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**[05/03/1998] [4]**

194

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Cynthia A. Rice ( CN=Cynthia A. Rice/OU=OPD/O=EOP [ OPD ] )

CREATION DATE/TIME: 3-MAY-1998 14:44:09.00

SUBJECT: Re: Electronic copies of McCain bill

TO: Cynthia Dailard ( CN=Cynthia Dailard/OU=OPD/O=EOP @ EOP [ OPD ] )

READ:UNKNOWN

TO: Elena Kagan ( CN=Elena Kagan/OU=OPD/O=EOP @ EOP [ OPD ] )

READ:UNKNOWN

TO: Laura Emmett ( CN=Laura Emmett/OU=WHO/O=EOP @ EOP [ WHO ] )

READ:UNKNOWN

TO: Bruce N. Reed ( CN=Bruce N. Reed/OU=OPD/O=EOP @ EOP [ OPD ] )

READ:UNKNOWN

TEXT:

Don't bother to print out the 103-page committee report -- I already have and will get you all copies.

----- Forwarded by Cynthia A. Rice/OPD/EOP on 05/03/98  
02:43 PM -----

Cynthia A. Rice  
05/03/98 02:28:25 PM  
Record Type: Record

To: See the distribution list at the bottom of this message  
cc:  
Subject: Electronic copies of McCain bill

Attached are the copies of the McCain bill posted on the Commerce Committee web site.

This is the report language, which we did not have.

This is the legislative language -- we have a hard copy dated earlier and marked "confidential" and "not final." I just left voice mail for committee staff to ask if anything changed from the version we have. If so, I will get a revised hard copy of the bill distributed to you all.

Message Sent

To: \_\_\_\_\_  
Bruce N. Reed/OPD/EOP  
Elena Kagan/OPD/EOP  
Laura Emmett/WHO/EOP  
Thomas L. Freedman/OPD/EOP  
Mary L. Smith/OPD/EOP  
Peter G. Jacoby/WHO/EOP  
Toby Donenfeld/OVP @ OVP  
Joshua Gotbaum/OMB/EOP  
Richard J. Turman/OMB/EOP



REPORT TO ACCOMPANY S. 1415--the National Tobacco Policy and Youth Smoking Reduction Act

**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 four hundred thousand 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 increases 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

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#### 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.

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#### 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

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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 constitutionally 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**

#### **Sec. 1. 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.

#### **Sec. 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.

#### **Sec. 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 establish youth consumption targets and subject the industry to financial penalties for failing to meet such targets.

#### **Sec. 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.

Sec. 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.

Sec. 6 Definitions

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

Sec. 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.

Sec. 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.

Sec. 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.

#### Sec. 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

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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 Secretary’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 effects 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 existing 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

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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

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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

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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 © 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

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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 in subsection © 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*

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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 FDCA

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 interstate 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.

**Automated Records Management System  
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*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 paragraph (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

Automated Records Management System  
Hex-Dump Conversion

requirements of section 802(f) are met. This approach is consistent with FDA's application of section 802(b) to devices.

**Subtitle B: Advertising**

*Sec. 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.

*Sec. 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.

*Sec. 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**

*Sec. 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

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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.

*Sec. 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.

Section (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 © 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 definitions relevant terms.

## **SUBTITLE B-STATE ENFORCEMENT INCENTIVES**

### *Sec. 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.

### *Sec. 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.

*Sec. 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 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**

*Sec. 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.

*Sec. 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.

**Automated Records Management System  
Hex-Dump Conversion**

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.

<b>YEAR</b>	<b>PRICE PER PACK INCREASE</b>	<b>EXPECTED VOLUME OF SALES</b>	<b>ANNUAL INDUSTRY PAYMENT</b>	<b>PRICE PER PACK</b>	
	(Increases	(cigarette		(1998	

Automated Records Management System  
Hex-Dump Conversion

	from 1998 price)	packs & spit tobacco equivalent)		Baseline: \$2.00 per pack)	
1999	\$.65	20.7b	\$14.4b	\$2.65	
2000	\$.70	19.9b	\$15.4b	\$2.79	
2001	\$.80	19.4b	\$17.7b	\$2.88	
2002	\$1.00	18.2b	\$21.4b	\$3.12	
2003	\$1.10	17.7b	\$23.6b	\$3.21	

\*\*Department of Treasury

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.

*Sec. 404 Adjustments*

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

*Sec. 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.

*Sec. 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.

*Sec. 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 required 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.

*Sec. 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***

***Sec. 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 than 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 *Venette* decision, and health-care delivery systems traditionally serving Alaska Native communities.

*Sec. 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**

*SEC. 701. Definitions*

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

*SEC. 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 judgement from its suits against tobacco manufacturers.

*SEC. 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.

*SEC. 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

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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.

*SEC. 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.

*SEC. 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 of 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.

*SEC. 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.

*SEC. 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.

*SEC. 709. Conforming Amendments*

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

*Sec. 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**

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*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 report 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 judgements.” 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