105th Congress 2d Session	SENATE	REPORT 105–180

NATIONAL TOBACCO POLICY AND YOUTH SMOKING REDUCTION ACT

R E P O R T

OF THE

COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION

on

S. 1415

MAY 1, 1998.—Ordered to be printed

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SENATE COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION

ONE HUNDRED FIFTH CONGRESS

SECOND SESSION

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105TH CONGRESS, *2d Session* | SENATE | REPORT 105–180

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Mr. MCCAIN, from the Committee on Commerce, Science, and Transportation, submitted the following

REPORT

together with

ADDITIONAL VIEWS

[To accompany S. 1415]

The Committee on Commerce, Science, and Transportation, to which was referred the bill (S. 1415) "A Bill to reform and restructure the processes by which tobacco products are manufactured, marketed, and distributed, to prevent the use of tobacco products by minors, to redress the adverse health effects of tobacco use, and for other purposes", having considered the same, reports favorably thereon with an amendment (in the nature of a substitute) and recommends that the bill (as amended) do pass.

PURPOSE OF THE BILL

The purpose of this bill is (1) to prevent children from using tobacco products; (2) to more effectively inform the public of the dangers of using tobacco products; (3) to ensure that nicotine and tobacco products are appropriately regulated by the Food and Drug Administration to better protect public health; (4) to settle claims of the various states against the tobacco industry; (5) to require payments from the industry to provide for the settlement of relevant state suits; (6) to increase the price-per-pack of cigarettes to deter youth consumption; (7) to provide a stream of revenue to finance smoking prevention, cessation and related health research

initiatives; and (8) to assist tobacco farmers and rural communities affected by reductions in the volume of tobacco consumption.

BACKGROUND AND NEED FOR THE LEGISLATION

The use of tobacco products poses a serious threat to public health. Health studies show that nicotine is an addictive substance and tobacco use is harmful to the human body. In the United States, over 400,000 people per year die from smoking related disease, including cancer, heart disease and emphysema. The human and economic toll of tobacco use is enormous. The Surgeon General reports that tobacco use is the number one preventable cause of disease and death.

The Secretary of HHS estimates that smoking related health care costs exceed $45 billion per year, including from Medicare and Medicaid, and the total economic cost of tobacco use exceed $145 billion per year, including the cost of fire damage and related injuries; absenteeism and lost productivity.

The vast majority of tobacco users (90 percent) take up the addiction in their teenage years. Four and one-half million underage Americans use tobacco. Three thousand youth begin smoking every day, one thousand of whom will die early from smoking related disease. The American Cancer Society calls youth consumption of tobacco a "pediatric epidemic."

According to the Center for Disease Control one out of three adolescents in the United States is using tobacco by age 18. Seventy-one percent of underage smokers smoke daily. Every living Surgeon General has signed a letter urging Congress to approve comprehensive legislation to address the public health problems associated with tobacco use..

Tobacco industry documents indicate that tobacco companies have long known the adverse health impact and addictiveness of tobacco use, and, nevertheless, have actively marketed to children and teens.

Forty-one states have filed suit against the tobacco industry to recover damages. On June 20, 1997, the state attorneys general, plaintiff attorneys and the industry reached an agreement in principle to settle state and other civil suits. Under the settlement, the industry would agree to tobacco advertising and marketing restrictions; nicotine and tobacco products would be submitted to FDA regulation; the industry would agree to meet youth tobacco use reduction targets and pay assessments for non-attainment of such targets; and the industry would pay up to $368 billion over the next 25 years. In return, under the June 20th agreement, the industry would receive certain limitations on liability.

The June 20th agreement cannot take effect without enactment of implementing legislation, and the execution of a National Protocol and state consent decrees. The protocol and consent decrees would bind the industry to obligations under the agreement that, due to constitutional limitations, may not be imposed on the industry without their consent to the waiver of certain constitutional rights.

The National Tobacco Policy and Youth Smoking Reduction Act mirrors the structural framework of the June 20th agreement, although there are significant differences. In general, the bill in-

creases industry payments from $368 billion over 25 years to $516 billion; approximately doubles the penalties the industry would pay for failure to attain targets for the reduction of youth tobacco use; and bolsters FDA regulatory authority over nicotine and tobacco products. The bill provides a yearly civil liability cap; settles only state and local government suits and the Castano class action claims based on tobacco addiction and dependency, and does not restrict the right of groups or individuals to sue and receive compensation from the industry.

LEGISLATIVE HISTORY

At least five comprehensive tobacco policy bills have been introduced in the Senate during the 105th Congress. The omnibus nature of these measures, including legislation to implement the June 20th Agreement, contained provisions within the jurisdiction of various Senate Committees.

The multi-jurisdictional nature of comprehensive tobacco legislation posed procedural and logistical difficulties for the Senate in determining how, and in what form, omnibus legislation would be reported to the full Senate. Legislation to implement the comprehensive tobacco settlement reached between state Attorneys General and the tobacco industry contained provisions that would customarily fall under the legislative jurisdiction of various Senate Committees including the Commerce, Science, and Transportation Committee, the Labor and Human Resources Committee, the Finance Committee, the Judiciary Committee, the Agriculture Committee, the Environment and Public Works Committee, and the Indian Affairs Committee. In order to ensure that a single comprehensive and bipartisan tobacco bill would be reported to the full Senate in a timely manner, the Senate Commerce Committee was selected to develop and report such a bill. Therefore, the Commerce Committee was required to address issues not otherwise within the scope of the Committee. The chairmen of the other directly relevant committees were subsequently invited to testify about their priorities for a tobacco bill before the Commerce Committee, as were other interested Senators.

To fulfill its charge of dealing with this comprehensive legislation, the Committee conducted ten hearings concerning proposed tobacco legislation. Each of those hearings is summarized below

HEARING I: JULY 29, 1997

The first full committee hearing to begin examination of the Global Settlement of Tobacco Litigation was held on July 29, 1997.

WITNESSES

Panel I

Dr. C. Everett Koop, Co-Chair, The Advisory Committee on Tobacco Policy and Public Health

Dr. David A. Kessler, Co-Chair, The Advisory Committee on Tobacco Policy and Public Health

Panel II

Hon. Hubert H. Humphrey III, Attorney General of Minnesota

Hon. Grant Woods, Attorney General of Arizona

Hon. Christine Gregoire, Attorney General of Washington
Hon. Mike Moore, Attorney General of Mississippi

PANEL I

The Co-Chairs of The Advisory Committee on Tobacco Policy and Public Health, Dr. C. Everett Koop and Dr. David A. Kessler, asked Congress to act urgently to enact legislation to protect the American people from smoking-related illnesses. They indicated there are 50 million tobacco "addicts" in this country, that each day 3,000 new children become addicted, and that one-third of them will die prematurely from smoking related disease. They also advised that the proposed tobacco settlement should be strengthened to meet public health goals, and that no special liability protections should be afforded to the industry.

PANEL II

Attorney General Hubert Humphrey III urged Congress to pass tobacco legislation. He agreed with Dr. Koop's and Dr. Kessler's proposals to strengthen the tobacco settlement and requested that Congress subpoena key tobacco documents that show that the tobacco industry has lied to Congress since the 1960s.

Attorney General Grant Woods stated that he believed that the negotiated tobacco settlement was an excellent agreement. He warned that it may not be possible to strengthen tobacco legislation due to constitutional limitations and the need for consent to waive constitutional rights.

Attorney General Christine Gregoire testified that the tobacco settlement was based on the need to prevent tobacco sales to children, and change the corporate culture of the tobacco industry to prevent tobacco advertising aimed at children.

Attorney General Mike Moore gave a background to the negotiations and purpose of the tobacco agreement. He also discussed the advertising and liability provisions of the settlement.

HEARING II: SEPTEMBER 16, 1997

The committee held its second hearing on September 16, 1997. The hearing examined the effect of advertising and marketing on children and explored the advertising restrictions included in the tobacco settlement.

WITNESSES

Panel I

Ms. Shirley Igo, Vice President For Legislation, National Parent Teacher Association

Mr. Matthew Myers, Executive Vice President & General Counsel, National Center for Tobacco Free Kids

Panel II

Dr. Joseph DiFranza, University of Massachusetts Medical Center

Dr. Alfred Munzer, Past President of the American Lung Association

Mr. D. Scott Wise, Partner, Davis, Polk & Wardwell

PANEL I

Shirley Igo, Vice President for Legislation, National Parent Teacher Association, testified that tobacco advertising is very influential in convincing children to start smoking. She also stated the National PTA supported only restrictions on advertising directed to children and youth to be sensitive to the First Amendment considerations.

Matthew Myers, Executive Vice-President for the Campaign for Tobacco-Free Kids, agreed that tobacco marketing and advertising is a major cause of increased smoking among youth. He also believed that the tobacco settlement between the attorneys general and the tobacco industry should be strengthened to restrict marketing and advertising to children and include a comprehensive program to reduce youth smoking.

PANEL II

Dr. Joseph DiFranza testified on the behalf of the non-profit organization Stop Teenage Addiction to Smoking (STAT). He said that there has been a reduction in teen smoking where there is strong enforcement of community laws that prohibit tobacco sales to children. He also alleged that the tobacco industry has played a key role in reducing the ability of communities to enforce their anti-teen smoking laws.

Dr. Alfred Munzer, Past President of the American Lung Association, testified that he did not support the proposed tobacco settlement because it failed to achieve meaningful public health protections. He also stated that the provisions of the tobacco settlement concerning tobacco advertising will not inhibit the tobacco industry's ability to appeal to teenagers.

D. Scott Wise, a partner with Davis, Polk, and Wardwell who has represented major tobacco companies, stated that provisions of the tobacco settlement concerning youth smoking were based on restrictions proposed by the U.S. Food and Drug Administration (FDA) in their rule, issued in 1996, concerning tobacco. Mr. Wise noted the agreement included every restriction the FDA proposed and added even more restrictions. He believes that these restrictions are strong enough to significantly diminish the allure and access to tobacco products by youth.

HEARING III: OCTOBER 9, 1997

The committee held its third hearing on October 9, 1997. The hearing examined the potential impact of the proposed tobacco settlement on public health.

WITNESSES

Dr. John Seffrin, CEO, American Cancer Society

Dr. Ronald M. Davis, Chair, Council on Scientific Affairs, American Medical Association

Mr. Cass Wheeler, CEO, American Heart Association

Dr. John Seffrin, the Chief Executive Officer of the American Cancer Society, stated that tobacco causes the largest number of preventable deaths in our country. It also annually costs the U.S. economy $100 billion of which $22 billion comes from taxpayers to

pay for treating smokers through Medicare, Medicaid, and VA programs. He also said that tobacco should be considered a "pediatric" disease, because ninety percent of all smokers start by age 18. He urged strong legislation to reduce the incidence of smoking and tobacco use.

Dr. Ronald M. Davis, Chair of the American Medical Association's Council on Scientific Affairs, testified that the proposed tobacco settlement is a promising beginning to meeting public health goals of reduced smoking. However, he suggested that the FDA should have more authority over tobacco products and the Look Back program (assessments on the industry for non-attainment of youth smoking reduction targets) should be redesigned to provide further incentives for the tobacco companies to reduce underage tobacco use.

M. Cass Wheeler, Chief Staff Executive Officer of the American Heart Association, agreed with earlier testimony that tobacco advertising played an important role in the increase in youth smoking. He supported measures to encourage the tobacco industry to stop marketing and promoting tobacco to children.

HEARING IV: FEBRUARY 24, 1998

At the Committee's fourth hearing, the chairmen of the five major tobacco companies testified.

WITNESSES

Mr. Geoffrey C. Bible, Chairman and CEO, Philip Morris Companies, Inc.

Mr. Nicholas G. Brooks, Chairman and CEO, Brown and Williamson Tobacco Corporation

Mr. Steven F. Goldstone, Chairman and CEO, RJR Nabisco, Inc.

Mr. Laurence A. Tisch, Co-Chairman of the Board and Co-CEO, Loews Corporation

Mr. Vincent A. Gierer, Jr., Chairman and CEO, UST Inc.

Geoffrey C. Bible, Chairman and Chief Executive Officer of the Philip Morris Companies, testified that the proposed tobacco settlement offered an opportunity for cooperation and progress in the debate over tobacco policy, and that a new era of responsible management was at the helm.

N.G. Brookes, Chairman and Chief Executive Officer of Brown and Williamson Tobacco Corporation agreed with Mr. Bible that the legislation offered an opportunity to achieve public health goals, and asked that the Committee to pursue legislation that will benefit the American people, rather than enacting legislation that would seek to punish the tobacco companies.

Steven F. Goldstone, Chairman and Chief Executive Officer of RJR Nabisco, Inc., stated that he believed the proposed settlement was an appropriate balance between the ability of the tobacco companies to sell a legal product and the country to establish a public health policy that educates people about health issues concerning tobacco products.

Laurence A. Tisch, Co-Chairman of the Board and Co-CEO, Loews Corporation, said that the tobacco settlement was a realistic plan to deal with cigarette smoking and other forms of tobacco use.

Vincent A. Gierer, Jr., Chairman and Chief Executive Officer of UST Inc., also agreed that the tobacco settlement was a comprehensive approach to resolving the different concerns about tobacco products. He warned that if the settlement was addressed in a piecemeal fashion, it might not achieve the shared goals of reducing youth access to tobacco products and achieving other public health objectives.

HEARING V: FEBRUARY 26, 1998

The committee held a fifth hearing on February 26, 1998. The hearing addressed the issue of civil liability for tobacco related harm.

WITNESSES

Panel I

Hon. Orrin Hatch, U.S. Senator, Utah

Panel II

Hon. Mike Moore, Attorney General of Mississippi
Hon. Carla Stovall, Attorney General of Kansas
Hon. Gale Norton, Attorney General of Colorado

Panel III

Mr. Stanley Chesley, Esq., Waite, Schneider, Bayless & Chesley Co., L.P.A.
Mr. Eugene Pavalon, Past President, Association of Trial Lawyers of America
Professor Kris Kobach, University of Missouri at Kansas City School of Law
Mr. Richard Scruggs, Scruggs, Millette, Lawson, Bozeman & Dent

PANEL I

Senator Orrin G. Hatch, Chairman of the Senate Committee on the Judiciary, stated his support for comprehensive tobacco legislation largely based on the proposed tobacco settlement. He warned that the advertising restrictions would violate the First Amendment unless they are based on consent. He urged the committee to find a constitutional way to obtain that consent and thus to achieve these restrictions.

PANEL II

Attorney General Mike Moore testified that the civil liability provisions play an important part in the proposed agreement as they are needed to get the tobacco companies to agree to waive their constitutional rights, among them, restrictions on their rights to advertise.

Attorney General Carla Stovall said that she felt that the benefits of the tobacco settlement outweighed the concerns about it and urged Congress to support legislation to enact the agreement.

Attorney General Gale Norton explained the provisions of the tobacco settlement concerning civil liability and related issues.

PANEL III

Stanley M. Chesley, of Waite, Schneider, Bayless & Chesley Co., L.P.A., explained that the tobacco settlement only settled state and local cases and the Castano class action. Although existing class actions would be decertified, individuals could still pursue their individual claims for smoking related injuries.

Eugene I. Pavalon, former President of the Association of Trial lawyers of America, said that the liability provisions are inadequate for those injured by tobacco companies, and urged that any legislation should include direct compensation to victims and meaningful penalties on the industry.

Professor Kris Kobach, Professor of Constitutional Law at the University of Missouri in Kansas City stated that congressional interference with the contracts between the States and their attorneys, concerning attorney's fees, would be unconstitutional and likely would be invalidated in the court if challenged.

Richard F. Scruggs, the Senior Partner in the law firm Scruggs, Millette, Lawson, Bozeman & Dent, P.A., testified that restricting class actions against the tobacco industry is a protection for individual plaintiffs because the restriction prevents the industry from collusively settling a class action and thereby evade liability to individual victims.

HEARING VI: MARCH 3, 1998

The committee held its sixth hearing on March 3, 1998. The hearing examined the advertising, marketing and labeling restrictions in the proposed tobacco settlement.

WITNESSES

Panel I

Honorable Connie Mack, U.S. Senator, Florida

Panel II

Mr. Robert Pitofsky, Chairman, Federal Trade Commission

Dr. Michael Eriksen, Director, Office on Smoking and Health, Centers for Disease Control and Prevention

Panel III

Mr. Matthew Myers, Executive V.P. & General Counsel, National Center for Tobacco Free Kids

Professor Richard Daynard, Northeastern University School of Law

Mr. David Versfelt, Esq., Donovan, Leisure, Newton & Irvine, LLP

Professor Martin Redish, Louis and Harriet Ancel Professor of Law and Public Policy, Northwestern University School of Law

PANEL I

Senator Connie Mack testified that the most effective way to improve the health of American citizens is for the Congress to pass bipartisan legislation based on a consensual agreement between the tobacco companies and the American people.

PANEL II

FTC Chairman Robert Pitofsky addressed proposed restrictions on the advertising, marketing and sale of tobacco products, as well as possible areas for FTC involvement. He also indicated an antitrust exemption was not necessary to implement proposed settlement.

Michael Eriksen, an official with the Centers for Disease Control and Prevention, discussed the problem of tobacco use by youth and ways to address it. According to Dr. Eriksen, tobacco use is the number one preventable cause of death and disease in our society. Each person who dies of tobacco-related lung cancer loses an average of 14 years from their predicted life expectancy.

PANEL III

Matthew Myers, from the Campaign for Tobacco-Free Kids, argued that congressional action is needed to insure that at least one federal agency has the authority to eliminate those forms of tobacco advertising that have the greatest impact on children. Specifically, Mr. Myers argued that it would not be difficult to amend Section 520(e) of the Food, Drug and Cosmetic Act to clarify that this section enables the Food and Drug Administration to regulate tobacco advertising.

Northeastern University School of Law Professor Richard Daynard testified that the contemplated advertising restrictions for tobacco products could be constitutionally imposed without the consent of the tobacco industry. Professor Daynard argued that Congress has the power to directly regulate the tobacco industry's commercial advertising.

The general counsel to the American Association of Advertising Agencies, David Versfelt, expressed concern that Congress might statutorily enact the unprecedented, sweeping advertising restrictions in the Proposed Settlement. Mr. Versfelt testified that such restrictions were not Constitutional and that Congressional imposition of content and format based commercial speech restrictions would also establish unfortunate precedents that go far beyond the subject of tobacco advertising.

Mr. Martin Redish, the Louis and Harriet Ancel Professor of Law and Public Policy at Northwestern University, evaluated the constitutionality of the suppression or restriction of tobacco advertising. Dr. Redish testified that, in his view, governmental restriction of tobacco advertising violates fundamental precepts underlying the First Amendment guarantee of free speech, as well as established Supreme Court doctrine concerning the protection of commercial speech.

HEARING VII: MARCH 11, 1998

The committee held its seventh hearing on March 11, 1998. At the hearing the Committee heard testimony from Senators concerning the various bills introduced concerning the tobacco settlement.

WITNESSES

Hon. Richard Lugar, U.S. Senator, Indiana
Hon. Max Baucus, U.S. Senator, Montana

Hon. Orrin G. Hatch, U.S. Senator, Utah
Hon. John H. Chaffee, U.S. Senator, Rhode Island
Hon. Kent Conrad, U.S. Senator, North Dakota

Senator Dick Lugar, Chairman of the Senate Committee on Agriculture, Nutrition and Forestry, testified that his support for tobacco legislation will be guided by three basic principles: (1) increasing the price per pack of cigarettes by at least $1.50; (2) opposing any limitation on the right of any individual or group to seek legal redress; and (3) his belief that it is simply wrong for the federal government to support tobacco farming, marketing, and warehousing.

Senator Max Baucus testified that the ultimate goals of Congress for national tobacco policy should be to: (1) protect kids from a product that is harmful to them; (2) make tobacco less available to kids; and (3) dedicate payments from the tobacco industry toward children including child care, child healthcare, education and programs to stop children from smoking).

Senator Orrin G. Hatch, Chairman of the Senate Committee on the Judiciary, testified in support of S. 1530, the Placing Restraints on Tobacco's Endangerment of Children and Teens Act (PROTECT) Act. Senator Hatch said his legislation is comprehensive and has worked through many of the tough questions associated with devising a national anti-tobacco program that would work well. He urged the Committee to use S. 1530 as a starting point in drafting legislation.

Senator John H. Chaffee, Chairman of the Senate Committee on Environment and Public Works, testified on Environmental Tobacco Smoke (ETS). According to the Senator, the ETS exposures of most concern are beyond the reach of the federal government. Those most vulnerable to ETS are children and non-smoking adults that live with smokers. ETS, better known as second-hand smoke, creates public health and policy dilemmas of its own because one cannot address ETS exposure in private homes but this is where the most significant exposures occur.

Senator Kent Conrad explained that the purpose of the bill he introduced, S. 1638, the Healthy Kids Act, is to protect children, promote the public health, help tobacco farmers, resolve Federal, State and local legal claims, invest in children and health care, and provide savings for Social Security and Medicare.

HEARING VIII: MARCH 17, 1998

The committee held its eighth hearing on March 17, 1998. The hearing addressed issues concerning tobacco and the Food and Drug Administration (FDA). The hearing also examined the regulatory issues raised by spit tobacco.

WITNESSES

Panel I

Mr. Bill Schultz, Deputy Commissioner for Policy, Food and Drug Administration

Dr. Gregory N. Connolly, Director, Massachusetts Tobacco Control Program, Massachusetts Department of Public Health

Panel II

Mr. Joe Garagiola, Former Baseball Player and anti-tobacco advocate

Mr. Richard Verheij, General Counsel, UST

PANEL I

Deputy FDA Commissioner Bill Schultz discussed three tobacco issues of concern to the FDA: (1) the Agency's tobacco program as formulated through regulation; (2) the Administration's position on tobacco legislation; and (3) some of the issues relevant to FDA's authority raised by pending bills.. Mr. Schultz emphasized that the FDA and the Administration strongly support comprehensive tobacco legislation which would significantly reduce young people's tobacco use and meet the other goals announced by the President.

Dr. Gregory N. Connolly is the Director of the Massachusetts Tobacco Control Program with the Massachusetts Department of Public Health. He testified on the health risk to consumers of spit tobacco products and efforts to develop spit tobacco cessation programs.

PANEL II

Joe Garagiola, a former baseball player and Baseball Hall of Fame member, testified on behalf of the National Spit Tobacco Education Program. Mr. Garagiola stated that spit tobacco is dangerous, addictive and potentially deadly. He discussed the use of spit tobacco in professional baseball and his campaign to stop it.

Richard H. Verheij, Executive Vice President and General Counsel of UST testified on his company's production and marketing of smokeless tobacco products. He discussed his support for the Proposed Resolution between the Attorneys General and the tobacco industry.

HEARING IX: MARCH 19, 1998

The committee held its ninth hearing on March 19, 1998. The hearing examined both how the tobacco settlement would change the price of cigarettes and the way tobacco products are sold at retail.

WITNESSES

Panel I

Mr. Raymond Scheppach, Executive Director, National Governors' Association

Mr. R. Timothy Columbus, Counsel, National Association of Convenience Stores

Panel II

Mr. Martin Feldman, Senior Analyst, Smith Barney, Inc.

PANEL I

Raymond C. Scheppach, Executive Director of the National Governors' Association, testified on the commitment of the nation's governors to reduce youth smoking and restrict access to tobacco products by underage Americans.

Washington attorney R. Timothy Columbus, testified on behalf of the National Association of Convenience Stores. Mr. Columbus told the Committee that the Association's primary concern regarding the proposed settlement are its proposed restrictions on access to, and promotion of, tobacco products in retail establishments. The Association seeks workable restrictions on tobacco access that reflect practical aspects of retailing. Mr. Columbus recommended that any regulations on the sale or advertisement of tobacco products at retail stores be equally and uniformly applied to all types of retailers that sell tobacco products.

PANEL II

Martin Feldman, equity analyst with Salomon Smith Barney, testified on the potential impact of various legislative proposals on the valuation of cigarette manufacturers. Mr. Feldman stated that the retail prices of cigarettes may experience a larger increase as a result of the tobacco settlement legislation than has been previously forecasted.

HEARING X: MARCH 23, 1998

The Committee held its tenth and final hearing on March 23, 1998. The hearing addressed issues concerning the constitutionality of certain legislative proposals, the implications of bankruptcy for creditors and future plaintiffs, and issues concerning the price of tobacco products under proposed tobacco legislation.

WITNESSES

Panel I

Hon. Jonathan Gruber, Deputy Assistant Secretary, Office of Economic Policy, Department of Treasury

Hon. Larry Summers, Deputy Secretary, Department of Treasury

Panel II

Mr. Floyd Abrams, Constitutional Lawyer, Cahil Gordon & Reindel

Mr. Scott Strand, Deputy Counsel, Office of the Attorney General, State of Minnesota

Panel III

Mr. Martin Feldman, Senior Analyst, Smith Barney, Inc.

Mr. Harvey Miller, Bankruptcy Lawyer, Weil Gotshal & Manges LLP

Mr. Harvey Rosen, Economist, Burke, Rosen & Associates

PANEL I

Treasury Deputy Secretary Lawrence Summers and Deputy Assistant Secretary Gruber testified on the Administration's budget proposal calling for a $1.10 increase in the price per pack of cigarettes. Secretary Summers also addressed concerns that comprehensive tobacco legislation, in line with the President's core principles, would impose unmanageable adjustment costs on tobacco suppliers and the tobacco industry as a whole. Secretary Summers concluded that the President's proposal would not inflict

an undue financial burden on the tobacco industry and that it would not push the industry into bankruptcy.

PANEL II

Floyd Abrams, a partner with Cahill Gordon & Reindel, testified on the First Amendment issues concerning limitations of tobacco advertising. Mr. Abrams indicated that given existing Supreme Court precedent, it is unlikely that the Food and Drug Administration's proposed regulations on advertising could survive First Amendment scrutiny. Mr. Abrams also indicated that the advertising restrictions contained in the Proposed Settlement could not be constitutionaly imposed on the tobacco companies without their consent.

Scott R. Strand, Deputy Counsel for the Minnesota State Attorney General's office, stated that Congress could impose strong restrictions on tobacco advertising without the consent of the tobacco industry. Mr. Strand also said that advertising restrictions achieved through consent agreements would not work; in part, due to the difficulty of enforcing such agreements. Mr. Strand also encouraged Congress to adopt strong youth smoking reduction standards.

PANEL III

Martin Feldman, equity analyst with Salomon Smith Barney, explained the effect of the tobacco settlement on the financial status of the tobacco companies and the prices of cigarettes.

Harvey R. Miller, Senior Partner with Weil, Gotshal & Manges LLP, Harvey S. Rosen, of Burke, Rose & Associates of Cleveland, Ohio, testified on the considerations a company undertakes when contemplating bankruptcy, the protections and procedures found in the Bankruptcy Code, and the implications of bankruptcy protection for interested parties, including those individuals with a legal claim against an entity which seeks bankruptcy protection.

SECTION-BY-SECTION ANALYSIS

Section l. Short title; table of contents

Section 1 provides that the bill may be cited as the "National Tobacco Policy and Youth Smoking Reduction Act of 1998." This section also contains the table of contents for the bill.

Section 2. Findings

Section 2 includes the findings of Congress with respect to tobacco and the need for comprehensive legislation to establish national tobacco policies to reduce youth consumption of tobacco, and to reduce the adverse public health, economic, and social impacts of tobacco use.

Section 3. Purpose

Section 3 establishes that the purposes of the Act are to confirm the authority of the Food and Drug Administration to regulate tobacco products under the Food, Drug and Cosmetic Act; to require the tobacco industry to fund tobacco regulation and other initiatives to prevent and redress the adverse economic and health impacts of tobacco use; to tighten youth access restrictions; to estab-

lish youth consumption targets and subject the industry to financial penalties for failing to meet such targets.

Section 4. Scope and Effect

Section 4 establishes that Congress does not intend the act to establish any precedent with regard to other industries, circumstances, situations or legal actions. This section also establishes that the act does not affect the authority of the Secretary of the Treasury, or state and local government with respect to the taxation of tobacco products. The Act also does not affect the authority of the Secretary of Agriculture concerning the growing, cultivation, or curing of raw tobacco.

Section 5 Non-Preemption of More Restrictive Laws

Section 5 establishes that the act does not prohibit federal, state, local or tribal governments from adopting and enforcing additional measures to restrict youth access to tobacco products, nor from adopting and/or enforcing any law, rule, regulation or other measure relating to or prohibiting the sale, distribution, possession or exposure to or use of tobacco products. Unless otherwise provided in the Act, nothing in the Act or in rules promulgated under its authority will supersede the authority of States, pursuant to State law, to expend funds provided under this Act.

Section 6 Definitions

Section 6 defines terms used in the act; including the definition of cigarette, brand, manufacturer, distributor, retailer, and tobacco product.

Section 7 Notification if youthful cigarette smoking restrictions increase youthful pipe and cigar smoking

Section requires the Secretary of Health and Human Services to notify Congress if underage use of cigars and pipe tobacco increase as a result of tightening youth access to cigarettes and spit tobacco.

Section 8 Liability limitations disappear if manufacturers challenge advertising limits

This section provides that the benefit of the annual liability cap on judgements and settlements will not apply to any tobacco manufacture which brings an action to have the advertising restrictions in the act ruled unconstitutional.

Section 9. FTC Jurisdiction Not Affected

Unless expressly provided in this Act, nothing in this Act limits or diminishes the authority of the Federal Trade Commission. Any advertising that violates this Act or the Protocol is an "unfair or deceptive act or practice" under Section 5(a) of the Federal Trade Commission Act.

Section 10. Congressional Review Provisions

Congress may review and disapprove any rule under this Act that is subject to Section 801, with the exception of the FDA's initial rule concerning tobacco as issued in 1996.

TITLE I—REGULATION OF THE TOBACCO INDUSTRY

SUBTITLE A—JURISDICTION OF FOOD AND DRUG ADMINISTRATION

I. INTRODUCTION AND SUMMARY

Title I, Subtitle A of this bill provides explicit authority to the Food and Drug Administration (FDA) to regulate tobacco products. To ensure that the August 28, 1996 regulations restricting the access to and promotion of cigarettes and smokeless tobacco to children and adolescents go into effect, section 901 deems FDA's regulations lawful and lawfully promulgated under this bill. The remainder of Subtitle A addresses the Secretary's statutory authority to regulate tobacco products. Tobacco products raise different public health issues than medical devices regulated under Chapter V of the Federal Food, Drug, and Cosmetic Act (FDCA). While maintaining to the greatest extent practical the full range of authorities that the Secretary and FDA would have exercised over these products as devices, the bill modifies and adapts certain FDCA device authorities so that they are more appropriate to address the unique problems encountered in regulating tobacco products. Therefore, the Committee believes that it is appropriate to create a separate chapter of the FDCA for the regulation of tobacco products.

New Chapter IX is created to provide for comprehensive regulation of tobacco products and incorporates almost all of the authorities available to the Secretary in regulating devices, including the authority to: (1) address the adulteration or misbranding of a product, (2) require manufacturers to register and list their products, (3) restrict the sale, distribution, and use of a product, (4) require manufacturers to comply with "good manufacturing practice" requirements, (5) require manufacturers to comply with performance standards, (6) require manufacturers of novel products to obtain premarket approval, (7) require manufacturers to notify users of unreasonable risks posed by a product, (8) require manufacturers to recall products associated with unusually serious risks, (9) require manufacturers to maintain records and make reports, and (10) require manufacturers to conduct postmarket surveillance, where appropriate. Other provisions of the bill extend to tobacco products FDA's authority to investigate and prosecute violations of the FDCA.

Some of the medical device authorities have, however, been modified to reflect the special concerns raised by the regulation of tobacco products. For example, in regulating devices under Chapter V, the Secretary must determine whether the regulatory actions taken will "provide reasonable assurance of the safety and effectiveness" of the device. Under the provisions of Chapter IX, this standard has been replaced with the requirement, to be used only for tobacco products, that the Secretary find that regulations and other requirements imposed on tobacco products "are appropriate for the protection of the public health." This change makes explicit FDA's authority to consider, among other things, the adverse consequences that could result from removal of a product that is dangerous but to which millions of Americans are addicted. In addition, section 906(d), which like all of Chapter IX does not affect other products regulated under the Act, makes explicit the Sec-

retary's authority to restrict the advertising and promotion of tobacco products as part of a regulation restricting the sale, distribution, and use of such a product. That provision also prohibits the Secretary from restricting tobacco products to prescription use. In addition, a special procedure is established for notifying Congress regarding any restriction on the sale of tobacco products in retail outlets. Because of the importance of any such decision by the Secretary, the committee strongly believes that Congress should have adequate opportunity, prior to implementation of any such restriction, to review such a decision and to enact legislation to override it. Therefore, the President must notify Congress that such a restriction has been issued and implementation of any such restriction is delayed for at least two years.

Chapter IX also omits a small number of device authorities that are unnecessary, duplicative, or not well-suited to the regulation of tobacco products. For example, Chapter IX does not require the Secretary to classify tobacco products, although it preserves the Secretary's authority to use all of the authorities available for each class (i.e., general controls, special controls, and premarket approval). Chapter IX contains no counterpart to section 516 of the FDCA, which authorizes FDA to ban devices that present "a substantial risk of illness and injury." A special procedure is established under section 907 for notifying Congress regarding the issuance of any performance standard that eliminates nicotine or specific categories of tobacco products. Because of the importance of any such decision, the committee strongly believes that Congress should have adequate opportunity, prior to implementation of any such performance standard, to review such a decision and to enact legislation to override it. Therefore, the President must notify Congress that such a performance standard has been issued and implementation of any such performance standard is delayed for at least two years. Chapter IX also omits provisions analogous to sections 502(j), 518(b), (c), 519(b), (c), (e), 520(b), (h), (j), (m), and makes small changes in a number of other provisions intended to tailor these provisions to the needs of regulating tobacco products.

Chapter IX includes certain new provisions that grant the Secretary explicit authority to undertake regulatory measures particularly relevant to tobacco regulation. For example, section 904 specifically requires manufacturers to submit to the Secretary information about (1) the ingredients, components, and substances in their products, (2) the content, delivery, and form of nicotine in their products, and (3) their research on the health, behavioral, or physiologic effects of tobacco products and their constituents, on reductions in risk associated with available technology, and on the marketing of tobacco products. Section 913 imposes certain requirements on manufacturers who wish to market "reduced risk" tobacco products.

The bill creates a separate chapter for tobacco products, and thus, expressly directs the Secretary to maintain a distinct regulatory program for tobacco products. However, the Secretary may follow precedents involving, decisions under, and interpretations of, comparable provisions governing devices under Chapter V to the extent the Secretary deems appropriate for tobacco products.

II. DEFINITIONS

Subtitle A defines "tobacco product" for purposes of the FDCA as 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). This definition potentially encompasses the full range of tobacco products marketed in the United States. As described below in section III of this report, however, the Secretary's authority to regulate tobacco products under Chapter IX is limited to those products specifically covered by regulations issued by the Secretary. Current regulations cover only cigarettes and smokeless tobacco products.

III. FDA AUTHORITY OVER TOBACCO PRODUCTS

The Committee expects that the Secretary will regulate tobacco products exclusively under Chapter IX, and any general provisions of the FDCA that encompass tobacco products, except where: (1) they are intended for diagnosis, cure, mitigation, treatment, or prevention of disease within the meaning of section 201(g)(1)(B) or (h)(2) of the FDCA, or (2) a health claim is made for them within the meaning of section 201(g)(1)(C) or (h)(3) of the FDCA. Sections 201(g)(1)(B) and are relevant portions of the definition of "drug" under the FDCA, and sections 201(h)(2) and (3) are corresponding portions of the definition of "device" under the FDCA. This provision would not limit FDA's traditional authority to regulate as a drug or device, for example, a cigarette marketed to assist smoking cessation, or to treat Parkinson's disease or depression. See, e.g., United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes, 178 F. Supp. 847, 851 (D.N.J. 1959). The term "health claim" as used in this provision is not intended to relate to, or to affect in any way, the agency's authority to regulate health claims for food.

Section 901(b) provides that Chapter IX shall apply to all tobacco products subject to 21 CFR part 897 (the regulations issued on August 28, 1996), and to any other tobacco products that the Secretary deems to be subject to Chapter IX by regulation. Cigarettes and smokeless tobacco products are currently covered by part 897, and are thus immediately subject to regulation under Chapter IX. To regulate other categories of tobacco product, the Secretary must issue regulations making them subject to Chapter IX.

As stated above, the bill incorporates the provisions of part 897 of title 21, Code of Federal Regulations, issued by the Secretary as a final rule on August 28, 1996, and therefore the Committee does not intend the Secretary to repromulgate these regulations. The bill therefore includes section 901(c), which deems the regulations lawful and lawfully enacted pursuant to the new chapter of the FDCA for tobacco products. The Secretary may choose to recodify these regulations in a different part of title 21, Code of Federal Regulations.

Section 901(d)(1) clarifies that nothing in chapter IX shall be construed to affect the regulation of drugs and devices under chapter V that are not tobacco products under the FDCA. Section 901(d)(2)

provides that chapter IX shall not apply to tobacco leaf that is not in the possession of the manufacturer, or to producers of tobacco leaf, including tobacco growers, tobacco warehouses, and tobacco grower cooperatives, and that FDA employees may not enter onto a farm owned by a producer of tobacco leaf without the producer's written consent. However, if the producer of tobacco leaf is also a tobacco product manufacturer or within the control of a manufacturer, then the grower will be subject to this chapter as a manufacturer. The bill also provides that chapter IX may not be construed to grant the Secretary authority to promulgate regulations affecting the production of tobacco leaf or a producer, other than activities by a manufacturer affecting production. This provision does not alter the Secretary's authority under the FDCA over tobacco manufacturers, including the Secretary's ability, through performance standards and other statutory authorities, to require modifications to tobacco products.

IV. STANDARD OF REVIEW OF CERTAIN REGULATORY ACTIONS UNDER CHAPTER IX

In regulating devices, the Secretary may undertake certain regulatory actions only if the Secretary finds that the action will "provide reasonable assurance of the safety and effectiveness" of the device. Meeting these standards for tobacco products requires taking into account factors not ordinarily considered when regulating devices. For example, FDA in developing the tobacco regulations acknowledged that in imposing restrictions on the availability of tobacco products, it is necessary to consider such factors as the development of a black market, or the risk to addicted users of precipitous withdrawal. Similarly, in allowing the sale of novel tobacco products likely to be perceived as safer than conventional tobacco products, it may be appropriate to consider the likelihood that such products will encourage more young people to use tobacco or discourage current users from quitting. The Committee believes that such factors can more readily be taken into consideration under the standard adopted in chapter IX.

In addition, reaching the conclusion that a particular regulatory measure will provide a reasonable assurance of the safety and effectiveness of a tobacco product may create controversy. Therefore, under the provisions of Chapter IX, wherever a reasonable assurance of safety and effectiveness was required to take action under the device authorities, this standard has been replaced with the requirement that the Secretary find that regulations imposed on a tobacco product "are appropriate for the protection of the public health." In making this finding, the Secretary is directed to consider the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account the increased or decreased likelihood that (1) existing users of tobacco products will stop using such products, and (2) those who do not use tobacco products will initiate use. This change clarifies that the Secretary need not find that a regulatory measure provides for the absolute safety of tobacco products, and that the Secretary may weigh a variety of consequences resulting from possible new regulations on tobacco products, including the use of contraband products and the development of black markets, and may consider the ef-

fects of the regulation on both users and nonusers of the products. The committee does not intend that this standard be applied to any other product regulated under the Act.

V. THE PROVISIONS OF CHAPTER IX

Section 902. Adulteration

The bill incorporates adulteration provisions that track adulteration provisions for devices that are relevant to the regulation of tobacco products under chapter IX (section 501(a)(1), (a)(2)(A), (a)(3), (e), (f), (h), and (I)). Minor modifications were made to conform the provisions to the requirements under the relevant chapter IX provisions. In addition, section 902(a)(1) includes products that are "otherwise contaminated by any poisonous or deleterious substance which may render the product injurious to health" to make clear that a tobacco product that contains contamination by something other than a filthy, putrid, or decomposed substance is adulterated under this section.

Section 903. Misbranding

The bill incorporates misbranding provisions that track misbranding provisions for devices that are relevant to the regulation of tobacco products under chapter IX (section 502(a), (b), (c), (e), (f), (o), (q), (r), (s), (t)). Minor modifications were made to conform the provisions to the requirements under the relevant chapter IX provisions. In addition, section 903(a)(4), which authorizes the Secretary to specify by regulation the established name of a tobacco product and requires the established name to appear on the product's label, employs simplified language that is consistent with the regulation at part 897 establishing the established names of tobacco products subject to the provisions of part 897. Section 903(a)(5), which authorizes the Secretary to issue regulations requiring adequate directions for use and adequate warnings against use by children, has also been simplified. Sections 903(a)(7) and 903(a)(8) apply to all tobacco products, and are not limited to tobacco products that are subject to regulations promulgated under section 906(d). Section 903(a)(8), which is based on section 502(r), deems tobacco product advertising misbranded unless it contains, among other items, "a brief statement of the uses of the tobacco product." Section 903(b) authorizes the Secretary to require by regulation the prior approval of statements made on the label of a tobacco product, and explicitly states that no regulation issued under this subsection may require the prior approval by the Secretary of the content of any advertisement. The remainder of section 903(b) tracks section 502(r).

Section 904. Submission of Health Information to the Secretary

The bill requires each manufacturer or importer of tobacco products, or their agents, to submit to the Secretary, within 6 months of the date of enactment and annually thereafter, information concerning their products and all documents related to research conducted on, or involving the use of, those products. Similar information must be submitted at least 90 days before the marketing of a new product not on the market as of the date of enactment. A manufacturer must also notify the Secretary within 60 days of the time a manufacturer adds a new additive, modifies the amount of an ex-

isting additive or of the nicotine content, delivery, or form, or eliminates an additive. The purpose of this provision is to clarify the Secretary's authority to obtain information useful in assessing the health risks of tobacco products, including their addictiveness, and in understanding how these products are being marketed. This section is intended to be in addition to, and separate from, the requirements for ingredient disclosure under section 7 of the Federal Cigarette and Labeling Act (15 U.S.C. 1335a).

Section 905. Registration of producers of tobacco products

Subsections (a) - (g) of section 905 track subsections (a) - (f), (h) of section 510. Minor changes were made to conform the provisions to the requirements in chapter IX.

Report preceding introduction into interstate commerce of certain tobacco products: Sections 905(j) and 910 adopt the substantial equivalence provisions of sections 510(k), 513(I) and 515(b), with certain modifications. Section 905(j) is analogous to section 510(k), which requires a manufacturer of a new device to notify the Secretary at least 90 days before beginning to market the new device and to state the basis for the manufacturer's determination that the new device is substantially equivalent to an already marketed device. Section 905(j) differs in two respects from section 510(k). First, section 905(j) requires that the already-marketed tobacco product have been commercially marketed as of August 11, 1995, the date of the issuance of FDA's proposed tobacco regulations. Test marketing before that date is not sufficient to satisfy this requirement. Within six months after enactment of the bill, persons who, before enactment of this bill, introduced into or delivered for introduction into interstate commerce for commercial distribution a tobacco product intended for human use that was not commercially marketed (other than for test marketing) in the United States as of August 11, 1995, are required to submit a report under this subsection to the Secretary if that tobacco product continues to be marketed in the United States. Second, section 905(j) requires that the Secretary issue regulations defining the applicability of that section. The Committee is aware that FDA's regulations under Part 897 do not appear to contemplate 510(k) submissions, at least for minor changes to existing tobacco products. Nothing in the bill restricts the Secretary's discretion to determine when and for what types of new products a 905(j) submission might be appropriate. The Committee expects that the Secretary will promptly issue guidance to the industry on when such submissions are needed for products introduced between August 11, 1995, and the date of enactment of this bill. Section 910, which governs premarket review and is discussed below, defines "substantial equivalence."

Section 906. General provisions respecting control of tobacco products

Section 906 addresses general issues respecting control of tobacco products. These provisions incorporate subsections of section 520 that are appropriate for the regulation of tobacco products. Subsections (a), (b), (c), and (g) of section 906, which relate to (1) the applicability of particular tobacco product requirements that are inconsistent with requirements imposed under section 906(d), 907, or 910, (2) notices and findings, (3) trade secret information, and (4)

research and development, track the parallel provisions in section 520 (subsections (a), (b), (c), and (k)).

Restrictions: Section 906(d) is the authority that parallels section 520(e), which is the statutory basis for the regulations restricting the sale and distribution of cigarettes and smokeless tobacco codified in part 897 of title 21, Code of Federal Regulations. Subsection (d) clarifies that the Secretary may by regulation require that a tobacco product be restricted to sale, distribution, or use upon such conditions, 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 bill includes factors that are to be taken into account in making a finding as to whether the restriction is appropriate for the protection of the public health. Under the bill, the Secretary may not 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. Because of the importance of any decision by the Secretary to restrict the sale of any class of tobacco products on the market on the date of enactment of this bill to specific categories of retail outlets, it is appropriate for Congress to have the opportunity to review such a decision and enact legislation to override it. Therefore, any such restriction may not take effect before a date that is two years after the President notifies Congress that a final regulation imposing the restriction has been issued.

Good manufacturing practice requirements: Section 906(e) authorizes the Secretary to promulgate 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, storage, and installation 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. This provision tracks section 520(f), the device provision for good manufacturing practice requirements. The bill makes explicit that the Secretary has the authority to grant either temporary or permanent exemptions or variances from a requirement. As discussed in the context of section 915, the bill establishes a single tobacco product advisory committee to perform the duties assigned to separate advisory committees that are established under various provisions in device law, including 520(f). Thus, the advisory committee established under section 915 will be afforded an opportunity to submit recommendations with respect to regulations proposed to be promulgated under this subsection. In addition, the Secretary may refer petitions for exemptions or variances to the advisory committee for recommendation.

Investigational use exemption: Section 906(f) provides the Secretary with authority to exempt tobacco products intended for investigational use from some or all of the provisions of chapter IX under such conditions as the Secretary may prescribe by regulation. Because of the unique circumstances under which a tobacco product would likely be intended for investigational use, the bill allows the Secretary broad discretion to develop regulations appropriate for the investigational use of tobacco products.

Section 907. Performance standards

The bill authorizes the Secretary to promulgate performance standards if the Secretary determines that a standard is appropriate for protection of the public health. This authority is the same as that in section 514, but makes explicit the Secretary's existing authority to reduce or eliminate nicotine or other harmful components pursuant to a performance standard. Because of the importance of any decision by the Secretary to eliminate all cigarettes, all smokeless tobacco products, or any similar class of tobacco products, or to require the reduction of nicotine yields to of a tobacco product to zero, it is appropriate for Congress to have the opportunity to review such a decision and enact legislation to override it. Therefore, any such standard may not take effect before a date that is two years after the President notifies Congress that a final regulation imposing the restriction has been issued. As noted above, the bill establishes a single tobacco product advisory committee to perform the duties assigned to separate advisory committees that are established under various provisions in device law, including section 514. The bill authorizes the Secretary to refer proposed regulations respecting performance standards to the advisory committee established under section 915 for a report and recommendation with respect to matters involved in the proposed regulation that require the exercise of scientific judgement.

Section 908. Notification and other remedies

The bill contains provisions that adopt the notification requirements and certain other remedies of section 518. Section 908(a), which permits the Secretary to require notification to users and other appropriate persons if such notification is necessary to eliminate an unreasonable risk of substantial harm to the public health, is the same as section 518(a). Likewise, section 908(b) parallels section 518(d), which makes clear that compliance with a notification order does not relieve persons from liability under Federal or State law. The bill does not incorporate the repair and reimbursement provisions of 518(b) and " because they are not required for the regulation of tobacco products. Section 908" provides the Secretary with the authority to issue cease and desist orders and to order recalls of particular tobacco products where the Secretary finds that a tobacco product contains a manufacturing or other defect that is not ordinarily contained in tobacco products on the market and would cause serious, adverse health consequences or death. The procedures of subsection (e) are the same as in section 518(e), the parallel provision for devices.

Section 909. Records and reports

The bill incorporates subsections (a) and (f) of section 519, but adopts a different threshold for requiring reports to be submitted under subsection (a). The bill authorizes the Secretary to require a report from a manufacturer or importer who 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. The provisions of 519 dealing with user

facilities and device tracking have been omitted because they are not suited to the needs of regulating tobacco products.

Section 910. Premarket review

Section 910 provides for premarket review of new tobacco products that are not substantially equivalent to products on the market as of August 11, 1995. This section provides the Secretary with authority to obtain needed data on the risks of novel tobacco products, and to assure that such products do not introduce more risks than conventional tobacco products. The provisions of section 910 are similar to those of section 515, with the following modifications: (1) full reports must be provided on the health risks of the product, rather than on safety and effectiveness; (2) the Secretary shall deny approval of the application if the Secretary finds that there is a lack of a showing that permitting the product to be marketed would be appropriate for the public health, rather than a lack of a showing of safety and effectiveness; (3) the opportunity for administrative review of an approval or denial of an application has been eliminated; (4) the standard for the evidence needed to support an application has been modified slightly to clarify that well-controlled investigations will be required only when necessary; and (5) the provisions related to product development protocols have been eliminated.

The bill provides that an approval of an application for premarket approval is not required for a tobacco product subject to section 910(a)(1) introduced into or delivered for introduction into interstate commerce for commercial distribution (other than for test marketing) in the United States between August 11, 1995, and the date of enactment of this bill if a report has been submitted pursuant to section 905(j) within six months of the enactment of this bill until the Secretary issues an order that requires premarket approval.

Definition of substantial equivalence: Subsection (a)(2) includes provisions, analogous to section 513(I) in the device provisions, that define "substantial equivalence" for purposes of this section and section 905(j). The definition in 910(a)(2) is largely the same as in section 513(I) with a few modifications. The principal changes are: (1) the standard for a finding by the Secretary that a product with different characteristics than an already marketed (predicate) product does not require premarket review is whether the information submitted by the manufacturer demonstrates that premarket review would not be appropriate because the new product does not raise different public health questions than the predicate product; (2) the term "characteristics" means the materials, ingredients, design, composition, heating source, or other features of a tobacco product; and (3) the summary of information required under 910(a)(3)(A) must cover "any health information related to the tobacco product" rather than safety and effectiveness information.

Section 911. Judicial review

The bill includes procedures for judicial review of certain actions under chapter IX that are the same as section 517. The bill also incorporates the requirement of section 517 that a regulation or order issued under certain sections of chapter IX must include a

statement of the reasons for its issuance and the basis in whatever proceedings that led to its issuance, for its issuance.

Section 912. Postmarket surveillance

The bill grants the Secretary discretion to require a manufacturer to conduct postmarket surveillance of a tobacco product if the Secretary determines that such surveillance is necessary to protect the public health or to provide information regarding the health risks and other safety issues involving the tobacco product.

Section 913. Reduced risk tobacco products

The bill contains a section not in device law that permits the Secretary to designate a tobacco product as a "reduced risk tobacco product" if the Secretary finds, based on an application by the manufacturer or other responsible person that includes data from studies as specified in the bill and as required by the Secretary, the product will significantly reduce harm to individuals caused by a tobacco product and is otherwise appropriate to protect the public health based on an application by the manufacturer or other responsible person. A tobacco product may be marketed as a "reduced risk tobacco product" only if the product is so designated by the Secretary, bears a label prescribed by the Secretary concerning the product's contribution to reducing harm to health, and complies with requirements prescribed by the Secretary relating to advertising, marketing, and other provisions of chapter IX. The Secretary may revoke such designation at any time after providing an opportunity for an informal hearing. The bill also provides that a manufacturer of a tobacco product shall provide written notice to the Secretary upon the development or acquisition of any technology that would reduce the risk of such products to the health of the user for which the manufacturer is not seeking designation as a "reduced risk tobacco product" under this section.

Section 914. Preservation of State and local authority

The bill includes provisions regarding state and local requirements affecting tobacco products that relate to matters under chapter IX. Section 914 incorporates portions of section 521, which relates to state and local requirements respecting devices. Preemption of state and local requirements affecting tobacco products under section 914 is more limited than under the device section. State or local requirements that are different from, or in addition to, any requirement applicable under chapter IX relating to performance standards, premarket approval, adulteration, misbranding, registration, reporting, good manufacturing standards, or reduced risk products, are preempted. As is the case in section 521, state or political subdivisions may apply for a waiver of preemption from the Secretary. The procedures are the same as in section 521. State and local 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, that are in addition to, or more stringent than, requirements under chapter IX are not preempted by the FDCA.

The bill makes clear that except as expressly provided in section 914, nothing shall in the FDCA shall be construed as prohibiting a State or political subdivision from adopting or enforcing a requirement applicable to a tobacco product that is in addition to, or

more stringent than requirements established under chapter IX. The bill provides that where a requirement of a State or political subdivision is more stringent than a requirement established under chapter IX, the requirement of the State or political subdivision shall apply. The bill also clarifies that no provisions of chapter IX relating to tobacco products shall be construed to modify or otherwise affect any action or the liability of any person under the product liability laws of any State.

Section 915. Tobacco Product Scientific Advisory Committee

Under the bill, the Secretary will establish a tobacco product scientific advisory committee. Several device sections that are incorporated into chapter IX include provisions that require the Secretary to establish an advisory committee for purposes of specific duties under each section. The approach used in chapter V, had it been adopted in chapter IX for tobacco products, would have required at least three separate advisory committees. The Committee has instead provided for a single tobacco product advisory committee to perform the responsibilities specified in sections 906(g), 907, and 910. In addition, the advisory committee will provide advice, information, and recommendations to the Secretary on the effects of the alteration of the nicotine yield from tobacco products; on whether there is a threshold level below which nicotine yields do not produce dependence on the tobacco product involved; and on other safety, dependence, or health issues relating to tobacco products as requested by the Secretary.

Section 916. Equal treatment of retail outlets

The bill provides that 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.

VI. SECTION 102. CONFORMING AND OTHER AMENDMENTS TO THE GENERAL PROVISIONS OF THE FFDCA

Chapter III of the FDCA, which contains prohibited acts and penalties, provides the mechanisms and remedies for enforcing the various requirements in the product-specific chapters. Chapter VII includes general administrative provisions for regulations and hearings, examinations and investigations, records of intestate commerce, inspections, publicity, the treatment of confidential information, and a presumption of interstate commerce. Chapter VIII pertains to imports and exports. Chapter X, as redesignated by this bill, contains miscellaneous sections. The basic approach of the bill is to expressly include "tobacco product" wherever "device" appeared in these provisions. In a few instances, new provisions based on provisions applicable to devices were added. The intent is to ensure that the full range of compliance, enforcement, and other general authorities available to the Secretary for devices continue when tobacco products are regulated pursuant to chapter IX.

EXPORTS

The amendments to sections 801(e) and 802, which include the addition of a new paragraph (4) to section 801(e) and a new para-

graph (3) to section 802(a), impose the same requirements for the export of tobacco products that do not meet the requirements of the FDCA that apply to devices.

Sections 801(e)(4) and 802 apply to tobacco products that do not comply with performance standards promulgated by the Secretary under section 907, do not comply with the premarket review requirements in section 910, if applicable, or are exempt from sections 907 or 910 pursuant to regulations promulgated under section 906(f). Tobacco products that comply with these requirements, but violate other provisions of the FDCA may be exported if they comply with the basic export requirements in section 801(e)(1).

The new section 801(e)(4) tracks the requirements of section 801(e)(2), which applies to certain device exports. Similarly, new paragraph (3) of section 802(a) parallels paragraph (3), which lists the statutory categories of devices to which section 802 applies.

Some concerns were raised in the Committee regarding the terms "approval of the country to which it is intended for export" and "valid marketing authorization" which appear in sections 801(e)(4) and 802, respectively. These terms apply to device exports in current law. Many foreign countries do not have affirmative approval systems for medical devices and others do not have medical device laws. FDA interprets the term "approval of the country to which it is intended for export" in section 801(e)(2) to mean that the importing country must approve of the importation of the device. This is frequently established through a letter to FDA from the relevant authority in that country indicating that the country will permit or does not object to the importation of the device. With respect to the phrase "valid marketing authorization" in section 802(b), in those countries in which the regulatory systems permit marketing of a device without an affirmative act or decision by the government, FDA considers the device to have "marketing authorization" if the country does not object to the product's marketing. These workable and effective approaches to the language of sections 801(e) and 802(b) are appropriate for tobacco product exports as well.

Thus, under section 802, a tobacco product that violates a performance standard promulgated under section 907, such as one prohibiting certain ingredients, could be exported to any country in which it can be legally marketed if at least one country "listed" in section 802(b)(1)(A) permits its sale, and the requirements of section 802(f) are met. This approach is consistent with FDA's application of section 802(b) to devices.

SUBTITLE B—ADVERTISING

Section 121. Advertising provisions in protocol

Section 121 indicates the advertising limitations the protocol must contain and that the tobacco product manufacturers must commit to observe.

Section 122. Tobacco product labeling and advertising

Section 122 identifies the various requirements that would be contained in the protocol. Under the protocol no tobacco product could be sold or distributed in the United States unless the numerous advertising and labeling requirements are met. Those limitations are the same as those contained in the agreement reached on

June 20, 1997 with the addition of animal figures and color advertising on the back of all magazines.

Section 123. Point-of-sale restrictions

Section 123 would require that the protocol contain various limitations on the use of point-of-sale advertising.

TITLE II—REDUCTIONS IN UNDERAGE TOBACCO USE

Section 201. Goals for reducing underage tobacco use

Section 201 requires the Secretary, in cooperation with state, local and tribal authorities, to take all actions under this act necessary to achieve prescribed reductions in youth usage of cigarettes and spit tobacco.

These reductions must be made from a baseline percentage of youth tobacco usage established by a comprehensive study conducted at the University of Michigan in 1995. This model identified the number of youth (age 13-17) who use tobacco daily and calculated the percentage of such tobacco users in relation to the total population in that age bracket.

This section requires that in years 3 and 4 after the date of enactment of this Act, the incidence of youth cigarette smoking among the underage population (age 13 to 17) be reduced by at least 15 percent of the baseline percentage; at least a 30 percent reduction from the 1995 baseline percentage in years 5 and 6; at least a 50 percent reduction from the baseline percentage for years 7, 8, and 9; and for year 10 and beyond a 60 percent reduction from the baseline percentage is required.

This section also sets targets for youth consumption reductions for smokeless (spit) tobacco. For year 3 and 4, a 12.5 percent reduction in youth consumption of smokeless or spit tobacco from the 1995 baseline percentage is required. For years 5 and 6, a 25 percent reduction from the 1995 baseline percentage is required. For years 7, 8, and 9 a 35 percent reduction from the 1995 baseline percentage is required. For year 10 and thereafter a 45 percent reduction from the 1995 baseline percentage is required.

Section 202. Look-back assessment

Section 202 sets forth: how the baseline of youth tobacco use is established, how non-attainment of youth tobacco targets is determined and, how financial assessments would be imposed on the industry for falling to meet youth tobacco use reduction targets.Subsection (a) calls on the Secretary to conduct annually a survey using the University of Michigan survey model or some other more accurate measurement method at the Secretary's discretion. Using the selected survey model, the Secretary shall calculate the incidence of underage tobacco use and measure the percentage reduction from the 1995 percentage baseline established in the University of Michigan study.

Subsection (b) calls on the Secretary to impose financial penalties for each percentage point that youth consumptions reductions fall short of the targets established in Section 201.

The financial penalties for cigarettes are as follows: from one to five percentage points short of the youth tobacco usage reduction goal, the industry must pay $80 million per point; from six to nine

points short, the industry must pay $160 million per point; from 10 or more points short, the industry must pay $240 million per point.

For instance, if in year five the incidence of youth tobacco usage falls by only 25 percent, rather than the required 30 percent, the industry would be assessed a penalty of $400 million ($80 million multiplied by each percentage point missed, in this case five). If youth tobacco usage falls by only 23 percent (or 7 points short of target), the industry would be assessed the $400 million for points 1-5, and an additional $320 million ($160 million multiplied by two for points six and seven) for a total penalty of $720 million.

The financial penalties for smokeless tobacco are $8 million per point for percentage points one through 5; $16 million per point for percentage points 5 through 10; and, $24 million per point beyond 10 percentage points.

The Committee believes that the severity of the penalty should increase with the severity of the non-attainment. Accordingly, for non-attainment of between 5 and 10 percentage points, the penalty is doubled from $80 million to $160 million per point; and for non-attainment of more than ten points, the penalty is tripled from $80 million to $240 million per point.

The financial penalties are assessed and calculated in the same manner for cigarettes and spit tobacco, although the penalties for smokeless are different from those for cigarettes.

Subsection (b)(3) establishes an annual cap on penalties of $3.5 billion. Financial penalties assessed under this Title shall not be tax deductible. The June 20th agreement capped penalties at $2 billion per year and provided that those penalties would be tax deductible. Furthermore, when the $3.5 billion annual cap under S. 1415 is reached, the industry and individual tobacco manufacturers may also lose the liability cap provided in Title VII.

Subsection (b)(4) provides that if the industry fails to attain the youth smoking reduction target in any year by more than 20 points, the Secretary of Health and Human Services shall determine which manufacturers are responsible for the industry failing to meet the target and shall take action to remove the liability limitations provided in Title VII from such manufacturer or manufacturers.

Subsection (c) provides that each manufacturer shall be jointly and severally liable for the payment. Under this provision, the Secretary may receive payment from any or all of the manufacturers. The manufacturers would then have the right to seek compensation from each other for equitable payment of industry penalties. This provision serves as a major incentive for individual companies to achieve reduction targets, and to hold non-performing companies individually liable.

Subsection (c)(4) provides a de-minimis exemption for payment of penalties to any manufacturer with less than one percent of domestic, unless such manufacturers product is used predominantly by underage users.

Subsection (f) provides that monetary penalty payments are non-tax deductible as ordinary and necessary business expenses.

Section 203. Substantial non-attainment of required reductions

This section provides for the procedures by which the Secretary of Health and Human Services would seek to remove the civil liability apportionment cap of any company that exceeds its non-attainment of the youth reduction target by greater than 20 points. The court of jurisdiction shall determine whether the preponderance of evidence shows that the manufacturer failed to comply with this act, or took any material action to undermine achievement of the youth tobacco use reduction goal.

The subsection provides that any loss of liability limitation under Title VII of this act shall be in effect the later of either two years, or until the manufacturer is in compliance with the Act; has ceased taking material actions to undermine achievement of the reduction target; and has pursued reasonable additional measures to achieve youth tobacco use targets.

Section 204. Definitions

Section 204 sets forth definitions of terms used in subtitle A of title II.

SUBTITLE B—STATE EMFORCEMENT INCENTIVES

Section 211. Compliance bonus fund

Section 211 establishes within the National Tobacco Settlement Trust Fund a separate account called the Compliance Bonus Account for States and Retailers.

Section 212. Block grants

The Secretary would award block grants each year to states where "fewer than 5 percent of all individuals under 18 years of age who attempt to purchase tobacco products in the State" are successful such purchase.

Section 213. State enforcement incentives

This section sets out requirements for State eligibility for grants authorized under Section 212, including state enforcement of state law requiring a minimum age of 18 years for the legal purchase of tobacco products, and the conduct of random testing of retail outlets to enforce compliance with youth access requirements. The FDA's youth access requirements require retailers to check the photo ID of customers under the age of 27 who are seeking to buy cigarettes or smokeless tobacco. States are required to send the results of their tobacco compliance checks to the FDA.

A state is deemed in non-compliance with this section if such state has not complied with the minimum number of random, unannounced inspections and other minimum guidelines established in this title. Likewise a state is deemed in non-compliance if the state inspections find that the retail outlets in such state do not achieve the following compliance targets with the applicable youth access restriction: 75 percent compliance in years 5 and 6 after enactment; at least 85 percent compliance in years 8, 9, and 10; at least 90 percent compliance in year 11 and every year thereafter.

The Secretary shall establish a reduction in the Section 1921 amount for non-compliance with this Section.

SUBTITLE C—OTHER PROGRAMS

Section 221. National smoking cessation program

This section authorizes the Secretary to award grants to public and nonprofit entities, and individuals for smoking cessation purposes. The creation of a national smoking cessation program is called for under the June 20th agreement. Funds to these entities shall be used to establish and administer approved tobacco product use cessation programs. The funds or vouchers received by individuals are intended to help citizens enroll in a program to permanently help them stop using cigarettes or other tobacco product. The Secretary will issue regulations for approved tobacco product cessation programs and products, based on the best scientific information available.

Approximately 48 million Americans currently smoke cigarettes, and most smokers are either actively trying to quit or want to quit. While prevention programs can prevent many young people from ever becoming addicted to nicotine, some will succumb and ten to twenty million current smokers will die from tobacco-related diseases unless they have access to treatment for tobacco addiction.

Although it is difficult to quit tobacco use because of the addictive nature of the product, quitting results in significant and immediate health benefits both for healthy people as well as for those suffering from tobacco-related diseases. For those who quit smoking fifteen years ago, for example, the risk of death today is similar to the risk for people who have never smoked at all. In addition, the health benefits of quitting tobacco are significant for the unborn children of pregnant women and for children and adults exposed to environmental tobacco smoke.

The Committee finds that tobacco use treatment will reduce the human toll of tobacco and is cost effective. Compared to the estimated $60 billion in direct medical care spent annually on smoking-related illnesses and another $47 billion accounted for lost productivity and forfeited earnings caused by smoking- related disabilities, the average estimated per smoker cost for smoking cessation is $165. The cost of each intervention varies according to the amount of counseling, whether and which pharmaceutical adjuncts are offered, and effectiveness of the intervention. For every dollar invested in a smoking cessation program for pregnant women, an estimated $6 is saved in neonatal intensive care costs and the long-term care associated with low birth weight.

However, a number of barriers impede the delivery of effective tobacco use cessation services.

Clinicians do not consistently assess whether their patients use tobacco, nor do they offer smoking cessation treatment to every smoker at every office visit. Evidence shows that 70 percent of U.S. smokers see their physician each year, and 60 percent of the U.S. population five years of age and older is seen by a dentist, giving physicians and dentists considerable access to smokers. If only half of all the U.S. physicians and dentists gave brief advice to their patients and 10 percent of them were successful in quitting, there would be nearly 2 million new nonsmokers in the U.S. each year.

Inadequate training, lack of time and lack of reimbursement for services have made it difficult for physicians and other health care

professionals to provide adequate tobacco cessation counseling and treatment.

Surveys indicate that tobacco cessation therapy is not consistently provided as paid services for subscribers of health insurance packages despite the fact that tobacco use cessation is considered a highly cost effective service. One survey demonstrated that as few as 11 percent of health insurance carriers provide coverage for treatment of nicotine addiction; another survey of 105 health maintenance organizations found that few knew about the prevalence of smoking within their membership. In addition, a 1994 study of California health insurance plans found that only two percent of the 48 insurance companies sold any policies that covered smoking cessation treatment. Even Medicare and Medicaid do not routinely cover smoking cessation services.

Tobacco users of low socioeconomic status tend to be under served by tobacco use cessation programs. They may be less likely to have health insurance; they may be unable to afford over-the-counter cessation products; or they may live in areas where these products are less easily obtainable and cessation services less accessible.

When financial barriers are removed, participation increases. For example, when Group Health Cooperative of Puget Sound included smoking cessation as a covered benefit, its program participation jumped ten-fold, from 175 participants to over 2,000 in the first year. In groups with a $42 co-payment, about 30 percent of registered participants did not participate. By contrast, only one percent of those with no co-payment do not participate after registering.

The Committee intends its bill to establish a national comprehensive tobacco use treatment program which includes: grants to states and localities; support of federal programs providing health services to low-income Americans, training of health care professionals, and other appropriate initiatives to fulfill the purposes of this section.

Finally, the Committee recognizes the tobacco use treatment methods as outlined in the 1996 Agency for Health Care Policy and Research (AHCPR) Clinical Practice Guideline on Smoking Cessation, and recommends that grant recipients who develop and administer such programs mirror these and/or other similar evidence based guidelines. AHCPR's cessation guidelines recommend that clinicians record the tobacco-use status of every patient and offer smoking cessation treatment to every smoker at every office visit. Any national cessation effort must ensure that health care systems are doing everything they can to identify and intervene with tobacco users. The Committee expects AHCPR to periodically update its guidelines as new research becomes available regarding tobacco use treatment methods. Furthermore, the Committee believes that dissemination of the guidelines to clinicians and other health professionals is essential.

Section 222. National tobacco-free public education program

Section 222 of the bill reported by the Committee would establish an independent board to enter into contracts with or award grants to both private and public entities to carry out public informational and educational activities designed to reduce the use of tobacco.

The creation of the National Tobacco Free Public Education Program is called for under the June 20th agreement. The Committee intends for this program to be multifaceted, but the primary focus should be on counter-advertising, and the programs should serve as a complement to the community based education programs outlined above.

The Committee has directed that the programs in this section be established because it believes they are necessary to offset the extensive marketing efforts of the industry. The tobacco industry spends over five billion dollars a year marketing and advertising its products. A 1998 study in the Journal of the American Medical Association provided evidence that tobacco industry advertising and promotional activities are causally related to the onset of smoking. In addition, a 1995 article in the Journal of the National Cancer Institute found that tobacco marketing has a greater influence than exposure to parents or peers who smoke in prompting children to take up smoking, and other studies have shown the vast majority of young smokers, unlike adults, prefer one of the most heavily advertised brands of cigarettes. In addition, recently released internal tobacco industry documents indicate a deliberate strategy by the tobacco industry to attract children. Research also shows that anti-tobacco advertisements are effective in reducing tobacco consumption. The 1994 Surgeon General's Report indicates that mass media are particularly appropriate channels for tobacco education among young people who are heavily exposed to and often greatly interested in the media. A coordinated national campaign can be quite effective, the Committee believes, in discouraging the use of tobacco products and inducing smokers to quit using tobacco products. The Committee intends for this section to provide for a national media campaign but to also provide for assistance to state and local efforts to discourage smoking and tobacco use. The Committee believes that while it is critical to have a national effort, local priorities and unique circumstances such as high rates of smokeless tobacco product use or particularly high rates among specific population groups must also be addressed.

At present, there is no national anti-tobacco public education campaign to counter the pro-tobacco imagery presented to both adults and children by tobacco industry marketing efforts. Several states (e.g., California, Arizona, and Massachusetts) have developed programs that have been shown to be effective, and several more have recently received funds for short term programs through settlements of lawsuits (Mississippi, Florida, Texas), but relatively few states have the resources to undertake the type of sustained, long term extensive public education and counter-advertising efforts that are necessary. In part this is due to the high cost of developing these programs and purchasing media. The federal approach outlined in this section will address this critical need.

These programs are to be media- and nonmedia-based. Paid mass media is an essential component of any effective public education effort. According to various studies, paid media is most effective when it is utilized in conjunction with other approaches. This section requires a multidisciplinary effort. Mass media prevention efforts should be coordinated with community and school-based prevention programs as well as clinical interventions. In addition, the

programs must address in a culturally appropriate way high-risk and special populations, especially because these groups have often been the target of marketing and advertising efforts directed specifically to them.

The Committee notes that it is essential that the advertising provided under this section be undertaken free from any connection to or influence by the tobacco industry, and so directs the Secretary to ensure that any resources and decision making utilized to carry out this section are unencumbered by any such connections or influence. The Committee believes that the independent board established in this section will allow for the creation of the most effective programs and will provide for the necessary flexibility to ensure that the needs of local communities are met. In addition, an independent board that includes experts in advertising, marketing, public health, adolescent psychology and education that are not in any affiliated with the tobacco industry will ensure that the programs provided for under this section are effective.

Section 223. National community action program

Section 223 of the bill reported by the Committee authorizes the establishment of a grant program to assist local communities in their efforts to educate the community and young people about the dangers of tobacco and ways to reduce tobacco use and to assist in encouraging the reduction of tobacco use. The creation of a National Community Action Program is called for under the June 20 agreement. The Committee regards community based prevention and education programs including school based programs to be critical aspects of a national tobacco control strategy and essential to discouraging tobacco use and reversing the upward trends in youth tobacco use.

Research demonstrates that well-designed, well-implemented school-based programs to prevent tobacco are effective and provide education during the years when the risk of becoming addicted to tobacco is greatest. The 1994 Surgeon General's Report, Preventing Tobacco Use Among Young People, indicates that school-based smoking prevention programs that identify social influences to smoke and teach skills to resist those influences have demonstrated consistent and significant reductions in adolescent smoking. In addition to the demonstrated reductions in tobacco use, the Centers for Disease Control and Prevention (CDC) has indicated that these school-based programs can also help prevent the use of other drugs.

Research, including the 1994 Surgeon General's Report, indicates that community-based strategies to prevent tobacco use are important adjuncts to school-based programs. The effectiveness of school-based tobacco prevention programs appears to be enhanced and sustained by community wide programs that involve parents, mass media, community organizations, and other elements of an adolescent's social environment. This report indicates that concerted use of multiple school and community channels for affecting adolescent tobacco-use behavior can produce a synergistic effect on the risk factors associated with adolescent tobacco use.

In the last 15 years, several major community-based prevention trials that target youth tobacco use have been undertaken and have proven to be effective in driving down youth smoking rates.

For example, the Minnesota Heart Health Program, addressed several cardiovascular risk factors for all age groups and used a variety of community strategies. Young people in this study received interventions through school and home-based programs indirectly through a community wide attempt to structure the overall social and physical environment to discourage young people from beginning to use tobacco. Young people in this study, had significantly lower smoking prevalence.

Several states are undertaking anti-tobacco campaigns. Minnesota was the first to use tobacco excise taxes to carry out such a program. More recently, California, Massachusetts, and Arizona have adopted state-based public education programs, and several other states are initiating them. While it is too early to evaluate the efforts of many of the programs, the available data demonstrate that both the California and Massachusetts programs both of which include large scale community-based components have been effective in reducing tobacco use. For example, three years after Massachusetts began its public education and tobacco control campaign, an independent evaluation found that tobacco consumption in Massachusetts declined at a rate three times that of the rate for the rest of the nation, and while smoking among high school students increased dramatically on the national level, it did not increase significantly in Massachusetts.

The American Stop Smoking Intervention Study for Cancer Prevention (ASSIST), which is funded through the National Cancer Institute at the National Institutes of Health, has provided further evidence regarding the effectiveness of comprehensive coordinated community efforts to reduce tobacco use. ASSIST provides funding to 17 states and is designed to promote broad social and environmental change. After just 4 years, tobacco consumption in ASSIST states was 10 percent lower than in non-ASSIST states—an estimated 70 million fewer packs of cigarettes being consumed each month in these states. ASSIST has been used as a model for the development of state-based tobacco control interventions in California, Massachusetts, as well as the Centers for Disease Control and Prevention's limited tobacco control program. The Committee intends that a significant portion of the funds from this section be used to fund the expansion of the ASSIST program or programs modeled after ASSIST.

Research in the United States and abroad has demonstrated that education and prevention programs work to both increase knowledge and decrease consumption. But, there have been insufficient resources and commitment, including from the federal government, and the Committee intends its bill to greatly increase the resources available to assist state and local community efforts to discourage tobacco use.

Section 224. State retail licensing program

This section provides for the establishment of a state retail licensing incentive grant program to be administered by the Secretary of Health and Human Services. To receive a grant, a state must enter into an agreement with the Secretary to assume responsibility for implementation and enforcement of a tobacco retailer licensing program. An effective licensing program which enlists tobacco product retailers and their employees in a systematic

effort to reduce illegal tobacco purchases by minors is vital to this legislation. The Committee intends that States be allowed the opportunity to design their own retailer licensing programs, in compliance with the basic licensing requirements set forth in this Section. If States demonstrate to the Secretary of HHS that their retailer licensing program meets these requirements, and abides by the Youth Access Restrictions promulgated by the FDA, the State shall receive a block grant out of settlement funds to pay for the licensing program's administration and enforcement. The Secretary will promulgate regulations for a retailer licensing system to apply in those States that do not seek to design and implement their own retailer licensing system.

Section 235(c) requires States seeking to design and implement their own licensing system (and receive settlement payments to do so) to demonstrate to the Secretary that their program includes the following core components. First, a State license is required for all retailers selling tobacco products to consumers, and the State provides notice to such businesses of their legal requirements pertaining to tobacco sales under State and Federal law. Second, criminal penalties will be imposed for the sale of tobacco products without a license, and civil penalties will be imposed for tobacco sales in violation State law by a licensee. The civil penalties enacted by States must include a graduated system of fines and suspension or revocation of licenses, for repeated violations by licensees. The monetary amount of fines are left to the discretion of States. Third, each State licensing plan must include some form of penalty imposed upon underage youths who possess, purchase, or attempt to purchase tobacco products. The penalties could include fines, suspension of driving privileges, or community service. Each State licensing program must provide procedures for judicial review of all State actions regarding license applications, suspensions, and revocations.

Section 235 (b) is the enforcement requirement for States establishing a licensing system with a settlement block grant. It requires States to enforce its tobacco licensing program in a manner reasonably expected to reduce the sale of tobacco products to underage youths. To ensure proper State action regarding enforcement, the Secretary can reduce the block grant of any State found to be not in compliance with this standard.

Section 235(c) authorizes the Secretary to establish a retailer licensing system in those States which did not establish their own. It authorizes the Secretary to promulgate regulations creating retailer licensing requirements, enforcement measures and applicable penalties. As under current law, the Secretary is authorized to enter into agreements with State officials for enforcement of federal regulations, and provide grant funding from tobacco settlement accounts for related costs.

TITLE III—TOBACCO PRODUCT WARNINGS AND SMOKE CONSTITUENT DISCLOSURE

SUBTITLE A: PRODUCT WARNINGS, LABELING AND PACKAGING

Section 301. Cigarette label and advertising warnings

Section 301 provides for new, more emphatic warnings for cigarette labels, packaging and advertising. These new warnings are achieved by amending Section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333).

In general, this section would require the warning statement to take-up the upper 25 percent of both the front and the back of the cigarette package. Cigarette advertising is also required to carry these warning statements in compliance with a defined format. The Secretary of Health and Human Services has the authority to modify the format for the warning statements as they appear on cigarette packaging and in cigarette advertising.

Section 302. Authority to revise cigarette warning label statements

The Secretary may by rulemaking modify the warning label statements if it would "promote greater public understanding of the risks associated with the use of tobacco products."

Section 303. Smokeless tobacco labels and advertising warnings

Section 303 provides for new, more emphatic warnings for smokeless tobacco labels, packaging and advertising. These new warnings are achieved by amending Section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4402).As with cigarettes, the warning statements required must appear in a defined format.

Section 304. Authority to revise smokeless tobacco product warning label statements

The Secretary may by rulemaking modify the warning label statements if it would "promote greater public understanding of the risks associated with the use of smokeless tobacco products."

Section 305. Tar, nicotine and other smoke constituent disclosure to the public

Section 305 transfers authority over the disclosure of cigarette constituents from the Federal Trade Commission to the Secretary of Health and Human Services. The Secretary would be given the authority to determine whether cigarette package labels and advertising will report tar and nicotine yields. The Secretary would have the authority to specify the format for such disclosures. The Secretary, by rulemaking, could also require the disclosure of any other smoke constituent.

SUBTITLE B: TESTING AND REPORTING OF TOBACCO PRODUCT SMOKE CONSTITUENTS

Section 311. Regulation requirement

Section 311 would require the Secretary to issue regulations, within one year of the Act's effectiveness, which would provide for the testing, reporting and disclosure to the public of "tobacco product smoke constituents and ingredients that the Secretary determine should be disclosed . . . to protect the public health."

TITLE IV—NATIONAL TOBACCO SETTLEMENT TRUST FUND

Section 401. National Tobacco Settlement Trust Fund

This Section establishes a National Tobacco Settlement Trust Fund within the United States Treasury. The up-front and annual payments received from tobacco manufacturers under Section 403; amounts equivalent to the fines or penalties paid by tobacco manufacturers for failure to meet youth tobacco use reduction targets under Section 202, including interest and penalties under shall be credited to the trust fund.

The Section provides that the receipts and disbursement of the Trust Fund shall not be included in the totals of the budget or subject to limitations imposed by other statutes.

Section 402. State Litigation Settlement Account

This section provides for the establishment, within the National Tobacco Settlement Trust Fund, of a separate account to be known as the State Litigation Settlement Account. From the amounts received into the Trust Fund pursuant to this act, $196 billion shall be credited to the State Litigation Settlement Account over 25 years. Amounts credited to the account shall be distributed to eligible states without further appropriation.

Subsection 402(c) provides that as state may use amounts received from the State Litigation Settlement Account as the state determines is appropriate, and that these funds will not be deemed as reimbursement for Medicaid expenditures or as Medicaid overpayments for purposes of recoupment.

Section 403. Payments by industry

This section requires five of the major participating manufacturers (those manufacturers that become a signatory of the Master Settlement Agreement and enter into state consent decrees) to make an up-front payment of $10 billion.

The up-front payment shall be paid in accordance with the following apportionment:

Phillip Morris Incorporated—65.8 percent
Brown and Williamson Tobacco Corporation—17.3 percent
Lorillard Tobacco Company—7.1 percent
R.J. Reynolds Tobacco Company—6.6 percent
United States Tobacco Company—3.2 percent

The five major participating manufacturers listed above, and other qualified participating manufacturers, shall contribute to annual payments beginning the first year after enactment of this act, as follows.

Year 1: $14.4 billion
Year 2: $15.4 billion
Year 3: $17.7 billion
Year 4: $21.4 billion
Year 5: $23.6 billion
Year 6 and every year thereafter: $23.6 billion.

The payments pursuant to this section, made by participating manufacturers, shall be deemed payments in settlement of civil suits in accordance with the Master Settlement Agreement and consent decrees.

The annual amount required to be paid by participating tobacco manufacturers in years one through five after enactment of this

act, except for the up-front payment, is calculated by multiplying the price-per-pack increase designated for that year, by the year's anticipated volume of per-pack sales. The price-per- pack increase schedule begins with a 65 cents hike in year one and graduates to $1.10 in year five, in compliance with the Administration's FY '99 budget request. Anticipated volumes have been calculated by the U.S. Department of Treasury factoring in reductions in demand due to yearly price increases. Accordingly the listed payments are pre-volume adjusted, and have also been adjusted for inflation.

The Committee received expert testimony that a substantial and immediate price increase in tobacco products is an essential component of a comprehensive effort to deter youth consumption. This section will achieve that objective.

In year six and every year thereafter, the participating tobacco manufacturers will be required to pay $23.6 billion, adjusted to inflation. The yearly payment beginning in year six is further volume adjusted. The payment of $23.6 billion each year will be increased or decreased by the same percentage increase or decrease in volume of sales from the established baseline.

According to the Department of the Treasury, the total sum of payments from tobacco manufacturers over 25 years, including the $10 billion up-front payment, and assuming no increase in sales volumes, would not be greater than $516 billion (not including look back assessments provided in Title III).

Annual payments are due in one-third installments to be paid on March 1, June 1, and September 1 of each year. The share of the annual payment apportioned to a participating manufacturer shall be equal to that manufacturer's adjusted unit sales. This section provides how adjusted units are calculated for cigarettes and smokeless tobacco.

Section 404. Adjustments

This section provides for the inflation and volume adjustments described above.

Section 405. Payments to be passed through to consumers

This section provides that the yearly payments from participating tobacco manufacturers required under Section 403, be passed through to the price of tobacco products sold by such manufacturer. This is to ensure that the act effects the increases in price necessary to deter youth consumption.

This section also provides for the assessment of a penalty against a participating manufacturer for the failure to pass through payments to product prices. The penalty is increased if such shortfall was intentional.

Section 406. Tax treatment of payments

This section provides that payments made under section 403 are considered ordinary and necessary business expenses for purposes of tax treatment in accordance with current law. The administration has expressed its concurrence that current law be applied with respect to the tax treatment of annual payments.

Section 407. Enforcement for nonpayment

This section provides for the imposition of a civil penalty on a participating manufacturer for the failure to make any payment re-

quired under Section 404 and 405. The section specifies a penalty of $100,000 for each day, after 60 days, a payment is due. The section provides relief from the penalty for any failure to pay that is not willful or intentional. If a participating manufacturer fails to make a payment within one year of when such payment is due, such manufacturer will be deemed a non-participating manufacturer and will be ineligible for any protections or assistance provided for under this Act.

Section 408. Implementing and enforcement funds

This section provides that not less than $300 million of the amounts available in the trust fund shall be available each year to the Commissioner of the Food and Drug Administration to reimburse the FDA for the cost of implementing and enforcing requirements related to tobacco products.

SUBTITLE B—GENERAL SPENDING PROVISIONS

Section 411. Improving child care and early childhood development

This section authorizes the Trustees to use funds from the Trust Fund to expand funding for the Child Care Development Block Grant to improve the affordability; quality, and availability of child care, including health services and improving services for children with disabilities. Proponents of the amendment by Senator Kerry, as adopted by the Committee, believe that good quality child care is key to the healthy development of children and constructive after-school activities are an important part of keeping school-age children from smoking. Proponents of the amendment believe that using tobacco settlement funds to expand the Child Care Development Block Grant, the major federal child care program for working families, by up to $4 billion a year would help accomplish these goals. This section provides that any funds made available by the trustees for the purposes of this section be further subject to appropriations.

TITLE V—STANDARDS TO REDUCE INVOLUNTARY EXPOSURE TO TOBACCO SMOKE

Title V provides regulations for a Smoke Free Environment Policy in public buildings in the U.S. Health and scientific studies show a causal relationship between secondhand tobacco smoke and disease in non-smokers. The presence of tobacco smoke in non-ventilated public buildings and corridors is an unhealthy and unfair imposition on the rights of non smokers. A smoke free atmosphere in public buildings will protect the health of all non-smokers from the ill-effects of tobacco smoke. This is of particular importance to adults and children who have medical ailments which are exacerbated by the presence of tobacco smoke. Importantly, Title V affords State officials the choice to determine whether the federal smoke free environment policies mandated herein are suitable for their States. The Committee recognizes that States have traditional authority over regulations pertaining to tobacco usage in public facilities, and the varying policy choices which will arise from new health-oriented requirements. Therefore, section 507 provides States to opt-out of these federal requirements by the enactment of contrasting State law.

Section 501 defines the type of buildings to which the federal policy for smoke free buildings will apply. The bill defines public buildings as those which are regularly entered by at least ten persons one day a week, including federally-owned or leased buildings, other than buildings used for residential purposes. Section 501(B) lists the buildings which are not considered to be public buildings for the purposes of this Title, and thus are not subject to the smoke free policy requirements. These are largely buildings patronized by adults, such as bars, casinos, hotels, private clubs, and restaurants. Importantly, fast food restaurants are specifically required under section 501 (B) and (C) to establish a smoke free policy in compliance with this bill. The Committee believes that the large numbers and frequency of children and teenagers who patronize fast food restaurants warrants the adoption of smoke free environment policies.

Section 502 provides the basic elements of the smoke free environment policy that the owners or controlling lessees public buildings must implement. The owner or lessee who operates the building must prohibit the smoking of tobacco products within the facility and in close proximity to the facility's entrance. They may establish a specially-designated smoking area in the building, under the following restrictions. The designated smoking areas must directly ventilated to the outside of the building and not allow tobacco smoke to enter other areas of the public building; the room must be maintained at negative pressure; and non-smoking individuals do not have to enter the room for any purpose. This section and Section 505 authorizes the OSHA Administrator to promulgate regulations to carry out this Title.

Enforcement of a smoke free environment policy is a key aspect of ensuring that non-smokers are not subject to an unhealthy environment due to violations of this Title. Section 503 authorizes any aggrieved person, OSHA, and any State or local governmental agency to bring suit in a proper federal district court to enforce these smoke free environment requirements. Defendants are subject to injunctions against violative practices and civil penalties fines of up to $5,000 per day of violation. However, to afford owners and lessors a fair opportunity to correct violations without unnecessary litigation, an aggrieved person must first provide notice to them about the violation. Section 503(c) stipulates that the owner or lessee that operates the building then has 60 days to correct the violation before the grievant can file an action under this Title.

Section 506 and section 507 establish the effective date of this title and the ability of States to opt- out of its requirements, respectively. The Committee believes that this title should not take effect in a State until that State has the opportunity to evaluate whether they are suitable public building requirements. Therefore this title's federal smoke free environment policies will take effect on the first day of the January, following the regular session of a State legislature in which a measure to opt out may have been considered.

Nothing in this title requires any public facility owner or lessee to make any structural change to such facility. If a public facility owner or lessee does not have a specially designated smoking area that meets the requirements of this title, and does not wish to

incur any expense to create such an area, the owner or lessee may choose not to have a specially designated smoking area.

TITLE VI—APPLICATION TO INDIAN TRIBES

Section 601. Short title

Section 601 provides that this title may be cited as the "Reduction in Tobacco Use and Regulation of Tobacco Products in Indian Country Act of 1998".

Section 602. Findings and purposes

Section 602 contains findings and purposes relevant to this Title.

Section 603. Application of tobacco-related provisions to native Americans

In making the provisions of the bill applicable to Indian tribes and the manufacture, distribution, and sale of tobacco or tobacco products (tobacco-related activities) on Indian lands, the Committee had various principal objectives, including: first, to ensure national, uniform application of the Act with respect to the activities of Indian tribes, their members, and tobacco-related activities on Indian lands; second, to recognize and preserve specified traditional, religious, and ceremonial uses of tobacco as part of the Native American culture; and third, to recognize the inherent tribal authority to make and enforce laws governing persons and activities occurring on lands within the tribes' jurisdiction. The Committee does not intend to modify current law with regard to jurisdiction on Indian lands.

Sections 601 through 603 of Title VI as reported by this Committee do not represent a final agreement by the Chairman and Committee members regarding a number of outstanding issues. It is the intent of the Committee to reach consensus on language to be included in a Manager's Amendment to be offered when the bill is considered by the full Senate. The Committee's intent, however, is clear with regard to a number of matters: to ensure national, uniform application of the Act with respect to the activities of Indian tribes, their members, and tobacco-related activities on Indian lands; to recognize and preserve specified traditional, religious, and ceremonial uses of tobacco as part of the Native American culture; to disburse tobacco trust fund monies to tribes or tribal organizations on an equitable basis; and to provide eligible Indian tribes resources to operate tobacco retailer licensing programs, as prescribed for states under section 224 of the Act. If tribes are unwilling, unqualified or ineligible (or are non- participating tobacco products manufacturers under the Act) to conduct such licensing programs, then states may conduct the licensing programs under voluntary cooperative agreements with those tribes, or the federal government shall conduct such licensing programs.

The Committee recognizes that language may have to be included to address the unique circumstances of Alaska, in particular, the Alaska Native Claims Settlement Act, the U.S. Supreme Court's Venetie decision, and health-care delivery systems traditionally serving Alaska Native communities.

Section 604. State tobacco excise tax compliance

Uniformly increasing the price of tobacco products and eliminating pricing disparities are basic functions of this Act, and Section

604 is designed to eliminate sources, for non-tribal members, of cheaper tobacco products. For the sale of tobacco products to non-tribal members, Section 604 requires Indian tribes to collect and remit to the U.S. Treasury all excise and sales taxes of the state within which the sale occurs. The Treasury, in turn, is required to remit these taxes to the state within which they were collected.

TITLE VII—CIVIL LIABILITY OF MANUFACTURERS OF TOBACCO PRODUCTS

Section 701. Definitions

Section 701 provides definitions for terms which are not defined elsewhere in the bill or which have unique meaning in Title VII.

Section 702. Application

Section 702 explains that the provisions of Title VII apply to all tobacco claims brought against participating manufacturers and various agents of the participating manufacturers, including retailers, wholesalers and growers. Section 702(b) clarifies that Title VII does not apply to non-participating manufacturers, nor does it apply to claims which are not tobacco claims, such as enforcement actions by the states, workers' compensation claims, securities actions, and actions brought by the United States. Section 702 also provides a one-time opt out mechanism for states to elect not to settle their pending actions. The Secretary of the Treasury would establish procedures for the execution of this opt-out. If a state opts-out, then its actions against the tobacco manufacturers would not be settled. The state would forgo payments from the National Tobacco Settlement Trust Fund, but would receive any funds it receives in settlement or judgment from its suits against tobacco manufacturers.

Section 703. Preemption and Relationship to Other Law

The Section preempts other bases in state law for tobacco claims to the extent that state law is inconsistent with Title VII. It also clarifies that Title VII does not limit any criminal liability of the tobacco manufacturers.

Section 704. Governmental Claims and Castano Civil Actions

This section prohibits any state governmental entity, or political subdivision, and Indian tribes from bringing a tobacco claim, except as provided in Title VII. Section 702(b) provides for the settlement of existing state claims by consent decree. Section 702(c) settles the pending private class actions based solely on addiction and dependence and known as the Castano cases. While the Castano class actions are decertified, the plaintiffs within the class could bring their actions on an individual basis in accordance with Title VII. Subsections (2) and (3) of 704(c) provides a mechanism for awarding attorneys' fees in the Castano cases.

Section 705. Concurrent Jurisdiction; Federal Cause of Action; Actions Damages; Liability; Removal

Section 705 establishes a federal cause of action for tobacco claims, based upon the substantive law of the state in which an action is brought. This federal cause of action is the exclusive cause of action for tobacco claims, and all other bases for claims are preempted. This approach of creating a federal cause of action allows

this Act to cover all tobacco claims, while both permitting existing state law to apply to those actions and avoiding bringing all tobacco claims into the Federal court system.

Section 705(b) provides that tobacco claims may only be brought against a tobacco manufacturer or the surviving entity of a tobacco manufacturer. This structure provides an incentive for tobacco manufacturers to elect to participate. Section (b)(2) preserves all causes of action which would have otherwise been viable under state law if the tobacco manufacturers are unable to make payments required by the Act. Subsection (c) prohibits addiction and dependence claims.

Subsection (d) provides evidentiary rules for tobacco claims: including authentication of documents produced from the national depository established by the Act, and a prohibition against introducing evidence related to reduced-risk tobacco products to thereby eliminate a significant disincentive to the development of safer tobacco products.

Section 705(e) establishes joint and several liability among the participating manufacturers, but provides that the participating manufacturers will not be jointly and severally liable with non-participating manufacturers. Participating manufacturers may be jointly and severally liable with any other person, except a non-participating manufacturer. Subsection (4) of (e) provides that trials in actions against a participating manufacturer and a non-participating manufacturer may be severed and heard by separate juries. Subsection (5) establishes an evidentiary rebuttable presumption that nicotine is addictive and that certain diseases are caused in whole or in part by use of tobacco products.

Section 706. Payment of Tobacco Claim Settlements and Judgments

This section established a system for payment of settlements and judgments of tobacco claims out of the fund set aside for these payments. This section coordinates the payment of judgments and settlements from all courts to ensure that the fund is distributed according to certain procedures and guidelines. Subsection (b) provides that the Secretary of the Treasury will maintain a record or judgments and settlements and will establish a priority for their payment. Payment is made according to the date when the judgment or settlement is registered with the Secretary. The annual payment cap is established at $6.5 billion. If that amount is insufficient to pay all the recorded judgments and settlements in any year, then the unpaid judgments and settlements will be paid in the following year. Subsection (d) permits a participating tobacco manufacturer to seek an injunction against any state court which attempts to enforce or execute any judgment in a manner inconsistent with this section. Section 706(e) provides that the participating tobacco manufacturers are jointly and severally liable for judgments and settlements payable under this section and shall enter into an agreement apportioning the amounts payable among themselves. The apportioned payments are to be given priority, and may not be avoided or discharged, in any bankruptcy proceeding or other insolvency proceeding.

Section 707. Attorneys' fees and Expenses

This section establishes an arbitration procedure for awarding plaintiff's attorney's fees in which the attorney is unable to agree with his client as to the fee to be paid. The arbitration panel shall consist of 3 people: 1 selected by the plaintiff, one selected by the attorney, and one chosen jointly by those 2 arbitrators. Subsection (4) sets forth the substantive criteria the panel must follow in making awards of fees, including the time and labor expended; the novelty and difficulty of the issues in the claim; the skill required; the extent to which the employment has precluded other employment; whether a fee agreement exists based upon a fixed fee or a percentage; time limitations imposed; the amount of the judgment or settlement; the experience and reputation of the attorney; the undesirability of the action; amounts already paid under the fee agreement in dispute; and such other factors as justice requires. Nothing in this section abrogates or restricts the rights of any parties to mediate, negotiate, or settle fee disputes, or to enter into fee agreements with respect to the allocation or division of fees.

Section 708. Non-participating Manufacturers

This section provides for fees to be paid by non-participating manufacturers, including fees equivalent to 150 percent of the annual payments made by participating manufacturers and an escrowed fee to cover potential tobacco claim related liability payments. This structure both provides an incentive for tobacco manufacturers to participate and ensures there will not be a price advantage for tobacco manufacturers that do not participate.

Section 709. Conforming Amendments

This section contains provisions necessary to provide consistency with other statutes.

Section 710. Trust Fund

This section establishes a Tort Trust Fund, as requested by the Administration, to ensure that individual claimants have a source for payment of judgments and settlements against the tobacco companies. This section is a place holder and will be revised.

TITLE VIII—TOBACCO INDUSTRY COMPLIANCE AND EMPLOYEE PROTECTION FROM REPRISALS

Section 801. Tobacco Industry Compliance Accountability Requirements

Section 801 would require the Commissioner of the Food and Drug Administration to establish an advisory panel called the "Tobacco Agreement Accountability Panel." Within one year of the effectiveness of the Act, each participating tobacco manufacturer must submit to the Commissioner a plan to reduce youth smoking. That plan will be reviewed by the Accountability Panel which may recommend additional measures to reduce youth smoking.

Annually, the Accountability Panel would be required to submit to the Commissioner and Congress a report which describes each tobacco manufacturer's compliance with the Act and determines whether the efforts undertaken by each tobacco manufacturer is likely to meet the youth smoking reduction targets. The Commissioner is, within 60 days of receiving this report, required to implement any recommendation made by the Accountability Panel or re-

port to Congress why the recommendation is not being implemented.

The panel would be permitted to declare a public health emergency if it unanimously determines that a tobacco manufacturer's "actions or inactions" concerning compliance with the Act would create a "clear and present danger to the attainment of the targets for underage smoking reduction." If the Commissioner determines that the Accountability Panel's determination is "supported by clear and convincing evidence" then the Commissioner would be required to bring an action, under provisions of the Act, to seek the "immediate suspension of the manufacturer's annual limitation cap on civil judgments." If the court then determines that "the Secretary has proved by clear and convincing evidence" that the tobacco manufacturer's actions or inactions present a "clear and present danger to the attainment of the targets for underage smoking reduction", the court may suspend the tobacco manufacturer's annual limitation on civil judgements.

If the Secretary determines that the tobacco manufacturer will miss its youth reduction targets by more than 20 percentage points, the Secretary would be required to either bring an action against the tobacco manufacturer under section 203 or issue a finding that the manufacturer made "reasonable efforts" to reach the attainment targets. Compliance with all Accountability Panel recommendations will be prima facie evidence that the tobacco manufacturer made "reasonable efforts" to achieve the targets for reduction of youth smoking.

Section 802. Tobacco Product Manufacturer Employee Protection

The Act would provide various whistle blower protections for employees of tobacco manufacturers. The Act would also give the Secretary certain investigatory and enforcement powers to protect such employees. The Act would provide for judicial review of such determinations.

Tobacco manufacturers would be prohibited from taking action against an employee that exposed the manufacturers's violations of the Act, testified in government proceedings concerning those violations or refused to engage in practices made unlawful by the act.

Employees that believe they have been adversely treated for their actions to expose tobacco manufacturer violations may file a complaint with the Secretary. The Secretary would be required to investigate the employee's complaint and may take action to reinstate a fired employee or take other actions to abate the violation if the employee makes a prima facie showing of discriminatory treatment due to the employee's actions to expose the tobacco company's violations. The Secretary may dismiss the employee's complaint if the tobacco manufacturer proves by clear and convincing evidence that it did not discriminate or retaliate against the employee.

TITLE IX—PUBLIC DISCLOSURE OF TOBACCO INDUSTRY DOCUMENTS

Over the past several decades, tobacco companies have amassed a truly massive amount of scientific, manufacturing, marketing, and company policy information. These documents, which include

internal tobacco company studies and strategic policy assessments, comprise literally millions of pages. They are of tremendous importance to public health officials interested in an effective national tobacco policy, as well as private citizens. The information that can be gleaned from these materials will be especially vital to individuals who have suffered medical problems due to tobacco products, and who are considering whether to file suit for compensation. Without a centralized tobacco document repository, citizen plaintiffs would face considerable costs, delays, and difficulties in investigating company information that may be relevant to the consideration of their claim. Discovery efforts could prove extremely burdensome and time consuming for many individuals. The Committee supports the State Attorneys General recommendation that a central document repository of appropriate, non-privileged tobacco company information be established. The repository will serve the Act's objective of a sound national tobacco policy by providing public access to documentary evidence of the industry's knowledge, policies, and conduct.

Section 901. Findings

Section 901 contains Congressional findings that the tobacco manufacturers have taken action in bad faith to protect internal documents from public disclosure when disclosure of those documents would promote public understanding of the tobacco industry's research and business practices.

Section 902. Applicability

This Title applies only to participating manufacturers of tobacco products as defined under the Act.

Section 903. National Tobacco Document Depository

Section 903 would require the participating tobacco product manufacturers to establish in the Washington DC area, within 180 days of the enactment of this Act, a document repository called the National Tobacco Document Depository. This document depository would greatly enhance the knowledge of both the public and the public health community concerning tobacco industry behavior and research concerning tobacco products. The document depository would also greatly facilitate individuals in bringing lawsuits against the tobacco manufacturers to gain compensation for injuries related to tobacco use.

Each participating tobacco product manufacturer would be required to place in the Depository all of its documents, and those of the Center of Tobacco Research or the Tobacco Institute, concerning: all original laboratory research; all industry documents produced in discovery in the actions brought by state attorneys general; any documents produced in conjunction with the Federal Trade Commission's investigation concerning Joe Camel; all documents produced to litigation adversaries during any private litigation and in specifically enumerated litigation; any trial-related documents; any documents referring to health research about tobacco products, dependency of consumers on tobacco products, and safer or less hazardous tobacco products; all indices of documents relating to tobacco products and health; and, various privilege and trade secrecy logs describing certain documents exempt from disclosure.

Section 903(d) would provide for the disclosure, by participating tobacco manufacturers, of documents created after the effective date of the Act. The following types of documents would have to be supplied to the depository within 90 days of the document's completion: all original laboratory research relating to the health effects or safety of tobacco products; all studies relating to tobacco product use by minors; all documents referring to the relationship between advertising and promotion of tobacco products and their use by minors; a privilege log to describe those documents that are exempt from disclosure; and, a trade secrecy log to describe such documents that are exempt from disclosure.

All documents supplied to the Depository would be sequentially numbered and coded to identify the tobacco manufacturer that is the source of the document.

Section 904. Privilege and Trade Secret Claims

Section 904 establishes procedures for handling documents the tobacco manufacturers claim should not be made available to the public due to attorney-client privilege, attorney work product protection or trade secret protection. The tobacco manufacturers would be required to submit such documents to the Depository but they would be marked as privileged documents. Submitting such documents to the Depository would not waive any claim of privilege or trade secret protection.

The tobacco manufacturers would be required to provide a comprehensive log that identifies all documents for which a privilege is asserted. The log of documents would describe each document and explain why a privilege is asserted. Tobacco manufacturers would be required to examine each document for which they had previously made a claim of privilege and make a good faith review as to whether that claim is still appropriate.

Section 905. Disclosure by the Depository

The Depository would be required to release to the public all documents that are not privileged by placing them on the Internet and through other appropriate methods.

Under Section 905(b), documents that are submitted to the Depository are to be treated for evidentiary purposes in the same manner as documents from the National Archives. In other words, if the document is certified as coming from the Depository, then it is authenticated as a matter of evidence and is treated as if it were the original document.

Under Section 905(c), if a document, protected as a trade secret, is released inappropriately by the Board or the Depository it is a criminal violation.

Section 906. National Tobacco Documents Review Board

Section 906 creates the National Tobacco Documents Review Board with 5 members, appointed by the President and confirmed by the Senate. The Board would have responsibility for maintaining and operating the Depository. The Board would be charged with applying the doctrines of attorney-client privilege and attorney work-product in a manner consistent with Federal law.

Section 907. Resolution of Disputed Privilege and Trade Secret Claims

The Board would be responsible for determining whether to uphold or reject a tobacco manufacturer's claim that a document should not be revealed to the public due to a claim that the document is protected by attorney client privilege, the attorney work product doctrine or trade secret protection. Such a determination could be made by a single member of the Board. The decision is to be made in writing and is subject to judicial review.

Section 908. Appeal of Board Decision

Any person may appeal a decision by the Board by filing a petition for review with the United States Court of Appeals for the Federal Circuit. In the Appeals Court's review, the Board's findings of fact are conclusive if supported by "substantial evidence on the record taken as a whole". The Appeals Court would be able to conduct a de novo review of the Board's legal decisions. The Supreme Court may review any decision made by the Appeals Court.

Once a final decision has been reached about the document, the Board would be required to make it available to the public within 30 days. Once a final decision has been reached no Federal or State court would have jurisdiction to again evaluate a claim of privilege as to that document.

If the Board decides that a document should not be made available to the public due to an appropriate claim of privilege, the Board's decision is not binding in a judicial proceeding concerning that document.

Section 907(f) would require participating tobacco manufacturers to supply to the Food and Drug Administration any document it submits to the Depository for public review and all documents for which it asserts a trade secret protection. Tobacco manufacturers would not have to supply documents for which it asserts attorney-client privilege or attorney work product protection.

Section 909. Miscellaneous

Section 909(a) appears to be a duplicate power of Section 908(f).

The disclosure process in this Title does not affect the Federal Rules of Civil Procedure or Criminal Procedure and the Title does not affect any Federal law that requires the disclosure of documents. The Title also does not affect any law the deals with attorney-client privilege, attorney work product protection, or trade secret protection.

Section 910. Penalties

Each tobacco manufacturer is required to act with good faith as to document disclosure. If the Board determines that a manufacturer has not acted in good faith then it may impose certain costs and attorney's fees on that manufacturer. The board would also be able to impose civil penalties of up to $10,000 per violation if it determines the tobacco manufacturer acted in bad faith.

If a participating tobacco manufacturer fails to produce indexes and documents in accord with the schedule outlined in this Title then a civil penalty of up to $500 may be assessed per violation. A separate violation occurs for each document that is not produced. The maximum penalty for a related series of violations is $10,000.

Section 911. Definitions

Section 911 defines relevant terms.

TITLE X—LONG-TERM ASSISTANCE FOR FARMERS

Section 1001. Short title

This section names title X as the "Long-Term Economic Assistance for Farmers (LEAF) Act."

Section 1002. Definitions

This section sets out the definitions applicable to title X.

SUBTITLE A—TOBACCO COMMUNITY REVITALIZATION TRUST FUND

Section 1011. Establishment of trust fund

This section establishes the "Tobacco Community Revitalization Trust Fund." The trust fund is to be funded by assessments to tobacco manufacturers and importers as designated in section 1012. It is not the Committee's intention to require that tobacco manufacturers that have made their full annual payment into the National Tobacco Settlement Trust Fund under section 403 also make a separate annual payment of their assessment for the Tobacco Community Revitalization Trust Fund. Rather, their obligation to make payments under this title will be satisfied by transfers from the National Tobacco Settlement Trust Fund of amounts equivalent to their annual assessment under this title. Funds deposited into the Tobacco Community Trust Fund are to be used for the following: payments for lost tobacco quota, payments for sale of quotas, payments for community economic development grants, worker transition program, higher education assistance programs, and to reimburse the federal government for the administration of the program. The legislation includes specific dollar limitations on annual payouts for each program. All monies and payments under the Trust Fund are deemed to constitute budget authority in advance of appropriations Acts. The legislation has earmarked $28.5 billion for the program, pursuant to section 1012. Of this amount, the following annual expenditures are to be made annually for fiscal years 1999-2023: (1) Payments for lost tobacco quota as delineated under section 1021, except that such payments are not exceed $1.65 billion annually, unless additional monies are needed for acceleration of lost tobacco quota; (2) Payments for the administration of the tobacco support program by the Department of Agriculture under section 1022; (3) Payments for the community economic development program under section 1023, which is not to exceed $375 million annually for fiscal years 1999-2008, and $450 million annually for fiscal years 2009-2023; (4) Payments for the worker transition program under section 1031, which is not to exceed $25 million in any fiscal year; and (5) Payments for the higher education opportunity grants under section 1032, which are not to exceed: $42.5 million for each of the academic years from 1999 to 2004; $50 million for each of the academic years from 2004 to 2009; $57.5 million for each of the academic years from 2009 to 2014; $65 million for each of the academic years from 2014 to 2019; and $72.5 million for each of the academic years from 2019 to 2024.

Section 1012. Contributions by tobacco product manufacturers and importers

This section specifies that contributions are to be made by tobacco manufacturers and importers to the Tobacco Community Revitalization Trust Fund on a market share basis. The total con-

tribution that is to be made by companies is $28.5 billion. The payments are to be pursuant to the following schedule: $2.1 billion annually for fiscal years 1999-2008 and $500 million annually for fiscal years 2009-2023.

SUBTITLE B—TOBACCO MARKET TRANSITION ASSISTANCE

Section 1021. Payments for lost tobacco quota

This section restructures the procedures for compensating tobacco quota holders, quota lessees, and quota tenants for lost tobacco quota as a result of declines in the tobacco market. Tobacco quota holders, lessees, and tenants are to be compensated on a lost quota basis. Reimbursements are to be made based on the average base quota of each party. The base quotas are to be determined as specified: (1) For quota holders, the base quota is the average tobacco farm marketing quota for the 1995-1997 marketing years; (2) For a quota lessee, the base quota level is fifty percent of the average number of pounds of tobacco quota established for a farm for the 1995-1997 marketing years that was leased or rented to the quota lessee minus twenty-five percent of the average number of pounds of that quota grown by a quota tenant; and (3) For a quota tenant, the base quota level is fifty percent of the average number of tobacco quota pounds for marketing years 1995-1997 which were leased to the tenant by a quota holder and produced by the tenant, plus twenty-five percent of the average number of tobacco quota pounds for marketing years 1995-1997 that were leased by a quota lessee and grown by the tenant.

MONETARY REIMBURSEMENTS FOR LOST QUOTA/REGULATIONS FOR SALE OF QUOTAS

The legislation has included set dollar amounts for determining the actual amount of reimbursement due to each party in the tobacco support program. Additionally, consistent with the Committee's desire to restructure the current quota system, so as to ensure quota owners are actual producers, provisions have been included to encourage the transfer of quotas by quota owners to persons who are actual producers. The Committee recognizes, however, that there are different market conditions regarding the nation's two prominent types of tobacco—burley and flue-cured. Accordingly, the legislation includes separate monetary payout and quota-buyout incentives for burley and flue-cured businesses. These procedures set out below:

COMPENSATION PROCEDURES FOR BURLEY TOBACCO

COMPENSATION FOR LOST QUOTA. Annual payments for lost quota for persons involved in the production of tobacco, other than flue-cured tobacco, are to made pursuant to the following formulas: (1) For quota holders, payments are to be based on the number of pounds by which the farm marketing quota is less than the base quota level for the quota holder times $4 per pound, subject to a lifetime limitation of $8 per pound; and (2) For lessees and tenants, the formula for determining actual payments is the percentage by which the national marketing quota is less than the national marketing quota for marketing years 1995-1997 times the base quota

level of the lessee or tenant times $4 per pound, subject to a lifetime limitation of $8 per pound.

If the amounts that are due to quota holders, lessees, and tenants exceed the amount available for lost quota payments under section 1011, the actual payments are to be adjusted and made on a pro-rata share. The amount of the reductions to each party, however, are to be rolled-over to such succeeding fiscal years as are necessary.

In general, payments are to be made on a yearly basis. However, payments are to be accelerated any time the national marketing quota is below 50 percent of the national tobacco marketing quota for the 1998 marketing year for three consecutive years, or if Congress abolishes the tobacco support program.

RELINQUISHMENT OF QUOTA BY QUOTA HOLDERS. Burley quota holders will be given an option to relinquish their quotas in return for a payment. Notification to exercise the option must be made by January 15, 1999. The payments to relinquishing quota holders are to be made annually in fiscal years 1999-2008, based on a lifetime payment of $8 per pound multiplied by the base quota level. The payments are to be made annually, and are to be equal to 1/10 of the lifetime payment. Quota holders who relinquish their quota are ineligible for any other payments for lost or relinquishing quota.

REISSUANCE OF QUOTA. Lessees and tenants of burley quota holders are to be given a one-year option of having an allotment of the farm or acreage marketing quota relinquished by the quota holder relocated to a farm owned by the quota tenant or lessee. The relocated amount is not to exceed 50% of the farm acreage owned by the quota lessee or tenant. Lessees and tenants that receive transferred quota allotments are not to receive any additional compensation for lost quota as a result of the reallocation. The recovery of payments as a quota holder and lessee or tenant is prohibited.

If the relinquished quota is not transferred to a quota lessee or tenant, the Secretary may transfer the quota to other quota holders. Such transfers are to be limited to quota holders in the same county, unless state law permits county-to-county transfers. Quota holders are not eligible for additional lost quota payments to quota holders as a result of the transfer of the relinquished quota.

DEATH OF QUOTA LESSEE OR TENANT. If a quota lessee or tenant dies, his or her lost quota payments are to transfer to his or her spouse or dependents.

TREATMENT OF FLUE-CURED TOBACCO

ABOLISHMENT OF QUOTA SYSTEM FOR FLUE-CURED TOBACCO. The legislation will abolish the quota system for flue-cured tobacco. The procedures for exchange of quotas for permits are set out in section 1024. Current quota holders who are producers, as well as lessees and tenants, will be given the option of transitioning to the permit system. All flue-cured quota owners, who are not actual producers, will be required to relinquish their quotas in exchange for a payment. The quotas are to be yielded by November 15, 1998. Relinquishing quota owners are to be paid annually 1/10 of a lifetime limitation of $8 per pound times their base quota level. The payments are to be made for fiscal years 1999-2008. The lessee or tenant of the quota will be given an automatic option under section

1024 of obtaining a permit to continue farming. However, if the lessee or tenant rejects the option of continuing to farm under the new permit system, each is eligible under section 1021 for a transition payment of $8 per pound times their base quota level as established by the legislation. The payments are to be made for fiscal years 1999-2008.

LOST QUOTA PAYMENTS FOR LESSEES AND TENANTS UNDER PERMIT SYSTEM. Lessees and tenants that have active permits are eligible for annual lost quota payments of $2 per pound times the number of pounds by which the production authorized under their permit is less than twice their base quota level, subject to a lifetime limitation of $4 per pound.

If the amounts that are due to quota holders, lessees, and tenants, exceed the amount available for lost quota payments under section 1011, the actual payments are to be adjusted and made on a pro-rata share. The amount of reductions to each party, however, are to be rolled-over to such succeeding fiscal years as are necessary.

In general, payments are to be made on a yearly basis. However, payments are to be accelerated any time the national marketing quota for flue-cured tobacco is below 50% of the national marketing quota allotment for the 1998 marketing year for three years in a row.

Section 1022. Industry payments for all department costs associated with tobacco production

This section authorizes the Department of Agriculture to use monies from the Tobacco Community Revitalization Trust Fund for the administration of the tobacco support programs.

Section 1023. Tobacco community economic development grants

This section authorizes the Department of Agriculture to award economic development grants to tobacco-growing communities. The amount of the grants is to be based on the amount of the state's farm income pursuant to the 1995-1997 marketing years. States must submit an application to the Department before a grant can be awarded. The application is to describe the purposes for which the grant will be used. The grants may be used for such programs as loan assistance programs for restructuring communities or for the support of new industries. Such funds, however, are reserved for counties in the state that had at least $100,000 in tobacco production in one or more of the 1995-1997 marketing years. Although states are given considerable latitude in determining the use of the grant funds, the legislation does include the following earmarks: (1) at least 20% of the funds must be used for economic development and agriculture-based rural development activities; (2) a minimum of 4% is to be used for technical assistance; and (3) no less than 6% of the funds are to be used to provide direct payments to tobacco warehouse owners based on declines in yearly volume sales as compared to sales during the 1998 marketing year.

Additionally, a state may require recipients of funds to provide preferences in hiring persons who, during the 1998 calendar year, were employed in farming, manufacturing, and processing of tobacco and are eligible for assistance under the tobacco worker tran-

sition program, as well as persons eligible for higher education grants under the bill.

Section 1024. Flue-cured tobacco production permits

This section replaces the tobacco quota system for flue-cured tobacco with a federal tobacco permit system. The federal tobacco permit system will require official permits to farm tobacco. These permits will be issued by the Department of Agriculture, which will include production and acreage allotment limitations. Permits will only be issued to actual producers. Lessees and tenants that produce flue-cured tobacco under agreements with quota owners will automatically be given the right to obtain permits to continue their farming. The permits will not be transferable, and will be prohibited from being used as an asset. Permits, however, will be permitted to be transferred to the permit owner's surviving spouse and descendants. Lessees and tenants that have permits that automatically revert to them will be given the option of relinquishing their permits for a payment. The payments are to be made on an annual basis from 1999 to 2008, subject to a lifetime limitation of $8 per pound times the base quota level (section 1021).

Section 1025. Modifications in Federal tobacco programs

This section includes technical changes to the tobacco quota program. The section provides that in cases where tobacco marketing quotas are still in effect following the enactment of the bill, the Department of Agriculture, on receipt of a petition from 5% of the producers of a particular type of tobacco in a state, is to conduct a statewide referendum on a proposal regarding the lease and transfer of tobacco quota. If a majority of the state's producers of that type of tobacco approve, the state is to implement quota transfers and leases according to the proposed procedures.

This section changes the penalties that are to be assessed to tobacco companies for failure to meet quota purchase agreements. The penalty is changed from the current penalty assessment of twice the per pound assessment times the quantity of purchasers that are less than 90% of the quantity of intended purchases, to 105% of the average market price times the quantity of purchasers that are less than 90% of the quantity of intended purchases.

SUBTITLE C—FARMER AND WORKER TRANSITION ASSISTANCE

Section 1031. Tobacco worker transition program

This section sets forth a program that is to be administered by the Department of Labor to assist workers in the tobacco industry. To benefit, a group of workers of a tobacco entity will be required to file a petition with the Labor Department for assistance. The workers will be required to show that: (1) they have or will become totally or partially separated; (2) the entity's sales production has decreased substantially; and (3) that the national tobacco settlement contributed importantly to the production declines. If the petition is approved, the workers are to be provided the following benefits and services: employment services; training for new employment; and adjustment allowances (payments to aid in the transition to a new job, except that these payments are to be made only if the person is in the job training program). No person who has received payments for tobacco lost quota is eligible for the program.

The program is to be funded at a rate of $25 million yearly through fiscal year 2008. At least $12.5 million is to be used for the job training program.

Section 1032. Farmer opportunity grants

This section provides for the establishment of educational grants to assist tobacco producers and their relatives in obtaining undergraduate degrees. To be eligible, a person has to be a member of a tobacco farm family. The section defines a tobacco farm family or member as an active tobacco producer or worker, and their spouse, son, daughter, stepson, stepdaughter, brother, sister, stepbrother, stepsister, son-in-law, or daughter-in-law. The bill sets forth the following yearly amounts of the grants: $1700 for each of the academic years from 1999 to 2004; $2000 for each of the academic years from 2004 to 2009; $2300 for each of the academic years from 2009 to 2014; $2600 for each of the academic years from 2014 to 2019; and $2600 for each of the academic years from 2019 to 2024. The monies are to be paid to the institution directly or to the student. A grantee may receive a scholarship for only one institution, and is required to maintain a qualifying average for student eligibility at the institution. A grantee is barred from receiving a grant if he or she is in default on a higher education loan or is indebted to an institution of higher education.

SUBTITLE D—IMMUNITY

Section 1041. General immunity for tobacco producers and tobacco warehouse owners

This section immunizes tobacco producers, tobacco-related growers associations, tobacco warehouse owners and employees from any liability associated with the failure of a tobacco product manufacturer, distributor, or retailer to comply with the national tobacco settlement legislation.

TITLE XI—MISCELLANEOUS

SUBTITLE A: PROHIBITIONS RELATING TO TOBACCO PRODUCTS AND CHILDREN

Section 1101. Short Title

This subtitle may be cited as the "Tobacco Use by Minors Prevention Act".

Section 1102. Prohibitions Relating to Tobacco Products and Children

Section 1102 would amend Chapter VIII of the Federal Food, Drug, and Cosmetic Act by adding two new sections at the end of that Chapter. The Committee does not intend for these provisions to have extraterritorial application.

Section 804 "Prohibition on Sale or Distribution of Tobacco Products to Children" would make in unlawful for any domestic tobacco concern to in any way contribute to the "sale or distribution of tobacco products in a foreign country to children" or to advertise or promote tobacco products in a foreign country in a manner that does not comply with Federal requirements for advertising or promotion within the United States.

Section 805, "Labeling" would make it unlawful for any domestic concern to in any way participate in the sale of a tobacco product

in a foreign country if that tobacco product does not contain a warning label, in that country's dominant language, that complies with the Federal labeling requirements for tobacco products sold in the United States. The only exception would be if the Secretary determines the foreign country's labeling requirements are "substantially similar" to those in the United States and those requirements are "adequately enforced" then the domestic concern may abide by the labeling laws of the country where the tobacco product is sold.

Section 1103. Enforcement

Enforcement would be provided under Section 301 of the Federal Food, Drug and Cosmetic Act.

Section 1104. Reward

A reward of up to $125,000 would be available to those providing information leading to a criminal conviction for a violation of the international sales and labeling requirements.

Section 1105. Definitions

Section 1105 defines the term "domestic concern".

Section 1106. Amendments to Public Health Service Act

This portion of the bill authorizes a major new medical research initiative to more effectively prevent and treat tobacco addiction and tobacco-related diseases.

Tobacco use kills more than 400,000 Americans each year and therefore is, according to former Surgeon General C. Everett Koop, "the chief, single avoidable cause of death in our society and the most important public health issue of our time." Yet despite the billions of dollars expended each year to research diseases caused by tobacco addiction, only a tiny fraction of medical research in the United States is devoted to understanding the causes of tobacco addiction, how to decrease the number of children who start, and how to best help people to quit. As a result, we know too little about how to prevent and treat this destructive behavior

For example, according to a report by the Society for Research on Nicotine and Tobacco, the National Institutes of Health (NIH) spends less than one percent of its budget to research a behavior that accounts for 20 percent of mortality in our nation. Despite the large increases in youth smoking rates and the leveling off of reductions in adult smoking, our nation's commitment to tobacco research has increased only slightly over the last ten years. Lack of funding has resulted in missed opportunities for advancement in tobacco control and has likely discouraged young behavioral researchers from pursuing this area of research. The research that does take place on this subject at NIH is spread across numerous Institutes and is inadequately coordinated.

Despite inadequate funding, tobacco researchers have in recent years made important preliminary findings about the health effects of tobacco, the addictiveness of nicotine, addictive behaviors in general, as well as treatments for cessation of tobacco use. Reflected in several reports of the Surgeon General, as well as in medical and scientific journals, these findings have played a vital role in the public demand for a national tobacco control policy. But much more research is needed to inform public policy. Significant new funding is warranted to support epidemiological, behavioral, phar-

macological, health services and social services research related to the prevention and treatment of tobacco addiction.

An increased commitment to tobacco-related research will help save lives and tobacco-related health care costs. For example, additional research will lead to increased knowledge about cost-effective prevention strategies such as counter-advertising, education, and community based activities. Enhanced research will also yield more affordable and effective cessation tools and perhaps safer tobacco products. The Committee intends for the research initiative in the Committee's bill to inform and ensure that the prevention programs, including the education and counter-advertising programs as well as the cessation programs that are also included in the Committee bill are effective and built on sound scientific evidence about how to reduce tobacco use.

Section 1106 of the Committee bill emphasizes the role of behavioral research in preventing and treating addiction to tobacco products. The Committee urges that the following topics be among those addressed by this research initiative:

Initiation. Smoking and other uses of tobacco are forms of addiction, involving physical and psychological factors. But smoking initiation is purely behavioral. Research should focus on why children begin to smoke and the role of such individual traits as risk taking, attitudes toward health, self- perception, decision making and the impact of tobacco industry marketing on decisions, and how childhood and adolescent development affects these and other relevant psychological processes.

Cessation. Not everyone tries smoking, and not everyone who tries it becomes addicted. Some who do become addicted quit on their own. What are the protective factors in these cases? How can those factors be encouraged in people who are at risk? It is also important to understand the effects of smoking on behavior, such as the changes in the brain and cognitive impairment that can result from smoking. Research is also needed on the behavioral effects of withdrawal, which range from anger and aggression to reduced motor and cognitive functioning.

Effective strategies. Smoking initiation and cessation are both influenced by social, economic and cultural factors. The effects of peer pressure on shaping beliefs and behaviors, the role of family in promoting or protecting against tobacco use, and other socially-based factors must be understood to help develop interventions that encourage and sustain healthy behavior.

The Committee believes that a narrow biomedical approach to tobacco addiction is shortsighted. We must expand scientific inquiry into the behavioral aspects of smoking in order to prevent children from smoking in the first place and to treat nicotine addiction more effectively. In addition, behavioral research on tobacco use will help policy makers address related health concerns, such as illicit drug abuse and underage drinking, and will help the development of effective interventions for those risky behaviors as well.

At the same time, the Committee anticipates that enactment of this bill will result in sufficient new resources at the NIH to justify increased expenditures on diseases associated with tobacco use,

such as cancer and heart disease. However, it is the Committee's intent that the NIH give the highest priority to epidemiological, behavioral and social science research on the prevention and treatment of tobacco addiction itself. The Committee believes very strongly that research focused on prevention and treatment of tobacco addiction will be very cost-effective and be instrumental in reducing tobacco use and avoiding the high human and economic costs associated with tobacco.

The Committee recognizes that aspects of tobacco related research will occur at federal agencies other than the NIH, including the Food and Drug Administration, the Centers for Disease Control, the Agency for Health Care Policy and Research, the Occupational Safety and Health Administration, and the Environmental Protection Agency. The Committee expects the Secretary of Health and Human Services acting through, among others, the Director of the Centers for Disease Control and the Director of the new Office of Tobacco-Related Research at NIH, to coordinate the work of these disparate agencies.

The Committee has also sought to spur coordination by means of the National Tobacco Task Force established in the new section 2802 of the Public Health Service Act. The Committee expects the Task Force, guided in part by the Institute of Medicine study mandated by the new section 2801 of the Public Health Service Act, to prepare a national tobacco research agenda, periodically update this agenda, and make policy recommendations based on the research findings.

Research on the use of tobacco and its effects must take into account the needs of special populations, especially those groups that have been targeted by the tobacco industry.

Section 1106(a) amends the Public Health Service Act by adding a new title at the end of the Act. That title, Title XXVIII, would require various research programs concerning youth smoking.

Section 2801, "Study By the Institute of Medicine", would require the Secretary to enter into a contract with the Institute of Medicine "for the conduct of a study on the framework for a research agenda and research priorities to be used by the National Tobacco Task Force". Various considerations are outlined for the development of the this framework. The Institute of Medicine would be required to report on its recommendations within 10 months of entering into the contract. Appropriations of $750,000 are authorized for this activity.

Section 2802, National Tobacco Task Force, would require the Secretary to establish a National Tobacco Task Force to "foster coordination" among entities undertaking tobacco-related research. The section outlines the composition of the Task Force, its duties and the research activities it shall undertake.

Section 2803, Research Activities of the Centers for Disease Control and Prevention, would require the expenditure of $4.195 Billion in research over 10 years. The funds are directed to be taken from the Tobacco Settlement Trust Fund.

Section 2804, Research Activities of the National Institutes of Health, would require expenditures of $20 Billion over 10 years for research by the NIH concerning tobacco. The Secretary would be required to establish a Tobacco-Related Research Initiative, headed

by the Director of the NIH, to provide funds to conduct research "related to the prevention and treatment of tobacco addiction, and the prevention and treatment of diseases associated with tobacco use. At least one-third of the funds provided must be used to address the "prevention and treatment of addiction."

The Director of NIH is to ensure appropriate coordination of these research efforts by cooperating with the National Tobacco Task Force and by establishing the Office of Tobacco-Related Research. The Office of Tobacco-Related Research will be headed by a director appointed by the Secretary and it shall undertake various administrative tasks to assure appropriate research coordination.

Section 1106(b) of this Act further amends the Public Health Service Act by adding further duties for the Secretary. The Secretary shall, with respect to minority health activities, seek interagency coordination of research and monitor and then report periodically to Congress the amount of Federal funds targeted for research related to minorities and tobacco.

The Committee is concerned about the significant rise in smoking among minority youth in the U.S. The most recent report by the Surgeon General found that smoking by high school age African Americans rose nearly 80% between 1991 and 1997, and that cigarette smoking among Hispanic teens rose by 34% in that period. These disturbing figures represent a growing public health problem among many of our nation's minority citizens, and the Secretary should advise the Congress about federal research activities targeted to remedy it.

Section 1107. Ban on Distribution of Tobacco Products Produced by Child Labor

This Section amends Section 307 of the Tariff Act of 1930 to include a ban on "tobacco products produced or manufactured wholly or in part in any foreign country by child labor."

SUBTITLE B: FEDERAL LICENSING OF TOBACCO PRODUCT DISTRIBUTION

Section 1121. Licensing of Tobacco Product Distribution

Section 1121 provides for a program to license any "domestic concern" that manufactures or distributes tobacco products. Tobacco retailers would not be covered by this program. Such manufacturers and distributors would require a license from the Secretary. The fee for that license would be $1 for every 1,000 cigarettes manufactured or distributed. Manufacturing or distributing tobacco products without a license would be a violation of Section 301 of the Federal Food, Drug and Cosmetic Act. The definition of "tobacco products" would include more than cigarettes, yet the licensing fee is based solely on a number of cigarettes. An appropriate conversion would be necessary to handle smokeless tobacco products.

The Committee does not intend for this provision to have extraterritorial application.

SUBTITLE C: INTERNATIONAL PROVISIONS

Section 1131. International Tobacco Control Trust Fund

Section 1131 would create within the Department of the Treasury the International Tobacco Control Trust Fund to be funded through the licensing fees established in Section 1121.

Annual funds of $150 million will be available to the American Center on Global Health and Tobacco from the International Tobacco Control Trust Fund. The Secretary may also use the resources in the International Trust Fund "for grants and other forms of assistance to foreign governments, nongovernmental organizations, and international organizations to support tobacco control activities in foreign countries." Furthermore, the Secretary may also use resources in the International Trust Fund to enforce "any requirements related to the sale, distribution, marketing, or promotion of tobacco products internationally."

Section 1132. American Center on Global Health and Tobacco

Section 1132 would establish the American Center on Global Health and Tobacco (ACT) "to assist organizations in other countries to reduce and prevent the use of tobacco" through public education programs and mass media campaigns.

ACT would be a not-for-profit corporation established within the District of Columbia and would not be and agency or establishment of the United States.

ACT would be funded through the creation within the National Tobacco Settlement Trust Fund of the Global Public Health and Education Resource Account which is to be credited with $150 million each fiscal year. The $150 million would be transferred each October 1 from the Resource Account to ACT.

ACT and its grantees would be subject to oversight by Congress and ACT would be required to annually report to Congress on its activities. ACT would only be permitted to fund private sector groups, it could not carry out programs directly. ACT's accounts are to be audited annually by independent certified public accountants. ACT's financial transactions may also be audited by the Comptroller General.

Section 1133. Prohibition On Use of Funds to Facilitate the Exportation or Promotion of Tobacco

Section 1133 would bar any appropriation or use of Federal funds to promote or encourage the export, sale, distribution or advertising of tobacco products in a foreign country, or to seek through negotiation or otherwise the removal or reduction by any foreign country of limitations on the importation, sale, distribution or advertising of tobacco products. This prohibition would not apply if the foreign country's restriction is "applied in a manner which constitutes a means of arbitrary or unjustified discrimination between countries". To invoke this exception the Secretary of Commerce would have to make a certification to Congress in writing concerning the nature of the actions by the foreign country and the Secretary of HHS would have to certify to Congress in writing that the restriction is not a "reasonable means of protecting the public health."

Section 1134. Harmonization with United States International Commitments and Obligations

The United States Trade Representative would be required to report to Congress, within 90 days of the Act's effectiveness, on "any provisions of this Act that are inconsistent with obligations of the United States . . . together with recommendations as to how to implement or modify the provision without violating international law."

SUBTITLE D: PREVENTION OF TOBACCO SMUGGLING

Section 1141. Definitions

Section 1141 defines terms used in this Subtitle.

Section 1142. Tobacco Product Labeling Requirements

Section 1142 would make it unlawful to in any way introduce into or receive from "interstate or foreign commerce" any tobacco product that is not packaged and labeled in conformity with the requirements of this section.

The Secretary of the Treasury would be required to promulgate regulations to require manufacturers of tobacco products to place a unique serial number on each package of tobacco products so that the manufacturer and the location and date of production may be determined. The package of each tobacco product produced for export must be labeled with the name of the country of final destination.

Section 1143. Requirements for the Tracking of Tobacco Products

Section 1143 would require the posting of a bond for all exports of tobacco products. Each export would require posting with the Secretary of the Treasury: a bond that indicates the country of final destination, a written statement from the recipient of the tobacco products that recipient will not violate any laws of that country concerning tobacco products and indicating they have never been convicted of any offense with respect to tobacco products.

The Secretary of the Treasury would be required to promulgate regulations to determine the amount and frequency of each bond that must be posted. The bond, however, cannot be less than the amount of Federal tax imposed, on tobacco products consumed in the United States, under Chapter 52 of the Internal Revenue Code of 1986.

The Secretary of the Treasury would return a bond upon determination the tobacco products had been received in the country of final destination as specified in the bond.

Section 1144. Tobacco Product Permits

Section 1144 would require the Secretary of the Treasury to establish a program to require permits for all persons involved in the distribution or receipt of tobacco products in interstate or foreign commerce. This section would not apply to retailers but retailers would need to maintain commercial records of the receipt of tobacco products and have those records available for inspection and audit.

The Secretary of the Treasury would be required to demand that permit holders "keep records concerning the chain of custody of the tobacco products that are the subject of the permit".

Section 1145. Prohibitions

Section 1145 would make it unlawful, without a permit issued under Section 1144, to import tobacco products, to engage in the business of manufacturing, packaging or warehousing tobacco products, or to engage in the business of purchasing tobacco products for resale at wholesale. These prohibitions are to come into effect 180 days after the date of enactment of this subtitle.

Section 1146. Pricing and Labeling of Products Sold on Military Installations or by Native Americans

Section 1146(a) would require the Secretary of the Treasury, in conjunction with the Secretary of Defense, to issue regulations to make sure the price of tobacco products sold on a military installation is equal to the greater of the average price of the tobacco product when sold in the nearest metropolitan area or the highest price for which the product is sold on military installations in the United States. Tobacco products intended for sale on a military installations would have to be labeled with that indication.

Section 1146(b) would require that tobacco products intended for sale on an Indian reservation be labeled with that indication.

Section 1147. Prohibition Against Sale of Tobacco Products in or to Duty-Free Shops or Forwarding Through or Manufacture in Trade Zones

Section 1147(a) would make it unlawful to sell any tobacco product in a duty-free shop located in the United States or to sell to any duty-free shop. Section 1147(b) would make it unlawful to forward through or manufacture a tobacco product in any foreign trade zone.

Section 1148. Jurisdiction; Penalties; Compromise of Liability

Federal District Courts have jurisdiction for suits brought by the Attorney General to prevent or restrain violations of any of the provisions of this subtitle.

In any conviction of the provisions of this subtitle, the provisions of section 3571 of Title 18 U.S.C. will apply as if the person were convicted of a felony under that title.

The Secretary of the Treasury is authorized to compromise the liability arising from a violation of this subtitle upon payment of fine not to exceed $10,000 per violation. In the case of repetitious violations and in order to avoid multiple criminal violations the United States may enter a consent decree to enjoin the repetition of the violation.

Section 1149. Amendments to the Contraband Cigarette Trafficking Act

Section 1149 would amend the Contraband Cigarette Trafficking Act in the following key ways: to have the Act apply to more than cigarettes by defining tobacco products to include cigars, cigarettes, smokeless tobacco and pipe tobacco; to lower the threshold amount of tobacco product which triggers the Act from 60,000 units to 30,000 units; to add prohibitions on knowingly failing to maintain distribution records, altering or obliterating required markings, or interfering with an inspection; and, by making it unlawful to knowingly transport tobacco products under a false bill of lading or without a bill of lading. Any proceeds from the unlawful distribution of tobacco products would be subject to seizure and forfeiture.

Section 1150. Authorization of Appropriations

Such sums as are necessary to carry out this subtitle are authorized for appropriations.

SUBTITLE E: ANTITRUST EXEMPTION

Section 1161. Limited Antitrust Exemption

Section 1161 would provide a limited antitrust exemption for participating tobacco manufactures to facilitate actions in conjunction with this Act. This limited exemption is necessary to protect certain business agreements by tobacco companies, as recommended by the State Attorneys General who negotiated the original tobacco settlement. The Act requires cooperation by tobacco companies regarding certain pricing, advertising, and compliance activities, in order to ensure a uniform and comprehensive national policy to regulate tobacco products in the public interest. Without a limited antitrust exemption, agreements by the tobacco companies to adopt similar pricing and advertising policies could be subject to antitrust challenges.

SUBTITLE F: SPECIAL PROVISIONS CONCERNING PROGRAMS FOR WOMEN, MINORITIES, AND OTHERS

Section 1171. Research Related to Patterns of Smoking by Women and Minorities

Research funded by this Act should where appropriate to the "scope and purpose investigation, include data and analysis with respect to different factors that may be present in the case of women or minorities."

Research funded under this Act to examine patterns of smoking among minorities "should be conducted in proportion to their prevalence in the smoking population and shall be conducted at minority education institutions, where available, or institutions that provide the greatest amount of health care to minority populations in a State."

Section 1172. Counter-Advertising Programs

Section 1172 would require the Secretary to carry out programs to reduce tobacco usage to "discourage the use of tobacco products by individuals and to encourage those who use such products to quit." To receive assistance through these programs an entity would apply to the Secretary and meet such eligibility requirements as the Secretary establishes. Funds necessary to carry out this section will be provided from the funds made available under Title IV of this Act.

Section 1173. Prevention Activities of Community and Migrant Health Centers

Section 1173 would provide $3 billion over 10 years from the National Tobacco Trust Fund to Community and Migrant Health Centers to "provide health services for diseases related to tobacco and to prevent tobacco-related diseases.

SUBTITLE G: SENSE OF THE SENATE

Subtitle G provides a list of purposes for which it would be the sense of the Senate that the proceeds of this Act may be applied. The Sense of the Senate would not limit the application of the proceeds to other purposes.

SUBTITLE H: BAN ON SALE OF TOBACCO PRODUCTS THROUGH THE USE OF VENDING MACHINES

Section 1191. Ban of Sale of Tobacco Products Through the Use of Vending Machines

The Committee is concerned about the fact that vending machines may represent a potential source of unrestricted access to cigarettes for underage youths. While a ban on tobacco vending machines enhances the Act's comprehensive program to prevent youth smoking, it also raises issues of economic injury and job loss to our nation's vending machine industry.

The vending machine industry relies heavily on revenues from the sales of tobacco products. There are over 2,000 vending machine companies spread throughout the U.S., most of them small, family-owned operations. The vending machine industry employs an estimated 10,000 individuals, over one-third of them minority citizens. There are an estimated 350,000 commercial vending machines in operation in the U.S. Vending machine industry representatives advised the Committee that 25% of these companies rely solely on the sale of tobacco products in their business operations, and that tobacco products produce the large majority of sales and profits for the remaining 75% of vending machine businesses.

Section 1191 would ban the use of vending machines to sell tobacco products, effective one year after the of enactment of this Act. Owners of tobacco vending machines would be "reimbursed for the fair market value of their businesses, including the cost of banned vending machines, compensation for lost profits, unexpired contracts, and for the owner's or operator's plant and equipment." Such reimbursal would be directed through the Tobacco Vending Reimbursement Corporation, which would be a private, not-for-profit corporation established in the District of Columbia. Certain guidelines and duties for that Corporation would be established by the Act.

The Secretary of the Treasury would be required to transfer to the Reimbursement Corporation "such sums as are necessary to make due compensation to owners and operators of tobacco vending machines and to carry out the duties of the Corporation." These funds would be taken from the funds paid by the tobacco manufacturers under Title IV of this Act.

TITLE XII—TOBACCO ASBESTOS TRUST FUND

Scientific evidence suggests that asbestos related health problems are greatly facilitated and enhanced by cigarette smoking. As a result, those injured by asbestos also believe they should be able to seek compensation for their damages from tobacco manufacturers.

Section 1201. Definitions

Section 1201 defines relevant terms used in this title.

Section 1202. Tobacco Asbestos Trust Fund

Section 1202 would establish in the United States Treasury a Tobacco Asbestos Trust Fund. There would be five trustees, two appointed by the Secretary of Health and Human Services to represent the interests of asbestos trusts and asbestos defendants, and

two appointed by the Secretary of Labor to represent asbestos claimants and labor unions with claimants as members, and one chosen by the other four, who shall be a health care professional with expertise in asbestos disease.

The Trust Fund receives funds from assessments made by the Secretary of the Treasury on the tobacco industry. The Trust would receive a total of $20 billion by the end of 2014.

Funds may be paid out of the Trust Fund only to victims harmed by tobacco and asbestos.

The Trust Fund is divided into two equal funds - Fund I and Fund II. Fund I would be administered by three trustees: the two appointed by the Secretary of HHS, and the health professional. Fund II would be administered by three trustees: the two appointed by the Secretary of Labor, and the health professional.

Fund I would assign credits to asbestos defendants and trusts in proportion to their past payments to claimants for tobacco-caused harm. The asbestos defendants, however, do not receive any funds. Rather, they may direct the Trust to use such funds to pay asbestos claims.

Fund II is used to pay the tobacco-caused portion of future tobacco/asbestos claims. The funds available to the Trust are allocated equally between Fund I and Fund II, but the trustees of Fund II may provide an advance from Fund II as a loan to Fund I.

Section 1203. Payments From Fund I

In order to determine the allocation of credits within Fund I, the trustees shall request that all asbestos trusts and defendants provide information as to the amount of payments or settlements of asbestos claims made by or on behalf of the defendants and trusts, and all bonded judgments as of the date of enactment. The trustees shall establish credits base on each trust's or defendant's payments as a percentage of the total. The trustees shall include twenty percent of unpaid settlements. In no event shall the total of the credits relating to these unpaid settlements constitute more than six percent of the total of Fund I.

Credits may be used only for the payment of asbestos claims. None of the credits may be used for the payment of corporate dividends, reimbursements of insurers, or any other corporate purpose.

An asbestos defendant may use a credit to direct payment from Fund I to any asbestos claimant. An asbestos trust shall use its credits for payment to victims according to the rules of the trust.

Section 1204. Payments From Fund II

Section 1204 would establish the rules for payment of funds out of Fund II. The trustees of Fund II would be required to establish the following: rules ensuring that funds can only be used for the portion of harm caused by tobacco to an asbestos claimant; rules ensuring that future and current claimants are treated equally, and in the event that future demands require limitations on current payments, those with the most serious disease or disability get priority; criteria establishing a minimum degree of asbestos- related disability or impairment for a claimant to receive compensation; criteria to establish an optional claims handling mechanism for asbestos caused harm in accordance with the Louisiana Agreement

Providing Administrative Alternative for Claimants with Asbestos Related Conditions; rules to insure fair and equitable administration of the claims process, including attorneys' fees; and, rules requiring Fund II recipients to execute a release of all liability for tobacco-caused harm.

Section 1205. Transfers from National Tobacco Settlement Trust Fund.

To provide the funds that would be needed under Section 1202, the Secretary of the Treasury would each year transfer from the National Tobacco Settlement Trust Fund with certain indicated amounts to a total of $21 billion by the year 2014.

Section 1206. Rules for Claims Against Asbestos Trusts, Asbestos Defendants, and Tobacco Companies

Section 1206 indicates the general purpose of the title is to ensure that asbestos claimants and asbestos/tobacco claimants receive compensation in a fair and timely manner.

Before a lawsuit for harm caused by tobacco and asbestos can proceed to trial or judgment, the plaintiff must submit a claim to Fund II for the tobacco-caused portion of the harm. The plaintiff would receive a determination within 120 days, or earlier if exigent circumstances exist. A claimant who rejects an offer from, or is denied an award by, Fund II may proceed to trial or judgment in a tort action.

A claimant who accepts an award from Fund II must execute a release of liability for all tobacco-caused harm.

Tobacco companies shall not be liable to asbestos trusts and defendants for claims arising from payments or obligations for payments to asbestos/tobacco claimants made or incurred prior to the date of enactment. Any existing lawsuits based on such claims are extinguished. For claims subsequent to the date of enactment, asbestos trusts and defendants may aggregate and establish them based on valid statistical proof of relative causation for each disease category.

A claimant who accepts an award from Fund II may not sue for tobacco-caused harm. A claimant who rejects an award may sue asbestos defendants for asbestos and tobacco harm in accordance with other applicable law. An asbestos defendant that pays for tobacco-caused harm may succeed to the claimant's rights to request compensation from Fund II, or may bring an indemnity or contribution action against a tobacco company.

In an asbestos action where the claimant had exposure to tobacco, the trier of fact must apportion the relative causation between asbestos and tobacco. The apportionment may be determined based upon valid statistical data.

Nothing in this legislation shall limit any existing joint liability among asbestos trusts or defendants for asbestos-caused harm, limit anyone's ability to claim disability caused by asbestos, or delay resolution of a claim.

TITLE XIII: VETERANS' BENEFITS

Section 1301. Recovery By Secretary of Veterans Affairs

Section 1301 would amend Title 38 of the United States Code by adding "Part VII: Recovery of Compensation Costs for Tobacco-Related Disability or Death."

Section 9101 of that Part VII would permit the Secretary of Veteran's Affairs to sue tobacco manufacturers for cost of compensation to be paid to veterans for their smoking related injuries associated with their military service.

The funds recovered from such suits would be paid into a revolving fund in the United States Treasury. The fund would be called the Department of Veterans Affairs Tobacco Recovery Fund. The "Fund shall be available to the Secretary without fiscal year limitation for purposes of veterans benefit programs, including administrative costs."

Section 9102 of Part VII would allow the Secretary to establish procedures to determine the present value of future benefits paid to a veteran in compensation of smoking related injury. No action taken by the Secretary to seek compensation from the tobacco manufacturers would "operate to deny the injured veteran . . . the recovery for that portion of his or her damage not covered" by compensation through the Veterans Administration.

Section 9104 would exclude any sums recovered through this Title by the Secretary from the annual limitations of damages available to participating manufacturers.

STATEMENT OF COMMITTEE INTENT

The Committee is working on additional amendments to S. 1415. These amendments would be offered on the Senate floor to make further technical and conforming changes, as well as substantive modifications to further improve the bill and to remedy language that does not correspond with the Committee's intent.

The Committee intends that any further amendments would be adopted by the Senate and considered as original text for purposes of amendment.

ADDITIONAL VIEWS OF SENATOR TED STEVENS AND SENATOR CONRAD BURNS

The Committee includes payments to the Federal Black Lung Program on the Sense of the Senate list of purposes to which the proceeds from the tobacco legislation may be used.

Epidemiological evidence strongly suggests that cigarette smoking is correlated to the decline in lung function of miners exposed to coal dust who now receive payments from the Federal Black Lung Program. The Committee therefore adopted the Sense of the Senate that proceeds from the tobacco legislation may be used for payments to the Federal Black Lung Program.

In 1985, the Surgeon General of the United States (C. Everett Koop) reported that "since the introduction of more effective controls to reduce the levels of coal dust exposure at the worksite, cigarette smoking has become the more significant contributor to reported cases of disabling airflow obstruction among coal miners" . . . and further, that "the prevalence of ventilatory disabilities in coal miners could be substantially reduced by reducing the prevalence of cigarette smoking, and efforts aimed at reducing ventilatory disability should include efforts to enhance successful smoking cessation."

Since the Surgeon General's Report, numerous medical and scientific studies have documented the direct relationship between cigarette smoking and black lung disease or pneumoconiosis. U.S. Department of Labor statistics reveal that non-smoking coal miners rarely are awarded disability compensation from the Black Lung Trust Fund while a substantial majority of black lung claimants who have received federal benefits are cigarette smokers. Medical studies have in fact reported "that the effect of (cigarette) smoking is five times that of coal dust" on decline in lung function while having "five to ten times greater negative effect on ventilatory capacity than coal dust." In short, the Federal Black Lung Program is likely paying for harm caused, in part, by cigarette smoking. Current estimates indicate that an infusion of $15 billion dollars from the tobacco industry would help keep the federal programs working for black lung victims.

We recommend, in light of the relationship between cigarette smoking and coal workers pneumoconiosis, and the fact that Federal Black Lung Programs have paid almost $60 billion in medical and disability benefits to those afflicted beneficiaries, that the tobacco industry should also contribute to the Federal Black Lung Program. We therefore recommend that adequate funding be allocated from revenues from tobacco legislation to ensure the solvency of the Federal Black Lung Program and to provide for future benefits.

ROLLCALL VOTES IN COMMITTEE

In accordance with paragraph 7(c) of rule XXVI of the Standing Rules of the Senate, the Committee provides the following description of the record votes during its consideration of S. 1415:

Senator Ashcroft offered an amendment to delete all references to limitations of liability. By rollcall vote of 2 yeas and 16 nays as follows, the amendment was defeated:

YEAS—2	NAYS—16
Mr. Ashcroft	Mr. McCain
Mr. Brownback	Mr. Stevens
	Mr. Burns
	Mr. Gorton
	Mrs. Hutchison
	Ms. Snowe
	Mr. Frist [1]
	Mr. Abraham [1]
	Mr. Hollings
	Mr. Inouye
	Mr. Rockefeller
	Mr. Kerry
	Mr. Breaux [1]
	Mr. Bryan
	Mr. Dorgan
	Mr. Wyden

[1] By proxy.

Senator Snowe offered an amendment to codify provisions relating to advertising and marketing. By rollcall vote of 5 yeas and 14 nays as follows, the amendment was defeated:

YEAS—5	NAYS—14
Ms. Snowe	Mr. McCain
Mr. Rockefeller	Mr. Stevens [1]
Mr. Breaux	Mr. Burns
Mr. Dorgan	Mr. Gorton
Mr. Wyden	Mrs. Hutchison
	Mr. Ashcroft
	Mr. Frist
	Mr. Abraham
	Mr. Brownback
	Mr. Hollings
	Mr. Inouye [1]
	Mr. Ford
	Mr. Kerry [1]
	Mr. Bryan

[1] By proxy.

Senator Ashcroft offered an amendment to provide legal standards and procedures for suppliers of raw materials and component parts for medical devices. By rollcall vote of 3 yeas and 13 nays as follows, the amendment was defeated:

YEAS—3	NAYS—13
Mr. Ashcroft	Mr. McCain
Mr. Abraham	Mr. Stevens [1]
Mr. Brownback	Mr. Burns [1]
	Mr. Gorton [1]
	Ms. Snowe
	Mr. Frist [1]
	Mr. Hollings
	Mr. Inouye [1]
	Mr. Ford
	Mr. Rockefeller
	Mr. Kerry
	Mr. Breaux
	Mr. Bryan

[1] By proxy.

Senator Dorgan offered an amendment to strike the cap on liability limitations. By rollcall vote of 4 yeas and 15 nays as follows, the amendment was defeated:

YEAS—4	NAYS—15
Mr. Ashcroft	Mr. McCain
Mr. Brownback	Mr. Stevens
Mr. Rockefeller	Mr. Burns
Mr. Dorgan	Mr. Gorton
	Mrs. Hutchison
	Ms. Snowe
	Mr. Frist [1]
	Mr. Abraham [1]
	Mr. Hollings
	Mr. Inouye
	Mr. Ford
	Mr. Kerry
	Mr. Breaux
	Mr. Bryan
	Mr. Wyden

[1] By proxy.

Senator Ashcroft offered an amendment to establish legal standards procedures for product liability litigation. By rollcall vote of 2 yeas and 16 nays as follows, the amendment was defeated:

YEAS—2	NAYS—16
Mr. Ashcroft	Mr. McCain
Mr. Brownback	Mr. Stevens [1]
	Mr. Burns [1]
	Mr. Gorton [1]
	Mrs. Hutchison
	Ms. Snowe
	Mr. Frist [1]
	Mr. Abraham

Mr. Hollings
Mr. Inouye [1]
Mr. Ford
Mr. Rockefeller
Mr. Kerry
Mr. Breaux
Mr. Bryan
Mr. Wyden

[1] By proxy.

Senator Ford offered an amendment to reduce annual payment amounts to those contained in the Clinton budget. By rollcall vote of 4 yeas and 13 nays as follows, the amendment was defeated:

YEAS—4	NAYS—13
Mr. Burns	Mr. McCain
Mr. Gorton	Mr. Stevens
Mr. Ashcroft	Ms. Snowe
Mr. Ford	Mr. Frist [1]
	Mr. Abraham
	Mr. Brownback
	Mr. Hollings
	Mr. Inouye
	Mr. Rockefeller
	Mr. Kerry
	Mr. Breaux
	Mr. Bryan
	Mr. Wyden

[1] By proxy.

Senator Ford offered an amendment to limit "real" annual payments to $506 billion over 25 years, as the legislation has been publicly described. By rollcall vote of 1 yea and 16 nays as follows, the amendment was defeated:

YEAS—1	NAYS—16
Mr. Ford	Mr. McCain
	Mr. Stevens [1]
	Mr. Burns
	Mr. Gorton
	Ms. Snowe
	Mr. Frist
	Mr. Abraham
	Mr. Brownback
	Mr. Hollings
	Mr. Inouye
	Mr. Rockefeller
	Mr. Kerry
	Mr. Breaux
	Mr. Bryan
	Mr. Dorgan
	Mr. Wyden

[1] By proxy.

Senator Dorgan offered an amendment to strike the limited antitrust exemption. By rollcall vote of 4 yeas and 15 nays as follows, the amendment was defeated:

YEAS—4	NAYS—16
Mr. Rockefeller	Mr. McCain
Mr. Kerry [1]	Mr. Stevens [1]
Mr. Dorgan	Mr. Burns
Mr. Wyden	Mr. Gorton
	Mrs. Hutchison
	Ms. Snowe
	Mr. Ashcroft [1]
	Mr. Frist [1]
	Mr. Abraham
	Mr. Brownback
	Mr. Hollings [1]
	Mr. Inouye
	Mr. Ford
	Mr. Breaux
	Mr. Bryan

[1] By proxy.

Senator Gorton offered an amendment to require Indian tribes to collect State taxes on tobacco and remit them to the State. Senator Bryan offered an amendment in the nature of a substitute to require the tribes to remit the taxes to the United States Treasury for distribution to the States. Senator Gorton accepted the Bryan amendment as a modification of his amendment. By rollcall vote of 10 yeas and 9 nays as follows, the amendment was agreed to:

YEAS—10	NAYS—9
Mr. Burns	Mr. McCain
Mr. Gorton	Mr. Stevens [1]
Mrs. Hutchison	Ms. Snowe
Mr. Ashcroft [1]	Mr. Hollings
Mr. Frist	Mr. Inouye
Mr. Abraham	Mr. Ford
Mr. Brownback [1]	Mr. Rockefeller
Mr. Kerry	Mr. Breaux
Mr. Bryan	Mr. Dorgan
Mr. Wyden	

[1] By proxy.

On a rollcall vote of 19 yeas and 1 nay as follows, the Committee ordered S. 1415 favorably reported:

YEAS—19	NAYS—1
Mr. McCain	Mr. Ashcroft
Mr. Stevens [1]	
Mr. Burns	
Mr. Gorton	
Mr. Lott [1]	
Mrs. Hutchison	
Ms. Snowe	
Mr. Frist	
Mr. Abraham	

Mr. Brownback
Mr. Hollings [1]
Mr. Inouye
Mr. Ford
Mr. Rockefeller
Mr. Kerry
Mr. Breaux
Mr. Bryan
Mr. Dorgan
Mr. Wyden

[1] By proxy.

Without objection, the Committee authorized the staff to make any necessary technical or conforming amendments to the bill.

ESTIMATED COSTS

In the opinion of the Committee, it is necessary under paragraph 11(a)(3) of Rule XXVI of the Standing Rules of the Senate to dispense with the requirements of paragraphs 11(a)(1) and (2) of the Rule and section 403 of the Congressional Budget Act of 1974 in order to expedite the business of the Senate.

REGULATORY IMPACT STATEMENT

In the opinion of the Committee, it is necessary under paragraph 11(b)(2) of rule XXVI of the Standing Rules of the Senate to dispense with the requirements of paragraph 11(b)(1) of Rule XXVI of the Standing Rules of the Senate in order to expedite the business of the Senate.

CHANGES IN EXISTING LAW

In the opinion of the Committee, it is necessary to dispense with the requirements of paragraph 12 of Rule XXVI of the Standing Rules of the Senate in order to expedite the business of the Senate.

ADDITIONAL VIEWS BY CHAIRMAN MCCAIN

The Committee is working on additional amendment to S. 1415. These amendment would be offered on the floor to make further technical and conforming changes, as well as substantive modifications to further improve the bill and to remedy language that does not correspond with Committee intent.

The Committee intends that any further amendments would be adopted by the Senate and considered as original text for purpose of amendment.

FUNDING FOR PUBLIC HEALTH PURPOSES AND FARMER ASSISTANCE

The Committee intends that precise funding level for the administration, enforcement and implementation of this act be developed in consultation with the full Senate and the administration prior to and during floor consideration of S.1415.

While in certain cases funding amount are identified in the legislation, the Committee recognizes that precise funding level must be reconciled with the needs, priorities and purposes of this Act.

The Committee intends to ensure that amounts reserved or authorized for any purpose are fully prioritized, justified and fiscally responsible.

SPIT TOBACCO

During the Executive Session on S. 1415 the Committee adopted an amendment by Senator Ford regarding small tobacco manufacturers. This amendment contained a formula by which spit tobacco is equated in volume to cigarettes for purpose of manufacturer payments and pricing.

The Committee subsequently learned that the effect of the amendment would be to reduce the price increase on spit tobacco pursuant to this act. Spit tobacco poses a substantial health risk to youth. It is the Committee's intent that the price of spit tobacco rise commensurately with cigarettes to effectively deter youth consumption. The Committee will work on a further amendment to repair this serious problem with the reported bill.

NATIVE AMERICANS

A fundamental debate in the course of drafting tobacco regulatory policy for our nation has centered on the question of a potential unregulated tobacco loophole in Indian country. Throughout the course of developing this tobacco proposal, I have respected the inherent authority of Indian tribes in the same manner as we do state governments. Certainly, no one disagrees that the intent and scope of this bill applies to the regulation of tobacco related activities of Indian tribes and their members while providing the necessary protections to Indian children from the dangers of tobacco.

It is clear that "Indian country" is an anomaly to many in the Congress and to the general public. Indeed, the course of federal policy with respect to Indian tribes has further convoluted the national sentiment toward tribal governments, with the actions of the Congress creating a matrix of regulatory laws and jurisdictional complexity. It is this intricate nature of federal policy and tribal governance which compels our fair and deliberative consideration of any policy we develop which affects multiple jurisdictional authorities.

An attempt was made in Section 604 of Title VI to broadly treat what has been interpreted as a tax evasion issue in Indian country in the collection of state taxes to non-members who buy cigarette products on tribal lands or from tribal retailers. However, a fundamental flaw exists within Section 604 to achieve this objective to "eliminate pricing disparity" as a "basic function of the Act."

I note that although "eliminating pricing disparity" is a "basic function of the Act," this is not an absolute objective. For example, each of the fifty states retain their ability to set their own cigarette tax rates notwithstanding the near certainty that this will result in significant (perhaps dramatic) interstate price disparities. In short, the national objective of uniformity pauses to recognize the sovereign nature of the state governments, in that states are permitted to establish their own tax rates, even if those rates frustrate and impede the policies of neighboring states. Indian tribal governments, however, are not to be afforded the same respect and discretion with regard to cigarette tax rates.

The Supreme Court has recognized that deference must be paid to the sovereign status of Indian tribal governments. Specifically, in Washington v. Colville, 447 U.S. 134 (1980) the Supreme Court stopped far short of endorsing the state's authority to "enter onto the reservations, seize stocks of cigarettes which are intended for sale to nonmembers, and sell theses stocks to nonmembers, and sell these stocks in order to obtain payment of the taxes due." The Court determined that the state's ability to take this action was not properly before the Court, but nevertheless, did recognize that seizure of on-reservation cigarettes was "considerably different" from the state's ability to seize off-reservation cigarettes "where state power over Indian affairs is considerably more expansive than it is within reservation boundaries." The Court explained that off-reservation seizure of cigarettes "polices against wholesale evasion of [state] taxes without unnecessarily intruding on core tribal interests."

Because of the federal trust responsibility to Indian tribes and their members, Congress has a strong responsibility to protect such "core tribal interests" even while seeking to achieve other federal objectives. In addition, Congress must consider these interests when enacting legislation or it risks judicial invalidation of these provisions, just as it must be solicitous of federalism concerns or it risks similar judicial invalidation.

I am concerned that some interpretation of Section 604 could result in a violation of the federal government's trust obligation to tribes. Specifically, where tribes and states have negotiated agreements providing for the collection of state taxes, there is simply no rational basis for Congress to de facto invalidate these agreement,

arrangements, or state laws simply because some tribes and states have not worked out such satisfactory arrangements. Of course, Section 604 need not be read to necessarily invalidate these freely negotiated arrangements. I am sure that no one believes the Treasury Department should implement this provision in a manner that preempts state law or tribal-state voluntary agreements.

Second, the provision should not be interpreted to impose state taxes on transactions that are otherwise exempt from state taxes. For example, in Colville, the Court found that in some circumstances states must credit tribes for the amount of tribal taxes applicable to transactions between tribes and nonmembers. The Supreme Court has encouraged Congress to address both sides of the tribal-state taxing equation: equity to tribes and states. Section 604 seeks to resolve state concerns without considering legitimate issues raised by Indian tribes.

If eliminating pricing disparities for those products is indeed a paramount objective of the proposed tobacco legislation, fundamental fairness as well as a desire to realistically achieve such an end require that uniform application of the principal be proposed. Short of that, the disparate treatment accorded tribal and state governments cannot be maintained as an equitable principal and will not succeed as a practical matter.

In my home state of Arizona, the state tax law does not apply to tribal or individual tribal retailers located on Indian reservations where the tribal government imposes a commensurate tax. Twelve tribes in the state enacted their own cigarette tax and the state has cooperative agreements with three other tribes which authorize the state to act as the tax collector for the tribe. I note that the State of Nevada enacted legislation in 1979 which authorizes tribes of the state to collect a tribal sales tax in lieu of the state sales tax, provided that the tax was equal to or greater than the commensurate state tax. This applies to cigarette sales. The tribes utilize the revenue from the tribal sales tax for governmental services and benefits for their tribal members. State-tribal tax agreements are operating in several states and tribes are operating pursuant to state laws in others.

In conclusion, I am most concerned with the provision for two reasons. First, as the Colville decision shows, even with respect to transactions between tribes and non-Indians, not all state retail sales are applicable. If this provision is interpreted to impose all state taxes, then this Committee has taken drastically needed tax revenues from this Nation's poorest citizens. Second, this provision should not be interpreted to discourage tribal-state agreements. There are far more examples of tribal-state cooperation than conflict in the field of tribal-state taxation. Our legislation should build on such cooperation and not nullify the fruits of cooperation.

ADDITIONAL VIEWS OF MR. HOLLINGS

I acknowledge that some believe it is necessary to have provisions in a comprehensive tobacco bill that relate to the international aspects of tobacco sales. However, I am concerned with the constitutionality and extraterritorial application of some of the international provisions of this bill. Ultimately, any such provisions must be constitutional, administrable, and not result in the loss of American jobs or harm to American farmers.

ADDITIONAL VIEWS OF SENATOR SPENCER ABRAHAM: EXPLANATION OF SELECTED VOTES

Now that the Committee has reported out tobacco settlement legislation—legislation that I know will require more work on the floor—I would like to comment on several of the more important votes that took place in Committee.

One of several contentious issues that arose during the mark-up was the amendment offered by Senator Snowe proposing to codify the provisions in the tobacco agreement relating to advertising and marketing by the tobacco companies. The problem with the Snowe amendment is that the vast majority of legal scholars agree that the amendment, by definition, is unconstitutional. The tobacco agreement negotiated between the tobacco companies and the attorneys general from various states was a very complex amalgam of legal and policy issues. To bring the agreement to fruition will require a number of actions, including laws passed by Congress (and obviously signed by the President) and executive branch directives. In addition, because the tobacco companies had expressed a willingness to curtail, voluntarily, many advertising and marketing tactics that are entirely legal under the Supreme Court's interpretation of commercial free speech, the tobacco companies also would have been required to enter into a consent decree in which they would agree to cease such constitutionally protected activities. In other words, what they could not be compelled to do through legislative or executive action, they have agreed to do voluntarily in order to obtain other aspects of the tobacco agreement.

By codifying these provisions via the Snowe amendment, Congress would have seriously risked "torpedoing" the entire tobacco agreement by preemptively and—as most observers agree—unconstitutionally restricting the companies' rights to advertise and market their products. Primarily out of constitutional concerns, the committee defeated the Snowe amendment on a 5-14 vote, and I voted against it on those grounds as well.

Several votes also occurred with respect to amendments offered by Senator Ashcroft on important legal reform issues, and they deserve some mention as well. I continue to be a strong advocate of legal reform, but it is important to include only reforms that belong in this legislation.

Senator Ashcroft first offered as an amendment to the tobacco settlement legislation the text of the Biomaterials Access Assurance Act, which the Committee had already reported out this Congress as part of product liability reform legislation. That amendment failed by a vote of 3-13, with the Committee members who spoke in opposition to it indicating that they supported the substance of the amendment but did not think that the place for it was on this legislation. I supported that amendment, however. Such important health-related legislation as the biomaterials bill would be

appropriate to include as part of tobacco settlement legislation, and, in my view, should in fact be directly linked to and included in the legislation.

While I support the substance of product liability reform legislation and broader civil justice reform generally, I did not support Senator Ashcroft's second amendment, which was defeated by a vote of 2-16, to add the entire product liability reform legislation to this bill. That legislation has already been reported out of the Commerce Committee. Moreover, it has been and still is the subject of sensitive negotiations, and also deals with a broad array of products that do not necessarily have anything to do with health. Including such legislation here would have only complicated an already difficult issue with a matter that the Committee has already dealt with separately.

Finally, Senator Ashcroft and Senator Dorgan both offered slightly different amendments to remove all liability limits from the tobacco legislation. Each was defeated by a wide margin. I opposed those amendments because the carefully circumscribed liability limits developed by the Chairman were central to the legislation that he was able to put together with sufficient support to be reported out of Committee. Nonetheless, Senator Ashcroft makes a valid point that if the Congress is not willing to grant liability protections to businesses and individuals that make and market safe and useful products, then perhaps Congress should not be protecting cigarette manufacturers, who produce a harmful product that contributes to the deaths of millions of Americans each year.

Passage of Senator Ashcroft's efforts, while well-intentioned, would simply have prevented any tobacco settlement legislation from moving forward. The Chairman was able to put together a piece of legislation on this complex and controversial issue only through striking a delicate balance. It is important for the Committee to move forward at this point and to report out tobacco settlement legislation so that the full Senate will have the opportunity to consider it this Session.

ADDITIONAL VIEWS OF SENATOR RON WYDEN

This bill takes an historic step toward reducing the negative health consequences of tobacco on future generations of Americans. It provides a comprehensive approach to addressing the problems of advertising and labeling at home and abroad, establishes youth smoking goals and addresses the unique concerns of tobacco farmers.

ACCOUNTABILITY

As we address the problem of youth smoking and changing the behavior of tobacco companies, it is important that there be an objective body that can report on the success or failure of those changes. The Accountability Panel will be the only "watch-dog" apparatus available to determine company specific behavior. It will report annually on the success or failure of specific company behavior in meeting the public health goal of this bill—reducing youth smoking.

At any time, the panel may recommend a specific company's liability protections be removed because the company's behavior is significant enough to hinder the achievement of youth smoking reduction goals. By creating the only link between public health and the company's continued receipt of its liability protection, the Accountability Panel will serve as a trigger to those protections. In addition, should action be initiated to remove liability protections, whether a company has adopted the panel's recommendations can be considered during the deliberations. Company specific accountability is even more important because the look back provisions are established on an industry-wide basis in this legislation.

The Accountability Panel would be composed of career public health officials, including a voice for minority communities that were targeted by tobacco companies. As unanticipated technology and behavior changes occur, this panel will provide the mechanism to identify the impact of specific company's behavior that we cannot now predict. Under this bill, only the Accountability Panel will provide an ongoing record of company specific behavior to reduce youth smoking with the power to recommend ending a company's liability protections.

MINORITY HEALTH

This bill is the first serious attempt to resolve minority health issues related to tobacco. While consumers are targeted every day by companies, the targeting of minorities and women by tobacco companies resulted in the lives of many individuals and families being decimated by smoking-related diseases. The importance of research and providing smoking prevention and cessation programs for minority communities cannot be understated. Research must focus on developing successful cessation programs and smoking-re-

lated minority health concerns. In addition, prevention and cessation programs should be culturally and linguistically appropriate; cessation programs must be affordable and community-based, including community health centers to reach migrant populations and others who might not have regular sources of health care.

INTERNATIONAL TOBACCO CONTROL

Another important aspect of this bill are the provisions that relate to international tobacco control. Nothing in these provisions is intended to prevent the U.S. government or tobacco companies themselves from working with other nations to develop strict standards against marketing to children. Through a code of conduct, restrictions on U.S. government institutions to promote tobacco exports, labeling and marketing standards, anti-smuggling efforts and the creation of a non-governmental organization to focus on tobacco control in developing nations, this bill ensures that any U.S. tobacco settlement is not paid for by selling tobacco to children overseas.

As one-in-three cigarettes produced in the U.S. is currently exported, the issue of the U.S. establishing a strong position concerning international tobacco control is critical to public health and as a foreign policy goal. The World Health Organization (WHO) projects that one-third of the world's population over the age of 15 currently smokes—equivalent to 1.1. billion smokers. Over 90 percent of the smokers are located outside the U.S., and 70 percent live in developing countries.

It has been demonstrated repeatedly that when a U.S. tobacco company enters a foreign market, overall consumption of cigarettes increases in that country. In Taiwan and Japan, U.S. brands jumped from one percent of the market to 20 percent in less than two years. U.S. tobacco companies, like other companies, know the image of the U.S. sells their products overseas. We should insure that image our national image is not used to promote tobacco products to children overseas.

ENVIRONMENTAL TOBACCO SMOKE (ETS)

This legislation sets a tough standard against environmental tobacco smoke, but creates exceptions for some public places and allows states to opt out of the standard completely. There should be no option for states to opt out. ETS causes or exacerbates a wide range of adverse health effects, including cancer, respiratory infections and asthma. ETS contains over 4000 chemical; 200 are poisons; 43 cause cancer. The Environmental Protection Agency has classified ETS as a known cause of cancer in human. Because one of the primary goals of this legislation is the health of children, it is unfortunate that the bill would allow ETS to harm children.

The Building Owners and Managers Association International have correctly stated that this provision as written gives the states the ability to "just say no" to protections against ETS. The opportunity to remove a significant health hazard should not be lost.

LOOK BACK PROVISIONS AND PENALTIES TO REDUCE YOUTH SMOKING

While this bill sets reasonable goals for reductions in youth smoking rates, it permits tobacco companies to miss the targets by 20 percentage points. In addition, while the penalties in a cumulative sense may appear large, they are capped and amount to a graduated cost to the company ranging from under one-third of a penny-a-pack to just a penny-per-pack.

The penalties, combined with the look back provision based on an industry-wide basis are not enough. Companies must be held accountable. One way to do that is to establish company specific look-backs and penalties. In addition, the current provision may result in smaller tobacco companies bearing a larger share of the burden than their market share, should other, larger companies not succeed in reducing youth smoking.

An amendment, which was offered in mark-up but was withdrawn, would have provided company-specific look back provisions, and imposed greater reductions in youth smoking goals. From a public health perspective, this approach would be better than the provisions of the current bill. Look back provisions should be on a company-by-company basis in order to achieve accountability for bad actors and to learn what strategies work for different companies in achieving reductions in youth smoking. Greater penalties should be required for missing those targets. Finally, language to assure minority children are appropriate counted in any look-back provisions would have been preferable.

CONCLUSION

Although some provisions of this bill could be strengthened, the Committee's product is comprehensive and provides the opportunity for Congress to take historic action to reduce one of the known preventable health problems. In doing so, Congress would increase the health status of all our communities and reduce the long-term health care costs for smoking-related diseases.

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