings against use by children, that are necessary for the protection of users unless its labeling conforms in all respects to such regulations;

''(6) if it was manufactured, prepared, propagated, compounded, or processed in any State in an establishment not duly registered under section 905(b), if it was not included in a list required by section 905(i), if a notice or other information respecting it was not provided as required by such section or section 905(j), or if it does not bear such symbols from the uniform system for identification of tobacco products prescribed under section 905(e) as the Secretary by regulation requires;

''(7) if, in the case of any tobacco product distributed or offered for sale in any State—

''(A) its advertising is false or misleading in any particular; or

''(B) it is sold or distributed in violation of regulations prescribed under section 906(d);

''(8) unless, in the case of any tobacco product distributed or offered for sale in any State, the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that tobacco product—

''(A) a true statement of the tobacco product's established name as defined in paragraph (4), printed prominently; and

''(B) a brief statement of—

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

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

''(9) if it is a tobacco product subject to a performance standard established under section 907, unless it bears such labeling as may be prescribed in such performance standard; or

''(10) if there was a failure or refusal—

''(A) to comply with any requirement prescribed under section 904 or 908;

''(B) to furnish any material or information required by or under section 909; or

''(C) to comply with a requirement under section 912.

''(b) PRIOR APPROVAL OF LABEL STATEMENTS.—The Secretary may, by regulation, require prior approval of statements made on the label of a tobacco product. No regulation issued under this subsection may require prior approval by the Secretary of the content of any advertisement. No advertisement of a tobacco product, published after the date of enactment of the Youth Smoking Prevention and Public Health Protection Act shall, with respect to the language of label statements as prescribed under section 4 of the Cigarette Labeling and Advertising Act and section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 or the regulations issued under such sections, be subject to the provisions of sections 12 through 15 of the Federal Trade Commission Act (15 U.S.C. 52 through 55).

''SEC. 904. SUBMISSION OF HEALTH INFORMATION TO THE SECRETARY.

''(a) REQUIREMENT.—Not later than 6 months after the date of enactment of the Youth Smoking Prevention and Public Health Protection Act, each tobacco product manufacturer or importer of tobacco products, or agents thereof, shall submit to the Secretary the following information:

''(1) A listing of all tobacco ingredients, substances and compounds that are, on such 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 thereof) on the health, behavioral, or physiologic 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 thereof) that relate to the issue of whether a reduction in risk to health from tobacco products can occur upon the employment of technology available or known to the manufacturer.

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

An importer of a tobacco product not manufactured in the United States shall supply the information required of a tobacco product manufacturer under this subsection.

''(b) ANNUAL SUBMISSION.—A tobacco product manufacturer or importer that is required to submit information under subsection (a) shall update such information on an annual basis under 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 Youth Smoking Prevention and Public Health Protection Act, the manufacturer of such product shall provide the information required under subsection (a) and such product shall be subject to the annual submission under subsection (b).

''(2) MODIFICATION OF EXISTING PRODUCTS.—If at any time a tobacco product manufacturer adds to its tobacco products a new tobacco additive, increases or decreases the quantity of an existing tobacco additive or the nicotine content, delivery, or form, or eliminates a tobacco additive from any tobacco product, the manufacturer shall within 60 days of such action so advise the Secretary in writing and reference such modification in submissions made under subsection (b).

''SEC. 905. ANNUAL REGISTRATION.

''(a) DEFINITIONS.—In this section:

''(1) MANUFACTURE, PREPARATION, COMPOUNDING, OR PROCESSING.—The term 'manufacture, preparation, compounding, or processing' shall include repackaging or otherwise changing the container, wrapper, or labeling of any tobacco product package in furtherance of the distribution of the tobacco product from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user.

''(2) NAME.—The term 'name' shall include in the case of a partnership the name of each partner and, in the case of a corporation, the name of each corporate officer and director, and the State of incorporation.

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

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

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

''(e) UNIFORM PRODUCT IDENTIFICATION SYSTEM.—The Secretary may by regulation prescribe a uniform system for the identification of tobacco products and may require that persons who are required to list such tobacco products under subsection (i) shall list such tobacco products in accordance with such system.

''(f) PUBLIC ACCESS TO REGISTRATION INFORMATION.—The Secretary shall make available for inspection, to any person so requesting, any registration filed under this section.

''(g) BIENNIAL INSPECTION OF REGISTERED ESTABLISHMENTS.—Every establishment in any State registered with the Secretary under this section shall be subject to inspection under section 704, and every such establishment engaged in the manufacture, compounding, or processing of a tobacco product or tobacco products shall be so inspected by one or more officers or employees duly designated by the Secretary at least once in the 2-year period beginning with the date of registration of such establishment under this section and at least once in every successive 2-year period thereafter.

''(h) FOREIGN ESTABLISHMENTS MAY REGISTER.—Any establishment within any foreign country engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products, may register under this section under regulations promulgated by the Secretary. Such regulations shall require such establishment to provide the information required by subsection (i) of this section and shall include provisions for registration of any such establishment upon condition that adequate and effective means are available, by arrangement with the government of such foreign country or otherwise, to enable the Secretary to determine from time to time whether tobacco products manufactured, prepared, compounded, or processed in such establishment, if imported or offered for import into the United States, shall be refused admission on any of the grounds set forth in section 801(a).

''(i) REGISTRATION INFORMATION.—

''(1) PRODUCT LIST.—Every person who registers with the Secretary under subsection (b), (c), or (d) shall, at the time of registration under any such subsection, file with the Secretary a list of all tobacco products which are being manufactured, prepared, compounded, or processed by that person for commercial distribution and which has not been included in any list of tobacco products filed by that person with the Secretary under this paragraph or paragraph (2) before such time of registration. Such list shall be prepared in such form and manner as the Secretary may prescribe and shall be accompanied by—

''(A) in the case of a tobacco product contained in the applicable list with respect to which a performance standard has been established under section 907 or which is subject to section 910, a reference to the authority for the marketing of such tobacco product and a copy of all labeling for such tobacco product;

''(B) in the case of any other tobacco product contained in an applicable list, a copy of all consumer information and other labeling for such tobacco product, a representative sampling of advertisements for such tobacco product, and, upon request made by the Secretary for good cause, a copy of all advertisements for a particular tobacco product; and

''(C) if the registrant filing a list has determined that a tobacco product contained in

such list is not subject to a performance standard established under section 907, a brief statement of the basis upon which the registrant made such determination if the Secretary requests such a statement with respect to that particular tobacco product.

''(2) BIANNUAL REPORT OF ANY CHANGE IN PRODUCT LIST.—Each person who registers with the Secretary under this section shall report to the Secretary once during the month of June of each year and once during the month of December of each year the following:

''(A) A list of each tobacco product introduced by the registrant for commercial distribution which has not been included in any list previously filed by that person with the Secretary under this subparagraph or paragraph (1). A list under this subparagraph shall list a tobacco product by its established name and shall be accompanied by the other information required by paragraph (1).

''(B) If since the date the registrant last made a report under this paragraph that person has discontinued the manufacture, preparation, compounding, or processing for commercial distribution of a tobacco product included in a list filed under subparagraph (A) or paragraph (1), notice of such discontinuance, the date of such discontinuance, and the identity of its established name.

''(C) If since the date the registrant reported under subparagraph (B) a notice of discontinuance that person has resumed the manufacture, preparation, compounding, or processing for commercial distribution of the tobacco product with respect to which such notice of discontinuance was reported, notice of such resumption, the date of such resumption, the identity of such tobacco product by established name, and other information required by paragraph (1), unless the registrant has previously reported such resumption to the Secretary under this subparagraph.

''(D) Any material change in any information previously submitted under this paragraph or paragraph (1).

''(j) REPORT PRECEDING INTRODUCTION OF CERTAIN SUBSTANTIALLY-EQUIVALENT PRODUCTS INTO INTERSTATE COMMERCE.—

''(1) IN GENERAL.—Each person who is required to register under this section and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a tobacco product intended for human use that was not commercially marketed (other than for test marketing) in the United States as of June 1, 2002, as defined by the Secretary by regulation shall, at least 90 days before making such introduction or delivery, report to the Secretary (in such form and manner as the Secretary shall by regulation prescribe)—

''(A) the basis for such person's determination that the tobacco product is substantially equivalent, within the meaning of section 910, to a tobacco product commercially marketed (other than for test marketing) in the United States as of June 1, 2002, that is in compliance with the requirements of this Act; and

''(B) action taken by such person to comply with the requirements under section 907 that are applicable to the tobacco product.

''(2) APPLICATION TO CERTAIN POST-JUNE 1, 2002 PRODUCTS.—A report under this subsection for a tobacco product that was first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after June 1, 2002, and before the date of enactment of the Youth Smoking Prevention and Public Health Protection Act shall be submitted to the Secretary within 6 months after the date of enactment of that Act.

''SEC. 906. GENERAL PROVISIONS RESPECTING CONTROL OF TOBACCO PRODUCTS.

''(a) IN GENERAL.—Any requirement established by or under section 902, 903, 905, or 909 applicable to a tobacco product shall apply to such tobacco product until the applicability of the requirement to the tobacco product has been changed by action taken under section 907, section 910, or subsection (d) of this section, and any requirement established by or under section 902, 903, 905, or 909 which is inconsistent with a requirement imposed on such tobacco product under section 907, section 910, or subsection (d) of this section shall not apply to such tobacco product.

''(b) INFORMATION ON PUBLIC ACCESS AND COMMENT.—Each notice of proposed rulemaking under section 907, 908, 909, or 910, or under this section, any other notice which is published in the Federal Register with respect to any other action taken under any such section and which states the reasons for such action, and each publication of findings required to be made in connection with rulemaking under any such section shall set forth—

''(1) the manner in which interested persons may examine data and other information on which the notice or findings is based; and

''(2) the period within which interested persons may present their comments on the notice or findings (including the need therefore) orally or in writing, which period shall be at least 60 days but may not exceed 90 days unless the time is extended by the Secretary by a notice published in the Federal Register stating good cause therefore.

''(c) LIMITED CONFIDENTIALITY OF INFORMATION.—Any information reported to or otherwise obtained by the Secretary or the Secretary's representative under section 904, 907, 908, 909, or 910 or 704, or under subsection (e) or (f) of this section, which is exempt from disclosure under subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of that section shall be considered confidential and shall not be disclosed, except that the information may be disclosed to other officers or employees concerned with carrying out this chapter, or when relevant in any proceeding under this chapter.

''(d) RESTRICTIONS.—

''(1) IN GENERAL.—The Secretary may by regulation require restrictions on the sale and distribution of a tobacco product, including restrictions on the access to, and the advertising and promotion of, the tobacco product, if the Secretary determines that such regulation would be appropriate for the protection of the public health. The Secretary may by regulation impose restrictions on the advertising and promotion of tobacco products consistent with and to full extent permitted by the first amendment to the Constitution. The finding as to whether such regulation would be appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and non-users of the tobacco product, and taking into account—

''(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

''(B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

No such regulation may require that the sale or distribution of a tobacco product be limited to the written or oral authorization of a practitioner licensed by law to prescribe medical products.

''(2) LABEL STATEMENTS.—The label of a tobacco product shall bear such appropriate statements of the restrictions required by a regulation under subsection (a) as the Secretary may in such regulation prescribe.

''(3) LIMITATION.—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 PRACTICE REQUIREMENTS.—

''(1) METHODS, FACILITIES, AND CONTROLS TO CONFORM.—

''(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), packing and storage of a tobacco product, conform to current good manufacturing practice, as prescribed in such regulations, to assure that the public health is protected and that the tobacco product is in compliance with this chapter.

''(B) REQUIREMENTS.—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 its recommendation with respect to proposed regulations under subparagraph (A); and

''(iv) in establishing the effective date of a regulation promulgated under this subsection, take into account the differences in the manner in which the different types of tobacco products have historically been produced, the financial resources of the different tobacco product manufacturers, and the state of their existing manufacturing facilities, and shall provide for a reasonable period of time for such manufacturers to conform to good manufacturing practices.

''(2) EXEMPTIONS; VARIANCES.—

''(A) PETITION.—Any person subject to any requirement prescribed under paragraph (1) may petition the Secretary for a permanent or temporary exemption or variance from such requirement. Such a petition shall be submitted to the Secretary in such form and manner as the Secretary shall prescribe and shall—

''(i) in the case of a petition for an exemption from a requirement, set forth the basis for the petitioner's determination that compliance with the requirement is not required to assure that the tobacco product will be in compliance with this chapter;

''(ii) in the case of a petition for a variance from a requirement, set forth the methods proposed to be used in, and the facilities and controls proposed to be used for, the manufacture, packing, and storage of the tobacco product in lieu of the methods, facilities, and controls prescribed by the requirement; and

''(iii) contain such other information as the Secretary shall prescribe.

''(B) REFERRAL TO ADVISORY COMMITTEE.—The Secretary may refer to an advisory committee any petition submitted under subparagraph (A). The advisory committee shall report its recommendations to the Secretary with respect to a petition referred to it within 60 days after the date of the petition's referral. Within 60 days after—

''(i) the date the petition was submitted to the Secretary under subparagraph (A); or

''(ii) the day after the petition was referred to an advisory committee,

whichever occurs later, the Secretary shall by order either deny the petition or approve it.

''(C) APPROVAL.—The Secretary may approve—

''(i) a petition for an exemption for a tobacco product from a requirement if the Secretary determines that compliance with such requirement is not required to assure that the tobacco product will be in compliance with this chapter; and

''(ii) a petition for a variance for a tobacco product from a requirement if the Secretary determines that the methods to be used in, and the facilities and controls to be used for, the manufacture, packing, and storage of the tobacco product in lieu of the methods, controls, and facilities prescribed by the requirement are sufficient to assure that the tobacco product will be in compliance with this chapter.

''(D) CONDITIONS.—An order of the Secretary approving a petition for a variance shall prescribe such conditions respecting the methods used in, and the facilities and controls used for, the manufacture, packing, and storage of the tobacco product to be granted the variance under the petition as may be necessary to assure that the tobacco product will be in compliance with this chapter.

''(E) HEARING.—After the issuance of an order under subparagraph (B) respecting a petition, the petitioner shall have an opportunity for an informal hearing on such order.

''(3) COMPLIANCE.—Compliance with requirements under this subsection shall not be required before the period ending 3 years after the date of enactment of the Youth Smoking Prevention and Public Health Protection Act.

''(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 respecting 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. 907. PERFORMANCE STANDARDS.

''(a) IN GENERAL.—

''(1) FINDING REQUIRED.—The Secretary may adopt performance standards for a tobacco product if the Secretary finds that a performance standard is appropriate for the protection of the public health. This 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—

''(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

''(B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

''(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 or elimination of nicotine yields of the product;

''(ii) for the reduction or elimination of other constituents or harmful components of the product; or

''(iii) relating to any other requirement under (B);

''(B) shall, where necessary to be appropriate for the protection of the 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;

''(iv) provisions requiring that the results of each or of certain of the tests of the tobacco product required to be made under clause (ii) show that the tobacco product is in conformity with the portions of the standard for which the test or tests were required; and

''(v) a provision requiring that the sale and distribution of the tobacco product be restricted but only to the extent that the sale and distribution of a tobacco product may be restricted under a regulation under section 906(d); and

''(C) shall, where appropriate, require the use and prescribe the form and content of labeling for the proper use of the tobacco product.

''(3) PERIODIC RE-EVALUATION OF PERFORMANCE STANDARDS.—The Secretary shall provide for periodic evaluation of performance standards established under this section to determine whether such standards should be changed to reflect new medical, scientific, or other technological data. The Secretary may provide for testing under paragraph (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 personnel, facilities, and other technical support available in other Federal agencies;

''(B) consult with other Federal agencies concerned with standard-setting and other nationally or internationally recognized standard-setting entities; and

''(C) invite appropriate participation, through joint or other conferences, workshops, or other means, by informed persons representative of scientific, professional, industry, or consumer organizations who in the Secretary's judgment can make a significant contribution.

''(b) ESTABLISHMENT 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) REQUIREMENTS OF NOTICE.—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) FINDING.—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 to be appropriate for the protection of the public health.

''(D) CONSIDERATION BY SECRETARY.—The Secretary shall 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 such demand, and shall issue the standard if the Secretary determines that the standard would be appropriate for the protection of the public health.

''(E) COMMENT.—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) respecting a performance standard and after consideration of such 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 such termination.

''(B) EFFECTIVE DATE.—A regulation establishing a performance standard shall set forth the date or dates upon which the standard shall take effect, but no such regulation may take effect before one year after the date of its publication unless the Secretary determines that an earlier effective date is necessary for the protection of the public health. Such date or dates shall be established so as to minimize, consistent with the public health, economic loss to, and disruption or dislocation of, domestic and international trade.

''(3) SPECIAL RULE FOR STANDARD BANNING CLASS OF PRODUCT OR ELIMINATING NICOTINE CONTENT.—Because of the importance of a decision of the Secretary to issue a regulation 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,

it is appropriate for the Congress to have the opportunity to review such a decision. Therefore, any such standard may not take effect before a date that is 2 years after the President notifies the Congress that a final regulation imposing the restriction has been issued.

''(4) AMENDMENT; REVOCATION.—

''(A) AUTHORITY.—The Secretary, upon the Secretary's own initiative or upon petition of an interested person may by a regulation, promulgated in accordance with the requirements of paragraphs (1) and (2)(B), amend or revoke a performance standard.

''(B) EFFECTIVE DATE.—The Secretary may declare a proposed amendment of a performance standard to be effective on and after its publication in the Federal Register and until the effective date of any final action taken on such amendment if the Secretary determines that making it so effective is in the public interest.

''(5) REFERENCE TO ADVISORY COMMITTEE.—The Secretary—

''(A) may, on the Secretary's own initiative, refer a proposed regulation for the establishment, amendment, or revocation of a performance standard; or

''(B) shall, upon the request of an interested person which demonstrates good cause for referral and which is made before the expiration of the period for submission of comments on such proposed regulation,

refer such proposed regulation to an advisory committee, for a report and recommendation

with respect to any matter involved in the proposed regulation which requires the exercise of scientific judgment. If a proposed regulation is referred under this paragraph to the advisory committee, the Secretary shall provide the advisory committee with the data and information on which such proposed regulation is based. The advisory committee shall, within 60 days after the referral of a proposed regulation and after independent study of the data and information furnished to it by the Secretary and other data and information before it, submit to the Secretary a report and recommendation respecting such regulation, together with all underlying data and information and a statement of the reason or basis for the recommendation. A copy of such report and recommendation shall be made public by the Secretary.

"SEC. 908. NOTIFICATION AND OTHER REMEDIES.

''(a) NOTIFICATION.—If the Secretary determines that—

''(1) a tobacco product which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm to the public health; and

''(2) notification under this subsection is necessary to eliminate the unreasonable risk of such harm and no more practicable means is available under the provisions of this chapter (other than this section) to eliminate such risk,

the Secretary may issue such order as may be necessary to assure that adequate notification is provided in an appropriate form, by the persons and means best suited under the circumstances involved, to all persons who should properly receive such notification in order to eliminate such risk. The Secretary may order notification by any appropriate means, including public service announcements. Before issuing an order under this subsection, the Secretary shall consult with the persons who are to give notice under the order.

''(b) NO EXEMPTION FROM OTHER LIABILITY.—Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided under such order shall be taken into account.

''(c) RECALL AUTHORITY.—

''(1) IN GENERAL.—If the Secretary finds that there is a reasonable probability that a tobacco product contains a manufacturing or other defect not ordinarily contained in tobacco products on the market that would cause serious, adverse health consequences or death, the Secretary shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the tobacco product) to immediately cease distribution of such tobacco product. The order shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order and on whether the order should be amended to require a recall of such tobacco product. If, after providing an opportunity for such a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

''(2) AMENDMENT OF ORDER TO REQUIRE RECALL.—

''(A) IN GENERAL.—If, after providing an opportunity for an informal hearing under paragraph (1), the Secretary determines that the order should be amended to include a recall of the tobacco product with respect to which the order was issued, the Secretary shall, except as provided in subparagraph (B), amend the order to require a recall. The Secretary shall specify a timetable in which the tobacco product recall will occur and shall require periodic reports to the Secretary describing the progress of the recall.

''(B) NOTICE.—An amended order under subparagraph (A)—

''(i) shall not include recall of a tobacco product from individuals; and

''(ii) shall provide for notice to persons subject to the risks associated with the use of such tobacco product.

In providing the notice required by clause (ii), the Secretary may use the assistance of retailers and other persons who distributed such tobacco product. If a significant number of such persons cannot be identified, the Secretary shall notify such persons under section 705(b).

''(3) REMEDY NOT EXCLUSIVE.—The remedy provided by this subsection shall be in addition to remedies provided by subsection (a) of this section.

"SEC. 909. RECORDS AND REPORTS ON TOBACCO PRODUCTS.

''(a) IN GENERAL.—Every person who is a tobacco product manufacturer or importer of a tobacco product shall establish and maintain such records, make such reports, and provide such information, as the Secretary may by regulation reasonably require to assure that such tobacco product is not adulterated or misbranded and to otherwise protect public health. Regulations prescribed under the preceding sentence—

''(1) may require a tobacco product manufacturer or importer to report to the Secretary whenever the manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed tobacco products may have caused or contributed to a serious unexpected adverse experience associated with the use of the product or any significant increase in the frequency of a serious, expected adverse product experience;

''(2) shall require reporting of other significant adverse tobacco product experiences as determined by the Secretary to be necessary to be reported;

''(3) shall not impose requirements unduly burdensome to a tobacco product manufacturer or importer, taking into account the cost of complying with such requirements and the need for the protection of the public health and the implementation of this chapter;

''(4) when prescribing the procedure for making requests for reports or information, shall require that each request made under such regulations for submission of a report or information to the Secretary state the reason or purpose for such request and identify to the fullest extent practicable such report or information;

''(5) when requiring submission of a report or information to the Secretary, shall state the reason or purpose for the submission of such report or information and identify to the fullest extent practicable such report or information; and

''(6) may not require that the identity of any patient or user be disclosed in records, reports, or information required under this subsection unless required for the medical welfare of an individual, to determine risks to public health of a tobacco product, or to verify a record, report, or information submitted under this chapter.

In prescribing regulations under this subsection, the Secretary shall have due regard for the professional ethics of the medical profession and the interests of patients. The prohibitions of paragraph (6) continue to apply to records, reports, and information concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

''(b) REPORTS OF REMOVALS AND CORRECTIONS.—

''(1) IN GENERAL.—Except as provided in paragraph (2), the Secretary shall by regulation require a tobacco product manufacturer or importer of a tobacco product to report promptly to the Secretary any corrective action taken or removal from the market of a tobacco product undertaken by such manufacturer or importer if the removal or correction was undertaken—

''(A) to reduce a risk to health posed by the tobacco product; or

''(B) to remedy a violation of this chapter caused by the tobacco product which may present a risk to health.

A tobacco product manufacturer or importer of a tobacco product who undertakes a corrective action or removal from the market of a tobacco product which is not required to be reported under this subsection shall keep a record of such correction or removal.

''(2) EXCEPTION.—No report of the corrective action or removal of a tobacco product may be required under paragraph (1) if a report of the corrective action or removal is required and has been submitted under subsection (a).

"SEC. 910. PREMARKET REVIEW OF CERTAIN TOBACCO PRODUCTS.

''(a) IN GENERAL.—

''(1) PREMARKET APPROVAL REQUIRED.—

''(A) NEW PRODUCTS.—Approval under this section of an application for premarket approval for any tobacco product that is not commercially marketed (other than for test marketing) in the United States as of June 1, 2002, is required unless the manufacturer has submitted a report under section 905(j), and the Secretary has issued an order that the tobacco product is substantially equivalent to a tobacco product commercially marketed (other than for test marketing) in the United States as of June 1, 2002, that is in compliance with the requirements of this Act.

''(B) PRODUCTS INTRODUCED BETWEEN JUNE 1, 2002, AND ENACTMENT OF THIS CHAPTER.—Subparagraph (A) does not apply to a tobacco product that—

''(i) was first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after June 1, 2002, and before the date of enactment of the Youth Smoking Prevention and Public Health Protection Act; and

''(ii) for which a report was submitted under section 905(j) within 6 months after such date,

until the Secretary issues an order that the tobacco product is substantially equivalent for purposes of this section or requires premarket approval.

''(2) SUBSTANTIALLY EQUIVALENT DEFINED.—

''(A) IN GENERAL.—For purposes of this section and section 905(j), the terms '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 found that the tobacco product—

''(i) has the same characteristics as the predicate tobacco product; or

''(ii) has different characteristics and the information submitted contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that it is not appropriate to regulate the product under this section because the product does not raise different questions of public health.

''(B) CHARACTERISTICS.—For purposes of subparagraph (A), the term 'characteristics' means the materials, ingredients, design, composition, heating source, or other features of a tobacco product.

''(C) LIMITATION.—A tobacco product may not be found to be substantially equivalent to a predicate tobacco product that has been removed from the market at the initiative of the Secretary or that has been determined by a judicial order to be misbranded or adulterated.

''(3) HEALTH INFORMATION.—

''(A) SUMMARY.—As part of a submission under section 905(j) respecting a tobacco product, the person required to file a premarket notification under such section shall provide an adequate summary of any health information related to the tobacco product or state that such information will be made available upon request by any person.

''(B) REQUIRED INFORMATION.—Any summary under subparagraph (A) respecting a tobacco product shall contain detailed information regarding data concerning adverse health effects and shall be made available to the public by the Secretary within 30 days of the issuance of a determination that such tobacco product is substantially equivalent to another tobacco product.

''(b) APPLICATION.—

''(1) CONTENTS.—An application for premarket approval shall contain—

''(A) full reports of all information, published or known to, or which should reasonably be known to, the applicant, concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products;

''(B) a full statement of the components, ingredients, and properties, and of the principle or principles of operation, of such tobacco product;

''(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such tobacco product;

''(D) an identifying reference to any performance standard under section 907 which would be applicable to any aspect of such tobacco product, and either adequate information to show that such aspect of such tobacco product fully meets such performance standard or adequate information to justify any deviation from such standard;

''(E) such samples of such tobacco product and of components thereof as the Secretary may reasonably require;

''(F) specimens of the labeling proposed to be used for such tobacco product; and

''(G) such other information relevant to the subject matter of the application as the Secretary may require.

''(2) REFERENCE TO ADVISORY COMMITTEE.—Upon receipt of an application meeting the requirements set forth in paragraph (1), the Secretary—

''(A) may, on the Secretary's own initiative; or

''(B) shall, upon the request of an applicant,

refer such application to an advisory committee and 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.

''(c) ACTION ON APPLICATION.—

''(1) DEADLINE.—

''(A) IN GENERAL.—As promptly as possible, but in no event later than 180 days after the receipt of an application under subsection (b), the Secretary, after considering the report and recommendation submitted under paragraph (2) of such subsection, shall—

''(i) issue an order approving the application if the Secretary finds that none of the grounds for denying approval specified in paragraph (2) of this subsection applies; or

''(ii) deny approval of the application if the Secretary finds (and sets forth the basis for such finding as part of or accompanying such denial) that one or more grounds for denial specified in paragraph (2) of this subsection apply.

''(B) RESTRICTIONS ON SALE AND DISTRIBUTION.—An order approving an application for a tobacco product may require as a condition to such 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 under section 906(d).

''(2) DENIAL OF APPROVAL.—The Secretary shall deny approval of an application for a tobacco product if, upon the basis of the information submitted to the Secretary as part of the application and any other information before the Secretary with respect to such tobacco product, the Secretary finds that—

''(A) there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health;

''(B) the methods used in, or the facilities or controls used for, the manufacture, processing, or packing of such tobacco product do not conform to the requirements of section 906(e);

''(C) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; or

''(D) such tobacco product is not shown to conform in all respects to a performance standard in effect under section 907, compliance with which is a condition to approval of the application, and there is a lack of adequate information to justify the deviation from such standard.

''(3) DENIAL INFORMATION.—Any denial of an application shall, insofar as the Secretary determines to be practicable, be accompanied by a statement informing the applicant of the measures required to place such application in approvable form (which measures may include further research by the applicant in accordance with one or more protocols prescribed by the Secretary).

''(4) BASIS FOR FINDING.—For purposes of this section, the finding as to whether approval of a tobacco product is appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and non-users of the tobacco product, and taking into account—

''(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

''(B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

''(5) BASIS FOR ACTION.—

''(A) INVESTIGATIONS.—For purposes of paragraph (2)(A), whether permitting a tobacco product to be marketed would be appropriate for the protection of the public health shall, when appropriate, be determined on the basis of well-controlled investigations, which may include one or more clinical investigations by experts qualified by training and experience to evaluate the tobacco product.

''(B) OTHER EVIDENCE.—If the Secretary determines that there exists valid scientific evidence (other than evidence derived from investigations described in subparagraph (A)) which is sufficient to evaluate the tobacco product the Secretary may authorize that the determination for purposes of paragraph (2)(A) be made on the basis of such evidence.

''(d) WITHDRAWAL AND TEMPORARY SUSPENSION.—

''(1) IN GENERAL.—The Secretary shall, upon obtaining, where appropriate, advice on scientific matters from 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—

''(A) that the continued marketing of such tobacco product no longer is appropriate for the protection of the public health;

''(B) that the application contained or was accompanied by an untrue statement of a material fact;

''(C) that the applicant—

''(i) has failed to establish a system for maintaining records, or has repeatedly or deliberately failed to maintain records or to make reports, required by an applicable regulation under section 909;

''(ii) has refused to permit access to, or copying or verification of, such records as required by section 704; or

''(iii) has not complied with the requirements of section 905;

''(D) on the basis of new information before the Secretary with respect to such tobacco product, evaluated together with the evidence before the Secretary when the application was approved, that the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or installation of such tobacco product do not conform with the requirements of section 906(e) and were not brought into conformity with such requirements within a reasonable time after receipt of written notice from the Secretary of nonconformity;

''(E) on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when the application was approved, that the labeling of such tobacco product, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary of such fact; or

''(F) on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when the application was approved, that such tobacco product is not shown to conform in all respects to a performance standard which is in effect under section 907, compliance with which was a condition to approval of the application, and that there is a lack of adequate information to justify the deviation from such standard.

''(2) APPEAL.—The holder of an application subject to an order issued under paragraph (1) withdrawing approval of the application may, by petition filed on or before the 30th day after the date upon which such holder receives notice of such withdrawal, obtain review thereof in accordance with subsection (e).

''(3) TEMPORARY SUSPENSION.—If, after providing an opportunity for an informal hearing, the Secretary determines there is reasonable probability that the continuation of distribution of a tobacco product under an 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. If the Secretary issues such an order, the Secretary shall proceed expeditiously under paragraph (1) to withdraw such application.

''(e) SERVICE OF ORDER.—An order issued by the Secretary under this section shall be served—

''(1) in person by any officer or employee of the department designated by the Secretary; or

''(2) by mailing the order by registered mail or certified mail addressed to the applicant at the applicant's last known address in the records of the Secretary.

"SEC. 911. JUDICIAL REVIEW.

''(a) RIGHT TO REVIEW.—

''(1) IN GENERAL.—Not later than 30 days after—

''(A) the promulgation of a regulation under section 907 establishing, amending, or revoking a performance standard for a tobacco product; or

''(B) a denial of an application for approval under section 910(c),

any person adversely affected by such regulation or order may file a petition with the United States Court of Appeals for the District of Columbia or for the circuit wherein such person resides or has his or her principal place of business for judicial review of such regulation or order.

''(2) REQUIREMENTS.—

''(A) COPY OF PETITION.—A copy of the petition filed under paragraph (1) shall be transmitted by the clerk of the court to the Secretary or other officer designated by the Secretary for that purpose.

''(B) RECORD OF PROCEEDINGS.—With respect to an action under paragraph (1), the Secretary shall file in the court the record of the proceedings on which the Secretary based the Secretary's regulation or order and each record or order shall contain a statement of the reasons for its issuance and the basis, on the record, for its issuance.

''(C) DEFINITION.—For purposes of this section, the term 'record' means all notices and other matter published in the Federal Register with respect to the regulation or order reviewed, all information submitted to the Secretary with respect to such regulation or order, proceedings of any panel or advisory committee with respect to such regulation or order, any hearing held with respect to such regulation or order, and any other information identified by the Secretary, in the administrative proceeding held with respect to such regulation or order, as being relevant to such regulation or order.

''(b) COURT MAY ORDER SECRETARY TO MAKE ADDITIONAL FINDINGS.—

''(1) IN GENERAL.—If the petitioner in an action under subsection (a)(1) applies to the court for leave to adduce additional data, views, or arguments respecting the regulation or order being reviewed and shows to the satisfaction of the court that such additional data, views, or arguments are material and that there were reasonable grounds for the petitioner's failure to adduce such data, views, or arguments in the proceedings before the Secretary, the court may order the Secretary to provide additional opportunity for the oral presentation of data, views, or arguments and for written submissions.

''(2) MODIFICATION OF OR ADDITIONAL FINDINGS.—The Secretary may modify the Secretary's findings, or make new findings by reason of the additional data, views, or arguments under paragraph (1) and shall file with the court such modified or new findings, and the Secretary's recommendation, if any, for the modification or setting aside of the regulation or order being reviewed, with the return of such additional data, views, or arguments.

''(c) STANDARD OF REVIEW.—Upon the filing of the petition under subsection (a) for judicial review of a regulation or order, the court shall have jurisdiction to review the regulation or order in accordance with chapter 7 of title 5, United States Code, and to grant appropriate relief, including interim relief, as provided in such chapter. A regulation or order described in paragraph (1) or (2) of subsection (a) shall not be affirmed if it is found to be unsupported by substantial evidence on the record taken as a whole.

''(d) FINALITY OF JUDGMENT.—The judgment of the court affirming or setting aside, in whole or in part, any regulation or order shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of title 28, United States Code.

''(e) OTHER REMEDIES.—The remedies provided for in this section shall be in addition to and not in lieu of any other remedies provided by law.

''(f) 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 906, 907, 908, 909, 910, or 914, each such regulation or order shall contain a statement of the reasons for its issuance and the basis, in the record of the proceedings held in connection with its issuance, for its issuance.

"SEC. 912. POSTMARKET SURVEILLANCE.

''(a) DISCRETIONARY SURVEILLANCE.—The Secretary may require a tobacco product manufacturer to conduct postmarket surveillance for a 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.

''(b) SURVEILLANCE APPROVAL.—Each tobacco product manufacturer required to conduct a surveillance of a tobacco product under subsection (a) shall, within 30 days after receiving notice that the manufacturer is required to conduct such surveillance, submit, for the approval of the Secretary, a protocol for the required surveillance. The Secretary, within 60 days of the receipt of such protocol, shall determine if the principal investigator proposed to be used in the surveillance has sufficient qualifications and experience to conduct such surveillance and if such protocol will result in collection of useful data or other information necessary to protect the public health. The Secretary may not approve such a protocol until it has been reviewed by an appropriately qualified scientific and technical review committee established by the Secretary.

"SEC. 913. REDUCED RISK TOBACCO PRODUCTS.

''(a) REQUIREMENTS.—

''(1) IN GENERAL.—For purposes of this section, the term 'reduced risk tobacco product' means a tobacco product designated by the Secretary under paragraph (2).

''(2) DESIGNATION.—

''(A) IN GENERAL.—A product may be designated by the Secretary as a reduced risk tobacco product if the Secretary finds that the product will significantly reduce harm to individuals caused by a tobacco product and is otherwise appropriate to protect public health, based on an application submitted by the manufacturer of the product (or other responsible person) that—

''(i) demonstrates through testing on animals and short-term human testing that use of such product results in ingestion or inhalation of a substantially lower yield of toxic substances than use of conventional tobacco products; and

''(ii) if required by the Secretary, includes studies of the long-term health effects of the product.

If such studies are required, the manufacturer may consult with the Secretary regarding protocols for conducting the studies.

''(B) BASIS FOR FINDING.—In making the finding under subparagraph (A), the Secretary shall take into account—

''(i) the risks and benefits to the population as a whole, including both users of tobacco products and non-users of tobacco products;

''(ii) the increased or decreased likelihood that existing users of tobacco products will stop using such products including reduced risk tobacco products;

''(iii) the increased or decreased likelihood that those who do not use tobacco products will start to use such products, including reduced risk tobacco products; and

''(iv) the risks and benefits to consumers from the use of a reduced risk tobacco product as compared to the use of products approved under chapter V to reduce exposure to tobacco.

''(3) MARKETING REQUIREMENTS.—A tobacco product may be marketed and labeled as a reduced risk tobacco product if it—

''(A) has been designated as a reduced risk tobacco product by the Secretary under paragraph (2);

''(B) bears a label prescribed by the Secretary concerning the product's contribution to reducing harm to health; and

''(C) complies with requirements prescribed by the Secretary relating to marketing and advertising of the product, and other provisions of this chapter as prescribed by the Secretary.

''(b) REVOCATION OF DESIGNATION.—At any time after the date on which a tobacco product is designated as a reduced risk tobacco product under this section the Secretary may, after providing an opportunity for an informal hearing, revoke such designation if the Secretary determines, based on information not available at the time of the designation, that—

''(1) the finding made under subsection (a)(2) is no longer valid; or

''(2) the product is being marketed in violation of subsection (a)(3).

''(c) LIMITATION.—A tobacco product that is designated as a reduced risk tobacco product that is in compliance with subsection (a) shall not be regulated as a drug or device.

''(d) DEVELOPMENT OF REDUCED RISK TOBACCO PRODUCT TECHNOLOGY.—A tobacco product manufacturer shall provide written notice to the Secretary upon the development or acquisition by the manufacturer of any technology that would reduce the risk of a tobacco product to the health of the user for which the manufacturer is not seeking designation as a 'reduced risk tobacco product' under subsection (a).

"SEC. 914. EQUAL TREATMENT OF RETAIL OUTLETS.

''The Secretary shall issue regulations to require that retail establishments for which the predominant business is the sale of tobacco products comply with any advertising restrictions applicable to retail establishments accessible to individuals under the age of 18.

"SEC. 915. JURISDICTION OF AND COORDINATION WITH THE FEDERAL TRADE COMMISSION.

''(a) JURISDICTION.—

''(1) IN GENERAL.—Except where expressly provided in this chapter, nothing in this chapter shall be construed as limiting or diminishing the authority of the Federal Trade Commission to enforce the laws under its jurisdiction with respect to the advertising, sale, or distribution of tobacco products.

''(2) ENFORCEMENT.—Any advertising that violates this chapter or a provision of the regulations referred to in section 102 of the Youth Smoking Prevention and Public Health Protection Act, is an unfair or deceptive act or practice under section 5(a) of the Federal Trade Commission Act (15 U.S.C. 45(a)) and shall be considered a violation of a rule promulgated under section 18 of that Act (15 U.S.C. 57a).

''(b) COORDINATION.—With respect to the requirements of section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C.

1333) and section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4402)—

''(1) the Chairman of the Federal Trade Commission shall coordinate with the Secretary concerning the enforcement of such Act as such enforcement relates to unfair or deceptive acts or practices in the advertising of cigarettes or smokeless tobacco; and

''(2) the Secretary shall consult with the Chairman of such Commission in revising the label statements and requirements under such sections.

''SEC. 916. CONGRESSIONAL REVIEW PROVISIONS.

''In accordance with section 801 of title 5, United States Code, the Congress shall review, and may disapprove, any rule under this chapter that is subject to section 801. This section does not apply to the regulations referred to in section 102 of the Youth Smoking Prevention and Public Health Protection Act.

''SEC. 917. REGULATION REQUIREMENT.

''(a) TESTING, REPORTING, AND DISCLOSURE.—Not later than 24 months after the date of enactment of the Youth Smoking Prevention and Public Health Protection Act, the Secretary, acting through the Commissioner of the Food and Drug Administration, shall promulgate regulations under this Act that meet the requirements of subsection (b).

''(b) CONTENTS OF RULES.—The regulations 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. Such constituents shall include tar, nicotine, carbon monoxide, and such other smoke constituents or ingredients as the Secretary may determine to be appropriate. The regulations may require that tobacco product manufacturers, packagers, or importers make such disclosures relating to tar and nicotine through labels or advertising, and make such disclosures regarding other smoke constituents or ingredients as the Secretary determines are necessary to protect the public health.

''(c) AUTHORITY.—The Food and Drug Administration shall have the authority under this chapter to conduct or to require the testing, reporting, or disclosure of tobacco product smoke constituents.

''SEC. 918. PRESERVATION OF STATE AND LOCAL AUTHORITY.

''(a) ADDITIONAL REQUIREMENTS.—

''(1) IN GENERAL.—Except as provided in paragraph (2), nothing in this chapter, or rules promulgated under this chapter, shall be construed to limit the authority of a Federal agency (including the Armed Forces), a State or political subdivision of a State, or the government of an Indian tribe to enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products, including laws, rules, regulations, or other measures relating to or prohibiting the sale, distribution, possession, exposure to, or use of tobacco products by individuals of any age that are in addition to, or more stringent than, requirements established under this chapter. No provision of this chapter shall limit or otherwise affect any State, Tribal, or local taxation of tobacco products.

''(2) PREEMPTION OF CERTAIN STATE AND LOCAL REQUIREMENTS.—

''(A) IN GENERAL.—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 which 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, reporting, good manufacturing standards, or reduced risk products.

''(B) EXCEPTION.—Subparagraph (A) does not apply to requirements relating to the sale, use, or distribution of a tobacco product including requirements related to the access to, and the advertising and promotion of, a tobacco product.

''(b) ADDITIONAL RESTRICTIONS ON UNDERAGE USAGE.—Nothing in this chapter shall be construed to prevent a Federal agency (including the Armed Forces), a State or a political subdivision of a State, or the government of an Indian tribe from adopting and enforcing additional measures that further restrict or prohibit tobacco product sale to, use by, and accessibility to individuals under the legal age of purchase established by such agency, State, subdivision, or government of an Indian tribe.

''(c) NO LESS STRINGENT.—Nothing in this chapter is intended to supersede any State, local, or Tribal law that is not less stringent than this chapter.

''(d) RULE OF CONSTRUCTION REGARDING PRODUCT LIABILITY.—No provision of this chapter relating to a tobacco product shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.

''(e) WAIVERS.—Upon the application of a State or political subdivision thereof, the Secretary may, by regulation promulgated after notice and an opportunity for an oral hearing, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a tobacco product if—

''(1) the requirement is more stringent than a requirement applicable under the provisions described in subsection (a)(1) which would be applicable to the tobacco product if an exemption were not in effect under this subsection; or

''(2) the requirement—

''(A) is required by compelling local conditions; and

''(B) compliance with the requirement would not cause the tobacco product to be in violation of any applicable requirement of this chapter.

''SEC. 919. TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE.

''(a) ESTABLISHMENT.—Not later than 1 year after the date of enactment of the Youth Smoking Prevention and Public Health Protection Act, the Secretary shall establish a 9-member advisory committee, to be known as the 'Tobacco Products Scientific Advisory Committee'.

''(b) MEMBERSHIP.—

''(1) IN GENERAL.—The Secretary shall appoint as members of the Tobacco Products Scientific Advisory Committee individuals who are technically qualified by training and experience in the medicine, medical ethics, science, or technology involving the manufacture, evaluation, or use of tobacco products, who are of appropriately diversified professional backgrounds. The committee shall be composed of—

''(A) 3 individuals who are officers or employees of a State or local government, or of the Federal government;

''(B) 2 individuals as representatives of interests of the tobacco manufacturing industry;

''(C) 2 individuals as representatives of interests of physicians and other health care professionals; and

''(D) 2 individuals as representatives of the general public.

''(2) LIMITATION.—The Secretary may not appoint to the Advisory Committee any individual who is in the regular full-time employ of the Food and Drug Administration or any agency responsible for the enforcement of this Act. The Secretary may appoint Federal officials as ex-officio members.

''(3) CHAIRPERSON.—The Secretary shall designate 1 of the members of the Advisory Committee to serve as chairperson.

''(c) DUTIES.—The Tobacco Products Scientific Advisory Committee shall provide advice, information, and recommendations to the Secretary—

''(1) as provided in this chapter;

''(2) on the effects of the alteration of the nicotine yields from tobacco products;

''(3) on whether there is a threshold level below which nicotine yields do not produce dependence on the tobacco product involved; and

''(4) on its review of other safety, dependence, or health issues relating to tobacco products as requested by the Secretary.

''(d) COMPENSATION; SUPPORT; FACA.—

''(1) COMPENSATION AND TRAVEL.—Members of the Advisory Committee who are not officers or employees of the United States, while attending conferences or meetings of the committee or otherwise engaged in its business, shall be entitled to receive compensation at rates to be fixed by the Secretary, which may not exceed the daily equivalent of the rate in effect for level 4 of the Senior Executive Schedule under section 5382 of title 5, United States Code, for each day (including travel time) they are so engaged; and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5, United States Code, for persons in the Government service employed intermittently.

''(2) ADMINISTRATIVE SUPPORT.—The Secretary shall furnish the Advisory Committee clerical and other assistance.

''(3) NONAPPLICATION OF FACA.—Section 14 of the Federal Advisory Committee Act (5 U.S.C. App.) does not apply to the Advisory Committee.

''(e) PROCEEDINGS OF ADVISORY PANELS AND COMMITTEES.—The Advisory Committee shall make and maintain a transcript of any proceeding of the panel or committee. Each such panel and committee shall delete from any transcript made under this subsection information which is exempt from disclosure under section 552(b) of title 5, United States Code.''.

SEC. 102. CONSTRUCTION OF CURRENT REGULATIONS.

(a) IN GENERAL.—The final regulations promulgated by the Secretary of Health and Human Services in the August 28, 1996, issue of the Federal Register (62 Fed. Reg. 44615–44618 beginning at ''part 897'') are hereby deemed to be lawful and shall have the same legal force and effect as if such regulations had been lawfully promulgated by the Secretary under chapter IX and section 701 of the Federal Food, Drug, and Cosmetic Act (as amended by this Act). Not later than 30 days after the date of enactment of this Act, the Secretary shall republish such regulations in the Federal Register. Such regulations shall take effect on the date that is 12 months after such date of enactment, except that the Secretary may designate an earlier effective date. The Secretary shall amend the designation of authority in such regulations in accordance with this subsection.

(b) LIMITATION ON ADVISORY OPINIONS.—As of the date of enactment of this Act, the following documents issued by the Food and Drug Administration shall not constitute advisory opinions under section 10.85(d)(1) of title 21, Code of Federal Regulations, except as they apply to tobacco products, and shall not be cited by the Secretary of Health and Human Services or the Food and Drug Administration as binding precedent:

(1) The preamble to the proposed rule in the document entitled ''Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents'' (60 Fed. Reg. 41314–41372 (August 11, 1995)).

(2) The document entitled ''Nicotine in Cigarettes and Smokeless Tobacco Products is a Drug and These Products Are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act'' (60 Fed. Reg. 41453–41787 (August 11, 1995)).

(3) The preamble to the final rule in the document entitled ''Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents'' (61 Fed. Reg. 44396–44615 (August 28, 1996)).

(4) The document entitled ''Nicotine in Cigarettes and Smokeless Tobacco is a Drug and These Products are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act; Jurisdictional Determination'' (61 Fed. Reg. 44619–45318 (August 28, 1996)).

SEC. 103. CONFORMING AND OTHER AMENDMENTS TO GENERAL PROVISIONS.

(a) AMENDMENT OF FEDERAL FOOD, DRUG, AND COSMETIC ACT.—Except as otherwise expressly provided, whenever in this section an amendment is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference is to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(b) SECTION 301.—Section 301 (21 U.S.C. 331) is amended—

(1) in subsection (a), by inserting ''tobacco product,'' after ''device,'';

(2) in subsection (b), by inserting ''tobacco product,'' after ''device,'';

(3) in subsection (c), by inserting ''tobacco product,'' after ''device,'';

(4) in subsection (e), by striking ''515(f), or 519'' and inserting ''515(f), 519, or 909'';

(5) in subsection (g), by inserting ''tobacco product,'' after ''device,'';

(6) in subsection (h), by inserting ''tobacco product,'' after ''device,'';

(7) in subsection (j), by striking ''708, or 721'' and inserting ''708, 721, 904, 905, 906, 907, 908, or 909'';

(8) in subsection (k), by inserting ''tobacco product,'' after ''device,'';

(9) by striking subsection (p) and inserting the following:

''(p) The failure to register in accordance with section 510 or 905, the failure to provide any information required by section 510(j), 510(k), 905(i), or 905(j), or the failure to provide a notice required by section 510(j)(2) or 905(j)(2).'';

(10) by striking subsection (q)(1) and inserting the following:

''(q)(1) The failure or refusal—

''(A) to comply with any requirement prescribed under section 518, 520(g), 906(f), or 908;

''(B) to furnish any notification or other material or information required by or under section 519, 520(g), 904, 906(f), or 909; or

''(C) to comply with a requirement under section 522 or 912.'';

(11) in subsection (q)(2), by striking ''device,'' and inserting ''device or tobacco product,'';

(12) in subsection (r), by inserting ''or tobacco product'' after ''device'' each time that it appears; and

(13) by adding at the end the following:

''(aa) The sale of tobacco products in violation of a no-tobacco-sale order issued under section 303(f).''.

(c) SECTION 303.—Section 303(f) (21 U.S.C. 333(f)) is amended—

(1) by striking the subsection heading and inserting the following:

''(f) CIVIL PENALTIES; NO-TOBACCO-SALE ORDERS.—'';

(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), and inserting after paragraph (2) the following:

''(3) If the Secretary finds that a person has committed repeated violations of restrictions promulgated under section 906(d) at a particular retail outlet then the Secretary may impose a no-tobacco-sale order on that person prohibiting the sale of tobacco products in that outlet. A no-tobacco-sale order may be imposed with a civil penalty under paragraph (1).'';

(4) in paragraph (4) as so redesignated—

(A) in subparagraph (A)—

(i) by striking ''assessed'' the first time it appears and inserting ''assessed, or a no-tobacco-sale order may be imposed,''; and

(ii) by striking ''penalty'' and inserting ''penalty, or upon whom a no-tobacco-order is to be imposed,'';

(B) in subparagraph (B)—

(i) by inserting after ''penalty,'' the following: ''or the period to be covered by a no-tobacco-sale order,''; and

(ii) by adding at the end the following: ''A no-tobacco-sale order permanently prohibiting an individual retail outlet from selling tobacco products shall include provisions that allow the outlet, after a specified period of time, to request that the Secretary compromise, modify, or terminate the order.''; and

(C) by adding at the end, the following:

''(D) The Secretary may compromise, modify, or terminate, with or without conditions, any no-tobacco-sale order.'';

(5) in paragraph (5) as so redesignated—

(A) by striking ''(3)(A)'' as redesignated, and inserting ''(4)(A)'';

(B) by inserting ''or the imposition of a no-tobacco-sale order'' after ''penalty'' the first 2 places it appears; and

(C) by striking ''issued.'' and inserting ''issued, or on which the no-tobacco-sale order was imposed, as the case may be.''; and

(6) in paragraph (6), as so redesignated, by striking ''paragraph (4)'' each place it appears and inserting ''paragraph (5)''.

(d) SECTION 304.—Section 304 (21 U.S.C. 334) is amended—

(1) in subsection (a)(2)—

(A) by striking ''and'' before ''(D)''; and

(B) by striking ''device.'' and inserting the following: '', (E) Any adulterated or misbranded tobacco product.'';

(2) in subsection (d)(1), by inserting ''tobacco product,'' after ''device,'';

(3) in subsection (g)(1), by inserting ''or tobacco product'' after ''device'' each place it appears; and

(4) in subsection (g)(2)(A), by inserting ''or tobacco product'' after ''device'' each place it appears.

(e) SECTION 702.—Section 702(a) (21 U.S.C. 372(a)) is amended—

(1) by inserting ''(1)'' after ''(a)''; and

(2) by adding at the end thereof the following:

''(2) For a tobacco product, to the extent feasible, the Secretary shall contract with the States in accordance with paragraph (1) to carry out inspections of retailers in connection with the enforcement of this Act.''.

(f) SECTION 703.—Section 703 (21 U.S.C. 373) is amended—

(1) by inserting ''tobacco product,'' after ''device,'' each place it appears; and

(2) by inserting ''tobacco products,'' after ''devices,'' each place it appears.

(g) SECTION 704.—Section 704 (21 U.S.C. 374) is amended—

(1) in subsection (a)(1)(A), by inserting ''tobacco products,'' after ''devices,'' each place it appears;

(2) in subsection (a)(1)(B), by inserting ''or tobacco product'' after ''restricted devices'' each place it appears; and

(3) in subsection (b), by inserting ''tobacco product,'' after ''device,''.

(h) SECTION 705.—Section 705(b) (21 U.S.C. 375(b)) is amended by inserting ''tobacco products,'' after ''devices,''.

(i) SECTION 709.—Section 709 (21 U.S.C. 379) is amended by inserting ''or tobacco product'' after ''device''.

(j) SECTION 801.—Section 801 (21 U.S.C. 381) is amended—

(1) in subsection (a)—

(A) by inserting ''tobacco products,'' after ''devices,'' the first time it appears;

(B) by inserting ''or subsection (j) of section 905'' after ''section 510''; and

(C) by striking ''drugs or devices'' each time it appears and inserting ''drugs, devices, or tobacco products'';

(2) in subsection (e)—

(A) in paragraph (1), by inserting ''tobacco product,'' after ''device,''; and

(B) by redesignating paragraph (4) as paragraph (5) and inserting after paragraph (3), the following:

''(4) Paragraph (1) does not apply to any tobacco product—

''(A) which does not comply with an applicable requirement of section 907 or 910; or

''(B) which under section 906(f) is exempt from either such section.

This paragraph does not apply if the Secretary has determined that the exportation of the tobacco product is not contrary to the public health and safety and has the approval of the country to which it is intended for export or the tobacco product is eligible for export under section 802.''.

(k) SECTION 802.—Section 802 (21 U.S.C. 382) is amended—

(1) in subsection (a), by striking ''device— '' and inserting ''device or tobacco product— '';

(2) in subsection (a)(1)(C), by striking ''and'' after the semicolon;

(3) in subsection (a)(2), by striking subparagraph (C) and all that follows in that subsection and inserting the following:

''(C) is a banned device under section 516; or

''(3) which, in the case of a tobacco product—

''(A) does not comply with an applicable requirement of section 907 or 910; or

''(B) under section 906(f) is exempt from either such section,

is adulterated, misbranded, and in violation of such sections or Act unless the export of the drug, device, or tobacco product is, except as provided in subsection (f), authorized under subsection (b), (c), (d), or (e) of this section or section 801(e)(2) or 801(e)(4). If a drug, device, or tobacco product described in paragraph (1), (2), or (3) may be exported under subsection (b) and if an application for such drug or device under section 505, 515, or 910 of this Act or section 351 of the Public Health Service Act (42 U.S.C. 262) was disapproved, the Secretary shall notify the appropriate public health official of the country to which such drug, device, or tobacco product will be exported of such disapproval.'';

(4) in subsection (b)(1)(A), by inserting ''or tobacco product'' after ''device'' each time it appears;

(5) in subsection (c), by inserting ''or tobacco product'' after ''device'' and inserting ''or section 906(f)'' after ''520(g).'';

(6) in subsection (f), by inserting ''or tobacco product'' after ''device'' each time it appears; and

(7) in subsection (g), by inserting ''or tobacco product'' after ''device'' each time it appears.

(l) SECTION 1003.—Section 1003(d)(2)(C) (as redesignated by section 101(a)) is amended—

(1) by striking ''and'' after ''cosmetics,''; and

(2) inserting a comma and ''and tobacco products'' after ''devices''.

(m) EFFECTIVE DATE FOR NO-TOBACCO-SALE ORDER AMENDMENTS.—The amendments made by subsection (c), other than the amendment made by paragraph (2) of such subsection, shall take effect only upon the promulgation of final regulations by the Secretary of Health and Human Services—

(1) defining the term ''repeated violation'', as used in section 303(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)) as amended by subsection (c), 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 a violation at a particular retail outlet unless the Secretary has provided notice to the retailer of all previous violations at that outlet;

(4) establishing a period of time during which, if there are no violations by a particular retail outlet, that outlet will not 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.

TITLE II—TOBACCO PRODUCT WARNINGS AND SMOKE CONSTITUENT DISCLOSURE

SEC. 201. CIGARETTE LABEL AND ADVERTISING WARNINGS.

(a) IN GENERAL.—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, one of the following labels:

''WARNING: Cigarettes are addictive''

''WARNING: Tobacco smoke can harm your children''

''WARNING: Cigarettes cause fatal lung disease''

''WARNING: Cigarettes cause cancer''

''WARNING: Cigarettes cause strokes and heart disease''

''WARNING: Smoking during pregnancy can harm your baby''

''WARNING: Smoking can kill you''

''WARNING: Tobacco smoke causes fatal lung disease in non-smokers''

''WARNING: Quitting smoking now greatly reduces serious risks to your health''

''(2) PLACEMENT; TYPOGRAPHY; ETC.—

''(A) IN GENERAL.—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. Except as provided in subparagraph (B), each label statement shall comprise at least the top 25 percent of the front and rear panels of the package. The word ''WARNING'' shall appear in capital letters and all text shall be in conspicuous and legible 17-point type, unless the text of the label statement would occupy more than 70 percent of such area, in which case the text may be in a smaller conspicuous and legible type size, provided that at least 60 percent of such area is occupied by required text. The text shall be black on a white background, or white on a black background, in a manner that contrasts, by typography, layout, or color, with all other printed material on the package, in an alternating fashion under the plan submitted under subsection (b)(4).

''(B) FLIP-TOP BOXES.—For any cigarette brand package manufactured or distributed before January 1, 2000, which employs a flip-top style (if such packaging was used for that brand in commerce prior to June 21, 1997), the label statement required by paragraph (1) shall be located on the flip-top area of the package, even if such area is less than 25 percent of the area of the front panel. Except as provided in this paragraph, the provisions of this subsection shall apply to such packages.

''(3) DOES NOT APPLY TO FOREIGN DISTRIBUTION.—The provisions of this subsection do not apply to a tobacco product manufacturer or distributor of cigarettes which does not manufacture, package, or import cigarettes for sale or distribution within the United States.

''(b) ADVERTISING REQUIREMENTS.—

''(1) IN GENERAL.—It shall be unlawful for any tobacco product manufacturer, importer, distributor, or retailer of cigarettes to advertise or cause to be advertised within the United States any cigarette unless its advertising bears, in accordance with the requirements of this section, one of the labels specified in subsection (a) of this section.

''(2) TYPOGRAPHY, ETC.—Each label statement required by subsection (a) of this section in cigarette advertising shall comply with the standards set forth in this paragraph. For press and poster advertisements, each such statement and (where applicable) any required statement relating to tar, nicotine, or other constituent yield shall comprise at least 20 percent of the area of the advertisement and shall appear in a conspicuous and prominent format and location at the top of each advertisement within the trim area. The Secretary may revise the required type sizes in such area in such manner as the Secretary determines appropriate. The word ''WARNING'' shall appear in capital letters, and each label statement shall appear in conspicuous and legible type. The text of the label statement shall be black if the background is white and white if the background is black, under the plan submitted under paragraph (4) of this subsection. The label statements shall be enclosed by a rectangular border that is the same color as the letters of the statements and that is the width of the first downstroke of the capital ''W'' of the word ''WARNING'' in the label statements. The text of such label statements shall be in a typeface pro rata to the following requirements: 45-point type for a whole-page broadsheet newspaper advertisement; 39-point type for a half-page broadsheet newspaper advertisement; 39-point type for a whole-page tabloid newspaper advertisement; 27-point type for a half-page tabloid newspaper advertisement; 31.5-point type for a double page spread magazine or whole-page magazine advertisement; 22.5-point type for a 28 centimeter by 3 column advertisement; and 15-point type for a 20 centimeter by 2 column advertisement. The label statements shall be in English, except that in the case of—

''(A) an advertisement that appears in a newspaper, magazine, periodical, or other publication that is not in English, the statements shall appear in the predominant language of the publication; and

''(B) in the case of any other advertisement that is not in English, the statements shall appear in the same language as that principally used in the advertisement.

''(3) ADJUSTMENT BY SECRETARY.—The Secretary may, through a rulemaking under section 553 of title 5, United States Code, adjust the format and type sizes for the label statements required by this section or the text, format, and type sizes of any required tar, nicotine yield, or other constituent disclosures, or to 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.). The text of any such label statements or disclosures shall be required to appear only within the 20 percent area of cigarette advertisements provided by paragraph (2) of this subsection. The Secretary shall promulgate regulations which provide for adjustments in the format and type sizes of any text required to appear in such area to ensure that the total text required to appear by law will fit within such area.

''(4) MARKETING REQUIREMENTS.—

''(A) The label statements specified in subsection (a)(1) shall be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer and approved by the Secretary.

''(B) The label statements specified in subsection (a)(1) shall be rotated quarterly in alternating sequence in advertisements for each brand of cigarettes in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer to, and approved by, the Secretary.

''(C) The Secretary shall review each plan submitted under subparagraph (B) and approve it if the plan—

''(i) will provide for the equal distribution and display on packaging and the rotation required in advertising under this subsection; and

''(ii) assures that all of the labels required under this section will be displayed by the tobacco product manufacturer, importer, distributor, or retailer at the same time.''.

(b) REPEAL OF PROHIBITION ON STATE RESTRICTION.—Section 5 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1334) is amended—

(1) by striking ''(a) ADDITIONAL STATEMENTS.—'' in subsection (a); and

(2) by striking subsection (b).

SEC. 202. AUTHORITY TO REVISE CIGARETTE WARNING LABEL STATEMENTS.

Section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333), as amended by section 301 of this title, is further amended by adding at the end the following:

''(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 subsection (a) of 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 tobacco products.''.

SEC. 203. 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) 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, one of the following labels:

''WARNING: This product can cause mouth cancer''
''WARNING: This product can cause gum disease and tooth loss''
''WARNING: This product is not a safe alternative to cigarettes''
''WARNING: Smokeless tobacco is addictive''

''(2) Each label statement required by paragraph (1) shall be—

''(A) located on the 2 principal display panels of the package, and each label statement shall comprise at least 25 percent of each such display panel; and

''(B) in 17-point conspicuous and legible type and in black text on a white background, or white text on a black background, in a manner that contrasts by typography, layout, or color, with all other printed material on the package, in an alternating fashion under the plan submitted under subsection (b)(3), except that if the text of a label statement would occupy more than 70 percent of the area specified by subparagraph (A), such text may appear in a smaller type size, so long as at least 60 percent of such warning area is occupied by the label statement.

''(3) The label statements required by paragraph (1) shall be introduced by each tobacco product manufacturer, packager, importer, distributor, or retailer of smokeless tobacco products concurrently into the distribution chain of such products.

''(4) The provisions of this subsection do not apply to a tobacco product manufacturer or distributor of any smokeless tobacco product that does not manufacture, package, or import smokeless tobacco products for sale or distribution within the United States.

''(b) REQUIRED LABELS.—

''(1) It shall be unlawful for any tobacco product manufacturer, packager, importer, distributor, or retailer of smokeless tobacco products to advertise or cause to be advertised within the United States any smokeless tobacco product unless its advertising bears, in accordance with the requirements of this section, one of the labels specified in subsection (a).

''(2) Each label statement required by subsection (a) in smokeless tobacco advertising shall comply with the standards set forth in this paragraph. For press and poster advertisements, each such statement and (where applicable) any required statement relating to tar, nicotine, or other constituent yield shall—

''(A) 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

''(B) the word ''WARNING'' shall appear in capital letters and each label statement shall appear in conspicuous and legible type. The text of the label statement shall be black on a white background, or white on a black background, in an alternating fashion under the plan submitted under paragraph (3).

''(3)(A) The label statements specified in subsection (a)(1) shall be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer and approved by the Secretary.

''(B) The label statements specified in subsection (a)(1) shall be rotated quarterly in alternating sequence in advertisements for each brand of smokeless tobacco product in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer to, and approved by, the Secretary.

''(C) The Secretary shall review each plan submitted under subparagraph (B) and approve it if the plan—

''(i) will provide for the equal distribution and display on packaging and the rotation required in advertising under this subsection; and

''(ii) assures that all of the labels required under this section will be displayed by the tobacco product manufacturer, importer, distributor, or retailer at the same time.

''(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.''.

SEC. 204. AUTHORITY TO REVISE SMOKELESS TOBACCO PRODUCT WARNING LABEL STATEMENTS.

Section 3 of, as amended by section 303 of this title, is further amended by adding at the end the following:

''(d) AUTHORITY TO REVISE WARNING LABEL STATEMENTS.—The Secretary may, by a rulemaking conducted under section 553 of title 5, United States Code, adjust the format, type size, and text of any of the warning label statements required by subsection (a) of 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.''.

SEC. 205. TAR, NICOTINE, AND OTHER SMOKE CONSTITUENT DISCLOSURE TO THE PUBLIC.

Section 4(a) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333 (a)), as amended by section 301 of this title, is further amended by adding at the end the following:

''(4)(A) The Secretary shall, by a rulemaking conducted under section 553 of title 5, United States Code, determine (in the Secretary's sole discretion) whether cigarette and other tobacco product manufacturers shall be required to include in the area of each cigarette advertisement specified by subsection (b) of this section, or on the package label, or both, the tar and nicotine yields of the advertised or packaged brand. Any such disclosure shall be in accordance with the methodology established under such regulations, shall conform to the type size requirements of subsection (b) of this section, and shall appear within the area specified in subsection (b) of this section.

''(B) 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.

''(C) In addition to the disclosures required by subparagraph (A) of this paragraph, 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. Any such disclosure may be required if the Secretary determines that disclosure would be of benefit to the public health, or otherwise would increase consumer awareness of the health consequences of the use of tobacco products, except that no such prescribed disclosure shall be required on the face of any cigarette package or advertisement. Nothing in this section shall prohibit the Secretary from requiring such prescribed disclosure through a cigarette or other tobacco product package or advertisement insert, or by any other means under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).''.

AMENDMENTS SUBMITTED AND PROPOSED

SA 3847. Mr. LEAHY (for himself and Mr. HATCH) proposed an amendment to the bill H.R. 3275, to implement the International Convention for the Suppression of Terrorist Bombings to strengthen criminal laws relating to attacks on places of public use, to implement the International Convention of the Suppression of the Financing of Terrorism, to combat terrorism and defend the Nation against terrorist acts, and for other purposes.

SA 3848. Mr. LEAHY (for himself and Mr. HATCH) proposed an amendment to the bill S. 1770, supra.

SA 3849. Mr. REID (for Mr. WELLSTONE (for himself and Mr. GRAHAM)) proposed an amendment to the bill S. Res. 283, recognizing the successful completion of democratic elections in the Republic of Colombia.

SA 3847. Mr. LEAHY (for himself and Mr. HATCH) proposed an amendment to the bill H.R. 3275, to implement the International Convention for the Suppression of Terrorist Bombings to strengthen criminal laws relating to attacks on places of public use, to implement the International Convention of the Suppression of the Financing of Terrorism, to combat terrorism and defend the Nation against terrorist acts, and for other purposes; as follows:

Strike all after the enacting clause and insert the following:

TITLE I—SUPPRESSION OF TERRORIST BOMBINGS

SEC. 101. SHORT TITLE.

This title may be cited as the ''Terrorist Bombings Convention Implementation Act of 2001''.

SEC. 102. BOMBING STATUTE.

(a) OFFENSE.—Chapter 113B of title 18, United States Code, relating to terrorism, is amended by inserting after section 2332e the following:

''§ 2332f. Bombings of places of public use, government facilities, public transportation systems and infrastructure facilities

''(a) OFFENSES.—

''(1) IN GENERAL.—Whoever unlawfully delivers, places, discharges, or detonates an explosive or other lethal device in, into, or against a place of public use, a state or government facility, a public transportation system, or an infrastructure facility—

''(A) with the intent to cause death or serious bodily injury, or

''(B) with the intent to cause extensive destruction of such a place, facility, or system, where such destruction results in or is likely to result in major economic loss,

shall be punished as prescribed in subsection (c).

''(2) ATTEMPTS AND CONSPIRACIES.—Whoever attempts or conspires to commit an offense under paragraph (1) shall be punished as prescribed in subsection (c).

''(b) JURISDICTION.—There is jurisdiction over the offenses in subsection (a) if—

''(1) the offense takes place in the United States and—

''(A) the offense is committed against another state or a government facility of such state, including its embassy or other diplomatic or consular premises of that state;

''(B) the offense is committed in an attempt to compel another state or the United States to do or abstain from doing any act;