

**NLWJC - KAGAN**

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**[05/03/1998] [2]**

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

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

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

*Section 904. Privilege and Trade Secret Claims*

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

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

*Section 905. Disclosure by the Depository*

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

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

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

*Section 906. National Tobacco Documents Review Board*

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

*Section 907. Resolution of Disputed Privilege and Trade Secret Claims*

The Board would be responsible for determining whether to uphold or reject a tobacco manufacturer's claim that a document should not be revealed to the public due to a claim that the

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document is protected by attorney client privilege, the attorney work product doctrine or trade secret protection. Such a determination could be made by a single member of the Board. The decision is to be made in writing and is subject to judicial review.

*Section 908. Appeal of Board Decision*

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

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

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

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

*Section 909. Miscellaneous*

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

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

*Section 910. Penalties*

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

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

*Section 911. Definitions*

Section 911 defines relevant terms.

**Title X: Long-Term Economic Assistance for Farmers**

**Section 1001 - Short Title**

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

**Section 1002 - Definitions.**

This section sets out the definitions applicable to title X.

**Subtitle A -- Tobacco Community Revitalization Trust Fund**

**Section 1011 - Establishment of Trust Fund**

This section establishes the "Tobacco Community Revitalization Trust Fund." The trust fund is to be funded by assessments to tobacco manufacturers and importers as designated in section 1012. Funds deposited into the Tobacco Community Trust Fund are to be used for the following: payments for lost tobacco quota, payments for sale of quotas, payments for community economic development grants, worker transition program, higher education assistance programs, and to reimburse the federal government for the administration of the program. The legislation includes specific dollar limitations on annual payouts for each program. All monies and payments under the Trust Fund are deemed to constitute budget authority in advance of appropriations Acts.

The legislation has earmarked \$28.5 billion for the program, pursuant to section 1012. Of this amount, the following annual expenditures are to be made annually for fiscal years 1999-2023:

Payments for lost tobacco quota as delineated under section 1021, except that such payments are not exceed \$1.65 billion annually, unless additional monies are needed for acceleration of lost tobacco quota;

Payments for the administration of the tobacco support program by the Department of Agriculture under section 1022;

Payments for the community economic development program under section 1023, which is not to exceed \$375 million annually for fiscal years 1999-2008, and \$450 million annually for fiscal years 2009-2023;

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Payments for the worker transition program under section 1031, which is not to exceed \$25 million in any fiscal year;

Payments for the higher education opportunity grants under section 1032, which are not to exceed: \$42.5 million for each of the academic years from 1999 to 2004; \$50 million for each of the academic years from 2004 to 2009; \$57.5 million for each of the academic years from 2009 to 2014; \$65 million for each of the academic years from 2014 to 2019; and \$72.5 million for each of the academic years from 2019 to 2024.

**Section 1012 - Contributions by Tobacco Product Manufacturers and Importers**

This section specifies that contributions are to be made by tobacco manufacturers and importers to the Tobacco Community Revitalization Trust Fund on a market share basis. The total contribution that is to be made by companies is \$28.5 billion. The payments are to be pursuant to the following schedule: \$2.1 billion annually for fiscal years 1999-2008 and \$500 million annually for fiscal years 2009-2023.

**Subtitle B - Tobacco Market Transition Assistance**

**Section 1021 - Payments for Lost Tobacco Quota**

This section restructures the procedures for compensating tobacco quota holders, quota lessees, and quota tenants for lost tobacco quota as a result of declines in the tobacco market. Tobacco quota holders, lessees, and tenants are to be compensated on a lost quota basis. Reimbursements are to be made based on the average base quota of each party. The base quotas are to be determined as specified:

For quota holders, the base quota is the average tobacco farm marketing quota for the 1995-1997 marketing years.

For a quota lessee, the base quota level is fifty percent of the average number of pounds of tobacco quota established for a farm for the 1995-1997 marketing years that was leased or rented to the quota lessee minus twenty-five percent of the average number of pounds of that quota grown by a quota tenant.

For a quota tenant, the base quota level is fifty percent of the average number of tobacco quota pounds for marketing years 1995-1997 which were leased to the tenant by a quota holder and produced by the tenant, plus twenty-five percent of the average number of tobacco quota pounds for marketing years 1995-1997 that were leased by a quota lessee and grown by the tenant.

#### **Monetary Reimbursements for Lost Quota/Regulations for Sale of Quotas**

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

#### **Compensation Procedures for Burley Tobacco**

**Compensation for Lost Quota.** Annual payments for lost quota for persons involved in the production of tobacco, other than flue-cured tobacco, are to made pursuant to the following formulas:

For quota holders, payments are to be based on the number of pounds by which the farm marketing quota is less than the base quota level for the quota holder times \$4 per pound, subject to a lifetime limitation of \$8 per pound.

For lessees and tenants, the formula for determining actual payments is the percentage by which the national marketing quota is less than the national marketing quota for marketing years 1995-1997 times the base quota level of the lessee or tenant times \$4 per pound, subject to a lifetime limitation of \$8 per pound.

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

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

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

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

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

**Death Of Quota Lessee or Tenant.** If a quota lessee or tenant dies, his or her lost quota payments are to transfer to his or her spouse or dependents.

**Treatment of Flue-cured Tobacco**

**Abolishment of Quota System for Flue-cured Tobacco.** The legislation will abolish the quota system for flue-cured tobacco. The procedures for exchange of quotas for permits are set out in section 1024. Current quota holders who are producers, as well as lessees and tenants, will be given the option of transitioning to the permit system. All flue-cured quota owners, who are not actual producers, will be required to relinquish their quotas in exchange for a payment. The quotas are to be yielded by November 15, 1998. Relinquishing quota owners are to be paid annually 1/10 of a lifetime limitation of \$8 per pound times their base quota level. The payments are to be made for fiscal years 1999-2008. The lessee or tenant of the quota will be given an automatic option under section 1024 of obtaining a permit to continue farming. However, if the lessee or tenant rejects the option of continuing to farm under the new permit system, each is

eligible under section 1021 for a transition payment of \$8 per pound times their base quota level as established by the legislation. The payments are to be made for fiscal years 1999-2008.

**Lost Quota Payments for Lessees and Tenants Under Permit System.** Lessees and tenants that have active permits are eligible for annual lost quota payments of \$2 per pound times the number of pounds by which the production authorized under their permit is less than twice their base quota level, subject to a lifetime limitation of \$4 per pound.

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

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

**Section 1022 - Industry Payments for All Department Costs Associated with Tobacco Production**

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

**Section 1023 - Tobacco Community Economic Development Grants.**

This section authorizes the Department of Agriculture to award economic development grants to tobacco-growing communities. The amount of the grants is to be based on the amount of the state's farm income pursuant to the 1995-1997 marketing years. States must submit an application to the Department before a grant can be awarded. The application is to describe the

purposes for which the grant will be used. The grants may be used for such programs as loan assistance programs for restructuring communities or for the support of new industries. Such funds, however, are reserved for counties in the state that had at least \$100,000 in tobacco production in one or more of the 1995-1997 marketing years. Although states are given considerable latitude in determining the use of the grant funds, the legislation does include the following earmarks:

- (1) at least 20% of the funds must be used for economic development and agriculture-based rural development activities;
- (2) a minimum of 4% is to be used for technical assistance;
- (3) no less than 6% of the funds are to be used to provide direct payments to tobacco warehouse owners based on declines in yearly volume sales as compared to sales during the 1998 marketing year.

Additionally, a state may require recipients of funds to provide preferences in hiring persons who, during the 1998 calendar year, were employed in farming, manufacturing, and processing of tobacco and are eligible for assistance under the tobacco worker transition program, as well as persons eligible for higher education grants under the bill.

#### **Section 1024 - Flue-cured Tobacco Production Permits.**

This section replaces the tobacco quota system for flue-cured tobacco with a federal tobacco permit system.

The federal tobacco permit system will require official permits to farm tobacco. These permits will be issued by the Department of Agriculture, which will include production and acreage allotment limitations. Permits will only be issued to actual producers. Lessees and tenants that produce flue-cured tobacco under agreements with quota owners will automatically be given the right to obtain permits to continue their farming. The permits will not be transferable, and will be

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prohibited from being used as an asset. Permits, however, will be permitted to be transferred to the permit owner's surviving spouse and descendants. Lessees and tenants that have permits that automatically revert to them will be given the option of relinquishing their permits for a payment. The payments are to be made on an annual basis from 1999 to 2008, subject to a lifetime limitation of \$8 per pound times the base quota level (section 1021).

**Section 1025 - Modifications in Federal Tobacco Programs.**

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

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

**Subtitle C - Farmer and Worker Transition Assistance**

**Section 1031 - Tobacco Worker Transition Program**

This section sets forth a program that is to be administered by the Department of Labor to assist workers in the tobacco industry. To benefit, a group of workers of a tobacco entity will be required to file a petition with the Labor Department for assistance. The workers will be required

to show that they (1) have or will become totally or partially separated; (2) the entity's sales production has decreased substantially; and (3) that the national tobacco settlement contributed importantly to the production declines. If the petition is approved, the workers are to be provided the following benefits and services: employment services, training for new employment, and adjustment allowances (payments to aid in the transition to a new job, except that these payments are to be made only if the person is in the job training program). No person who has received payments for tobacco lost quota is eligible for the program. The program is to be funded at a rate of \$25 million yearly through fiscal year 2008. At least \$12.5 million is to be used for the job training program.

#### **Section 1032 - Farmer Opportunity Grants.**

This section provides for the establishment of educational grants to assist tobacco producers and their relatives in obtaining undergraduate degrees. To be eligible, a person has to be a member of a tobacco farm family. The section defines a tobacco farm family or member as (1) an active tobacco producer or worker, and their spouse, son, daughter, stepson, stepdaughter, brother, sister, stepbrother, stepsister, son-in-law, or daughter-in-law. The bill sets forth the following yearly amounts of the grants: \$1700 for each of the academic years from 1999 to 2004; \$2000 for each of the academic years from 2004 to 2009; \$2300 for each of the academic years from 2009 to 2014; \$2600 for each of the academic years from 2014 to 2019; and \$2600 for each of the academic years from 2019 to 2024. The monies are to be paid to the institution directly or to the student. A grantee may receive a scholarship for only one institution, and is required to maintain a qualifying average for student eligibility at the institution. A grantee is barred from receiving a grant if he or she is in default on a higher education loan or is indebted to an institution of higher education.

#### **Subtitle D - Immunity**

#### **Section 1041 - General Immunity for Tobacco Producers and Tobacco Warehouse Owners**

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

## **Title XI: Miscellaneous**

### **Subtitle A: Prohibitions Relating to Tobacco Products and Children**

#### *Section 1101. Short Title*

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

#### *Section 1102. Prohibitions Relating to Tobacco Products and Children*

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

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

Section 805, “Labeling” would make it unlawful for any domestic concern to in any way participate in the sale of a tobacco product in a foreign country if that tobacco product does not contain a warning label, in that country’s dominant language, that complies with the Federal labeling requirements for tobacco products sold in the United States. The only exception would be if the Secretary determines the foreign country’s labeling requirements are “substantially

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similar” to those in the United States and those requirements are “adequately enforced” then the domestic concern may abide by the labeling laws of the country where the tobacco product is sold.

*Section 1103. Enforcement*

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

*Section 1104. Reward*

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

*Section 1105. Definitions*

Section 1105 defines the term “domestic concern”.

*Section 1106. Amendments to Public Health Service Act*

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

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

For example, according to a report by the Society for Research on Nicotine and Tobacco, the National Institutes of Health (NIH) spends less than one percent of its budget to research a behavior that accounts for 20 percent of mortality in our nation. Despite the large increases in

youth smoking rates and the leveling off of reductions in adult smoking, our nation's commitment to tobacco research has increased only slightly over the last ten years. Lack of funding has resulted in missed opportunities for advancement in tobacco control and has likely discouraged young behavioral researchers from pursuing this area of research. The research that does take place on this subject at NIH is spread across numerous Institutes and is inadequately coordinated.

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

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

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

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

decisions, and how childhood and adolescent development affects these and other relevant psychological processes.

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

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

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

At the same time, the Committee anticipates that enactment of this bill will result in sufficient new resources at the NIH to justify increased expenditures on diseases associated with tobacco use, such as cancer and heart disease. However, it is the Committee's intent that the NIH give the highest priority to epidemiological, behavioral and social science research on the prevention and treatment of tobacco addiction itself. The Committee believes very strongly that research focused on prevention and treatment of tobacco addiction will be very cost-effective and be instrumental in reducing tobacco use and avoiding the high human and economic costs associated with tobacco.

The Committee recognizes that aspects of tobacco related research will occur at federal agencies other than the NIH, including the Food and Drug Administration, the Centers for Disease

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Control, the Agency for Health Care Policy and Research, the Occupational Safety and Health Administration, and the Environmental Protection Agency. The Committee expects the Secretary of Health and Human Services acting through, among others, the Director of the Centers for Disease Control and the Director of the new Office of Tobacco-Related Research at NIH, to coordinate the work of these disparate agencies.

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

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

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

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

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

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

Section 2804, Research Activities of the National Institutes of Health, would require expenditures of \$20 Billion over 10 years for research by the NIH concerning tobacco. The Secretary would be required to establish a Tobacco-Related Research Initiative, headed by the Director of the NIH, to provide funds to conduct research “related to the prevention and treatment of tobacco addiction, and the prevention and treatment of diseases associated with tobacco use. At least one-third of the funds provided must be used to address the “prevention and treatment of addiction.”

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

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

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

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

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

**Subtitle B: Federal licensing of Tobacco Product Distribution**

*Section 1121. Licensing of Tobacco Product Distribution*

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

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

**Subtitle C: International Provisions**

*Section 1131. International Tobacco Control Trust Fund*

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

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

*Section 1132. American Center on Global Health and Tobacco*

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

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

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

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

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

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

*Section 1134. Harmonization with United States International Commitments and Obligations*

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

**Subtitle D: Prevention of Tobacco Smuggling**

*Section 1141. Definitions*

Section 1141 defines terms used in this Subtitle.

*Section 1142. Tobacco Product Labeling Requirements*

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

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

*Section 1143. Requirements for the Tracking of Tobacco Products*

Section 1143 would require the posting of a bond for all exports of tobacco products. Each export would require posting with the Secretary of the Treasury: a bond that indicates the country of final destination, a written statement from the recipient of the tobacco products that that

recipient will not violate any laws of that country concerning tobacco products and indicating they have never been convicted of any offense with respect to tobacco products.

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

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

*Section 1144. Tobacco Product Permits*

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

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

*Section 1145. Prohibitions*

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

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

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

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

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

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

*Section 1148. Jurisdiction; Penalties; Compromise of Liability*

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

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

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

*Section 1149. Amendments to the Contraband Cigarette Trafficking Act*

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

*Section 1150. Authorization of Appropriations*

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

**Subtitle E: Antitrust Exemption**

*Section 1161. Limited Antitrust Exemption*

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

**Subtitle F: Special Provisions Concerning Programs for Women, Minorities, and Others**

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

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

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

*Section 1172. Counter-Advertising Programs*

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

*Section 1173. Prevention Activities of Community and Migrant Health Centers*

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

**Subtitle G: Sense of the Senate**

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

**Subtitle H: Ban on Sale of Tobacco Products Through the Use of Vending Machines**

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

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

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

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

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

## **Title XII: Tobacco Asbestos Trust Fund**

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

### *Section 1201. Definitions*

Section 1201 defines relevant terms used in this title.

### *Section 1202. Tobacco Asbestos Trust Fund*

Section 1202 would establish in the United States Treasury a Tobacco Asbestos Trust Fund. There would be five trustees, two appointed by the Secretary of Health and Human Services to represent the interests of asbestos trusts and asbestos defendants, and two appointed by the Secretary of Labor to represent asbestos claimants and labor unions with claimants as members, and one chosen by the other four, who shall be a health care professional with expertise in asbestos disease.

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

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

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

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

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

*Section 1203. Payments From Fund I*

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

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

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

*Section 1204. Payments From Fund II*

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

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

*Section 1205. Transfers from National Tobacco Settlement Trust Fund.*

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

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

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

Before a lawsuit for harm caused by tobacco and asbestos can proceed to trial or judgement, the plaintiff must submit a claim to Fund II for the tobacco-caused portion of the harm.

The plaintiff would receive a determination within 120 days, or earlier if exigent circumstances exist. A claimant who rejects an offer from, or is denied an award by, Fund II may proceed to trial or judgement in a tort action.

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

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

A claimant who accepts an award from Fund II may not sue for tobacco-caused harm. A claimant who rejects an award may sue asbestos defendants for asbestos and tobacco harm in

accordance with other applicable law. An asbestos defendant that pays for tobacco-caused harm may succeed to the claimant's rights to request compensation from Fund II, or may bring an indemnity or contribution action against a tobacco company.

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

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

### **Title XIII: Veterans' Benefits**

#### *Section 1301. Recovery By Secretary of Veterans Affairs*

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

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

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

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

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

#### **Statement of Committee Intent**

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

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

#### **Additional Views**

##### **ADDITIONAL VIEWS OF MR. HOLLINGS**

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

##### **ADDITIONAL VIEWS OF SENATOR TED STEVENS AND SENATOR CONRAD**

###### **BURNS**

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

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

proceeds from the tobacco legislation may be used for payments to the Federal Black Lung Program.

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

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

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

**Additional Views of Senator Spencer Abraham: Explanation of Selected Votes**

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

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

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

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

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

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

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

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

tobacco settlement legislation so that the full Senate will have the opportunity to consider it this Session.

### **Views of Senator Ron Wyden**

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

### **Accountability**

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

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

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

### **Minority Health**

This bill is the first serious attempt to resolve minority health issues related to tobacco. While consumers are targeted every day by companies, the targeting of minorities and women by tobacco companies resulted in the lives of many individuals and families being decimated by smoking-related diseases. The importance of research and providing smoking prevention and cessation programs for minority communities cannot be understated. Research must focus on developing successful cessation programs and smoking-related minority health concerns. In addition, prevention and cessation programs should be culturally and linguistically appropriate; cessation programs must be affordable and community-based, including community health centers to reach migrant populations and others who might not have regular sources of health care.

### **International Tobacco Control**

Another important aspect of this bill are the provisions that relate to international tobacco control. Nothing in these provisions is intended to prevent the U.S. government or tobacco companies themselves from working with other nations to develop strict standards against marketing to children. Through a code of conduct, restrictions on U.S. government institutions to promote tobacco exports, labeling and marketing standards,

anti-smuggling efforts and the creation of a non-governmental organization to focus on tobacco control in developing nations, this bill ensures that any U.S. tobacco settlement is not paid for by selling tobacco to children overseas.

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

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

### **Environmental Tobacco Smoke (ETS)**

This legislation sets a tough standard against environmental tobacco smoke, but creates exceptions for some public places and allows states to opt out of the standard completely.

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

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

### **Look Back Provisions and Penalties to Reduce Youth Smoking**

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

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

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

## **Conclusion**

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

## **Additional Views by Chairman McCain**

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

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

## **ADDITIONAL VIEWS ON FUNDING**

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

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

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

## SPIT TOBACCO

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

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

## NATIVE AMERICANS

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

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

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

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

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

Because of the federal trust responsibility to Indian tribes and their members, Congress has a strong responsibility to protect such “core tribal interests” even while seeking to achieve other

federal objectives. In addition, Congress must consider these interests when enacting legislation or it risks judicial invalidation of these provisions, just as it must be solicitous of federalism concerns or it risks similar judicial invalidation.

I am concerned that some interpretation of Section 604 could result in a violation of the federal government's trust obligation to tribes. Specifically, where tribes and states have negotiated agreements providing for the collection of state taxes, there is simply no rational basis for Congress to *de facto* invalidate these agreement, arrangements, or state laws simply because some tribes and states have not worked out such satisfactory arrangements. Of course, Section 604 need not be read to necessarily invalidate these freely negotiated arrangements. I am sure that no one believes the Treasury Department should implement this provision in a manner that preempts state law or tribal-state voluntary agreements.

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

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

In my home state of Arizona, the state tax law does not apply to tribal or individual tribal retailers located on Indian reservations where the tribal government imposes a commensurate tax. Twelve tribes in the state enacted their own cigarette tax and the state has cooperative agreements

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with three other tribes which authorize the state to act as the tax collector for the tribe. I note that the State of Nevada enacted legislation in 1979 which authorizes tribes of the state to collect a tribal sales tax in lieu of the state sales tax, provided that the tax was equal to or greater than the commensurate state tax. This applies to cigarette sales. The tribes utilize the revenue from the tribal sales tax for governmental services and benefits for their tribal members. State-tribal tax agreements are operating in several states and tribes are operating pursuant to state laws in others.

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

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415,asinintroduced,insertedhereinlinetype] SECTION1.SHORTTITLE;TABLEOFCONTENTS.(a)  
ShortTitle.\_ThisActmaybecitedasthe`NationalTobaccoPolicyandYouthSmokingReducti

onAct'. (b) Table of Contents. The table of contents for this Act is as follows: Sec. 1. Short title; table of contents. Sec. 2. Findings. Sec. 3. Purpose. Sec. 4. Scope and effect. Sec. 5. Nonpreemption of more restrictive laws. Sec. 6. Definitions. Sec. 7. Notification if youthful cigarette smoking restrictions increase youthful pipe and cigar smoking. Sec. 8. Liability limitations disappear if manufacturers challenge advertising limits. Sec. 9. FTC jurisdiction not affected. Sec. 10. Congressional review provisions. Title I \_ Regulation of the Tobacco Industry Subtitle A \_ Jurisdiction, Etc., of Food and Drug Administration Sec. 101. Amendment of Federal Food, Drug, and Cosmetic Act of 1938. ``Chapter IX \_ Tobacco Products`` Sec. 901. FDA authority over tobacco products ``Sec. 902. Adulterated tobacco products.`` Sec. 903. Misbranded tobacco products. -@), ``Sec. 904. Submission of health information to the Secretary.`` Sec. 905. Registration. ``Sec. 906. 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sociatedwithtobaccoproduction.Sec.1023.Tobaccocommunityeconomicdevelopmentgrant s.Sec.1024.Fluecuredtobaccoproductionpermits.``Sec.317a.Fluecuredtobaccoproduct ionpermits.Sec.1025.Modificationsinfederaltobaccoprograms.SubtitleC\_FarmerandWo rkerTransitionAssistance -@), Sec.1031.Tobaccoworkertransitionprogram.Sec.103 Farmeropportunitygrants.``Subpart9\_FarmerOpportunityGrants``Sec.420d.Statemento fpurpose.``Sec.420e.Programauthority;amountanddeterminations;applications.``Sec .420f.Studenteligibility.SubtitleD\_ImmunitySec.1041.Generalimmunityfortobaccopr oducersandtobaccowarehouseowners.TitleXI\_MiscellaneousSubtitleA\_ProhibitionsRel atingtoTobaccoProductsandChildrenSec.1101.Shorttitle.Sec.1102.Prohibitionsrelat ingtotobaccoproductsandchildren.``Sec.804.Prohibitiononsaleordistributionoftoba ccoproductstochildren.``Sec.805.Labeling.Sec.1103.Enforcement.Sec.1104.Reward.S ec.1105.Definitions.Sec.1106.AmendmentstoPublicHealthServiceAct.``TitleXXVIII\_N ationalEffortstoReduceYouthSmoking``SubtitleE\_ReducingYouthSmokingandTobaccoRel atedDiseasesThroughResearch``Sec.2801.StudybytheInstituteofMedicine.``Sec.2802. Nationaltobaccotaskforce.``Sec.2803.ResearchactivitiesoftheCentersforDiseaseCon trolandPrevention.``Sec.2804.ResearchactivitiesoftheNationalInstitutesofHealth. Sec.1107.Banondistributionoftobaccoproductsproducedbychildlabor.SubtitleB\_Feder alLicensingofTobaccoProductDistributionSec.1121.LicensingofTobaccoProductDistri bution.SubtitleC\_InternationalProvisionsSec.1131.Internationaltobaccocontroltru stfund.Sec.1132.Americancenteronglobalhealthandtobacco.Sec.1133.Prohibitiononus eoffundstofacilitatetheexportationorpromotionoftobacco. -@), Sec.1134.Harmoniza tionwithUnitedStatesinternationalcommitmentsandobligations.SubtitleD\_Prevention ofTobaccoSmugglingSec.1141.Definitions.Sec.1142.Tobaccoproductlabelingrequireme nts.Sec.1143.Requirementsforthetrackingoftobaccoproducts.Sec.1144.Tobaccoproduc tpermits.Sec.1145.Prohibitions.Sec.1146.Pricingandlabelingofproductssoldonmilit aryinstallationsorbynativeAmericans.Sec.1147.Prohibitionagainstsaleoftobaccopro ductsinortodutyfreeshopsorforwardingthroughormanufactureintradezones.Sec.1148.J urisdiction;penalties;compromiseofliability.Sec.1149.AmendmentstotheContrabandC igaretteTraffickingAct.Sec.1150.Authorizationofappropriations.SubtitleE\_Antitru stExemptionSec.1161.LimitedAntitrustExemption.SubtitleF\_SpecialProvisionsConcer ningProgramsforWomen,Minorities,andOthersSec.1171.Researchrelatedtopatternsofsm okingbywomenandminorities.Sec.1172.Counteradvertisingprograms.Sec.1173.Preventi onactivitiesofcommunityandmigranthealthcenters.SubtitleG\_SenseoftheSenateSec.11 81.SenseoftheSenate.SubtitleH\_BanOnSaleOfTobaccoProductsThroughTheUseOfVendingM achinesSec.1191.Banofsaleoftobaccoproductsthroughtheuseofvendingmachines.TitleX II\_TobaccoAsbestosTrustFundSec.1201.Definitions.Sec.1202.TobaccoAsbestosTrustFu nd.Sec.1203.PaymentsfromfundI.Sec.1204.PaymentsfromfundII.Sec.1205.Transfersfro mNationalTobaccoSettlementTrustFund.Sec.1206.Rulesforclaimsaagainstasbestostrus ts,asbestosdefendants,andtobaccocompanies.TitleXIII\_Veterans'BenefitsSec.1301.Re coverybysecretaryofveteransaffairs.``PartVII\_RecoveryofCompensationCostsforToba ccoRelatedDisabilityorDeath -@), ``Chapter91\_TortLiabilityforDisabilityorDeathD uetoTobaccoUse``9101.RecoverybySecretaryofVeteransAffairs``9102.Regulations``91 03.Limitationorrepealofotherprovisionsforrecoveryofcompensation``9104.Exemption fromannuallimitationondamagesSEC.2.FINDINGS.TheCongressfindsthefollowing:(1)The useoftobaccoproductsbytheNation'schildrenisapediatricdiseaseofepicandworseningp roportionsthatresultsinnewgenerationsoftobaccodependentchildrenandadults.(2)Aco nsensusexistswithinthescientificandmedicalcommunitieshattobaccoproductsareinhe rentlydangerousandcausecancer,heartdisease,andotherseriousadversehealtheffects. (3)Nicotineisanaddictivedrug.(4)Virtuallyallnewusersoftobaccoproductsareunderth eminimumlegalagetopurchasesuchproducts.(5)Tobaccoadvertisingandmarketingcontrib utesignificantlytotheuseofnicotinecontainingtobaccoproductsbyadolescents.(6)Bec ausepasteffortstorestrictadvertisingandmarketingoftobaccoproductshavefailedadeq uatelytocurbtobaccousebyadolescents,comprehensiverestrictionsonthesale,promotio n, anddistributionofsuchproductsareneeded.(7)FederalandStategovernmentshavelacke dthelegalandregulatoryauthorityandresourcestheyneedtoaddresscomprehensivelythep ublichealthandsocietalproblemscausedbytheuseoftobaccoproducts.(8)FederalandStat epublichealthofficials,thepublichealthcommunity,andthepublicatlargerecognizetha ttetobaccoindustryshouldbesubjecttoongoingoversight.(9)UnderArticleI,Section8o ftheConstitution,theCongressisvestedwiththeresponsibilityforregulatinginterstat ecommerceandcommercewithIndiantribes.(10)Thesale,distribution,marketing,adverti

sing, and use of tobacco products are activities in and substantially affecting interstate commerce. Such products are sold, marketed, advertised, and distributed in interstate commerce on a nationwide basis, and have a substantial effect on the Nation's economy. -@), (11) The sale, distribution, marketing, advertising, and use of such products substantially affect interstate commerce through the health care and other costs attributable to the use of tobacco products. (12) Civil actions against tobacco product manufacturers and others are pending in Federal and State courts arising from the use, marketing, and sale of tobacco products. Among these actions are cases brought by the attorneys general of more than 40 States, certain cities and counties, and the Commonwealth of Puerto Rico, and other parties, including Indian tribes, and class actions brought by private claimants (such as in the Castano Civil Actions), seeking to recover monies expended to treat tobacco related diseases and for the protection of minors and consumers, as well as penalties and other relief for violations of antitrust, health, consumer protection, and other laws. (13) Civil actions have been filed throughout the United States against tobacco product manufacturers and their distributors, trade associations, law firms, and consultants on behalf of individuals or classes of individuals claiming to be dependent upon and injured by tobacco products. (14) These civil actions are complex, time consuming, expensive, and burdensome for both the litigants and Federal and State courts. To date, these civil actions have not resulted in sufficient redress for smokers or non-governmental third party payers. To the extent that governmental entities have been or may in the future be compensated for tobacco related claims they have brought, it is not now possible to identify what portion of such past or future recoveries can be attributed to their various antitrust, health, consumer protection, or other causes of action. (15) It is in the public interest for Congress to adopt comprehensive public health legislation because of tobacco's unique position in the Nation's history and economy; the need to prevent the sale, distribution, marketing and advertising of tobacco products to persons under the minimum legal age to purchase such products; and the need to educate the public, especially young people, regarding the health effects of using tobacco products. (16) The public interest requires a timely, fair, equitable, and consistent result that will serve the public interest by (A) providing that a portion of the costs of treatment for diseases and adverse health effects associated with the use of tobacco products is borne by the manufacturers of these products, and (B) restricting throughout the Nation the sale, distribution, marketing, and advertising of tobacco products only to persons of legal age to purchase such products. (17) Public health authorities estimate that at the benefit to the Nation of enacting Federal legislation to accomplish these goals would be significant in human and economic terms. (18) Reducing the use of tobacco by minors by 50 percent would prevent well over 60,000 early deaths each year and save up to \$43 billion each year in reduced medical costs, improved productivity, and the avoidance of premature deaths. (19) Advertising, marketing, and promotion of tobacco products have been especially directed to -@), attract young persons to use tobacco products and these efforts have resulted in increased use of such products by youth. Past efforts to oversee these activities have not been successful in adequately preventing such increased use. (20) In 1995, the tobacco industry spent close to \$4,900,000,000 to attract new users, retain current users, increase current consumption, and generate favorable long term attitudes towards smoking and tobacco use. (21) Tobacco product advertising often misleadingly portrays the use of tobacco as socially acceptable and healthful to minors. (22) Tobacco product advertising is regularly seen by persons under the age of 18, and persons under the age of 18 are regularly exposed to tobacco product promotional efforts. (23) Through advertisements during and sponsorship of sporting events, tobacco has become strongly associated with sports and has become portrayed as an integral part of sports and the healthy lifestyle associated with rigorous sporting activity. (24) Children are reexposed to substantial and unavoidable tobacco advertising that leads to favorable beliefs about tobacco use, plays a role in leading young people to overestimate the prevalence of tobacco use, and increases the number of young people who begin to use tobacco. (25) Tobacco advertising increases the size of the tobacco market by increasing consumption of tobacco products including increasing tobacco use by young people. (26) Children are more influenced by tobacco advertising than adults, they smoke the most advertised brands, and children as young as 3 to 6 years old can recognize each character associated with smoking at the same rate as they recognize cartoons and fast food characters. (27) Tobacco company documents indicate that young people are an important and often crucial segment of the tobacco market. (28) Comprehensive advertising restrictions will have a positive effect on the smoking rates of young people. (29) Restrictions on advertising are necessary to prevent unrestricted tobacco advertising from undermining legislation prohibiting access to young people and providing for education ab

out tobacco use. (30) International experiences show that advertising regulations that are stringent and comprehensive have a greater impact on overall tobacco use and young people's use than weaker or less comprehensive ones. Text-only requirements, while not as stringent as a ban, will help reduce underage use of tobacco products while preserving the informational function of advertising. -@), (31) It is in the public interest for Congress to adopt legislation to address the public health crisis created by actions of the tobacco industry. (32) If, as a direct or indirect result of this Act, the consumption of tobacco products in the United States is reduced significantly, then tobacco farmers, their families, and their communities may suffer economic hardship and displacement, notwithstanding their lack of involvement in the manufacturing and marketing of tobacco products.

SEC. 3. PURPOSE. The purposes of this Act are (1) to confirm the authority of the Food and Drug Administration to regulate tobacco products under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), by recognizing it as the primary Federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products; (2) to require the tobacco industry to fund both Federal and State oversight of the tobacco industry from ongoing payments by tobacco product manufacturers; (3) to require tobacco product manufacturers to provide ongoing funding to enforce an aggressive Federal, State, and local enforcement program and for a national wider retail licensing system to prevent minors from obtaining tobacco products, while expressly permitting the State to adopt additional measures that further restrict or eliminate the products' use; (4) to ensure that the Food and Drug Administration and the States may continue to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco; (5) to impose severe financial surcharges on tobacco product manufacturers if they do not substantially reduce tobacco use by young people during the next decade; (6) to authorize appropriate agencies of the Federal government to set national standards controlling the manufacture of tobacco products and the identity, public disclosure, and amount of ingredients used in such products; (7) to provide new and flexible enforcement authority to ensure that the tobacco industry makes efforts to develop and introduce less harmful tobacco products; (8) to confirm the Food and Drug Administration's authority to regulate the level of tar, nicotine, and other harmful components of tobacco products; (9) in order to ensure that adults are better informed, to require tobacco product manufacturers to disclose all research which has not previously been made available, as well as research generated in the future, relating to the health and dependency effects or safety of tobacco products; -@),

(10) to impose on tobacco product manufacturers the obligation to provide funding for a variety of public health initiatives; (11) to establish a minimum Federal standard for stringent restrictions on smoking in public places, with funding to enforce such standard derived from payments made by tobacco product manufacturers, while also to permit State, Tribal, and local governments to enact additional and more stringent standards so long as they are not covered by the Federal standard; (12) to authorize and fund from payments by tobacco product manufacturers a continuing national counter advertising and tobacco control campaign which seeks to educate consumers and discourage children and adolescents from beginning to use tobacco products, and which encourages current users of tobacco products to discontinue using such products; (13) to establish a mechanism to compensate the States in settlement of their various claims against tobacco product manufacturers; (14) to authorize and to fund from payments by tobacco product manufacturers a nationwide program of smoking cessation administered through State and Tribal governments and the private sector; (15) to establish and fund from payments by tobacco product manufacturers a National Tobacco Settlement Fund; (16) to affirm the right of individuals to access to the courts, to civil trial by jury, and to damages to compensate them for harm caused by tobacco products; (17) to continue to permit the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage purchasers; (18) to impose appropriate regulatory control on the tobacco industry; and (19) to protect tobacco farmers and their communities from the economic impact of this Act by providing full funding for and the continuation of the Federal tobacco program and by providing funds for farmers and communities to develop new opportunities in tobacco dependent communities. SEC. 4. SCOPE AND EFFECT. (a) Intended Effect. This Act is not intended to (1) establish a precedent with regard to any other industry, situation, circumstance, or legal action; (2) express any position of the Congress with regard to the imposition of punitive damages in general or as applied to any specific industry, case, controversy, or product other than as provided in this Act; (3) provide any authority regarding the imposition of, or the appropriateness of imposing, punitive damages; or (4) except as provided in this Act, affect any action pending in State, Tribal, or Federal court, or any agreement, consent decree, or contract of an

ykind. (b) Taxation. Notwithstanding any other provision of law, this Act and the amendment made by this Act shall not affect any authority of the Secretary of the Treasury (including any authority assigned to the Bureau of Alcohol, Tobacco and Firearms) or of State or local governments with regard to taxation for tobacco or tobacco products. (c) Agricultural Activities. The provision of this Act which authorizes the Secretary to take certain actions with regard to tobacco or tobacco products shall not be construed to affect any authority of the Secretary of Agriculture under existing law regarding the growing, cultivation, or curing of raw tobacco. SEC. 5. NONPREEMPTION OF MORE RESTRICTIVE LAWS. (a) Age Restrictions. Nothing in this Act or the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), as amended by this Act, shall prevent a Federal agency (including the Armed Forces), a State or its political subdivisions, or the government of an Indian tribe from adopting and enforcing additional measures that further restrict or prohibit tobacco products sale to, use by, and accessibility to persons under the legal age of purchase established by such agency, State, subdivision, or government of an Indian tribe. (b) Additional Measures. Except as otherwise expressly provided in this Act, nothing in this Act, the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), or rules promulgated under such Acts, shall limit the authority of a Federal agency (including the Armed Forces), a State or its political subdivisions, or the government of an Indian tribe to enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products, including laws, rules, regulations, or other measures relating to or prohibiting the sale, distribution, possession, exposure to, or use of tobacco products by persons of any age that are in addition to the provision of this Act and the amendments made by this Act. No provision of this Act or amendment made by this Act shall limit or otherwise affect any State, Tribal, or local taxation of tobacco products. (c) State Law Not Affected. Except as otherwise expressly provided in this Act, nothing in this Act, the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), or rules promulgated under such Acts, shall supersede the authority of the States, pursuant to State law, to expend funds provided by this Act. SEC. 6. DEFINITIONS. -@), In this Act: (1) Brand. The term "brand" means a variety of tobacco product distinguished by the tobacco used, tar content, nicotine content, flavoring used, size, filtration, or packaging, logo, registered trademark or brand name, identifiable pattern of colors, or any combination of such attributes. (2) Cigarette. The term "cigarette" has the meaning given that term by section 3 (1) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1332 (1)), but also includes tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as a roll-your-own tobacco. (3) Cigarette tobacco. The term "cigarette tobacco" means any product that consists of loose tobacco that is intended for use by consumers in a cigarette. Unless otherwise stated, the requirements for cigarettes shall also apply to cigarette tobacco. (4) Commerce. The term "commerce" has the meaning given that term by section 3 (2) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1332 (2)). (5) Consent decree. The term "consent decree" means a consent decree among participating tobacco product manufacturers whose substantial terms are substantially equivalent to the form consent decree published for purposes of this paragraph in the Congressional Record. (6) Distributor. The term "distributor" as regards a tobacco product means any person who further the distribution of cigarettes or smokeless tobacco, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Common carriers are not considered distributors for purposes of this Act. (7) Indian country; Indian lands. The terms "Indian country" and "Indian lands" have the meaning given the term "Indian country" by section 1151 of title 18, United States Code, and includes lands under the jurisdiction of an Indian tribe or tribal organization. (8) Indian tribe. The term "Indian tribe" has the meaning given such term in section 4 (e) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b (e)). (9) Little cigar. The term "little cigar" has the meaning given that term by section 3 (7) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1332 (7)). (10) Tobacco product manufacturer. Except in titles V, II, and X, the term "tobacco product manufacturer" means any person, including any repacker or relabeler, who manufactures, fabricates, assembles, processes, or labels a finished cigarette or smokeless tobacco product. (11) Nicotine. The term "nicotine" means the chemical substance named 3-(1-methyl-2-pyrrolidinyl)pyridine or C[10]H[14]N[2], including any salt or complex of nicotine. -@), (12) Package. The term "package" means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which cigarettes or smokeless tobacco are offered for sale, sold, or otherwise distributed to

consumers. (13) Point of sale. The term "point of sale" means any location at which a consumer can purchase or otherwise obtain cigarettes or smokeless tobacco for personal consumption. (14) Retailer. The term "retailer" means any person who sells cigarettes or smokeless tobacco to individuals for personal consumption, or who operates a facility where self-service display of tobacco products are permitted. (15) Rollyourown tobacco. The term "rollyourown tobacco" means any tobacco which, because of its appearance, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco for making cigarettes. (16) Secretary. Except in title VII and where the context otherwise requires, the term "Secretary" means the Secretary of Health and Human Services. (17) Smokeless tobacco. The term "smokeless tobacco" means any product that consists of cut, ground, powdered, or leaf tobacco that contains nicotine and that is intended to be placed in the oral cavity. (18) State. The term "State" means any State of the United States and, for purposes of this Act, includes the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, Johnston Atoll, the Northern Mariana Islands, and any other trust territory or possession of the United States. (19) Tobacco product. The term "tobacco product" means cigarettes, cigarette tobacco, smokeless tobacco, little cigars, rolyourown tobacco, and fine cut products. (20) United States. The term "United States" means the 50 States of the United States of America and the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, Johnston Atoll, the Northern Mariana Islands, and any other trust territory or possession of the United States. (21) Master Settlement Agreement. The term "Master Settlement Agreement" means the agreement either previously entered into to be entered into by the States, the participating tobacco product manufacturers, and the Trade Associations implementing the June 20, 1997, Proposed Resolution, and published in the Congressional Record for purposes of this Act. (22) Participating tobacco product manufacturer. The term "participating tobacco product manufacturer" means (A) a tobacco product manufacturer that, within 45 days after the date of enactment of this Act (or within 45 days after the date on which such manufacturer first manufactures tobacco products -@), for sale or distribution in the United States, if such date is after the date of enactment of this Act) (i) becomes a signatory to the Master Settlement Agreement; and (ii) enters into consent decree with each State that made a request within the time period described in section 704 (b); or (B) a surviving entity established by a participating tobacco product manufacturer. (23) Nonparticipating tobacco product manufacturer. The term "nonparticipating tobacco product manufacturer" means a tobacco product manufacturer that is not a participating tobacco product manufacturer. (24) Protocol. The term "Protocol" means the agreement to be entered into by the Secretary of Health and Human Services with the participating tobacco product manufacturers under this Act.

SEC. 7. NOTIFICATION IF YOUTHFUL CIGARETTE SMOKING RESTRICTIONS INCREASE YOUTHFUL PIPE AND CIGAR SMOKING. The Secretary shall notify the Congress if the Secretary determines that a decrease in underage use of tobacco products resulting from the enactment of this Act has produced an increase in underage use of pipe tobacco and cigars.

SEC. 8. LIABILITY LIMITATIONS DISAPPEAR IF TOBACCO PRODUCT MANUFACTURER CHALLENGES ADVERTISING LIMITS. If a tobacco product manufacturer, or any party acting on behalf of, in collusion with, or at the request of, a tobacco product manufacturer brings an action to have the advertising restrictions imposed on tobacco products under this Act, or the amendments made by this Act, or the application of those regulations to any person or circumstance held to be unconstitutional or otherwise invalid under the laws of the United States then the provision of title VII relating to limitations on liability shall not apply to that manufacturer, beginning on the date on which the action is filed in a court of competent jurisdiction, and continuing until such time as the action is withdrawn or dismissed.

SEC. 9. FTC JURISDICTION NOT AFFECTED. (a) In General. Except where expressly provided in this Act, nothing in this Act shall be construed as limiting or diminishing the authority of the Federal Trade Commission to enforce the laws under its jurisdiction with respect to the advertising, sale, or distribution of tobacco products. -@),

(b) Enforcement by FTC. Any advertising that violates this Act, part 897 of title 21, Code of Federal Regulations, or the Protocol is an unfair or deceptive act or practice under section 5 (a) of the Federal Trade Commission Act (15 U.S.C. 45 (a)) and shall be considered a violation of a rule promulgated under section 18 of that Act (15 U.S.C. 57a).

SEC. 10. CONGRESSIONAL REVIEW PROVISIONS. In accordance with section 801 of title 5, United States Code, the Congress shall review, and may disapprove, any rule under this Act that is subject to section 801. This section does not apply to the rules set forth in part 897 of title 21, Code of Federal Regulations. TITLE I. REGULATION OF THE TOBACCO INDUSTRY Subtitle A. Jurisdiction, etc., of Food and Drug Admin

istration SEC. 101. AMENDMENT OF FEDERAL FOOD, DRUG, AND COSMETIC ACT OF 1938. (a) Definition of Tobacco Products. Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following: "(k) The term 'tobacco product' means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw material other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)." (b) FDA Authority over Tobacco Products. The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is amended (1) by redesignating chapter IX as chapter X; (2) by redesignating sections 901 through 907 as sections 1001 through 1007; and (3) by inserting after section 803 the following: "CHAPTER IX. TOBACCO PRODUCTS" "SEC. 901. FDA AUTHORITY OVER TOBACCO PRODUCTS" (a) In General. Tobacco products shall be regulated by the Secretary under this chapter and shall not be subject to the provisions of chapter V, unless (1) such products are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease (within the meaning of section 201(g)(1)(B) or section 201(h)(2)); or (2) a health claim is made for such products under section 201(g)(1)(C) or 201(h)(3). (b) Applicability. This chapter shall apply to all tobacco products subject to the provisions of part 897 of title 21, Code of Federal Regulations, and to any other tobacco products that the Secretary by regulation deems to be subject to this chapter. (c) FDA Rule in Effect. The provisions of part 897 of title 21, Code of Federal Regulations, shall be deemed to be lawful and to have been lawfully promulgated under the authority of this chapter. The provisions of such part that are not in effect on the date of enactment of this chapter shall take effect as in such part or upon such later date as determined by the Secretary by order. (d) Scope. (1) Nothing in this chapter shall be construed to affect the regulation of drugs and devices under chapter V that are not tobacco products by the Secretary under the Federal Food, Drug and Cosmetic Act. (2) The provisions of this chapter shall not apply to tobacco leaf that is not in the possession of the manufacturer, or to the producers of tobacco leaf, including tobacco growers, tobacco warehouses, and tobacco grower cooperatives, nor shall any employee of the Food and Drug Administration have any authority whatsoever to enter onto a farm owned by a producer of tobacco leaf without the written consent of such producer. Notwithstanding any other provision of this subparagraph, if a producer of tobacco leaf is also a tobacco product manufacturer or controlled by a tobacco product manufacturer, the producer shall be subject to this chapter in the producer's capacity as a manufacturer. Nothing in this chapter shall be construed to grant the Secretary authority to promulgate regulations on any matter that involves the production of tobacco leaf for a producer thereof, other than activities by a manufacturer affecting production. For purposes of the preceding sentence, the term 'controlled by' means a member of the same controlled group of corporations as that term is used in section 52(a) of the Internal Revenue Code of 1986, or under common control within the meaning of the regulations promulgated under section 52(b) of such Code. SEC. 902. ADULTERATED TOBACCO PRODUCTS. A tobacco product shall be deemed to be adulterated if (1) it consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise contaminated by any poisonous or deleterious substance that may render the product injurious to health; (2) it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; (3) its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; (4) it is, or purports to be or is represented as, a tobacco product which is subject to performance standard established under section 907 unless such tobacco product in all respects (a) conforms with such standard; (b) it is required by section 910(a) to have premarket approval, is not exempt under section 906(f), and does not have an approved application in effect; (c) the methods used in, or the facilities or controls used for, its manufacture, packing or storage are not in conformity with applicable requirements under section 906(e)(1) or an applicable condition prescribed by an order under section 906(e)(2); or (d) it is a tobacco product for which an exemption has been granted under section 906(f) for investigational use and the person who was granted such exemption or any investigator who uses such tobacco product under such exemption fails to comply with a requirement prescribed by or under such section. SEC. 903. MISBRANDED TOBACCO PRODUCTS. (a) In General. A tobacco product shall be deemed to be misbranded (1) if its labeling is false or misleading in any particular; (2) if in package form unless it bears a label containing (A) the name and place of business of the tobacco product manufacturer, packer, or distributor; and (B) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count, except that under subparagraph (B) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by r

egulations prescribed by the Secretary; `` (3) if any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements or designs in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use; `` (4) if it has an established name, unless its label bears, to the exclusion of any other nonproprietary name, its established name prominently printed in type as required by the Secretary by regulation; `` (5) if the Secretary has issued regulations requiring that its labeling bear adequate directions for use, or adequate warnings against use by children, that are necessary for the protection of users unless its labeling conforms in all respects to such regulations; -@), `` (6) if it was manufactured, prepared, propagated, compounded, or processed in any State in an establishment not duly registered under section 905 (b), if it was not included in a list required by section 905 (i), if a notice or other information respecting it was not provided as required by such section or section 905 (j), or if it does not bear such symbols from the uniform system for identification of tobacco products prescribed under section 905 (e) as the Secretary by regulation requires; `` (7) if, in the case of any tobacco product distributed or offered for sale in any State, `` (A) its advertising is false or misleading in any particular; or `` (B) it is sold, distributed, or used in violation of regulations prescribed under section 906 (d); `` (8) unless, in the case of any tobacco product distributed or offered for sale in any State, the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that tobacco product, `` (A) a true statement of the tobacco product's established name as defined in paragraph (4) of this subsection, printed prominently; and `` (B) a brief statement of `` (i) the uses of the tobacco product and relevant warnings, precautions, side effects, and contraindications; and `` (ii) in the case of specific tobacco products made subject to a finding by the Secretary after notice and opportunity for comment that such action is necessary to protect the public health, a full description of the components of such tobacco product or the formula showing quantitatively each ingredient of such tobacco product to the extent required in regulations which shall be issued by the Secretary after an opportunity for a hearing; `` (9) if it is a tobacco product subject to a performance standard established under section 907, unless it bears such labeling as may be prescribed in such performance standard; or `` (10) if there was a failure or refusal, `` (A) to comply with any requirement prescribed under section 904 or 908; `` (B) to furnish any material or information required by or under section 909; or `` (C) to comply with a requirement under section 912. `` (b) Prior Approval of Statements on Label. The Secretary may, by regulation, require prior approval of statements made on the label of a tobacco product. No regulation issued under this subsection may require prior approval by the Secretary of the content of any advertisement and -@), no advertisement of a tobacco product, published after the date of enactment of the National Tobacco Policy and Youth Smoking Reduction Act shall, with respect to the matters specified in this section or covered by regulations issued hereunder, be subject to the provisions of sections 12 through 15 of the Federal Trade Commission Act (15 U.S.C. 52 through 55). This subsection does not apply to any printed matter which the Secretary determines to be labeling as defined in section 201 (m). `` SEC. 904. SUBMISSION OF HEALTH INFORMATION TO THE SECRETARY. `` (a) Requirement. Not later than 6 months after the date of enactment of the National Tobacco Policy and Youth Smoking Reduction Act, each tobacco product manufacturer or importer of tobacco products, or agent thereof, shall submit to the Secretary the following information: `` (1) A listing of all tobacco ingredients, substances and compounds that are, on such date, added by the manufacturer to the tobacco, paper, filter, or other component of each tobacco product by brand and by quantity in each brand and subbrand. `` (2) A description of the content, delivery, and form of nicotine in each tobacco product measured in milligrams of nicotine. `` (3) All documents (including underlying scientific information) relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer (or agent thereof) on the health, behavioral, or physiologic effects of tobacco products, their constituents, ingredients, and components, and tobacco additives, described in paragraph (1). `` (4) All documents (including underlying scientific information) relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer that relate to the issue of whether a reduction in risk to health from tobacco products can occur upon the employment of technology available or known to the manufacturer. `` (5) All documents (including underlying scientific information) relating to marketing research involving the use of tobacco products. An importer of a tobacco product not manufactured in the United States shall supply the information re

quired of a tobacco product manufacturer under this subsection. `` (b) Annual Submission. \_ A tobacco product manufacturer or importer that is required to submit information under subsection (a) shall update such information on an annual basis under a schedule determined by the Secretary. `` (c) Time for Submission. \_ `` (1) New products. \_ At least 90 days prior to the delivery for introduction into interstate commerce of a tobacco product not on the market on the date of enactment of this chapter, the manufacturer of such product shall provide the information required under subsection (a) and such product shall be subject to the annual submission under subsection (b). \_ @), `` (2) Modification of existing products. \_ If at any time a tobacco product manufacturer adds to its tobacco products a new tobacco additive, increases or decreases the quantity of an existing tobacco additive or the nicotine content, delivery, or form, or eliminates a tobacco additive from any tobacco product, the manufacturer shall within 60 days of such action so advise the Secretary in writing and reference such modification in submissions made under subsection (b). `` SEC. 905. ANNUAL REGISTRATION. `` (a) Definitions. \_ As used in this section \_ `` (1) the term 'manufacture, preparation, compounding, or processing' shall include repackaging or otherwise changing the container, wrapper, or labeling of any tobacco product package in furtherance of the distribution of the tobacco product from the original place of manufacture to the person whom makes final delivery or sale to the ultimate consumer or user; and `` (2) the term 'name' shall include in the case of a partnership the name of each partner and, in the case of a corporation, the name of each corporate officer and director, and the State of incorporation. `` (b) Registration by Owners and Operators. \_ On or before December 31 of each year every person who owns or operates any establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products shall register with the Secretary the name, places of business, and all such establishments of that person. `` (c) Registration of New Owners and Operators. \_ Every person upon first engaging in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products in any establishment owned or operated in any State by that person shall immediately register with the Secretary that person's name, place of business, and such establishment. `` (d) Registration of Added Establishments. \_ Every person required to register under subsection (b) or (c) shall immediately register with the Secretary any additional establishment which that person owns or operates in any State and in which that person begins the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products. `` (e) Uniform Product Identification System. \_ The Secretary may by regulation prescribe a uniform system for the identification of tobacco products and may require that persons who are required to list such tobacco products under subsection (i) of this section shall list such tobacco products in accordance with such system. `` (f) Public Access to Registration Information. \_ The Secretary shall make available for inspection, to any persons so requesting, any registration filed under this section. `` (g) Biennial Inspection of Registered Establishments. \_ Every establishment in any State registered with the Secretary under this section shall be subject to inspection under section 704, and every such establishment engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products shall be so inspected by one or more officers or employees \_ @), duly designated by the Secretary at least once in the 2 year period beginning with the date of registration of such establishment under this section and at least once in every successive 2 year period thereafter. `` (h) Foreign Establishments May Register. \_ Any establishment within any foreign country engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products, may register under this section under regulations promulgated by the Secretary. Such regulations shall require such establishment to provide the information required by subsection (i) of this section and shall include provisions for registration of any such establishment upon condition that adequate and effective means are available, by arrangement with the government of such foreign country or otherwise, to enable the Secretary to determine from time to time whether tobacco products manufactured, prepared, compounded, or processed in such establishment, if imported or offered for import into the United States, shall be refused admission on any of the grounds set forth in section 801 (a). `` (i) Registration Information. \_ `` (1) Product list. \_ Every person who registers with the Secretary under subsection (b), (c), or (d) of this section shall, at the time of registration under any such subsection, file with the Secretary a list of all tobacco products which are being manufactured, prepared, compounded, or processed by that person for commercial distribution and which has not been included in any list of tobacco products filed by that person with the Secretary under this paragraph or paragraph (2) before such time of registration. Such list shall be prepared in such form and manner as the Secretary may prescribe and shall be accompanied by \_ `` (A) in the case of a tobacco product contained in

the applicable list with respect to which a performance standard has been established under section 907 or which is subject to section 910, a reference to the authority for the marketing of such tobacco product and a copy of all labeling for such tobacco product; `` (B) in the case of any other tobacco product contained in an applicable list, a copy of all consumer information and other labeling for such tobacco product, a representative sampling of advertisements for such tobacco product, and, upon request made by the Secretary for good cause, a copy of all advertisements for a particular tobacco product; and `` (C) if the registrant filing a list has determined that a tobacco product contained in such list is not subject to a performance standard established under section 907, a brief statement of the basis upon which the registrant made such determination if the Secretary requests such a statement with respect to that particular tobacco product. `` (2) Biannual Report of Any Change in Product List. \_ Each person who registers with the Secretary under this section shall report to the Secretary once during the month of June of each year and once during the month of December of each year the following: `` (A) A list of each tobacco product introduced by the registrant for commercial distribution -@), which has not been included in any list previously filed by that person with the Secretary under this subparagraph or paragraph (1) of this subsection. A list under this subparagraph shall list a tobacco product by its established name and shall be accompanied by the other information required by paragraph (1). `` (B) If since the date the registrant last made a report under this paragraph that person has discontinued the manufacture, preparation, compounding, or processing for commercial distribution of a tobacco product included in a list filed under subparagraph (A) or paragraph (1), notice of such discontinuance, the date of such discontinuance, and the identity of its established name. `` (C) If since the date the registrant reported under subparagraph (B) a notice of discontinuance that person has resumed the manufacture, preparation, compounding, or processing for commercial distribution of the tobacco product with respect to which such notice of discontinuance was reported, notice of such resumption, the date of such resumption, the identity of such tobacco product by established name, and other information required by paragraph (1), unless the registrant has previously reported such resumption to the Secretary under this subparagraph. `` (D) Any material change in any information previously submitted under this paragraph or paragraph (1). `` (j) Report Preceding Introduction of Certain Substantially Equivalent Products into Interstate Commerce. \_ `` (1) In General. \_ Each person who is required to register under this section and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a tobacco product intended for human use that was not commercially marketed (other than for test marketing) in the United States as of August 11, 1995, as defined by the Secretary by regulation shall, at least 90 days before making such introduction or delivery, report to the Secretary (in such form and manner as the Secretary shall by regulation prescribe) \_ `` (A) the basis for such person's determination that the tobacco product is substantially equivalent, within the meaning of section 910, to a tobacco product commercially marketed (other than for test marketing) in the United States as of August 11, 1995, that is in compliance with the requirements of this Act; and `` (B) action taken by such person to comply with the requirements under section 907 that are applicable to the tobacco product. `` (2) Application to certain post August 11th products. \_ A report under this subsection for a tobacco product that was first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after August 11, 1995, and before the date of enactment of the National Tobacco Policy and Youth Smoking Reduction Act shall be submitted to the Secretary within 6 months after the date of enactment of that Act. -@), `` SEC. 906. GENERAL PROVISIONS RESPECTING CONTROL OF TOBACCO PRODUCTS. `` (a) In General. \_ Any requirement established by or under section 902, 903, 905, or 909 applicable to a tobacco product shall apply to such tobacco product until the applicability of the requirement to the tobacco product has been changed by action taken under section 907, section 910, or subsection (d) of this section, and any requirement established by or under section 902, 903, 905, or 909 which is inconsistent with a requirement imposed on such tobacco product under section 907, section 910, or subsection (d) of this section shall not apply to such tobacco product. `` (b) Information on Public Access and Comment. \_ Each notice of proposed rulemaking under section 907, 908, 909, or 910, or under this section, any other notice which is published in the Federal Register with respect to any other action taken under any such section and which states the reasons for such action, and each publication of findings required to be made in connection with rulemaking under any such section shall set forth \_ `` (1) the manner in which interested persons may examine data and other information which the notice or findings is based; and `` (2) the period within which interested persons may present their comments on the notice or findings (including the need therefor) orally or in writing,

which period shall be at least 60 days but may not exceed 90 days unless the time is extended by the Secretary by a notice published in the Federal Register stating good cause therefor. `` (c) Limited Confidentiality of Information. Any information reported to or otherwise obtained by the Secretary or the Secretary's representative under section 904, 907, 908, 909, or 910 or 704, or under subsection (e) or (f) of this section, which is exempt from disclosure under subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b) (4) of that section shall be considered confidential and shall not be disclosed, except that the information may be disclosed to other officers or employees concerned with carrying out this chapter, or when relevant in any proceeding under this chapter. `` (d) Restrictions. `` (1) 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, as the Secretary may prescribe in such regulation if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that such regulation would be appropriate for the protection of the public health. The finding as to whether such regulation would be appropriate for the protection of the public health shall be determined with respect to other risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account `` (A) the increased or decreased likelihood that existing users of tobacco products will stop @), using such products; and `` (B) the increased or decreased likelihood that those who do not use tobacco products will start using such products. No such condition may require that the sale or distribution of a tobacco product be limited to the written or oral authorization of a practitioner licensed by law to prescribe medical products. `` (2) The label of a tobacco product shall bear such appropriate statements of the restrictions required by a regulation under subsection (a) as the Secretary may in such regulation prescribe. `` (3) 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 the National Tobacco Policy and Youth Smoking Reduction Act to specified categories of retail outlets, it is appropriate for the Congress to have the opportunity to review such a decision. Therefore, any such restriction may not take effect before the date that is 2 years after the President notifies the Congress that a final regulation imposing the restriction has been issued. `` (e) Good Manufacturing Practice Requirements. `` (1) Methods, facilities, and controls to conform. `` (A) The Secretary may, in accordance with subparagraph (B), prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, production, design, validation (including a gap process to assess the performance of a tobacco product), packing and storage of a tobacco product, conform to current good manufacturing practice, as prescribed in such regulations, to assure that the public health is protected and that the tobacco product is in compliance with this chapter. `` (B) The Secretary shall `` (i) before promulgating any regulation under subparagraph (A), afford the Tobacco Products Scientific Advisory Committee established under section 915 an opportunity to submit recommendations with respect to the regulation proposed to be promulgated; `` (ii) before promulgating any regulation under subparagraph (A), afford opportunity for an oral hearing; `` (iii) provide the advisory committee a reasonable time to make its recommendation with respect to proposed regulations under subparagraph (A); and `` (iv) in establishing the effective date of a regulation promulgated under this subsection, take into account the differences in the manner in which the different types of tobacco products have historically been produced, the financial resources of the different tobacco product manufacturers, and the state of their existing manufacturing facilities; and shall provide for a @), reasonable period of time for such manufacturer to conform to good manufacturing practices. `` (2) Exemptions; variances. `` (A) Any person subject to any requirement prescribed under paragraph (1) may petition the Secretary for a permanent or temporary exemption or variance from such requirement. Such a petition shall be submitted to the Secretary in such form and manner as the Secretary shall prescribe and shall `` (i) in the case of a petition for an exemption from a requirement, set forth the basis for the petitioner's determination that compliance with the requirement is not required to assure that the tobacco product will be in compliance with this chapter; `` (ii) in the case of a petition for a variance from a requirement, set forth the methods proposed to be used in, and the facilities and controls proposed to be used for, the manufacture, packing, and storage of the tobacco product in lieu of the methods, facilities, and controls prescribed by the requirement; and `` (iii) contain such other information as the Secretary shall prescribe. `` (B) The Secretary may refer to the Tobacco Products Scientific Advisory Committee established under section 915 any petition submitted under subparagraph (A). The advisory committee shall report its recommendation to the Secretary with

threspecttoapetitionreferredtoitwithin60daysafterthedateofthepetition'sreferral. Within60daysafter\_` (i) thedatethepetitionwassubmittedtotheSecretaryundersubpar  
agraph(A);or` (ii) thedayafterthepetitionwasreferredtoanadvisorycommittee,whiche  
veroccurslater, theSecretaryshallbyordereitherdenythepetitionorapproveit.` (C)Th  
eSecretarymayapprove\_` (i) apetitionforanexemptionforatobaccoproductfromarequire  
mentiftheSecretarydeterminesthatcompliancewithsuchrequirementisnotrequiredtoass  
urethatthetobaccoproductwillbeincompliancewiththischapter;and` (ii) apetitionfor  
avarianceforatobaccoproductfromarequirementiftheSecretarydeterminesthatthemetho  
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herequirementaresufficienttoassurethatthetobaccoproductwillbeincompliancewith  
ischapter.` (D) AnorderoftheSecretaryapprovingapetitionforavariationshallprescrib  
esuchconditionsrespectingthethodsusedin, andthefacilitiesandcontrolusedfor, th  
e -@), manufacture, packing, andstorageofthetobaccoproducttobegantedthevariance  
nderthepetitionasmaybe necessarytoassurethatthetobaccoproductwillbeincompliance  
iththischapter.` (E) Aftertheissuanceofanorderundersubparagraph(B) respectingapet  
ition, thepetitionershallhaveanopportunityforaninformalhearingonsuchorder.` (3) C  
ompliancewithrequirementsunderthissubsectionshallnotberequiredbeforetheperioden  
ding3yearsafterthedateofenactmentoftheNationalTobaccoPolicyandYouthSmokingReduc  
tionAct.` (f) ExemptionforInvestigationalUse. \_TheSecretarymayexempttobaccoproduct  
tsintendedforinvestigationalusefromthischapterundersuchconditionsastheSecretary  
mayprescribebyregulation.` (g) ResearchandDevelopment. \_TheSecretarymayenterintoc  
ontractsforresearch, testing, anddemonstrationsrespectingtobaccoproductsandmayobt  
aintobaccoproductsforresearch, testing, anddemonstrationpurposeswithoutregardtose  
ction3324 (a) and(b) oftitle31, UnitedStatesCode, andsection5oftitle41, UnitedStatesC  
ode.` SEC. 907. PERFORMANCESTANDARDS.` (a) InGeneral. \_` (1) Findingrequired. \_TheSec  
retarymayadoptperformancestandardsforatobaccoproductiftheSecretaryfindsthataper  
formancestandardisappropriateforthe protectionofthepublichealth. Thisfindingshall  
bedeterminedwithrespecttotherisksandbenefitstothe populationasawhole, includingus  
ersandnonusersofthetobaccoproduct, andtakingintoaccount\_` (A) theincreasedordecre  
asedlikelihoodthatexistingusersoftobaccoproductswillstopusingsuchproducts;and`  
(B) theincreasedordecreasedlikelihoodthatthosewhodonotusetobaccoproductswillstar  
tusingsuchproducts.` (2) Contentofperformancestandards. \_Aperformancestandardesta  
blishedunderthissectionforatobaccoproduct\_` (A) shallincludeprovisionstoprovidep  
erformance thatis appropriateforthe protectionofthepublichealth, includingprovision  
s, whereappropriate\_` (i) forthereductionoreliminationofnicotinyieldsoftheproduc  
t;` (ii) forthereductionoreliminationofotherconstituentsorharmfulcomponentsofthe  
product;or -@), ` (iii) relatingtoanyotherrequirementunder(B);` (B) shall, where  
cessarytobe appropriateforthe protectionofthepublichealth, include\_` (i) provisions  
respectingthe construction, components, ingredients, andpropertiesofthetobaccoprodu  
ct;` (ii) provisionsforthetesting (onasamplebasisor, ifnecessary, onanindividualbas  
is) ofthetobaccoproduct;` (iii) provisionsforthemeasurementofthepformancecharac  
teristicsofthetobaccoproduct;` (iv) provisionsrequiringthattheresultsofeachorofc  
ertainofthetestsofthetobaccoproductrequiredtobemadeunderclause(ii) showthattheto  
baccoproductisinconformitywiththeportionsofthestandardforwhichthetestortestsw  
erequired;and` (v) aprovisionrequiringthatthesaleanddistributionofthetobaccoprod  
uctberestrictedbutonlytotheextentthatthesaleanddistributionofatobaccoproductmay  
berestrictedunderaregulationundersection906 (d); and` (C) shall, whereappropriate, r  
equiretheuseandprescribetheformandcontentoflabelingforthe properuseofthetobaccop  
roduct.` (3) Periodicreevaluationofperformancestandards. \_TheSecretaryshallprovid  
eforperiodicevaluationofperformancestandardsestablishedunderthissectiontodeterm  
inewhethersuchstandardsshouldbechangedtoreflectnewmedical, scientific, orothertec  
hnologicaldata. TheSecretarymayprovidefortestingunderparagraph(2) byanyperson.` (4  
) Involvementofotheragencies; informedpersons. \_Incarryingoutdutiesunderthissecti  
on, theSecretaryshall, tothemaximumextentpracticable\_` (A) usepersonnel, facilities  
, andothertechnicalsupportavailableinotherFederalagencies;` (B) consultwithotherF  
ederalagenciesconcernedwithstandardsettingandother nationallyor internationallyre  
cognizedstandardsettingentities; and` (C) inviteappropriate participation, throughj  
ointorotherconferences, workshops, orothermeans, byinformedpersonsrepresentativeof  
scientific, professional, industry, orconsumerorganizationswhointheSecretary'sjudg

ment can make a significant contribution. `` (b) Establishment of Standards. `` (1) Notice. `` (A) The Secretary shall publish in the Federal Register a notice of proposed rulemaking for the establishment, amendment, or revocation of any performance standard for a tobacco product. `` (B) A notice of proposed rulemaking for the establishment or amendment of a performance standard for a tobacco product shall `` (i) set forth a finding with supporting justification that the performance standard is appropriate for the protection of the public health; `` (ii) set forth proposed findings with respect to the risk of illness or injury that the performance standard is intended to reduce or eliminate; and `` (iii) invite interested persons to submit an existing performance standard for the tobacco product, including a draft or proposed performance standard, for consideration by the Secretary. `` (C) A notice of proposed rulemaking for the revocation of a performance standard shall set forth a finding with supporting justification that the performance standard is no longer necessary to be appropriate for the protection of the public health. `` (D) The Secretary shall consider all information submitted in connection with a proposed standard, including information concerning the countervailing effects of the performance standard on the health of adolescent tobacco users, adult tobacco users, or non-tobacco users, such as the creation of a significant demand for contraband of other tobacco products that do not meet the requirements of this chapter and the significance of such demand, and shall issue the standard if the Secretary determines that the standard would be appropriate for the protection of the public health. `` (E) The Secretary shall provide for a comment period of not less than 60 days. `` (2) Promulgation. `` (A) After the expiration of the period for comment on a notice of proposed rulemaking published under paragraph (1) respecting a performance standard and after consideration of such comments and any report from the Tobacco Products Scientific Advisory Committee under section 915, the Secretary shall `` (i) promulgate a regulation establishing a performance standard and publish in the Federal Register findings on the matters referred to in paragraph (1); or `` (ii) publish a notice terminating the proceeding for the development of the standard together with the reasons for such termination. `` (B) A regulation establishing a performance standard shall set forth the date and dates upon which the standard shall take effect, but no such regulation may take effect before one year after the date of its publication unless the Secretary determines that an earlier effective date is necessary for the protection of the public health. Such date or dates shall be established so as to `` (i) minimize, consistent with the public health, economic loss to, and disruption or dislocation of, domestic and international trade. `` (3) Special rule for standard and banning class of product to eliminate nicotine content. `` Because of the importance of a decision of the Secretary to issue a regulation establishing a performance standard `` (A) eliminating all cigarettes, all smokeless tobacco products, or any similar class of tobacco products, or `` (B) requiring the reduction of nicotine yields of a tobacco product to zero, it is appropriate for the Congress to have the opportunity to review such a decision. Therefore, any such standard may not take effect before a date that is 2 years after the President notifies the Congress that a final regulation imposing the restriction has been issued. `` (4) Amendment; revocation. `` (A) The Secretary, upon the Secretary's own initiative or upon petition of an interested person, may by a regulation, promulgated in accordance with the requirements of paragraphs (1) and (2) (B) of this subsection, amend or revoke a performance standard. `` (B) The Secretary may declare a proposed amendment of a performance standard to be effective on and after its publication in the Federal Register and until the effective date of any final action taken on such an amendment if the Secretary determines that making it so effective is in the public interest. `` (5) Reference to Advisory Committee. `` The Secretary `` (A) may, on the Secretary's own initiative, refer a proposed regulation for the establishment, amendment, or revocation of a performance standard; or `` (B) shall, upon the request of an interested person which demonstrates good cause for referral and which is made before the expiration of the period for submission of comments on such proposed regulation, refer such proposed regulation to the Tobacco Products Scientific Advisory Committee established under section 915, for a report and recommendation with respect to any matter involved in the proposed regulation which requires the exercise of scientific judgment. If a proposed regulation is referred under this subsection to the advisory committee, the Secretary shall provide the advisory committee with the data and information on which such proposed regulation is based. The advisory committee shall, within 60 days after the referral of a proposed regulation and after independent study of the data and information furnished to it by the Secretary and other data and information before it, submit to the Secretary a report and recommendation respecting such regulation, together with all underlying data and information `` (i) supporting the recommendation, and a statement of the reason or basis for the recommendation. A copy of such report and recommendations shall be made public by the Sec-

retary. ``SEC. 908. NOTIFICATION AND OTHER REMEDIES`` (a) Notification. \_If the Secretary determines that `` (1) a tobacco product which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm to the public health; and `` (2) notification under this subsection is necessary to eliminate the unreasonable risk of such harm and no more practicable means is available under the provisions of this chapter (other than this section) to eliminate such risk, the Secretary may issue such order as may be necessary to assure that adequate notification is provided in a appropriate form, by the persons and means best suited under the circumstances involved, to all persons who should properly receive such notification in order to eliminate such risk. The Secretary may order notification by any appropriate means, including public service announcements. Before issuing an order under this subsection, the Secretary shall consult with the persons who are to give notice under the order. `` (b) No Exemption from Other Liability. \_Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided under such orders shall be taken into account. `` (c) Recall Authority. \_ `` (1) In General. \_If the Secretary finds that there is a reasonable probability that a tobacco product contains a manufacturing or other defect not ordinarily contained in tobacco products on the market that would cause serious, adverse health consequences or death, the Secretary shall issue an order requiring the appropriate person (including the manufacturer, importers, distributors, or retailers of the tobacco product) to immediately cease distribution of such tobacco product. The orders shall provide the persons subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order and on whether the orders should be amended to require a recall of such tobacco product. If, after providing an opportunity for such a hearing, the Secretary determines that inadequate ground exists to support the actions required by the order, the Secretary shall vacate the order. `` (2) Amendment to Order to Require Recall. \_ `` (A) If, after providing an opportunity for an informal hearing under paragraph (1), the Secretary determines that the orders should be amended to include a recall of the tobacco product with respect to which the order was issued, the Secretary shall, except as provided in -@), subparagraph (B), amend the order to require a recall. The Secretary shall specify a timetable in which the tobacco product recall will occur and shall require periodic reports to the Secretary describing the progress of the recall. `` (B) An amended order under subparagraph (A) \_ `` (i) shall not include a recall of a tobacco product from individuals; and `` (ii) shall provide for notice to persons subject to other risks associated with the use of such tobacco product. In providing the notice required by clause (ii), the Secretary may use the assistance of retailers and other persons who distribute such tobacco product. If a significant number of such persons cannot be identified, the Secretary shall notify such persons under section 705 (b). `` (3) Remedy not exclusive. \_The remedy provided by this subsection shall be in addition to remedies provided by subsection (a) of this section. ``SEC. 909. RECORDS AND REPORTS ON TOBACCO PRODUCTS. `` (a) In General. \_Every person who is a tobacco product manufacturer or importer of a tobacco product shall establish and maintain such records, make such reports, and provide such information, as the Secretary may by regulation reasonably require to assure that such tobacco product is not adulterated or misbranded and to otherwise protect public health. Regulations prescribed under the preceding sentence \_ `` (1) may require a tobacco product manufacturer or importer to report to the Secretary whenever the manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed tobacco products may have caused or contributed to a serious unexpected adverse experience associated with the use of the product or any significant increase in the frequency of a serious, expected adverse product experience; `` (2) shall require reporting of other significant adverse tobacco product experiences as determined by the Secretary to be necessary to be reported; `` (3) shall not impose requirements unduly burdensome to a tobacco product manufacturer or importer, taking into account the cost of complying with such requirements and the need for the protection of the public health and the implementation of this chapter; `` (4) when prescribing the procedure for making requests for reports or information, shall require that each request made under such regulations for submission of a report or information to the Secretary state the reason or purpose for such request and identify to the fullest extent practicable such report or information; `` (5) when requiring submission of a report or information to the Secretary, shall state the reason or purpose for the submission of such report or information and identify to the fullest extent -@), practicable such report or information; and `` (6) may not require that the identity

fanypatientoruserbedisclosedinrecords, reports, orinformationrequiredunderthissub  
 sectionunlessrequiredforthemedicalwelfareofanindividual, todetermineriskstopubli  
 chealthofatobaccoproduct, ortoverifyarecord, report, orinformationsubmittedunderth  
 ischapter. Inprescribingregulationsunderthissubsection, theSecretaryshallhavedue  
 egardfortheprofessionalethicsofthemedicalprofessionandtheinterestsofpatients. Th  
 eprohibitionsofparagraph(6)ofthissubsectioncontinuetoapplytorecords, reports, and  
 informationconcerninganyindividualwhohasbeenapatient, irrespectivewhetherorwhe  
 nheceasestobeapatient. `` (b) ReportsofRemovalsandCorrections. \_ (1) Exceptasprovided  
 inparagraph(3), theSecretaryshallbyregulationrequireatobaccoproductmanufacturero  
 rimporterofatobaccoproducttoreportpromptlytotheSecretaryanycorrectiveactiontake  
 norremovalfromthemarketofatobaccoproductundertakenbysuchmanufacturerorimporter  
 iftheremovalorcorrectionwasundertaken\_ `` (A) toreducearisktohealthposedbythetobacc  
 oproduct; or`` (B) toremedyaviolationofthischaptercausedbythetobaccoproductwhichma  
 ypresentarisktohealth. Atobaccoproductmanufacturerorimporterofatobaccoproductwho  
 undertakesacorrectiveactionorremovalfromthemarketofatobaccoproductwhichisnotreq  
 uiredtobereportedunderthissubsectionshallkeeparecordofsuchcorrectionorremoval. `

^ (2) Noreportofthecorrectiveactionorremovalofatobaccoproductmayberequiredunderpa  
 ragraph(1) ifareportofthecorrectiveactionorremovalisrequiredandhasbeensubmittedu  
 ndersubsection(a) ofthissection. `` SEC. 910. PREMARKETREVIEWOFCERTAINTOBACCPRODUCT  
 S. `` (a) InGeneral. \_ `` (1) Premarketapprovalrequired. \_ `` (A) Newproducts. \_ Approvalun  
 derthissectionofanapplicationforpremarketapprovalforanytobaccoproductthatisnotco  
 mmerciallymarketed(otherthanfortestmarketing) intheUnitedStatesofAugust11, 1995  
 , isrequiredunless.themanufacturerhassubmittedareportundersection905(j), andtheSec  
 retaryhasissuedanorderthatthetobaccoproductissubstantiallyequivalenttoatobaccop  
 roductcommerciallymarketed(otherthanfortestmarketing) intheUnitedStatesofAugus  
 t11, 1995, thatisincompliancewiththerequirementsofthisAct. \_ @), `` (B) Productsin  
 oducedbetweenAugust11, 1995, andenactmentofthischapter. \_ Subparagraph(A) doesnotapp  
 lytoatobaccoproductthat\_ `` (i) wasfirstintroducedordeliveredforintroductionintoin  
 terstatecommerceforcommerceforcommercialdistributionintheUnitedStatesafterAugus  
 t11, 1995, andbeforethedateofenactmentoftheNationalTobaccoPolicyandYouthSmokingRe  
 ductionAct; and`` (ii) forwhichareportwassubmittedundersection905(j) within6months  
 aftersuchdate, untiltheSecretaryissuesanorderthatthetobaccoproductissubstantially  
 equivalentforpurposesofthissectionorrequirespremarketapproval. `` (2) Substantiall  
 yequivalentdefined. \_ `` (A) Forpurposesofthissectionandsection905(j), theterm`subst  
 antiallyequivalent'or`substantialequivalence' mean, withrespecttothetobaccoproduct  
 beingcomparedtothepredicatetobaccoproduct, thattheSecretarybyorderhasfoundthat  
 hetobaccoproduct\_ `` (i) hasthesamecharacteristicsasthepredicatetobaccoproduct; or`

` (ii) hasdifferentcharacteristicsandtheinformationsubmittedcontainsinformation, i  
 ncludingclinicaldataifdeemednecessarybytheSecretary, thatdemonstratesthatitisnot  
 appropriatetoregulateheproductunderthissectionbecausetheproductdoesnotraisedif  
 ferentquestionsofpublichealth. `` (B) Forpurposesofsubparagraph(A), theterm`charact  
 eristics' meansthematerials, ingredients, design, composition, heating source, orother  
 featuresofatobaccoproduct. `` (C) Atobaccoproductmaynotbefoundtobesubstantiallyequ  
 ivalenttoapredicatetobaccoproductthat hasbeenremovedfromthemarketattheinitiative  
 oftheSecretaryorthathasbeendeterminedbyajudicialordertobemisbrandedoradulterate  
 d. `` (3) HealthInformation. \_ `` (A) Aspartofasubmissionundersection905(j) respectinga  
 tobaccoproduct, thepersonrequiredtofileapremarketnotificationundersuchsections  
 shallprovideanadequatesummaryofanyhealthinformationrelatedtothetobaccoproductorst  
 atethatsuchinformationwillbemadeavailableuponrequestbyanyperson. `` (B) Anysummary  
 under subparagraph(A) respectingatobaccoproductshallcontaindetailedinformationrega  
 rdingdataconcerningadversehealtheffectsandsuchshallbemadeavailabletothepublicbytheS  
 ecretarywithin30daysoftheissuanceofadeterminationthatsuchtobaccoproductissubsta  
 ntiallyequivalenttoanother tobaccoproduct. `` (b) Application. \_ @), `` (1) Contents.

\_ Anapplicationforpremarketapprovalshallcontain\_ `` (A) fullreportsofallinformation  
 , publishedorknowntoorwhichshouldreasonablybeknowntotheapplicant, concerninginves  
 tigationwhichhavebeenmadetoshowthehealthrisksofsuchtobaccoproductandwhethersuc  
 htobaccoproductpresentslessriskthanother tobaccoproducts; `` (B) afullstatementofth  
 ecomponents, ingredients, andproperties, andoftheprincipleorprinciplesofoperation,  
 ofsuchtobaccoproduct; `` (C) afulldescriptionofthemethodsusedin, andthefacilitiesan  
 dcontrolsusedfor, themanufacture, processing, and, whenrelevant, packingandinstallat

ion of, such tobacco product; (D) an identifying reference to any performance standard under section 907 which would be applicable to any aspect of such tobacco product, and either adequate information to show that such aspect of such tobacco product fully meets such performance standard or adequate information to justify any deviation from such standard; (E) such samples of such tobacco product and of components thereof as the Secretary may reasonably require; (F) specimens of the labeling proposed to be used for such tobacco product; and (G) such other information relevant to the subject matter of the application as the Secretary may require.

(2) Reference to Advisory Committee. Upon receipt of an application meeting the requirements set forth in paragraph (1), the Secretary (A) may, on the Secretary's own initiative; or (B) shall, upon the request of an applicant, refer such application to the Tobacco Products Scientific Advisory Committee established under section 915 and for submission (within such period as the Secretary may establish) of a report and recommendation respecting approval of the application, together with all underlying data and the reasons or basis for the recommendation.

(c) Action on Application. (1) Deadline. (A) As promptly as possible, but in no event later than 180 days after the receipt of an application under subsection (b) of this section, the Secretary, after considering the report and recommendation submitted under paragraph (2) of such subsection, shall (i) issue an order approving the application if the Secretary finds that none of the grounds for denying approval specified in paragraph (2) of this subsection applies; or (ii) deny approval of the application if the Secretary finds (and sets forth the basis for such finding as part of or accompanying such denial) that one or more grounds for denial specified in paragraph (2) of this subsection apply. (B) An order approving an application for a tobacco product may require as a condition to such approval that the sale and distribution of the tobacco product be restricted but only to the extent that the sale and distribution of a tobacco product may be restricted under a regulation under section 906 (d).

(2) Denial of approval. The Secretary shall deny approval of an application for a tobacco product if, upon the basis of the information submitted to the Secretary as part of the application and any other information before the Secretary with respect to such tobacco product, the Secretary finds that (A) there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health; (B) the methods used in, or the facilities or controls used for, the manufacture, processing, or packaging of such tobacco product do not conform to the requirements of section 906 (e); (C) based on a fair valuation of all material facts, the proposed labeling is false or misleading in any particular; or (D) such tobacco product is not shown to conform in all respects to a performance standard in effect under section 907, compliance with which is a condition to approval of the application, and there is a lack of adequate information to justify the deviation from such standard.

(3) Denial of Information. Any denial of an application shall, insofar as the Secretary determines to be practicable, be accompanied by a statement informing the applicant of the measures required to place such application in an approvable form (which measures may include further research by the applicant in accordance with one or more protocols prescribed by the Secretary).

(4) Basis for finding. For purposes of this section, the finding as to whether approval of a tobacco product is appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account (A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and (B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

(5) Basis for action. (A) For purposes of paragraph (2) (A), whether permitting a tobacco product to be marketed would be appropriate for the protection of the public health shall, when appropriate, be determined on the basis of well-controlled investigations, which may include one or more clinical investigations by experts qualified by training and experience to evaluate the tobacco product. (B) If the Secretary determines that there exists valid scientific evidence (other than evidence derived from investigations described in subparagraph (A)) which is insufficient to evaluate the tobacco product the Secretary may authorize that the determination for purposes of paragraph (2) (A) be made on the basis of such evidence.

(d) Withdrawal and Temporary Suspension. (1) In general. The Secretary shall, upon obtaining, where appropriate, advice on scientific matters from the Tobacco Products Scientific Advisory Committee established under section 915, and after due notice and opportunity for informal hearing to the holder of an approved application for a tobacco product, issue an order withdrawing approval of the application if the Secretary finds (A) that the continued marketing of such tobacco product no longer is appropriate for the protection of the public health; (B) that the application contained or was accompanied by an untrue

atement of a material fact; (C) that the applicant (i) has failed to establish a system for maintaining records, or has repeatedly or deliberately failed to maintain records or to make reports, required by an applicable regulation under section 909; (ii) has refused to permit access to, or copying or verification of, such records as required by section 704; or (iii) has not complied with the requirements of section 905; (D) on the basis of new information before the Secretary with respect to such tobacco product, evaluated together with the evidence before the Secretary when the application was approved, that the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or installation of such tobacco product do not conform with the requirements of section 906(e) and were not brought into conformity with such requirements within a reasonable time -@), after receipt of written notice from the Secretary of nonconformity; (E) on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when the application was approved, that the labeling of such tobacco product, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary of such fact; or (F) on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when the application was approved, that such tobacco product is not shown to conform in all respects to a performance standard which is in effect under section 907, compliance with which was a condition to approval of the application, and that there is a lack of adequate information to justify the deviation from such standard. (2) Appeal. The holder of an application subject to an order issued under paragraph (1) withdrawing approval of the application may, by petition filed on or before the thirtieth day after the date upon which here receives notice of such withdrawal, obtain review thereof in accordance with subsection (e) of this section. (3) Temporary suspension. If, after providing an opportunity for an informal hearing, the Secretary determines there is reasonable probability that the continuation of distribution of a tobacco product under an approved application would cause serious, adverse health consequences or death, that is greater than ordinarily caused by tobacco products on the market, the Secretary shall by order temporarily suspend the approval of the application approved under this section. If the Secretary issues such an order, the Secretary shall proceed expeditiously under paragraph (1) to withdraw such application. (e) Service of Order. An order issued by the Secretary under this section shall be served (1) in person by any officer or employee of the department designated by the Secretary; or (2) by mailing the order by registered mail or certified mail addressed to the applicant at the applicant's last known address in the record of the Secretary. SEC. 911. JUDICIAL REVIEW. (a) In General. Not later than 30 days after (1) the promulgation of a regulation under section 907 establishing, amending, or revoking a performance standard for a tobacco product; or (2) a denial of an application for approval under section 910(c), any person adversely affected by such regulation or order may file a petition with the United States Court of Appeals for the District of Columbia or for the circuit where in such person resides or has his principal place of business for judicial review of such regulation or order. A -@), copy of the petition shall be transmitted by the clerk of the court to the Secretary or other officer designated by the Secretary for that purpose. The Secretary shall file in the court the record of the proceedings on which the Secretary based the Secretary's regulation or order and each record or order shall contain a statement of the reasons for its issuance and the basis, on the record, for its issuance. For purposes of this section, the term 'record' means all notices and other matter published in the Federal Register with respect to the regulation or order reviewed, all information submitted to the Secretary with respect to such regulation or order, proceedings of any panel or advisory committee with respect to such regulation or order, any hearing held with respect to such regulation or order, and any other information identified by the Secretary, in the administrative proceeding held with respect to such regulation or order, as being relevant to such regulation or order. (b) Court May Order Secretary to Make Additional Findings. If the petitioner applies to the court for leave to adduce additional data, views, or arguments respecting the regulation or order being reviewed and shows to the satisfaction of the court that such additional data, views, or arguments are material and that there were reasonable grounds for the petitioner's failure to adduce such data, views, or arguments in the proceedings before the Secretary, the court may order the Secretary to provide additional opportunity for the oral presentation of data, views, or arguments and for written submissions. The Secretary may modify the Secretary's findings, or make new findings by reason of the additional data, views, or arguments so taken and shall file with the court such modified or new findings, and the Secretary's recommendation, if any, for the modification or setting aside of the regulation or order being reviewed, with the return of

uch additional data, views, or arguments. `` (c) Standard of Review. \_ Upon the filing of the petition under subsection (a) of this section for judicial review of a regulation or order, the court shall have jurisdiction to review the regulation or order in accordance with chapter 7 of title 5, United States Code, and to grant appropriate relief, including interim relief, as provided in such chapter. A regulation or order described in paragraph (1) or (2) of subsection (a) of this section shall not be affirmed if it is found to be unsupported by substantial evidence on the record taken as a whole. `` (d) Finality of Judgment. \_ The judgment of the court affirming or setting aside, in whole or in part, any regulation or order shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of title 28, United States Code. `` (e) Other Remedies. \_ The remedies provided for in this section shall be in addition to and not in lieu of any other remedies provided by law. `` (f) Regulations and Orders Must Recite Basis in Record. \_ To facilitate judicial review under this section or under any other provision of law of a regulation or order issued under section 906, 907, 908, 909, 910, or 914, each such regulation or order shall contain a statement of the reasons for its issuance and the basis, in the record of the proceedings held in connection with its issuance, for its issuance. `` SEC. 912. POSTMARKETSURVEILLANCE -@), `` (a) Discretionary Surveillance. \_ The Secretary may require a tobacco product manufacturer to conduct postmarket surveillance for a tobacco product of the manufacturer if the Secretary determines that postmarket surveillance of the tobacco product is necessary to protect the public health or is necessary to provide information regarding the health risks and other safety issues involving the tobacco product. `` (b) Surveillance Approval. \_ Each tobacco product manufacturer required to conduct a surveillance of a tobacco product under subsection (a) of this section shall, within 30 days after receiving notice that the manufacturer is required to conduct such surveillance, submit, for the approval of the Secretary, a protocol for the required surveillance. The Secretary, within 60 days of the receipt of such protocol, shall determine if the principal investigator proposed to be used in the surveillance has sufficient qualifications and experience to conduct such surveillance and if such protocol will result in collection of useful data or other information necessary to protect the public health. The Secretary may not approve such a protocol until it has been reviewed by an appropriately qualified scientific and technical review committee established by the Secretary. `` SEC. 913. REDUCED RISK TOBACCO PRODUCTS. `` (a) Requirements. \_ `` (1) In general. \_ For purposes of this section, the term "reduced risk tobacco product" means a tobacco product designated by the Secretary under paragraph (2). `` (2) Designation. \_ `` (A) In general. \_ A product may be designated by the Secretary as a reduced risk tobacco product if the Secretary finds that the product will significantly reduce harm to individuals caused by a tobacco product and is otherwise appropriate to protect public health, based on an application submitted by the manufacturer of the product (or the responsible person) that \_ `` (i) demonstrates through testing on animals and short-term human testing that use of such product results in ingestion or inhalation of a substantially lower yield of toxic substances than use of conventional tobacco products in the same category as the proposed reduced risk product; and `` (ii) if required by the Secretary, includes studies of the long-term health effects of the product. If such studies are required, the manufacturer may consult with the Secretary regarding protocols for conducting the studies. `` (B) Basis for finding. \_ In making the finding under subparagraph (A), the Secretary shall take into account \_ `` (i) the risks and benefits to the population as a whole, including both users of tobacco products and nonusers of tobacco products; -@), `` (ii) the increased or decreased likelihood that existing users of tobacco products will stop using such products including reduced risk tobacco products; `` (iii) the increased or decreased likelihood that those who do not use tobacco products will start to use such products, including reduced risk tobacco products; and `` (iii) the risks and benefits to consumers from the use of a reduced risk tobacco product as compared to the use of products approved under chapter V to reduce exposure to tobacco. `` (3) Marketing requirements. \_ A tobacco product may be marketed and labeled as a reduced risk tobacco product if it \_ `` (A) has been designated as a reduced risk tobacco product by the Secretary under paragraph (2); `` (B) bears a label prescribed by the Secretary concerning the product's contribution to reducing harm to health; and `` (C) complies with requirements prescribed by the Secretary relating to marketing and advertising of the product, and other provisions of this chapter as prescribed by the Secretary. `` (b) Revocation of Designation. \_ At any time after the date on which a tobacco product is designated as a reduced risk tobacco product under this section the Secretary may, after providing an opportunity for an informal hearing, revoke such designation if the Secretary determines, based on information not available at the time of the designation, that \_ `` (1) the finding made under subsection (a) (2) is no longer valid; or `

(2) the product is being marketed in violation of subsection (a) (3). (c) Limitation. A tobacco product that is designated as a reduced risk tobacco product that is in compliance with subsection (a) shall not be regulated as a drug or device. (d) Development of reduced risk tobacco product technology. A tobacco product manufacturer shall provide written notice to the Secretary upon the development or acquisition by the manufacturer of any technology that would reduce the risk of a tobacco product to the health of the user for which the manufacturer is not seeking designation as a reduced risk tobacco product under subsection (a). SEC. 914. PRESERVATION OF STATE AND LOCAL AUTHORITY. (a) Additional Requirements. (1) In general. Except as provided in paragraph (2), nothing in this Act shall be construed as prohibiting a State or political subdivision thereof from adopting or enforcing a requirement applicable to a tobacco product that is in addition to, or more stringent than, requirements established under this chapter. (2) Preemption of certain state and local requirements. (A) Except as provided in subparagraph (B), no State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement applicable under the provisions of this chapter relating to performance standards, premarket approval, adulteration, misbranding, registration, reporting, good manufacturing standards, or reduced risk products. (B) Subparagraph (A) does not apply to requirements relating to the sale, use, or distribution of a tobacco product including requirements related to the access to, and the advertising and promotion of, a tobacco product. (b) Rule of Construction Regarding Product Liability. No provision of this chapter relating to a tobacco product shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State. (c) Waivers. Upon the application of a State or political subdivision thereof, the Secretary may, by regulation promulgated after notice and an opportunity for an oral hearing, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a tobacco product if (1) the requirement is more stringent than a requirement applicable under the provisions described in subsection (a) (3) which would be applicable to the tobacco product if an exemption were not in effect under this subsection; or (2) the requirement (A) is required by compelling local conditions; and (B) compliance with the requirement would not cause the tobacco product to be in violation of any applicable requirement of this chapter. SEC. 915. TOBACCO PRODUCT SCIENTIFIC ADVISORY COMMITTEE. (a) Establishment. Not later than one year after the date of enactment of the National Tobacco Policy and Youth Smoking Reduction Act, the Secretary shall establish a 9 member advisory committee, to be known as the Tobacco Products Scientific Advisory Committee. (b) Membership. (1) In general. The Secretary shall appoint as members of the Tobacco Products Scientific Advisory Committee individuals who are technically qualified by training and experience in the (i) medicine, medical ethics, science, or technology involving the manufacture, evaluation, or use of tobacco products, who are of appropriately diversified professional backgrounds. The committee shall be composed of (A) 3 individuals who are officers or employees of a State or local government, or of the Federal government; (B) 2 individuals as representatives of interest of the tobacco manufacturing industry; (C) 2 individuals as representatives of interest of physicians and other health care professionals; and (D) 2 individuals as representatives of the general public. (2) Limitation. The Secretary may not appoint to the Advisory Committee any individual who is in the regular full time employ of the Food and Drug Administration or any agency responsible for the enforcement of this Act. The Secretary may appoint Federal officials as ex officio members. (3) Chairperson. The Secretary shall designate one of the members of the Advisory Committee to serve as chairperson. (c) Duties. The Tobacco Products Scientific Advisory Committee shall provide advice, information, and recommendations to the Secretary (1) as provided in this chapter; (2) on the effects of the alteration of the nicotine yields from tobacco products; (3) on whether there is a threshold level below which nicotine yields do not produce dependence on the tobacco product involved; and (4) on its review of other safety, dependence, or health issues relating to tobacco products as requested by the Secretary. (d) Compensation; Support; FACA. (1) Compensation and travel. Members of the Advisory Committee who are not officers or employees of the United States, while attending conferences or meetings of the committee or (i) otherwise engaged in its business, shall be entitled to receive compensation at a rate to be fixed by the Secretary, which may not exceed the daily equivalent of the rate in effect for level 4 of the Senior Executive Schedule under section 5382 of title 5, United States Code, for each day (including travel time) they are so engaged; and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including

per diem in lieu of subsistence, as authorized by section 5703 of title 5, United States Code, for persons in the Government service employed intermittently. `` (2) Administrative support. The Secretary shall furnish the Advisory Committee clerical and other assistance. `` (3) Nonapplication of FACA. Section 14 of the Federal Advisory Committee Act (5 U.S.C. App.) does not apply to the Advisory Committee. `` (e) Proceedings of Advisory Panels and Committees. The Advisory Committee shall make and maintain a transcript of any proceeding of the panel or committee. Each such panel and committee shall delete from any transcript made under this subsection information which is exempt from disclosure under section 552 (b) of title 5, United States Code. `` SEC. 916. EQUAL TREATMENT OF RETAIL OUTLETS. `` The Secretary shall issue regulations to require that retail establishments for which the predominant business is the sale of tobacco products comply with any advertising restrictions applicable to retail establishments accessible to individuals under the age of 18. `` SEC. 102. CONFORMING AND OTHER AMENDMENTS TO GENERAL PROVISIONS. (a) Amendment of Federal Food, Drug, and Cosmetic Act. Except as otherwise expressly provided, whenever in this section an amendment is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference is to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.). (b) Section 301. Section 301 (21 U.S.C. 331) is amended (1) by inserting `` tobacco product, ' ' in subsection (a) after `` device, ' ' ; (2) by inserting `` tobacco product, ' ' in subsection (b) after `` device, ' ' ; (3) by inserting `` tobacco product, ' ' in subsection (c) after `` device, ' ' ; (4) by striking `` 515 (f), or 519 ' ' in subsection (e) and inserting `` 515 (f), 519, or 909 ' ' ; (5) by inserting `` tobacco product, ' ' in subsection (g) after `` device, ' ' ; (6) by inserting `` tobacco product, ' ' in subsection (h) after `` device, ' ' ; (7) by striking `` 708, or 721 ' ' in subsection (j) and inserting `` 708, 721, 904, 905, 906, 907, 908, or 909 ' ' ; -@), (8) by inserting `` tobacco product, ' ' in subsection (k) after `` device, ' ' ; (9) by striking subsection (p) and inserting the following: `` (p) The failure to register in accordance with section 510 or 905, the failure to provide any information required by section 510 (j), 510 (k), 905 (i), or 905 (j), or the failure to provide a notice required by section 510 (j) (2) or 905 (j) (2). ' ' ; (10) by striking subsection (q) (1) and inserting the following: `` (q) (1) The failure or refusal (A) to comply with any requirement prescribed under section 518, 520 (g), 906 (f), or 908; `` (B) to furnish any notification or other material or information required by or under section 519, 520 (g), 904, 906 (f), or 909; or `` (C) to comply with a requirement under section 522 or 912. ' ' ; (11) by striking `` device, ' ' in subsection (q) (2) and inserting `` device or tobacco product, ' ' ; and (12) by inserting `` or tobacco product ' ' in subsection (r) after `` device ' ' each time that it appears. (c) Section 303. Section 303 (f) (1) (A) (21 U.S.C. 333 (f) (1) (A)) is amended by inserting `` or tobacco products ' ' after `` devices ' ' . (d) Section 304. Section 304 (21 U.S.C. 334) is amended (1) by striking `` and ' ' before `` (D) ' ' in subsection (a) (2); (2) by striking `` device. ' ' in subsection (a) (2) and inserting a comma and `` (E) Any adulterated or misbranded tobacco product. ' ' ; (3) by inserting `` tobacco product, ' ' in subsection (d) (1) after `` device, ' ' ; (4) by inserting `` or tobacco product ' ' in subsection (g) (1) after `` device ' ' each place it appears; and (5) by inserting `` or tobacco product ' ' in subsection (g) (2) (A) after `` device ' ' each place it appears. (e) Section 702. Section 702 (a) (21 U.S.C. 372 (a)) is amended (1) by inserting `` (1) ' ' after `` (a) ' ' ; and (2) by adding at the end thereof the following: `` (2) For a tobacco product, to the extent feasible, the Secretary shall contract with the States in -@), in accordance with paragraph (1) to carry out inspections of retailers in connection with the enforcement of this Act. ' ' . (f) Section 703. Section 703 (21 U.S.C. 373) is amended (1) by inserting `` tobacco product, ' ' after `` device, ' ' each place it appears; and (2) by inserting `` tobacco products, ' ' after `` devices, ' ' each place it appears. (g) Section 704. Section 704 (21 U.S.C. 374) is amended (1) by inserting `` tobacco products, ' ' in subsection (a) (1) (A) after `` devices, ' ' each place it appears; (2) by inserting `` or tobacco products ' ' in subsection (a) (1) (B) after `` restricted devices ' ' each place it appears; and (3) by inserting `` tobacco product, ' ' in subsection (b) after `` device, ' ' . (h) Section 705. Section 705 (b) (21 U.S.C. 375 (b)) is amended by inserting `` tobacco products, ' ' after `` devices, ' ' . (i) Section 709. Section 709 (21 U.S.C. 379) is amended by inserting `` or tobacco product ' ' after `` device ' ' . (j) Section 801. Section 801 (21 U.S.C. 381) is amended (1) by inserting `` tobacco products, ' ' after `` devices, ' ' in subsection (a) the first time it appears; (2) by inserting `` or subsection (j) of section 905 ' ' in subsection (a) after `` section 510 ' ' ; and (3) by striking `` drugs or devices ' ' each time it appears in subsection (a) and inserting `` drugs, devices, or tobacco products ' ' ; (4) by inserting `` tobacco product, ' ' in subsection (e) (1) after `` device, ' ' ; (2) by redesignating paragraph (4) of subsection (e) as paragraph (5) and inserting after paragraph (3), the following: `` (4) Paragraph (1) does not apply to any tobacco

accproduct\_ (A) which does not comply with an applicable requirement of section 907 or 910; or (B) which under section 906 (f) is exempt from either such section. This paragraph does not apply if the Secretary has determined that the exportation of the tobacco product is not contrary to the public health and safety and has the approval of the country to which it is intended for export or the tobacco product is eligible for export under section 802. (k) Section 802. Section 802 (21 U.S.C. 382) is amended (1) by striking "device" in subsection (a) and inserting "device or tobacco product"; (2) by striking "and" after the semicolon in subsection (a) (1) (C); (3) by striking subparagraph (C) of subsection (a) (2) and all that follows in that subsection and inserting the following: "(C) is a banned device under section 516; or (3) which, in the case of a tobacco product (A) does not comply with an applicable requirement of section 907 or 910; or (B) under section 906 (f) is exempt from either such section, is adulterated, misbranded, and in violation of such sections or Act unless the export of the drug, device, or tobacco product is, except as provided in subsection (f), authorized under subsection (b), (c), (d), or (e) of this section or section 801 (e) (2) or 801 (e) (4). If a drug, device, or tobacco product described in paragraph (1), (2), or (3) may be exported under subsection (b) and if an application for such drug or device under section 505, 515, or 910 of this Act or section 351 of the Public Health Service Act (42 U.S.C. 262) was disapproved, the Secretary shall notify the appropriate public health official of the country to which such drug, device, or tobacco product will be exported of such disapproval."; (4) by inserting "or tobacco product" in subsection (c) after "device" and inserting "or section 906 (f)" after "520 (g)"; (6) by inserting "or tobacco product" in subsection (f) after "device" each time it appears; and (7) by inserting "or tobacco product" in subsection (g) after "device" each time it appears. (l) Section 1003. Section 1003 (d) (2) (C) (as redesignated by section 101 (a)) is amended (1) by striking "and" after "cosmetics,"; and (2) inserting "and tobacco products" after "devices". Subtitle B. Advertising. SEC. 121. ADVERTISING PROVISIONS IN PROTOCOL. The Protocol shall contain provisions enforceable at law under which tobacco product (a) manufacturers commit to observe limitations on advertising that meet the requirements set forth in this subtitle. SEC. 122. TOBACCO PRODUCT LABELING AND ADVERTISING. (a) In General. The Protocol shall require that not a tobacco product will be sold or distributed in the United States (1) unless its advertising and labeling (including the package) (A) contain no human image, animal image, or cartoon character; (B) are not outdoor advertising, including advertising in enclosed stadiums and advertising from within a retail establishment that is directed toward or visible from the outside of the establishment; (C) a reacompany that is disclaimed in the advertising that wordssuch as "light" or "low tar" describing the product do not render the product less hazardous than any other tobacco product, in addition to such other requirements as the Secretary may impose; (D) at the time the advertising or labeling is first used are submitted to the Secretary so that the Secretary may conduct a regular review of the advertising and labeling; (E) comply with any applicable requirement of the Federal Food, Drug, and Cosmetic Act, the Federal Cigarette Labeling and Advertising Act, and any regulation promulgated under either of those Acts; (F) do not appear on the international computer network of both Federal and non-Federal interoperable packet-switched data networks (the "Internet"), unless such advertising is designed to be inaccessible in or from the United States to all individuals under the age of 18 years; (G) use only black text on white background, other than (i) those locations where self-service displays are permitted under subsection 123, if the advertising is not visible from outside the establishment and is affixed to a wall or fixture in the establishment; and (ii) advertisements appearing in any publication which the tobacco product manufacturer, distributor, or retailer demonstrates to the Secretary is a newspaper, magazine, periodical, or other publication whose readers under the age of 18 years constitute 15 percent or less of the total readership as measured by competent and reliable survey evidence, and that is read by less than 2 million persons under the age of 18 years as measured by competent and reliable survey evidence; (H) for video formats, use only static black text on a white background, and any accompanying audio uses only words without music or sound effects; and (I) for audio formats, use only words without music or sound effects; (2) if a logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification of the tobacco product is contained in a movie, program, or video game for which a director or indirect payment has been made to ensure its placement; (3) if a director or indirect payment has been made by any tobacco product manufacturer, distributor, or retailer to any entity for the purpose of promoting the image or use of the tobacco product through print or film media that appeal to individuals under the age of 18 years or thro