

FOIA MARKER

This is not a textual record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

Collection/Record Group: Clinton Presidential Records
Subgroup/Office of Origin: Office of Science and Technology Policy
Series/Staff Member: Jerold Mande
Subseries:

OA/ID Number: 13037
FolderID:

Folder Title:
Tobacco Bills [2]

Stack:	Row:	Section:	Shelf:	Position:
S	66	4	3	3

Decisions on Tobacco

Page 1

FDA AUTHORITY

Issue 1: Should FDA be given unfettered authority to regulate the manufacturing, advertising and marketing of tobacco products?

- Option 1: Yes
- Option 2: No, FDA's authority should be subject to the provisions of the proposed settlement.
- Option 3: Generally yes, but some restrictions should be imposed on FDA's authority to regulate nicotine content of tobacco products.
- Option 4: Other

Discussion: The proposed settlement would give FDA authority to regulate tobacco, but it includes several substantive and procedural requirements that FDA would have to satisfy in order to regulate tobacco. The Clinton Administration and several public health groups have expressed serious concerns about the potential effect of these requirements on FDA's ability to take actions that would result in the production of safer cigarettes. At the staff level, there appeared to be broad agreement that FDA should have unfettered authority.

Decisions on Tobacco

Page 2

MONEY

Issue 1: How big should the per pack price increase for cigarettes be?

- Option 1: \$0.62/pack (economists' estimates of the proposed resolution)
- Option 2: \$1.50/pack in combination of price increase and penalties after 10 years (Clinton)
- Option 3: \$1.50/pack after three years, indexed for inflation (Lautenberg; Kennedy)
- Option 4: \$2/pack (Lugar; Koop-Kessler)
- Option 5: Other

Discussion: Economists agree that a price increase will reduce consumption of tobacco products and also reduce youth smoking rates, but they disagree on the magnitude of the response. Most analysts agree that tobacco consumption declines about 4% for each 10% increase in price (i.e., that there is a price elasticity of demand of -0.4), but different studies have produced varying results, from a low of about 2% to a high of around 12%. Also, analysts note that these results come from studying relatively small price increases: large, sudden price increases may produce a greater response. Moreover, these studies have not focused on youth smoking response. Some analysts argue that youths are more responsive to price changes than the general population because they are less likely to be addicted and have less income; according to this analysis, youths may be twice as responsive to price changes. Other analysts argue that youths are less responsive to price changes because they smoke less and/or because they do not purchase cigarettes but instead obtain them by other means; they estimate that youths may be only half as responsive to price changes.

In addition, it is important to note that the proposed settlement sets targets for youth smoking rates, not for cigarette smoking by youths. That is, even if the number of cigarettes smoked by youths declines by a certain percentage, the smoking rate (percentage of youths who are smoking) could stay the same. Thus, only a portion of the change in consumption will show up as a decline in youth smoking rates. The most recent analysis on this issue suggests that youths are more responsive to price than adults and produces a "participation elasticity" of -0.6 (or 1.5 times the price elasticity); that is, youth smoking rates will decline 6% for each 10% increase in price. Finally, experts agree that other factors affect the decision to smoke, and that the price change cannot be considered in isolation.

The proposed settlement calls for a 60% reduction in youth smoking from the average youth smoking rate over the past 10 years; this would represent a 66% reduction from current youth smoking rates. If one assumes the -0.6 participation elasticity, a real price increase of 111% (or about \$2.20) would be sufficient, on its own, to produce the 66% drop in youth smoking rates set forth as the goal of the proposed settlement. If one accepts the tobacco industry's outside estimate that adult price elasticity is -0.75 and assumes that the youth participation elasticity is 1 ½ times the adult price elasticity (or -1.125), a 59% real price increase (or about \$1.20) would be needed to achieve the youth smoking goal.

At the staff level, there appeared to be broad support for a real price increase of \$1.50/pack.

Decisions on Tobacco

Page 3

MONEY (cont'd)

Issue 2a: How big should lookback penalties be?

Option 1: \$80 million per percentage point with rebate and \$2 B cap (proposed settlement)

Option 2: difference between price increase and \$1.50/pack (Clinton)

Option 3: 50 cents per pack (Kessler)

Option 4: 2 cents/pack/percentage point for the first five percentage points by which a manufacturer misses the target; 3 cents for missing by 6-10 points, 4 cents for missing by 11-15 percentage points, 5 cents for missing by 16-20 percentage points, and 6 cents for missing by 21-25 percentage points; the applicable penalties would be doubled if a manufacturer missed the target in two or more consecutive years (Kennedy)

Option 5: Other

Discussion: The proposed settlement imposes a “look-back” penalty designed to remove any financial incentive for companies to encourage youth smoking by setting the penalty equal to the expected lifetime profits from each youth smoker above the target level. Critics argue that these penalties are insufficient to reverse company behavior or deter youth smoking. They argue that the industry knows better than anyone what is likely to achieve reductions in youth smoking and that large penalties are needed to reverse the current financial incentive for tobacco companies to want youths to start smoking. The industry argues that it is unfair to assess arbitrarily large penalties if it is doing everything it can to reduce youth smoking but youth smoking rates fail to decline because of factors beyond the companies’ control.

Issue 2b: Should there be flat penalty for missing the target, penalties proportional to distance from target, or graduated penalties that increase faster as distance from target increases?

Discussion: The settlement envisions payments that increase directly in proportion to the number of percentage points by which youth smoking rates miss the designated targets. A flat fee has the advantage of creating a relatively large penalty for missing the target by a small amount, and therefore a larger incentive to make the target. However, if a company makes the calculation that it will not make the target, it has no incentive to keep trying to reduce youth smoking rates in order to avoid greater penalties. A proportionally increasing penalty keeps the pressure on companies to always strive to reduce youth smoking. A more steeply increasing penalty structure could harshly penalize those companies that do not come close to meeting the targets.

Decisions on Tobacco

Page 4

MONEY (cont'd)

Issue 3: How should lookback penalties be structured -- industry-wide, by company, by brand, or a mixture of industry-wide and company specific? If by company or brand, should there be a de minimis exemption?

Discussion: The proposed settlement would impose penalties on an industry-wide basis. Critics argue that this will create a disincentive for individual companies to take actions to reduce youth smoking, because if they are successful but no other company follows suit they will both lose current and future market share, and still have to pay a penalty. For this reason, they argue that company or brand specific penalties would be preferable. Some experts, however, have raised concerns that a brand specific penalty could be manipulated by manufacturers without resulting in a significant reduction in youth smoking rates. Others point out that a company-specific penalty could allow other companies to raise prices and capture windfall profits. A penalty structure that combined industry-wide payments with company-specific payments for those manufacturers whose efforts lag behind the rest of the industry could avoid the concerns raised about both approaches individually, but it might be more complicated to explain and administer. A de minimis exemption would account for concerns that sampling error would result in unfair penalty assessments on very small manufacturers. This would be popular among smaller manufacturers, but could potentially be exploited by larger companies if the penalties were assessed on a brand-by-brand basis.

Decisions on Tobacco

Page 5

CIVIL LIABILITY

Deferred

Decisions on Tobacco

Page 6

DOCUMENTS

Issue: Should the industry be forced to reveal documents relating to public health issues, such as nicotine manipulation, health risks, addiction, and marketing to kids? What about documents that contain trade secrets or for which the industry is claiming attorney-client privilege?

Option 1: Yes, make all documents public

Option 2: No, only documents not subject to trade secrets or privilege claims should be made public

Option 3: All documents would be made available to the FDA. The FDA would make public all documents not subject to claims of trade secret or attorney client privilege. For documents for which the industry claims attorney client privilege, FDA would decide on a case-by-case basis whether the claim should be sustained or whether the documents should be made public (either because the claim is not well founded or because there is an over-riding public interest in having these documents in the public domain).

Option 4: Other

Discussion: The proposed settlement would create a document depository. The industry would be permitted to withhold documents that are privileged or contain trade secrets. A panel of judges would decide any disputes relating to these claims. Some critics of the proposed settlement have claimed that this process would be unwieldy and allow the industry to withhold documents with important public health implications. They argue that the industry should be required to make public all documents with public health implications, even if this means stripping attorney client privilege. In their view, such an action would be justified by the alleged abuse of this privilege by the industry and/or because the industry is seeking protection from lawsuits. Still others, while not satisfied with the proposed settlement, are very reluctant to set a precedent of removing attorney client privilege, even after considering the special circumstances surrounding these documents.

Decisions on Tobacco

Page 7

FARMERS

Issue: What form should compensation for tobacco farmers take?

Option 1: Lugar proposal

Option 2: Ford proposal

Option 3: Robb proposal

Option 4: other

Discussion: Comprehensive tobacco legislation will result in reduced demand for US tobacco, which will have a negative economic impact on tobacco farmers and their communities. Three types of solutions have been proposed.

Senator Lugar has proposed a buyout of tobacco quotas and an end to the Federal tobacco program. This approach would most benefit those who own a lot of quota (including those who do not actively farm this quota) but would not be as helpful to those who have only a small quota or who lease quota. With the end of the tobacco program, production could increase and price could fall, making tobacco products cheaper (although raw tobacco accounts for only a small portion of retail cigarette prices).

Senator Ford has proposed retaining the tobacco program but compensate tobacco farmers with per-pound payments for reductions in aggregate demand for domestic tobacco. These payments would be capped at \$8/pound for quota holders and \$4/pound for those who lease quota or are tenant farmers. Senator Ford argues that this would keep prices higher and relatively stable by maintaining limits on production. Senator Ford's proposal also would provide \$8 billion in assistance for rural communities, \$500 million in retraining for workers, and \$1.4 billion for educational assistance for tobacco farmers and their families.

Senator Robb has proposed that the existing Federal tobacco program be phased out and replaced by a private tobacco program that would limit production in a manner similar to the current Federal program. Current quotas would be bought out for \$8/pound over a five year period. Once the quota has been bought out, production licenses would be granted to tobacco farmers (including those who currently lease quota) based on historical average production for the farmer. Senator Robb argues that, because the value of the quota will have been removed, this will lower domestic prices for tobacco and make U.S. tobacco more competitive with foreign tobacco, helping to keep demand high for U.S. tobacco. The proposal would also allocate \$250 million annually for economic development, and may include income protection during the phase-out of the current system.

Decisions on Tobacco

Page 8

OTHER

Issue 1: What should Federal law be on environmental tobacco smoke?

Option 1: No change in Federal law

Option 2: Smoking in public buildings restricted to properly ventilated smoking areas. Restaurants (except fast food restaurants), bars, private clubs, hotel guest rooms, casinos, tobacco stores, and prisons exempted (proposed settlement); state and local governments explicitly permitted to enact stricter prohibitions

Option 3: Same as above, except that there would be no exemption for restaurants.

Option 4: Smoking restricted in all public buildings (Lautenberg/Waxman)

Option 5: Other

Discussion: ETS has been classified by the EPA as a carcinogen. Tobacco control proponents are pushing for a very broad restriction on smoking in public buildings. Others argue that this is better left to state and local governments.

Issue 2: How should the legislation address exports of US tobacco products?

Option 1: Funding for international tobacco control efforts

Option 2: Fund international tobacco control efforts, and ban any US government export promotion funding to support exports of US tobacco products.

Option 3: Fund international tobacco control efforts, ban US government export assistance funding, ban USTR from attacking foreign tobacco control/public health measures (except those applied on a discriminatory basis)

Option 4: Fund international tobacco control efforts, ban US government export assistance funding, ban USTR from attacking foreign tobacco control/public health measures or taking any other action to open foreign markets to US tobacco products, require warning labels on all exports (same warning labels required in US, in language of destination country)

Option 5: Other

Discussion: Proponents of strong action on exports of US tobacco products argue that it is immoral to take action to reduce smoking in this country without taking strong action to protect youths and adults overseas. Opponents argue that harsh measures will be ineffective because US firms will simply manufacture the product overseas, where fewer restrictions will apply. Sales of US brand-name products will not change, but US manufacturing and farming jobs will be placed at risk.

from the office of

Senator Edward M. Kennedy

of Massachusetts

THE ACT FOR SMOKEFREE AND HEALTHY CHILDREN SHORT SUMMARY

1. Increase tobacco tax by \$1.50 per pack over three years to reduce youth smoking.
2. The federal share of funds raised by the increase tax will be approximately \$20 billion per year. (\$15 billion from the 85¢ increase above the level of the Attorneys' General settlement, and \$5 billion from the federal share of the Attorneys' General settlement.) These funds will be divided equally between biomedical research and investments in early child development.
 - Approximately \$10 billion per year will be directed to the National Institutes of Health, almost doubling the NIH budget.
 - Approximately \$10 billion per year will be directed to research and investments in early childhood development, including initiatives for children aged zero to three and expanded Head Start and child care.
3. Legislation affirms broad FDA authority to regulate tobacco.
4. Legislation includes key public health initiatives in the Attorneys' General agreement to reduce tobacco use.
5. First comprehensive tobacco control initiative structured in Congress, and responding to the concerns of the public health community

from the office of

Senator Edward M. Kennedy

of Massachusetts

For Immediate Release:
November 7, 1997

Contact:

Jim Marley/Kathleen McKiernan
(202) 224-2633

STATEMENT BY SENATOR EDWARD KENNEDY ON THE HEALTHY AND SMOKEFREE CHILDREN ACT

Congress has an historic opportunity in the next session to protect current and future generations from nicotine addiction and early death caused by tobacco.

We know the enormous adverse health consequences of youth smoking. Each day, three thousand children begin smoking. A thousand of them will die prematurely from tobacco-induced illnesses. Ninety percent of current adult smokers began to smoke before they reached the age of 18.

Today we introduce legislation to deal with this serious problem. Our primary goal is to reduce youth smoking and help children. Our legislation will raise the price of cigarettes by \$1.50 a pack over three years. A substantial portion of the revenues raised by the increase will be used to fund major new initiatives in biomedical research, child health, and child development.

The legislation will affirm the authority of the Food and Drug Administration to regulate tobacco products. It also provides for strongly worded warning labels on packs of cigarettes, for a large-scale anti-tobacco advertising campaign, new restrictions on youth access to tobacco products, new protections against secondhand smoke, and transitional assistance to farmers.

Public health experts tell us that the most effective way to reduce youth smoking is by a significant increase in the price of cigarettes. Teenagers have less money to spend on tobacco products than adults, and those who are not yet addicted will be less likely to spend their dollars on smoking. In fact, price increases are three times more likely to deter youth from smoking than adults.

The 65 cent increase in the Attorneys' General settlement is not enough to do the job. If the national goal is to cut teenage smoking by 70% in ten years, a price increase of at least \$1.50 a pack will be needed. Even with a price increase of that magnitude, cigarettes in America will still cost less than the current price in many European countries.

It would be irresponsible to wait another decade while we test the impact of lesser measures on youth smoking. Too many children are becoming addicted to tobacco each day. The most effective way to reduce youth smoking is a substantial price increase, and we should do it now.

The \$1.50 increase will enable us to provide approximately \$20 billion per year to be divided equally between medical research and child development investments. Under our proposal, half of these additional funds will be used for an unprecedented expansion of biomedical research to solve the scientific mysteries of the most severe diseases and medical conditions. We stand on the threshold of extraordinary medical breakthroughs against cancer, heart disease, Alzheimer's Disease, AIDS, diabetes, mental illness, and many other conditions. The benefits of greater research will save millions of lives and improve the quality of life for countless more.

The other half of the new funds will be directed to child health and child development. The brain research conducted in recent years has demonstrated the critical importance of the first three years of life to a child's learning potential. Additional resources will enable us to build on that foundation of knowledge, and implement it in ways that will enrich the lives of the next generation of children. By expanding Head Start to reach the large number of eligible pre-school children who are not now being served, and by improving the quality and availability of child care for working families, we can give far more children a better foundation on which to build their lives.

In addition, under our proposal, the key public health provisions in the Attorneys General agreement will be implemented, and smokers seeking to stop will be able to obtain help in overcoming their addiction. States will receive compensation from the tobacco industry for their Medicaid costs attributable to smoking, and will not have to reimburse the federal government for the federal share of the Medicaid costs recovered. These funds will be available to the states to address the unmet needs of children.

A strong FDA with broad authority to regulate tobacco is also essential. Our legislation affirms FDA's finding that nicotine is an addictive drug and that cigarettes are a drug delivery device. The scope of regulation will include manufacturing, marketing, advertising, and distributing tobacco products. The FDA will be freed from the numerous procedural roadblocks which the tobacco industry has placed in its path.

This legislation will substantially reduce smoking in America, enhance medical research, and help millions of children reach their full potential.

I want to commend Senators Lautenberg and Durbin for their outstanding leadership on tobacco issues. Again and again, they have fought to protect the public health from the dangers of smoking. I am extremely pleased to have them as partners in this historic effort.

Congress has a unique opportunity. We owe it to America's children and America's future to act now.

— 30-30-30 —

THE HEALTHY AND SMOKEFREE CHILDREN ACT A COMPREHENSIVE TOBACCO CONTROL INITIATIVE

I. National Tobacco Use Reduction, Health and Child Development Research Initiative

- funded with the proceeds of 85 cents of the \$1.50 per pack tobacco tax, over \$15 billion dollars per year
- one-half of the annual amount to be used for a major biomedical health and allied sciences research initiative
 - National Institutes of Health
 - National Science Foundation
 - nationally recognized research hospitals
 - network of comprehensive cancer research centers
 - addiction prevention and treatment research centers
 - universities with recognized programs of health research
 - graduate fellowships and subsidized loan programs for training in medical and allied science research
- one-half of the annual amount to be utilized for research related to children's health and development, and for investments into essential services for children and families;
 - Child Development Research and Training
 - research into pediatric medical conditions, childhood disabilities, and early childhood development,
 - training, through grants, fellowships, and loans to expand the early childhood workforce, as well as through pre-service and in-service training programs to enhance skills
 - demonstration projects including public-private partnerships for paid leave to enable mothers with infants to stay at home
 - Children's Services
 - fund the Early Head Start program in response to the research documenting the importance of early learning (0-3 years)
 - expand Head Start to meet the needs of the tremendous number of eligible preschoolers currently not being served
 - expand Child Care Development Block Grants by certificates and grants to increase the availability and affordability of quality child care for children of working families ages birth to school age

- provide grants to increase the availability and affordability of quality before and after school care
- create a quality fund within CCDBG, half of which is an incentive fund to reward states that improve the quality of their child care programs by adopting the essential components of proven models, such components include training, increased wages, improved standards and enforcement, lower ratios, higher rates for accredited programs and infant care, and consumer education
- funding provided to these programs under this Act will supplement, not supplant, existing appropriations

II. Excise Tax on Tobacco Manufacturers

- impose a \$1.50 per pack excise tax on cigarettes implemented over three years, and then indexed for inflation. This tax is in addition to the currently enacted excise tax, including the increases scheduled to take effect in 2000 and 2002
 - 50 cents per pack July 1, 1998
 - 50 cents per pack July 1, 1999
 - 50 cents per pack July 1, 2000
- \$1.50 per pack is the increase which public health experts have determined is necessary to effectively deter youth smoking and to achieve the national youth smoking reduction standards
- the \$1.50 per pack increase will generate approximately \$650 billion over 25 years
- comparable increases for smokeless tobacco and other tobacco products

III. Funding for States

- states will be compensated for that portion of their Medicaid expenditures attributable to treatment for tobacco induced illnesses and conditions. Compensation will be on the same terms and conditions as set forth in the attorneys-general draft settlement with the tobacco industry

- states will be permitted to retain the federal share of the reimbursement for Medicaid expenditures on the condition that those funds be utilized to serve the needs of children through one or more of the following programs:
 - Child Care Development Block Grant
 - Head Start
 - Early Start
 - State Children's Health Insurance Program
 - Maternal and Child Health Block Grant
 - Individuals with Disabilities Education Act
 - Child Nutrition Act
 - state initiated programs serving the health and developmental needs of children which have been approved for the use of these funds by the Secretary of Health and Human Services

IV. Tobacco Use Reduction and Education Block Grant

- national counter-advertising program to educate the public on the dangers of smoking
- states would receive funding to be used for the following purposes:
 - smoking cessation programs
 - reduction of tobacco usage through counter advertising
 - tobacco free public education programs
 - tobacco free community action programs
 - licensing of tobacco sellers and enforcement of youth deterrence
- a tobacco victims' assistance fund will be created to provide financial help to persons suffering from serious tobacco induced health problems

V. Regulation of Tobacco Products

A. Authority of the Secretary of HHS Acting Through the FDA

- Statutorily affirm the authority of the Food and Drug Administration to regulate tobacco as a drug and a drug delivery device. The scope of regulation will include the manufacturing, marketing, advertising, and distribution of tobacco products.
- FDA will have the express authority to require product modification of tobacco products based on public health findings, including the regulation of nicotine content and yield, and the regulation of other constituents deemed by the Agency to be harmful. FDA will not be

required to make any findings regarding the impact of a proposed rule on the demand for contraband tobacco products.

- The FDA's authority to regulate tobacco advertising and marketing, and to set restrictions on the sale of tobacco products to minors is affirmed.
- The authority of the FDA to regulate tobacco may be exercised through "notice and comment" rulemaking; and the applicable evidentiary standard and the scope of judicial review will be the same for the regulation of tobacco as for the regulation of drugs and medical devices generally.
- Industry funds raised from the licensing fee will be used to support the cost of effective tobacco regulation.

B. Warning Labels

- The legislation would mandate strong new rotating warnings on all tobacco product packages and cartons, and in all advertisements.
- The warnings required for cigarettes and smokeless tobacco products will be those set forth in the settlement agreement between the Attorneys General and the tobacco industry. The warnings will include "cigarettes are addictive," "cigarettes cause cancer," and "smoking can kill you."

C. Ingredient Disclosure

- tobacco product manufacturers will be required to disclose to the FDA the nature and amount of each ingredient, substance, and compound contained in each brand of cigarette or other tobacco product, and the Agency will, after review, make such information public unless it determines that specific information identified by the company properly constitutes a trade secret.

D. Regulations Not Intended to Preempt

- the provisions of this statute are not intended to pre-empt state and local laws which place additional restrictions on tobacco products

VI. Reduction of Involuntary Exposure to Tobacco Smoke

- restrict indoor smoking in public facilities to areas in which the air is

vented directly to the outside

- prohibition on smoking in schools, child care facilities and other facilities utilized primarily by children
- exempt adult only facilities such as bars, and designated hotel guest rooms
- federal rules establish a floor for protecting non-smokers from second hand smoke. State and localities may enact more restrictive measures.

VII. Youth Smoking Reduction Targets

- establish national goals for the reduction of underage smoking and comparable reduction goals for smokeless tobacco use
- to the extent that specific cigarette or smokeless tobacco manufacturers fail to meet the tobacco use reduction goals, an escalating surcharge of as much as \$1.00 per pack will be imposed on the sale of tobacco products manufactured by that company
- there will be no ceiling on the total amount of the surcharges nor will any portion of the surcharges be rebated

VIII. No Tax Deductibility

- tobacco companies will be prohibited from deducting any of the payments required under this act from their corporate income taxes as ordinary and necessary business expenses

VIII. Assistance to Farmers and Farming Communities

- transition assistance for tobacco farmers and displaced tobacco industry workers. This program would provide compensation for tobacco farmers agreeing to retire their tobacco acreage, and to assist both farmers and tobacco industry workers who wish to train for new careers
- economic development assistance to those communities most heavily impacted by changes in the tobacco industry

IX. Document Disclosure & Industry Compliance

- the tobacco companies must disclose all relevant documents, including those related to the health effects of its products, to scientific studies of tobacco components and other cigarette constituents, to the addictiveness of their products, to the health impacts of proposed product modifications, and to marketing and advertising strategies.
- an oversight board with subpoena power will be created to monitor industry compliance with all of the provisions of the Act

ORIGINAL

105TH CONGRESS
1ST SESSION

S. _____

IN THE SENATE OF THE UNITED STATES

_____ introduced the following bill; which was read twice and
referred to the Committee on _____

A BILL

To reform and restructure the processes by which tobacco products are manufactured, marketed, and distributed, to prevent the use of tobacco products by minors, to redress the adverse health effects of tobacco use, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “[_____ Act]”.

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

Sec. 1. Short title; table of contents.
Sec. 2. Findings.
Sec. 3. Purposes.

TITLE I—REGULATION OF THE TOBACCO INDUSTRY

Sec. 100. Definitions.

Subtitle A—Restriction on Marketing and Advertising

- Sec. 101. Prohibitions on advertising.
- Sec. 102. General restrictions.
- Sec. 103. Format and content requirements for labeling and advertising.
- Sec. 104. Statement of intended use.
- Sec. 105. Ban on nontobacco items and services, contests and games of chance, and sponsorship of events.
- Sec. 106. Use of product descriptors.

Subtitle B—Warnings, Labeling and Packaging

- Sec. 111. Cigarette warnings.
- Sec. 112. Smokeless tobacco warnings.
- Sec. 113. Ingredients.
- Sec. 114. Enforcement, regulations, and construction.
- Sec. 115. Preemption.
- Sec. 116. Reports.
- Sec. 117. Exports.
- Sec. 118. Repeals.

Subtitle C—Restriction on Access to Tobacco Products

- Sec. 121. Requirements relating to retailers.
- Sec. 122. Manufacture, sale, and distribution.

Subtitle D—Licensing of Retail Tobacco Sellers

- Sec. 131. Establishment of program.
- Sec. 132. Requirements.
- Sec. 133. Penalties, revocations and suspensions.
- Sec. 134. Federal licensing of military and other entities.

Subtitle E—Regulation of Tobacco Product Development and Manufacturing

- Sec. 141. Reference.
- Sec. 142. Treatment of tobacco products as drugs.
- Sec. 143. Health and safety regulation of tobacco products.

Subtitle F—Compliance Plans and Corporate Culture

- Sec. 151. Compliance plans.
- Sec. 152. Compliance programs.
- Sec. 153. Whistleblower protections.
- Sec. 154. Provisions relating to lobbying.
- Sec. 155. Termination of certain entities.
- Sec. 156. Enforcement.

TITLE II—REDUCTION IN UNDERAGE TOBACCO USE

- Sec. 201. Purpose.
- Sec. 202. Determination of underage use base percentages.
- Sec. 203. Annual daily incidence of underage use of tobacco products.
- Sec. 204. Required reduction in underage tobacco use.
- Sec. 205. Application of surcharges.

Sec. 206. Abatement procedures.

TITLE III—STANDARDS TO REDUCE INVOLUNTARY EXPOSURE TO TOBACCO SMOKE

- Sec. 301. Definitions.
- Sec. 302. Smoke-free environment policy.
- Sec. 303. Citizen actions.
- Sec. 304. Preemption.
- Sec. 305. Regulations.
- Sec. 306. Effective date.

TITLE IV—NATIONAL TOBACCO SETTLEMENT TRUST FUND

- Sec. 401. Establishment of Trust Fund.
- Sec. 402. Liability of industry sources.
- Sec. 403. Enforcement.

TITLE V—PUBLIC HEALTH AND OTHER PROGRAMS

Subtitle A—Public Health Block Grant Program

- Sec. 501. Public Health Trust Fund.
- Sec. 502. Block grants to States.
- Sec. 503. Allotments.
- Sec. 504. Use of funds.
- Sec. 505. Withholding of funds.

Subtitle B—Other Programs

- Sec. 511. National Smoking Cessation Program.
- Sec. 512. National Reduction in Tobacco Usage Program.
- Sec. 513. National Tobacco-Free Public Education Program.
- Sec. 514. National Event Sponsorship Program.
- Sec. 515. National Community Action Program.
- Sec. 516. National Cessation Research Program.
- Sec. 517. Use of surcharge payments.

TITLE VI—CONSENT DECREES, NON-PARTICIPATING MANUFACTURERS, AND STATE ENFORCEMENT

- Sec. 601. Purposes.

Subtitle A—Consent Decrees and Non-Participating Manufacturers

- Sec. 611. Consent decrees.
- Sec. 612. National tobacco control protocol.
- Sec. 613. Non-participating manufacturers.

Subtitle B—State Enforcement

- Sec. 621. Requirement of no sale to minors law.
- Sec. 622. State reporting.
- Sec. 623. Reduction in State payments.

TITLE VII—PROVISIONS RELATING TO TOBACCO-RELATED CIVIL ACTIONS

- Sec. 701. General immunity.

- Sec. 702. Civil liability for past conduct.
- Sec. 703. Civil liability for future conduct.
- Sec. 704. Non-participating manufacturers.

TITLE VIII—PUBLIC DISCLOSURE OF HEALTH RESEARCH

- Sec. 801. Purpose.
- Sec. 802. National Tobacco Document Depository.

TITLE IX—EFFECTIVE DATES AND OTHER PROVISIONS

- Sec. 901. Effective dates.
- Sec. 902. Native Americans.
- Sec. 903. Preemption.

1 SEC. 2. FINDINGS.

2 (a) GENERAL FINDINGS.—Congress makes the fol-
3 lowing findings:

4 (1) The Food and Drug Administration and
5 other public health authorities view the use of to-
6 bacco products by the nation's children as a "pedi-
7 atric disease" of epic and worsening proportions that
8 results in new generations of tobacco-dependent chil-
9 dren and adults.

10 (2) There is a consensus within the scientific
11 and medical communities that tobacco products are
12 inherently dangerous and cause cancer, heart dis-
13 ease, and other serious adverse health effects.

14 (3) The Food and Drug Administration and
15 other health authorities have concluded that virtually
16 all new users of tobacco products are under the age
17 of 18. Virtually all Federal, State, and local officials
18 and entities believe that tobacco advertising and
19 marketing contribute significantly to the use of nico-

1 tine-containing tobacco products by adolescents and
2 as such, sweeping new restriction on the sale, pro-
3 motion, and distribution of such products are need-
4 ed.

5 (4) Federal, State, and local governments lack
6 many of the legal means and resources needed to ad-
7 dress the societal problems caused by the use of to-
8 bacco products.

9 (5) Public health authorities believe that the so-
10 cietal benefits of enacting tobacco settlement legisla-
11 tion in human and economic terms would be vast.
12 The Food and Drug Administration found that re-
13 ducing underage tobacco use 50 percent "would pre-
14 vent well over 60,000 early deaths". The Food and
15 Drug Administration has estimated that the mone-
16 tary value of the regulations promulgated as a result
17 of this Act will be worth up to \$43,000,000,000 per
18 year in reduced medical costs, improved productivity,
19 and the benefit of avoiding the premature death of
20 loved ones.

21 (6) The unique position occupied by tobacco in
22 the history and economy of the United States, the
23 magnitude of the actual and potential tobacco-relat-
24 ed litigation, the need to avoid the cost, expense, un-
25 certainty, and inconsistency associated with such

1 protracted litigation, the need to limit the sale, dis-
2 tribution, marketing, and advertising of tobacco
3 products to persons of legal age, and the need to
4 educate the public (especially young people) of the
5 health effects of using tobacco products all dictate
6 that it would be in the public interest to enact legis-
7 lation to facilitate a resolution of such matters.

8 (b) FINDINGS RELATED TO INTERSTATE COMMERCE
9 AND THE JUDICIAL SYSTEM.—Congress makes the follow-
10 ing findings:

11 (1) The sale, distribution, marketing, advertis-
12 ing, and use of tobacco products are activities sub-
13 stantially affecting interstate commerce. Such prod-
14 ucts are sold, marketed, advertised, and distributed
15 in interstate commerce on a nationwide basis and
16 have a substantial effect on the economy of the
17 United States.

18 (2) The sale, distribution, marketing, advertis-
19 ing, and use of tobacco products are activities that
20 substantially affect interstate commerce by virtue of
21 the health care and other costs that Federal and
22 State governmental authorities have incurred be-
23 cause of the usage of tobacco products.

24 (3) Various civil actions brought by State attor-
25 neys general, cities, counties, the Commonwealth of

1 Puerto Rico, third-party payors, and other private
2 classes and individuals to recover damages relating
3 to tobacco-related diseases, conditions and products
4 are pending throughout the United States, of these
5 actions are slow-moving, expensive, and burdensome
6 not only for the litigants but also for Federal and
7 State judicial systems.

8 **SEC. 3. PURPOSES.**

9 It is the purpose of this Act to—

10 (1) reiterate and enhance the authority of the
11 Food and Drug Administration to regulate tobacco
12 products and provide for tobacco industry funding of
13 the oversight activities of the Administration;

14 (2) ban all outdoor tobacco advertising and ban
15 all cartoon characters and human figures used in
16 connection with tobacco advertising;

17 (3) provide for the funding by the tobacco in-
18 dustry of an aggressive Federal enforcement pro-
19 gram relating to tobacco advertising and distribu-
20 tion, including a State-administered retail licensing
21 system to prevent minors from obtaining tobacco
22 products;

23 (4) subject the tobacco industry to severe finan-
24 cial penalties in the event that underage tobacco

1 usage does not decline radically over the next 10
2 years;

3 (5) provide for the establishment of national
4 standards to control the manufacturing of tobacco
5 products and the ingredients used in such products;

6 (6) provide certain regulatory powers to the
7 Food and Drug Administration to encourage the de-
8 velopment and marketing by the tobacco industry of
9 "less hazardous tobacco products", including the
10 power to regulate the level of nicotine in such prod-
11 ucts;

12 (7) require the manufacturers of tobacco prod-
13 ucts to disclose all present and future non-public in-
14 ternal laboratory research regarding tobacco prod-
15 ucts;

16 (8) establish a minimum Federal standard to
17 limit smoking in public places;

18 (9) provide for the establishment of a National
19 Tobacco Settlement Trust Fund to be funded by the
20 tobacco industry and used in accordance with this
21 Act;

22 (10) provide for the establishment of a national
23 education-oriented counter advertising and tobacco
24 control campaign to be funded through the National
25 Tobacco Settlement Trust Fund;

1 (11) provide annual payments to States to fund
2 health benefits programs and to create a tobacco
3 products liability judgments and settlements fund to
4 be funded through the National Tobacco Settlement
5 Trust Fund; and

6 (12) provide for the establishment of a national
7 program of smoking cessation to be funded through
8 the National Tobacco Settlement Trust Fund.

9 **TITLE I—REGULATION OF THE** 10 **TOBACCO INDUSTRY**

11 SEC. 100. DEFINITIONS.

12 In this Act:

13 (1) BRAND.—The term “brand” means a vari-
14 ety of a tobacco product distinguished by the tobacco
15 used, tar content, nicotine content, flavoring used,
16 size, filtration, or packaging.

17 (2) CIGAR.—The term “cigar” means any roll
18 of tobacco wrapped in leaf tobacco or in any sub-
19 stance containing tobacco (other than any roll of to-
20 bacco which is a cigarette or cigarillo within the
21 meaning of paragraph (3) or (4)).

22 (3) CIGARETTE.—The term “cigarette” means
23 any product which contains nicotine, is intended to
24 be burned under ordinary conditions of use, and con-
25 sists of—

1 (A) any roll of tobacco wrapped in paper
2 or in any substance not containing tobacco; and

3 (B) any roll of tobacco wrapped in any
4 substance containing tobacco which, because of
5 its appearance, the type of tobacco used in the
6 filler, or its packaging and labeling, is likely to
7 be offered to, or purchased by, consumers as a
8 cigarette described in subparagraph (A).

9 (4) CIGARILLOS.—The term “cigarillos” means
10 any roll of tobacco wrapped in leaf tobacco or any
11 substance containing tobacco (other than any roll of
12 tobacco which is a cigarette within the meaning of
13 paragraph (3)) and as to which 1,000 units weigh
14 not more than 3 pounds.

15 (5) CIGARETTE TOBACCO.—The term “cigarette
16 tobacco” means any product that consists of loose
17 tobacco that contains or delivers nicotine and is in-
18 tended for use by persons in a cigarette. Unless oth-
19 erwise stated, the requirements of this Act pertain-
20 ing to cigarettes shall also apply to cigarette to-
21 bacco.

22 (6) COMMERCE.—The term “commerce”
23 means—

24 (A) commerce between any State, the Dis-
25 trict of Columbia, the Commonwealth of Puerto

1 Rico, Guam, the Virgin Islands, American
2 Samoa, the Northern Mariana Islands or any
3 territory or possession of the United States;

4 (B) commerce between points in any State,
5 the District of Columbia, the Commonwealth of
6 Puerto Rico, Guam, the Virgin Islands, Amer-
7 ican Samoa, the Northern Mariana Islands or
8 any territory or possession of the United States;
9 or

10 (C) commerce wholly within the District of
11 Columbia, Guam, the Virgin Islands, American
12 Samoa, the Northern Mariana Islands, or any
13 territory or possession of the United States.

14 (7) COMMISSIONER.—The term “Commis-
15 sioner” means the Commissioner of Food and
16 Drugs.

17 (8) DISTRIBUTOR.—The term “distributor”
18 means any person who furthers the distribution of
19 tobacco products, whether domestic or imported, at
20 any point from the original place of manufacture to
21 the person who sells or distributes the product to in-
22 dividuals for personal consumption. Such term shall
23 not include common carriers.

24 (9) LITTLE CIGAR.—The term “little cigar”
25 means any roll of tobacco wrapped in leaf tobacco or

1 any substance containing tobacco (other than any
2 roll of tobacco which is a cigarette within the mean-
3 ing of subsection (1)) and as to which 1,000 units
4 weigh not more than 3 pounds.

5 (10) MANUFACTURER.—The term “manufac-
6 turer” means any person, including any repacker or
7 relabeler, who manufactures, fabricates, assembles,
8 processes, or labels a finished tobacco product.

9 (11) NICOTINE.—The term “nicotine” means
10 the chemical substance named 3-(1-Methyl-2-
11 pyrrolidiny)pyridine or $C_{10}H_{14}N_2$, including any salt
12 or complex of nicotine.

13 (12) PACKAGE.—The term “package” means a
14 pack, box, carton, or container of any kind in which
15 tobacco products are offered for sale, sold, or other-
16 wise distributed to consumers.

17 (13) PERSON.—The term “person” means an
18 individual, partnership, corporation, or any other
19 business or legal entity.

20 (14) PIPE TOBACCO.—The term “pipe tobacco”
21 means any loose tobacco that, because of its appear-
22 ance, type, packaging, or labeling, is likely to be of-
23 fered to, or purchased by, consumers as a tobacco
24 product to be smoked in a pipe.

1 (15) POINT OF SALE.—The term “point of
2 sale” means any location at which an individual can
3 purchase or otherwise obtain tobacco products for
4 personal consumption.

5 (16) RETAILER.—The term “retailer” means
6 any person who sells tobacco products to individuals
7 for personal consumption, or who operates a facility
8 where vending machines or self-service displays are
9 permitted under this title.

10 (17) SALE.—The term “sale” includes the sell-
11 ing, providing samples of, or otherwise making to-
12 bacco products available for personal consumption in
13 any place within the scope of this Act.

14 (18) SECRETARY.—The term “Secretary”
15 means the Secretary of Health and Human Services.

16 (19) SMOKELESS TOBACCO.—The term “smoke-
17 less tobacco” means any product that consists of
18 cut, ground, powdered, or leaf tobacco that contains
19 nicotine and that is intended to be placed in the oral
20 or nasal cavity.

21 (20) STATE.—The term “State” includes the
22 several States, the District of Columbia, the Com-
23 monwealth of Puerto Rico, Guam, the Virgin Is-
24 lands, American Samoa, the Northern Mariana Is-
25 lands, and any other territory or possession of the

1 United States. Such term includes any political divi-
2 sion of any State.

3 (21) TOBACCO.—The term “tobacco” means to-
4 bacco in its unmanufactured form.

5 (22) TOBACCO PRODUCT.—The term “tobacco
6 product” means cigars, cigarettes, cigarillos, ciga-
7 rette tobacco, little cigars, pipe tobacco, and smoke-
8 less tobacco.

9 (23) TRUST FUND.—The term “Trust Fund”
10 means the National Tobacco Settlement Trust Fund
11 established under section 401.

12 **Subtitle A—Restriction on**
13 **Marketing and Advertising**

14 **SEC. 101. PROHIBITIONS ON ADVERTISING.**

15 (a) PROHIBITION ON OUTDOOR ADVERTISING.—

16 (1) IN GENERAL.—No manufacturer, distribu-
17 tor, or retailer may use any form of outdoor tobacco
18 product advertising, including billboards, posters, or
19 placards.

20 (2) STADIA AND ARENAS.—Except as otherwise
21 provided in this title, a manufacturer, distributor, or
22 retailer shall not advertise tobacco products in any
23 arena or stadium where athletic, musical, artistic, or
24 other social or cultural events or activities occur.

1 (b) PROHIBITION ON USE OF HUMAN IMAGES AND
2 CARTOONS.—No manufacturer, distributor, or retailer
3 may use a human image or a cartoon character or cartoon-
4 type character in its advertising, labeling, or promotional
5 material with respect to a tobacco product.

6 (c) PROHIBITION ON ADVERTISING ON THE
7 INTERNET.—No manufacturer, distributor, or retailer
8 may use the Internet to advertise tobacco products unless
9 such an advertisement is inaccessible in or from the Unit-
10 ed States.

11 (d) PROHIBITION ON POINT-OF-SALE ADVERTIS-
12 ING.—

13 (1) IN GENERAL.—Except as otherwise pro-
14 vided in this subsection, no manufacturer, distribu-
15 tor, or retailer may use point-of-sale advertising of
16 tobacco products.

17 (2) ADULT-ONLY STORES AND TOBACCO OUT-
18 LETS.—Paragraph (1) shall not apply to point of
19 sale advertising at adult-only stores and tobacco out-
20 lets [need definitions for such stores and outlets].

21 (3) PERMISSIBLE ADVERTISING.—

22 (A) IN GENERAL.—Each manufacturer of
23 tobacco products may display not more than 2
24 separate point-of-sale advertisements in or at

1 each location at which tobacco products are of-
2 fered for sale.

3 (B) MARKET SHARE MANUFACTURERS.—A
4 manufacturer with at least 25 percent of the
5 market share of the tobacco product involved
6 may display an additional point-of-sale adver-
7 tisement in or at each location at which tobacco
8 products are offered for sale.

9 (C) RETAILERS.—A retailer may have not
10 more than 1 point-of-sale advertisement relating
11 to the retailer's own or its wholesaler's con-
12 tracted retailer or private label brand of tobacco
13 product. No manufacturer or distributor may
14 enter into any arrangement with a retailer to
15 limit the ability of the retailer to display any
16 form of permissible point-of-sale advertisement
17 or promotional material originating with an-
18 other manufacturer or distributor.

19 (4) LIMITATIONS.—

20 (A) IN GENERAL.—A point of sale adver-
21 tisement permitted under this subsection shall
22 be comprised of a display area that is not larg-
23 er than 576 square inches (either individually
24 or in the aggregate) and shall consist only of
25 black letters on a white background or other

1 recognized typographical marks. Such advertise-
2 ment shall not be attached to nor located within
3 2 feet of any fixture on which candy is dis-
4 played for sale.

5 (B) AUDIO AND VIDEO FORMATS.—Audio
6 and video advertisements permitted under sec-
7 tion 103(c) may be distributed to individuals
8 who are 18 years of age or older at point of sale
9 but may not be played or viewed at such point
10 of sale.

11 (C) DISPLAY FIXTURES.—[Display fix-
12 tures in the form of signs consisting of brand
13 name and price and not larger than 2 inches in
14 height are permitted.?!] [Do we need to define
15 display fixtures in the form of signs?]

16 (5) DEFINITION.—For purposes of this sub-
17 section, the term “point-of-sale advertising” means
18 all printed or graphical materials bearing the brand
19 name (alone or in conjunction with any other word),
20 logo, motto, selling message, recognizable color or
21 pattern of colors, or any other indicia of product
22 identification similar or identical to those used for
23 tobacco products which, when used for its intended
24 purpose, can reasonably be anticipated to be seen by

1 customers at a location at which tobacco products
2 are offered for sale.

3 **SEC. 102. GENERAL RESTRICTIONS.**

4 (a) **RESTRICTION ON PRODUCT NAMES.**—A manu-
5 facturer shall not use a trade or brand name of a non-
6 tobacco product as the trade or brand name for a cigarette
7 or smokeless tobacco product, except for a tobacco product
8 whose trade or brand name was on both a tobacco product
9 and a nontobacco product that were sold in the United
10 States on or before January 1, 1995.

11 (b) **ADVERTISING LIMITED TO FDA SPECIFIED**
12 **MEDIA.**—

13 (1) **IN GENERAL.**—A manufacturer, distributor,
14 or retailer may, in accordance with this title, dis-
15 seminate or cause to be disseminated advertising or
16 labeling which bears a tobacco product brand name
17 (alone or in conjunction with any other word) or any
18 other indicia of tobacco product identification only in
19 newspapers, in magazines, in periodicals or other
20 publications (whether periodic or limited distribu-
21 tion), on billboards, posters and placards in accord-
22 ance with section 101(a), in nonpoint-of-sale pro-
23 motional material (including direct mail), in point-
24 of-sale promotional material, and in audio or video
25 formats delivered at a point-of-sale.

1 (2) LIMITATION.—A manufacturer, distributor,
2 or retailer that intends to disseminate, or to cause
3 to be disseminated, advertising or labeling for a to-
4 bacco product in a medium that is not described in
5 paragraph (1) shall notify the Commissioner not less
6 than 30 days prior to the date on which such me-
7 dium is to be used. Such notice shall describe the
8 medium and discuss the extent to which the adver-
9 tising or labeling may be seen by individuals who are
10 under 18 years of age.

11 (3) ACTION BY COMMISSIONER.—[What does
12 Commissioner do after receiving notice?]

13 (c) RESTRICTION ON PLACEMENT IN ENTERTAIN-
14 MENT MEDIA.—

15 (1) IN GENERAL.—No payment shall be made
16 by any manufacturer, distributor, or retailer for the
17 placement of any tobacco product or tobacco product
18 package or advertisement—

19 (A) as a prop in any television program or
20 motion picture produced for viewing by the gen-
21 eral public; or

22 (B) in a video or on a video game machine.

23 (2) VIDEO GAME.—The term “video game”
24 means any electronic amusement device that utilizes
25 a computer, microprocessor, or similar electronic cir-

1 cuntry and its own cathode ray tube, or is designed
2 to be used with a television set or a monitor, that
3 interacts with the user of the device.

(d) RESTRICTIONS ON GLAMORIZATION OF TOBACCO PRODUCTS.—No direct or indirect payment shall be made by any manufacturer, distributor, or retailer to any entity for the purpose of promoting the image or use of a tobacco product through print or film media that appeals to individuals under 18 years of age or through a live performance by an entertainment artist that appeals to such individuals.

12 SEC. 103. FORMAT AND CONTENT REQUIREMENTS FOR LA-
13 BELING AND ADVERTISING.

(a) IN GENERAL.—Except as provided in subsections (b) and (c), each manufacturer, distributor, and retailer advertising or causing to be advertised, disseminating or causing to be disseminated, any labeling or advertising for a tobacco product shall use only black text on a white background.

20 (b) CERTAIN ADVERTISING EXCEPTED.—

21 (1) IN GENERAL.—Subsection (a) shall not
22 apply to advertising—

23 (A) in any facility where vending machines
24 and self-service displays are permitted under
25 this title if the advertising involved—

1 (i) is not visible from outside of the
2 facility; and

3 (ii) is affixed to a wall or fixture in
4 the facility;

5 (B) that appears in any publication
6 (whether periodic or limited **【controlled】** dis-
7 tribution) that the manufacturer, distributor, or
8 retailer demonstrates is an adult publication.

9 (2) ADULT PUBLICATION.—For purposes of
10 paragraph (1)(B), the term “adult publication”
11 means a newspaper, magazine, periodical, or other
12 publication—

13 (A) whose readers under 18 years of age
14 constitute 15 percent or less of the total reader-
15 ship as measured by competent and reliable
16 survey evidence; and

17 (B) that is read by fewer than 2,000,000
18 individuals who are under 18 years of age as
19 measured by competent and reliable survey evi-
20 dence.

21 (c) AUDIO OR VIDEO FORMATS.—Each manufac-
22 turer, distributor, and retailer advertising or causing to
23 be advertised any advertising for a tobacco product in an
24 audio or video format shall comply with the following:

1 (1) With respect to an audio format, the adver-
2 tising shall be limited to words only with no music
3 or sound effects.

4 (2) With respect to a video format, the advertis-
5 ing shall be limited to static black text only on a
6 white background. Any audio with the video adver-
7 tising shall be limited to words only with no music
8 or sound effects.

9 **SEC. 104. STATEMENT OF INTENDED USE.**

10 (a) **REQUIREMENT.**—Each manufacturer, distribu-
11 tor, and retailer advertising or causing to be advertised,
12 disseminating or causing to be disseminated, advertising
13 concerning cigarettes, cigarette tobacco, or smokeless to-
14 bacco products otherwise permitted under this title shall
15 include, as provided in section 502 of the Federal Food,
16 Drug, and Cosmetic Act (21 U.S.C. 352), the established
17 name of the product and a statement of the intended use
18 of the product as provided for in subsection (b).

19 (b) **USE STATEMENTS.**—

20 (1) **CIGARETTES.**—A statement of intended use
21 for cigarettes or cigarette tobacco is as follows
22 (whichever is appropriate):

23 Cigarettes—A Nicotine-Delivery Device for Per-
24 sons 18 or Older.

1 Cigarette Tobacco—A Nicotine-Delivery Device
2 for Persons 18 or Older.

3 (2) SMOKELESS TOBACCO.—A statement of in-
4 tended use for a smokeless tobacco product is as fol-
5 lows (whichever is appropriate):

6 Loose Leaf Chewing Tobacco—A Nicotine-De-
7 livery Device for Persons 18 or Older.

8 Plug Chewing Tobacco—A Nicotine-Delivery
9 Device for Persons 18 or Older.

10 Twist Chewing Tobacco—A Nicotine-Delivery
11 Device for Persons 18 or Older.

12 Moist Snuff—A Nicotine-Delivery Device for
13 Persons 18 or Older.

14 Dry Snuff—A Nicotine-Delivery Device for Per-
15 sons 18 or Older.

16 (c) TYPE AND LOCATION.—[How big, in what color,
17 and where on package or in advertisement does statement
18 go?]

19 **SEC. 105. BAN ON NONTOBACCO ITEMS AND SERVICES,**
20 **CONTESTS AND GAMES OF CHANCE, AND**
21 **SPONSORSHIP OF EVENTS.**

22 (a) BAN ON ALL NONTOBACCO MERCHANDISE.—No
23 manufacturer, importer, distributor, or retailer shall mar-
24 ket, license, distribute, sell, or cause to be marketed, li-
25 censed, distributed or sold any item (other than tobacco

1 products) or service which bears the brand name (alone
2 or in conjunction with any other word), logo, symbol,
3 motto, selling message, recognizable color or pattern of
4 colors, or any other indicia of product identification simi-
5 lar or identifiable to those used for any brand of tobacco
6 products.

7 (b) GIFTS, CONTESTS, AND LOTTERIES.—No manu-
8 facturer, distributor, or retailer shall offer or cause to be
9 offered to any person purchasing tobacco products any gift
10 or item (other than a tobacco product) in consideration
11 of the purchase of such products, or to any person in con-
12 sideration of furnishing evidence, such as credits, proofs-
13 of-purchase, or coupons, of such a purchase.

14 (c) SPONSORSHIP.—

15 (1) IN GENERAL.—No manufacturer, distribu-
16 tor, or retailer shall sponsor or cause to be spon-
17 sored any athletic, musical, artistic, or other social
18 or cultural event, or any entry or team in any event,
19 in which the brand name (alone or in conjunction
20 with any other word), logo, motto, selling message,
21 recognizable color or pattern of colors, or any other
22 indicia of product identification similar or identical
23 to those used for tobacco products is used.

24 (2) USE OF CORPORATE NAME.—A manufac-
25 turer, distributor, or retailer may sponsor or cause

1 to be sponsored any athletic, musical, artistic, or
2 other social or cultural event in the name of the cor-
3 poration which manufactures the tobacco product
4 if—

5 (A) both the corporate name and the cor-
6 poration were registered and in use in the Unit-
7 ed States prior to January 1, 1995; and

8 (B) the corporate name does not include
9 any brand name (alone or in conjunction with
10 any other word), logo, symbol, motto, selling
11 message, recognizable color or pattern of colors,
12 or any other indicia or product identification
13 identical or similar to, or identifiable with,
14 those used for any brand of tobacco products.

15 **SEC. 106. USE OF PRODUCT DESCRIPTORS.**

16 (a) **IN GENERAL.**—With respect to a tobacco product,
17 the label of which bears a product description (such as
18 “light” or “low tar”), such label shall also contain, and
19 any advertisement concerning such product shall contain,
20 a mandatory disclaimer, to be established by the Sec-
21 retary, that states that such product has not been shown
22 to be less hazardous than another product of that type.

23 (b) **RULE OF CONSTRUCTION.**—Nothing in this sec-
24 tion shall be construed to limit the authority of the Food

1 and Drug Administration with respect to words used as
2 product descriptors.

3 **Subtitle B—Warnings, Labeling**
4 **and Packaging**

5 **SEC. 111. CIGARETTE WARNINGS.**

6 (a) IN GENERAL.—

7 (1) PACKAGING.—It shall be unlawful for any
8 person to manufacture, package, or import for sale
9 or distribution within the United States any ciga-
10 rettes the package of which fails to bear, in accord-
11 ance with the requirements of this section, one of
12 the following labels:

13 WARNING: Cigarettes Are Addictive.

14 WARNING: Tobacco Smoke Can Harm Your
15 Children.

16 WARNING: Cigarettes Cause Fatal Lung Dis-
17 ease.

18 WARNING: Cigarettes Cause Cancer.

19 WARNING: Cigarettes Cause Strokes And
20 Heart Disease.

21 WARNING: Smoking During Pregnancy Can
22 Harm Your Baby.

23 WARNING: Smoking Can Kill You.

24 WARNING: Tobacco Smoke Causes Fatal
25 Lung Disease In Nonsmokers.

1 WARNING: Quitting Smoking Now Greatly
2 Reduces Serious Risks To Your Health.

3 (2) ADVERTISING.—It shall be unlawful for any
4 manufacturer or importer of cigarettes to advertise
5 or cause to be advertised within the United States
6 any cigarette unless the advertising bears, in accord-
7 ance with the requirements of this section, one of
8 the following labels:

9 WARNING: Cigarettes Are Addictive.

10 WARNING: Tobacco Smoke Can Harm Your
11 Children.

12 WARNING: Cigarettes Cause Fatal Lung Dis-
13 ease.

14 WARNING: Cigarettes Cause Cancer.

15 WARNING: Cigarettes Cause Strokes And
16 Heart Disease.

17 WARNING: Smoking During Pregnancy Can
18 Harm Your Baby.

19 WARNING: Smoking Can Kill You.

20 WARNING: Tobacco Smoke Causes Fatal
21 Lung Disease In Nonsmokers.

22 WARNING: Quitting Smoking Now Greatly
23 Reduces Serious Risks To Your Health.

24 (b) REQUIREMENTS FOR LABELING.—

1 (1) LOCATION.—Each label statement required
2 by paragraph (1) of subsection (a) shall be located
3 on the upper portion of the front panel of the ciga-
4 rette package (or carton) and occupy not less than
5 25 percent of such front panel.

6 (2) TYPE AND COLOR.—With respect to each
7 label statement required by paragraph (1) of sub-
8 section (a), the phrase “WARNING” shall appear in
9 capital letters and the label statement shall be print-
10 ed in 17 point type with adjustments as determined
11 appropriate by the Commissioner to reflect the
12 length of the required statement. All the letters in
13 the label shall appear in conspicuous and legible
14 type, in contrast by typography, layout, or color with
15 all other printed material on the package, and be
16 printed in an alternating black-on-white and white-
17 on-black format as determined appropriate by the
18 Commissioner.

19 (3) EXCEPTION.—The provisions of paragraph
20 (1) shall not apply in the case of a flip-top cigarette
21 package (offered for sale on the date of enactment
22 of this Act) where the front portion of the flip-top
23 does not comprise at least 25 percent of the front
24 panel. In the case of such a package, the label state-

1 ment required by paragraph (1) of subsection (a)
2 shall occupy the entire front portion of the flip top.

3 (c) REQUIREMENTS FOR ADVERTISING.—

4 (1) LOCATION.—Each label statement required
5 by paragraph (2) of subsection (a) shall occupy not
6 less than 20 percent of the area of the advertisement
7 involved.

8 (2) TYPE AND COLOR.—

9 (A) TYPE.—With respect to each label
10 statement required by paragraph (2) of sub-
11 section (a), the phrase “WARNING” shall ap-
12 pear in capital letters and the label statement
13 shall be printed in the following types:

14 (i) With respect to whole page adver-
15 tisements on broadsheet newspaper—45
16 point type.

17 (ii) With respect to half page adver-
18 tisements on broadsheet newspaper—39
19 point type.

20 (iii) With respect to whole page adver-
21 tisements on tabloid newspaper—39 point
22 type.

23 (iv) With respect to half page adver-
24 tisements on tabloid newspaper—27 point
25 type.

1 (v) With respect to DPS magazine ad-
2 vertisements—31.5 point type.

3 (vi) With respect to whole page maga-
4 zine advertisements—31.5 point type.

5 (vii) With respect to 28cm x 3 column
6 advertisements—22.5 point type.

7 (viii) With respect to 20cm x 2 col-
8 umn advertisements—15 point type.

9 The Commissioner may revise the required type
10 sizes as the Commissioner determines appro-
11 priate within the 20 percent requirement.

12 (B) COLOR.—All the letters in the label
13 under this paragraph shall appear in conspicu-
14 ous and legible type, in contrast by typography,
15 layout, or color with all other printed material
16 on the package, and be printed in an alternat-
17 ing black-on-white and white-on-black format as
18 determined appropriate by the Commissioner.

19 (d) ROTATION OF LABEL STATEMENTS.—

20 (1) IN GENERAL.—Except as provided in para-
21 graph (2), the label statements specified in para-
22 graphs (1) and (2) of subsection (a) shall be rotated
23 by each manufacturer or importer of cigarettes quar-
24 terly in alternating sequence on packages of each
25 brand of cigarettes manufactured by the manufac-

1 turer or importer and in the advertisements for each
2 such brand of cigarettes in accordance with a plan
3 submitted by the manufacturer or importer and ap-
4 proved by the Federal Trade Commission. The Fed-
5 eral Trade Commission shall approve a plan submit-
6 ted by a manufacturer or importer of cigarettes
7 which will provide the rotation required by this sub-
8 section and which assures that all of the labels re-
9 quired by paragraphs (1) and (2) will be displayed
10 by the manufacturer or importer at the same time.

11 (2) APPLICATION OF OTHER ROTATION RE-
12 QUIREMENTS.—

13 (A) IN GENERAL.—A manufacturer or im-
14 porter of cigarettes may apply to the Federal
15 Trade Commission to have the label rotation
16 described in subparagraph (C) apply with re-
17 spect to a brand style of cigarettes manufac-
18 tured or imported by such manufacturer or im-
19 porter if—

20 (i) the number of cigarettes of such
21 brand style sold in the fiscal year of the
22 manufacturer or importer preceding the
23 submission of the application is less than
24 $\frac{1}{4}$ of 1 percent of all the cigarettes sold in
25 the United States in such year; and

1 (ii) more than $\frac{1}{2}$ of the cigarettes
2 manufactured or imported by such manu-
3 facturer or importer for sale in the United
4 States are packaged into brand styles
5 which meet the requirements of clause (i).

6 If an application is approved by the Commis-
7 sion, the label rotation described in subpara-
8 graph (C) shall apply with respect to the appli-
9 cant during the 1-year period beginning on the
10 date of the application approval.

11 (B) PLAN.—An applicant under subpara-
12 graph (A) shall include in its application a plan
13 under which the label statements specified in
14 paragraph (1) of subsection (a) will be rotated
15 by the applicant manufacturer or importer in
16 accordance with the label rotation described in
17 subparagraph (C).

18 (C) OTHER ROTATION REQUIREMENTS.—
19 Under the label rotation which the manufac-
20 turer or importer with an approved application
21 may put into effect, each of the labels specified
22 in paragraph (1) of subsection (a) shall appear
23 on the packages of each brand style of ciga-
24 rettes with respect to which the application was
25 approved an equal number of times within the

1 12-month period beginning on the date of the
2 approval by the Commission of the application.

3 (e) APPLICATION OF REQUIREMENT.—Subsection (a)
4 does not apply to a distributor, a retailer of cigarettes who
5 does not manufacture, package, or import cigarettes for
6 sale or distribution within the United States.

7 (f) TELEVISION AND RADIO ADVERTISING.—It shall
8 be unlawful to advertise cigarettes and little cigars on any
9 medium of electronic communications subject to the juris-
10 diction of the Federal Communications Commission.

11 **SEC. 112. SMOKELESS TOBACCO WARNINGS.**

12 (a) IN GENERAL.—

13 (1) PACKAGING.—It shall be unlawful for any
14 person to manufacture, package, or import for sale
15 or distribution within the United States any smoke-
16 less tobacco product the package of which fails to
17 bear, in accordance with the requirements of this
18 section, one of the following labels:

19 WARNING: This Product May Cause Mouth
20 Cancer.

21 WARNING: This Product May Cause Gum
22 Disease And Tooth Loss.

23 WARNING: This Product Is Not A Safe Alter-
24 native To Cigarettes.

25 WARNING: Smokeless Tobacco Is Addictive.

1 (2) ADVERTISING.—It shall be unlawful for any
2 manufacturer or importer of smokeless tobacco prod-
3 ucts to advertise or cause to be advertised within the
4 United States any smokeless tobacco product unless
5 the advertising bears, in accordance with the re-
6 quirements of this section, one of the following la-
7 bels:

8 WARNING: This Product May Cause Mouth
9 Cancer.

10 WARNING: This Product May Cause Gum
11 Disease And Tooth Loss.

12 WARNING: This Product Is Not A Safe Alter-
13 native To Cigarettes.

14 WARNING: Smokeless Tobacco Is Addictive.

15 (b) REQUIREMENTS FOR LABELING.—

16 (1) LOCATION.—Each label statement required
17 by paragraph (1) of subsection (a) shall be located
18 on the principal display panel of the product and oc-
19 cupy not less than 25 percent of such panel.

20 (2) TYPE AND COLOR.—With respect to each
21 label statement required by paragraph (1) of sub-
22 section (a), the phrase “WARNING” shall appear in
23 capital letters and the label statement shall be print-
24 ed in 17 point type with adjustments as determined
25 appropriate by the Commissioner to reflect the

length of the required statement. All the letters in the label shall appear in conspicuous and legible type in contrast by typography, layout, or color with all other printed material on the package and be printed in an alternating black on white and white on black format as determined appropriate by the Commissioner.

(c) ADVERTISING AND ROTATION.—The provisions of subsections (c) and (d)(1) of section 111 shall apply to advertisements for smokeless tobacco products and the rotation of the label statements required under subsection (a)(1) on such products.

(d) APPLICATION OF REQUIREMENT.—Subsection (a) does not apply to a distributor or a retailer of smokeless tobacco products who does not manufacture, package, or import such products for sale or distribution within the United States.

(e) TELEVISION AND RADIO ADVERTISING.—It shall be unlawful to advertise smokeless tobacco on any medium of electronic communications subject to the jurisdiction of the Federal Communications Commission.

SEC. 113. INGREDIENTS.

Each person who manufactures, packages, or imports cigarettes or smokeless tobacco products shall annually provide the Secretary with the information required under

1 section 910 of the Federal Food, Drug, and Cosmetic Act
2 (as added by section 143(3) of this Act).

3 **SEC. 114. ENFORCEMENT, REGULATIONS, AND CONSTRUC-**
4 **TION.**

5 (a) **ENFORCEMENT.—**

6 (1) **IN GENERAL.**—A violation of section 111 or
7 112 or the regulations promulgated pursuant to this
8 subtitle shall be considered a violation of section 5
9 of the Federal Trade Commission Act.

10 (2) **FINES.**—Any person who is found to violate
11 any provision of sections 111, 112, or 113(a) shall
12 be guilty of a misdemeanor and shall, on conviction
13 thereof, be subject to a fine of not more than
14 \$10,000.

15 (b) **INJUNCTIONS.**—The several district courts of the
16 United States are vested with jurisdiction, for cause
17 shown, to prevent and restrain violations of this subtitle
18 upon the application of the Federal Trade Commission in
19 the case of a violation of section 111 or 112 or upon appli-
20 cation of the Attorney General of the United States acting
21 through the several United States attorneys in their sev-
22 eral districts in the case of a violation of section 113.

23 (c) **REGULATIONS.**—Not later than 180 days after
24 the date of the enactment of this Act, the Federal Trade

1 Commission shall promulgate such regulations as it may
2 require to implement sections 111 and 112.

3 (d) CONSTRUCTION.—Nothing in this subtitle (other
4 than the requirements of sections 111, 112, and 113) shall
5 be construed to limit, restrict, or expand the authority of
6 the Federal Trade Commission with respect to unfair or
7 deceptive acts or practices in the advertising of cigarettes
8 or smokeless tobacco products.

9 **SEC. 115. PREEMPTION.**

10 (a) FEDERAL ACTION.—No statement relating to the
11 use of cigarettes or smokeless tobacco products and
12 health, other than the statements required by sections 111
13 or 112, shall be required by any Federal agency to appear
14 on any package or in any advertisement of cigarettes or
15 a smokeless tobacco product.

16 (b) STATE AND LOCAL ACTION.—No statement relat-
17 ing to the use of cigarettes or smokeless tobacco products
18 and health, other than the statements required by sections
19 111 and 112, shall be required by any State or local stat-
20 ute or regulation to be included on any package or in any
21 advertisement of cigarettes or a smokeless tobacco prod-
22 uct.

23 (c) EFFECT ON LIABILITY LAW.—Except as other-
24 wise provided in this Act, nothing in this subtitle shall re-

1 lieve any person from liability at common law or under
2 State statutory law to any other person.

3 **SEC. 116. REPORTS.**

4 (a) SECRETARY'S REPORT.—Not later than
5 [], and biennially thereafter, the Sec-
6 retary shall prepare and submit to Congress a report con-
7 taining—

8 (1) a description of the effects of health edu-
9 cation efforts on the use of cigarettes and smokeless
10 tobacco products;

11 (2) a description of the use by the public of
12 cigarettes and smokeless tobacco products;

13 (3) an evaluation of the health effects of ciga-
14 rettes and smokeless tobacco products and the iden-
15 tification of areas appropriate for further research;
16 and

17 (4) such recommendations for legislation and
18 administrative action as the Secretary considers ap-
19 propriate.

20 (b) FTC REPORT.—Not later than
21 [], and biennially thereafter, the Fed-
22 eral Trade Commission shall prepare and submit to Con-
23 gress a report containing—

1 (1) a description of the current sales, advertis-
2 ing, and marketing practices associated with ciga-
3 rettes and smokeless tobacco products; and

4 (2) such recommendations for legislation and
5 administrative action as the Commission deems ap-
6 propriate.

7 **SEC. 117. EXPORTS. [Is this correct policy?]**

8 Packages of cigarettes or smokeless tobacco products
9 manufactured, imported, or packaged—

10 (1) for export from the United States; or

11 (2) for delivery to a vessel or aircraft, as sup-
12 plies, for consumption beyond the jurisdiction of the
13 internal revenue laws of the United States;

14 shall be exempt from the requirements of this subtitle, but
15 such exemptions shall not apply to cigarettes or smokeless
16 tobacco products manufactured, imported, or packaged for
17 sale or distribution to members or units of the Armed
18 Forces of the United States located outside of the United
19 States.

20 **SEC. 118. REPEALS.**

21 The following Acts are repealed:

22 (1) The Federal Cigarette Labeling and Adver-
23 tising Act (15 U.S.C. 1331 et seq.).

1 (2) The Comprehensive Smokeless Tobacco
2 Health Education Act of 1986 (15 U.S.C. 4401 et
3 seq.)

4 [NOTE: The purposes of this subtitle could
5 be achieved through amendments to the Acts
6 referred to in this section, or alternatively,
7 amending such Acts to read as follows. For
8 purposes of clarity, the subtitle was drafted as
9 a new freestanding provision.]

10 **Subtitle C—Restriction on Access**
11 **to Tobacco Products**

12 **SEC. 121. REQUIREMENTS RELATING TO RETAILERS.**

13 (a) SALES TO MINORS PROHIBITED.—No retailer
14 may distribute a tobacco product to any individual who
15 is under 18 years of age.

16 (b) PHOTO IDENTIFICATION.—

17 (1) REQUIREMENT.—Except as provided in
18 paragraph (2), each retailer shall verify, by means of
19 photographic identification containing the date of
20 birth of the bearer, that no individual purchasing a
21 tobacco product is under 18 years of age.

22 (2) EXCEPTION.—No verification under para-
23 graph (1) is required for any individual who is at
24 least 27 years of age.

1 (3) LOCATION OF PRODUCTS.—Except as pro-
2 vided in section 122(d), a retailer shall ensure that
3 all tobacco products are located in areas where cus-
4 tomers do not have access to the products [(either
5 behind the counter or in a locked display case)].

6 (c) FACE-TO-FACE TRANSACTIONS.—Except as pro-
7 vided in section 122(c)(1), a retailer may sell tobacco
8 products only in a direct, face-to-face exchange without
9 the assistance of any electronic or mechanical device.

10 (d) OUT-OF-PACKAGE DISTRIBUTION.—No retailer
11 may break or otherwise open a tobacco product to sell or
12 distribute to individuals portions of such product (includ-
13 ing individual cigarettes or a number of cigarettes that
14 is smaller than the quantity in the minimum package size,
15 or any quantity of cigarette tobacco or smokeless tobacco
16 that is smaller than the smallest package distributed by
17 the retailer for individual consumer use).

18 (e) RETAILER COMPLIANCE WITH RESPECT TO
19 SELF-SERVICE.—Each retailer shall ensure that all to-
20 bacco-related self-service displays, advertising, labeling,
21 and other items that are located in the establishment of
22 the retailer and that do not comply with the requirements
23 of this title are removed or are brought into compliance
24 with the requirements of this title.

1 SEC. 122. MANUFACTURE, SALE, AND DISTRIBUTION.

2 (a) MINIMUM CIGARETTE PACKAGE SIZE.—Except
3 as otherwise provided in this section, no manufacturer,
4 distributor, or retailer may sell or cause to be sold, or dis-
5 tribute or cause to be distributed, any cigarette package
6 that contains fewer than 20 cigarettes. [What is the Puer-
7 to Rico minimum pack size?]

8 (b) PROHIBITION ON SAMPLING.—No manufacturer,
9 distributor, or retailer may distribute or cause to be dis-
10 tributed any free samples of any tobacco product.

11 (c) PROHIBITION ON DISTRIBUTION THROUGH SELF-
12 SERVICE MODES OF SALE.—

13 (1) VENDING MACHINES.—No manufacturer,
14 distributor, or retailer may distribute or cause to be
15 distributed any tobacco product through a vending
16 machine.

17 (2) OTHER DISPLAYS.—Except as provided in
18 subsection (d)(1)(B), no manufacturer, distributor,
19 or retailer may distribute or cause to be distributed
20 any tobacco product through a self-service display.

21 (d) PERMITTED SELF-SERVICE MODES OF SALE.—

22 (1) IN GENERAL.—Notwithstanding this sub-
23 title, the following methods of distributing tobacco
24 products are permitted:

25 (A) Mail-order sales as provided for in
26 paragraph (2), except that mail-order redemp-

1 tion of coupons and the distribution of free
2 samples through the mail shall be prohibited.

3 (B) Self-service displays that are located in
4 facilities where the retailer ensures that no indi-
5 viduals under 18 years of age are present or
6 permitted to enter at any time.

7 (2) MAIL-ORDER SALES.—

8 (A) IN GENERAL.—A manufacturer, dis-
9 tributor, or retailer may distribute or cause to
10 be distributed a tobacco product through mail-
11 order sales only if such sales are subject to a
12 procedure for verifying that no individual pur-
13 chasing such products is under 18 years of age.

14 (B) REVIEW BY COMMISSIONER.—Not
15 later than 2 years after the date of enactment
16 of this Act, the Commissioner shall review the
17 verification procedures implemented under sub-
18 paragraph (A) to determine whether individuals
19 under 18 years of age are obtaining tobacco
20 products through the mail. [If the Commis-
21 sioner determines that a significant number of
22 underage individuals are obtaining such prod-
23 ucts through the mail, the Commissioner may
24 promulgate regulations to ban the distribution
25 of tobacco products through the mail.]

1 **Subtitle D—Licensing of Retail**
2 **Tobacco Sellers**

3 **SEC. 131. ESTABLISHMENT OF PROGRAM.**

4 (a) **IN GENERAL.**—The **【Secretary/Commissioner】**
5 shall establish a program under which an entity would be
6 required to obtain a State or local license to sell or other-
7 wise distribute tobacco products directly to consumers.

8 (b) **PROHIBITION ON DISTRIBUTION.**—No entity
9 shall sell or otherwise distribute tobacco products directly
10 to consumers unless such entity has in effect a tobacco
11 license issued or renewed in accordance with the laws of
12 the State in which the products are to be sold or otherwise
13 distributed.

14 **【(c) ELIGIBILITY OF STATE FOR PAYMENTS.**—To be
15 eligible to receive a block grant under section 502, a State
16 shall have in effect laws that meet the standards described
17 in this subtitle that provide for the licensing of entities
18 engaged in the sale or distribution of tobacco products di-
19 rectly to consumers and shall enforce such laws in accord-
20 ance with section 133.】

21 **SEC. 132. REQUIREMENTS.**

22 (a) **LICENSURE AND NOTICE.**—

23 (1) **IN GENERAL.**—The State shall require that
24 each person engaged in the sale or distribution of to-
25 bacco products directly to consumers obtain a license

1 that is issued by the State. A separate license shall
2 be required for each place of business where tobacco
3 products are distributed or sold at retail.

4 (2) NOTICE.—The State shall notify every per-
5 son in the State who is engaged in the distribution
6 at retail of tobacco products of the license require-
7 ment of this section and of the date by which such
8 person shall have obtained a license in order to dis-
9 tribute such products.

10 (b) FEE.—The State may assess an annual licensing
11 fee in an amount not to exceed \$_____ with respect to each
12 entity that desires to obtain a license under subsection (a).
13 Amounts derived from such fees shall be used to offset
14 the administrative costs incurred by the State in issuing
15 and renewing licenses under this subtitle.

16 (c) APPLICATION.—

17 (1) IN GENERAL.—An entity shall prepare and
18 submit to the State an application for a license (in-
19 cluding the renewal of a license) under this section,
20 on such form as the State may require, that shall
21 set forth the name under which the applicant trans-
22 acts or intends to transact business, the location of
23 the place of business for which the license is to be
24 issued, the street address to which all notices rel-
25 evant to the license are to be sent (in this Act re-

1 ferred to as "notice address"), and any other identi-
2 fying information that the State may require.

3 (2) ACTION BY STATE.—

4 (A) IN GENERAL.—The State shall issue or
5 renew a license or deny an application for a li-
6 cense or the renewal of a license within 30 days
7 of receiving a properly completed application
8 and the licensing fee. The State shall provide
9 notice to an applicant of an action on an appli-
10 cation denying the issuance of a license or re-
11 fusing to renew a license.

12 (B) FINDING BY STATE.—The State shall
13 deny the issuance or renewal of a license upon
14 an application if the State determines that the
15 applicant has failed to comply with the require-
16 ments of this title.

17 (3) SCOPE AND RENEWAL.—Every license is-
18 sued by the State shall be valid for ____ years from
19 the date of issuance and shall be renewed upon ap-
20 plication except as otherwise provided in this section.

21 **SEC. 133. PENALTIES, REVOCATIONS AND SUSPENSIONS.**

22 (a) PENALTIES.—

23 (1) CRIMINAL PENALTIES APPLICABLE TO UN-
24 LICENSED SELLERS.—Any individual who sells or
25 otherwise distributes tobacco products to a consumer

1 without a tobacco license in effect as provided for in
2 this subtitle shall be subject, under the applicable
3 State law, to a fine of not less than \$1,000, or im-
4 prisonment of not less than 6 months, or both. With
5 respect to any corporate employer of such an indi-
6 vidual, the corporation shall be subject to a fine of
7 not more than \$50,000.

8 (2) CIVIL PENALTIES APPLICABLE TO SELLERS
9 IN VIOLATION OF LICENSE.—

10 (A) IN GENERAL.—In addition to any
11 criminal penalties that may be imposed under
12 paragraph (1), a State may, in accordance with
13 subsection (b), impose civil penalties on any en-
14 tity that has sold or distributed tobacco prod-
15 ucts in the State in violation of the State to-
16 bacco licensing laws.

17 (B) LIMITATIONS.—The civil penalties that
18 may be imposed under subparagraph (A) shall
19 not exceed the following:

20 (i) For the first offense within any 2-
21 year period, \$500, or a 3-day suspension of
22 the tobacco license, or both.

23 (ii) For a second offense within any 2-
24 year period, \$1,000, or a 7-day suspension
25 of the tobacco license, or both.

1 (iii) For a third offense within any 2-
2 year period, \$2,000, or a 30-day suspen-
3 sion of the tobacco license, or both.

4 (iv) For a fourth offense within any 2-
5 year period, \$5,000, or a 6-month suspen-
6 sion of the tobacco license, or both.

7 (v) For a fifth offense within any 2-
8 year period, \$10,000, or a 1-year suspen-
9 sion of the tobacco license, or both.

10 (vi) For a sixth and any subsequent
11 offense within any 2-year period, \$25,000,
12 or a 3-year revocation of the tobacco li-
13 cense.

14 (vii) For a tenth offense within any 2-
15 year period, the permanent revocation of
16 the tobacco license.

17 (b) REVOCATION AND SUSPENSIONS.—

18 (1) NOTICE.—Upon a finding that a tobacco li-
19 censee has been determined by a court of competent
20 jurisdiction to have violated a provision of State law
21 under this subtitle during the license term, the State
22 shall notify the licensee in writing, served personally
23 or by registered mail at the principal place of busi-
24 ness of the licensee, that any subsequent violation of
25 such law at the same place of business may result

1 in an administrative action to suspend the license
2 for a period determined by the State in accordance
3 with subsection (a)(2)(B).

4 (2) SUSPENSION.—Upon finding that a further
5 violation by the tobacco licensee has occurred involv-
6 ing the same place of business for which the license
7 was issued and the licensee has been provided notice
8 under paragraph (1), the State may initiate an ad-
9 ministrative action to suspend the license for a pe-
10 riod to be determined in accordance with subsection
11 (a)(2)(B). If an administrative action to suspend a
12 license is initiated, the State shall immediately notify
13 the licensee, in writing at the principal place of busi-
14 ness of the licensee, of the initiation of the action
15 and the reasons therefore and permit the licensee an
16 opportunity, at least 30 days after written notice is
17 served personally or by registered mail upon the li-
18 censee, to show why suspension of the license would
19 be unwarranted or unjust.

20 (3) REVOCATION.—The State may initiate an
21 administrative action to revoke a tobacco license that
22 previously has been suspended under paragraph (2)
23 if, during the 2-year period described in subsection
24 (a)(2)(B), a further violation of this subtitle is com-
25 mitted after the suspension by the licensee involving

1 the same place of business for which the license was
2 issued. If an administrative action to revoke a li-
3 cense is initiated, the State shall immediately notify
4 the licensee, in writing at the principal place of busi-
5 ness of the licensee, of the initiation of the action
6 and the reasons therefore and permit the licensee an
7 opportunity, at least 30 days after written notice is
8 served personally or by registered mail upon the li-
9 censee, to show why revocation of the license would
10 be unwarranted or unjust.

11 [(c) JUDICIAL REVIEW.—A tobacco licensee may
12 seek judicial review of an action of the State suspending,
13 revoking, denying, or refusing to renew a license under
14 this section by filing a complaint in a court of competent
15 jurisdiction. A complaint shall be filed within 30 days after
16 the date on which notice of the action involved is received
17 by the licensee. The court shall review the evidence de
18 novo.]

19 **SEC. 134. FEDERAL LICENSING OF MILITARY AND OTHER**
20 **ENTITIES.**

21 (a) IN GENERAL.—The Commissioner, in consulta-
22 tion with the Secretary of Defense, Secretary of State, and
23 other appropriate Federal officials, shall establish and im-
24 plement a Federal tobacco licensing program to be applied
25 to entities that sell or distribute tobacco products—

- 1 (1) on any military installation (as defined in
2 section 2801(c)(2) of title X, United States Code);
3 (2) in any United States embassy;
4 (3) in any facility **【owned and operated】** by the
5 Federal Government either in the United States or
6 in a foreign country;
7 (4) in any duty-free shop located within the
8 United States; or
9 (5) through any other Federal entity or on any
10 other Federal property as determined appropriate by
11 the Commissioner.

12 (b) REQUIREMENTS OF PROGRAM.—The program es-
13 tablished under subsection (a) shall apply requirements
14 (including those for penalties, suspensions, and revoca-
15 tions) similar to those required to be implemented by
16 States under this subtitle.

17 **【(c) INDIAN TRIBES AND TRIBAL LANDS.—For pur-**
18 poses of applying and enforcing the provisions of this sub-
19 title to entities that sell or otherwise distribute tobacco
20 products on Indian reservations (as defined in section
21 403(9) of the Indian Child Protection and Family Violence
22 Prevention Act (25 U.S.C. 3202(9))), an Indian tribe or
23 tribal organization (as such terms are defined in section
24 4 of the Indian Self Determination and Education Assist-
25 ance Act (25 U.S.C. 450b)) shall be treated as a State.】

1 **Subtitle E—Regulation of Tobacco**
2 **Product Development and Man-**
3 **ufacturing**

4 **SEC. 141. REFERENCE.**

5 Whenever in this subtitle an amendment or repeal is
6 expressed in terms of an amendment to, or repeal of, a
7 section or other provision, the reference shall be consid-
8 ered to be made to a section or other provision of the Fed-
9 eral Food, Drug, and Cosmetic Act (21 U.S.C. 301 et
10 seq.).

11 **SEC. 142. TREATMENT OF TOBACCO PRODUCTS AS DRUGS.**

12 **[NOTE: Though amendments to the Food,**
13 **Drug, and Cosmetic Act are probably the most**
14 **appropriate way of carrying out the intent of**
15 **this subtitle, many of the provisions in the next**
16 **2 sections may be accomplished through the use**
17 **of freestanding language.]**

18 **(a) DEFINITIONS.—**

19 **(1) DRUG.—**

20 **(A) IN GENERAL.—**Section 201(g)(1) (21
21 U.S.C. 321(g)(1)) is amended by inserting be-
22 fore the first period “; and (E) tobacco prod-
23 ucts”.

24 **(B) EXCEPTION.—**Section 201(p) of such
25 Act is amended in paragraphs (1) and (2) by

1 striking "(except a new animal drug" and in-
2 serting "(except a tobacco product, a new ani-
3 mal drug,". **【Is this correct policy?】**

4 (2) DEVICES.—Section 201(h) (21 U.S.C.
5 321(h)) is amended by adding at the end the follow-
6 ing: "Such term includes a tobacco product which
7 shall be classified as a class II device." **【Is this cor-
8 rect policy or will only certain tobacco products be
9 considered as devices (i.e. cigarettes, etc.)? Addition-
10 ally, will the Secretary ever be able to provide rea-
11 sonable assurances of the safety and effectiveness of
12 tobacco products as required for class II devices?】**

13 (3) OTHER DEFINITIONS.—Section 201 (21
14 U.S.C. 321) is amended by adding at the end there-
15 of the following new paragraphs:

16 "(ii) TOBACCO ADDITIVE.—The term 'tobacco addi-
17 tive' means any substance the intended use of which re-
18 sults or may reasonably be expected to result, directly or
19 indirectly, in the substance becoming a component of, or
20 otherwise affecting the characteristics of, any tobacco
21 product, including any substance that may have been re-
22 moved from the tobacco product and then readded in the
23 substance's original or modified form.

24 "(jj) TAR.—The term 'tar' means mainstream total
25 articulate matter minus nicotine and water.

1 “(kk) TOBACCO PRODUCT.—The term ‘tobacco prod-
2 uct’ has the meaning given such term in section 100(22)
3 of the _____ Act.”.

4 (b) ENFORCEMENT.—Section 301 (21 U.S.C. 331) is
5 amended by adding at the end thereof the following new
6 subsection:

7 “(x) The manufacture, labeling, distribution, and sale
8 of any adulterated or misbranded tobacco product in viola-
9 tion of—

10 “(1) regulations issued pursuant to section 903;

11 “(2) title I of the
12 _____ Act.”.

13 (c) ADULTERATED OR MISBRANDED PROVISIONS.—

14 (1) ADULTERATION.—Section 501 (21 U.S.C.
15 351) is amended by adding at the end the following:

16 “(j) If it is a tobacco product and it does not comply
17 with the provisions of chapter IX.”.

18 (2) MISBRANDING.—Section 502 (21 U.S.C.
19 352) is amended by adding at the end the following:

20 “(u) If it is a tobacco product and its labeling does
21 not comply with the provisions of chapter IX and the pro-
22 visions of title I of the _____
23 Act.”.

24 【Note: Should tobacco products be exempted from
25 section 503(b)(1)?】

1 【Note: Will provisions of section 510 apply to tobacco
2 product manufacturers?】

3 (d) CLASSIFICATION OF TOBACCO PRODUCTS.—Sec-
4 tion 512(a)(1)(B) (21 U.S.C. 360c(a)(1)(B)) is amended
5 by adding at the end the following: “For purposes of this
6 Act, a tobacco product shall be classified as a class II de-
7 vice with performance standards applicable under chapter
8 IX”.

9 【Should section 519(c) of the FDCA be amended to
10 provide an exemption from reporting with respect to to-
11 bacco products?】

12 **SEC. 143. HEALTH AND SAFETY REGULATION OF TOBACCO**
13 **PRODUCTS.**

14 The Act (21 U.S.C. 301 et seq.) is amended—

15 (1) by redesignating chapter IX as chapter X;

16 (2) by redesignating sections 901, 902, 903,
17 904, and 905 as sections 1001, 1002, 1003, 1004,
18 and 1005, respectively; and

19 (3) by adding after chapter VIII the following
20 new chapter:

21 **“CHAPTER IX—TOBACCO PRODUCTS**

22 **“SEC. 901. DEFINITIONS.**

23 “For purposes of this chapter and in addition to the
24 definitions contained in section 201, the definitions under

1 section 100 of the _____ Act

2 shall apply.

3 **"SEC. 902. PURPOSE.**

4 "It is the purpose of this chapter to impose a regu-
5 latory scheme applicable to the developinent and manufac-
6 turing of [cigarettes and smokeless tobacco products/to-
7 bacco products]. Such scheme shall include the approval
8 of the ingredients used in such products and the imposi-
9 tion of standards to reduce the level of certain constituents
10 contained in such products, including nicotine.

11 **"SEC. 903. PROMULGATION OF REGULATIONS.**

12 "The Commissioner shall promulgate regulations gov-
13 erning the misbranding, adulteration, and dispensing of
14 tobacco products that are consistent with this chapter and
15 with the manner in which other products that are ingested
16 into the body are regulated under this Act, except that
17 the Commissioner may not promulgate a regulation that
18 prohibits the sale and distribution of a tobacco product
19 solely on the basis of the fact that tobacco causes disease.
20 Such regulations shall be promulgated not later than ____
21 months after the date of enactment of the
22 _____ Act.

23 **"SEC. 904. MINIMUM REQUIREMENTS.**

24 "(a) MISBRANDING.—The regulations promulgated
25 under section 903 shall at a minimum require that a to-

1 bacco product be deemed to be misbranded if the labeling
2 of the package of such product is not in compliance with
3 the provisions of this chapter, of other applicable provi-
4 sions of this Act, or of sections 102(a), 103, 111, 112,
5 and 113 (as applicable to the type of product involved)
6 of the _____ Act.

7 “(b) ADULTERATION.—The regulations promulgated
8 under section 903 shall at a minimum require that a to-
9 bacco product be deemed to be adulterated if the Commis-
10 sioner determines that any tobacco additive in such prod-
11 uct, regardless of the amount of such tobacco additive, ei-
12 ther by itself or in conjunction with any other tobacco ad-
13 ditive or ingredient [significantly increases the risk to
14 human health or the risk of addiction to such product].
15 [Is this correct policy?]

16 **“SEC. 905. PERFORMANCE STANDARDS FOR TOBACCO**
17 **PRODUCTS.**

18 [Note: How is this reconciled with FDCA safe and
19 effective requirements?]

20 “(a) IN GENERAL.—With respect to tobacco prod-
21 ucts, the special controls required by section 513(a)(1)(B)
22 shall include performance standards for such products as
23 established in accordance with this section.

24 “(b) REQUIREMENTS.—A performance standard es-
25 tablished under this section for a tobacco product—

1 “(1) shall include provisions to require the
2 modification of the product to minimize the illness
3 or injury that may result in consumers as a result
4 of the use of such products, including the compo-
5 nents of such products that produce dependence
6 among such consumers; and

7 “(2) include, where appropriate—

8 “(A) provisions with respect to the con-
9 struction, components, ingredients, and prop-
10 erties of the tobacco product;

11 “(B) provisions for the testing (on a sam-
12 ple basis or, if necessary, on an individual
13 basis) of the tobacco product or, if it is deter-
14 mined that no other more practicable means are
15 available to the Secretary to assure the con-
16 formity of the device to the standard, provisions
17 for the testing (on a sample basis or, if nec-
18 essary, on an individual basis) by the Secretary
19 or by another person at the direction of the
20 Secretary;

21 “(C) provisions for the measurement of the
22 performance characteristics of the tobacco prod-
23 uct;

24 “(D) provisions requiring that the results
25 of each or of certain of the tests of the device

1 required to be made under subparagraph (B)
2 demonstrate that the tobacco product is in con-
3 formity with the portions of the standard for
4 which the test or tests were required; and

5 “(E) a provision requiring that the sale
6 and distribution of the device be restricted but
7 only to the extent that the sale and distribution
8 of a device may be otherwise restricted under
9 this Act of title I of the
10 _____ Act.

11 “(c) EVALUATION.—The Secretary shall provide for
12 the periodic evaluation of a performance standard estab-
13 lished under this section to determine if such standards
14 should be changed to reflect new medical, scientific, or
15 other technological data.

16 “(d) PROCEDURES.—In carrying out this section, the
17 Secretary shall, to the maximum extent practicable—

18 “(1) use personnel, facilities, and other tech-
19 nical support available in other Federal agencies;

20 “(2) consult with the Scientific Advisory Com-
21 mittee established under section 906 and other Fed-
22 eral agencies concerned with standard-setting and
23 other nationally or internationally recognized stand-
24 ard-setting entities; and

1 “(3) invite appropriate participation, through
2 joint or other conferences, workshops, or other
3 means, by informed persons representative of sci-
4 entific, professional, industry, or consumer organiza-
5 tions who in the judgment of the Secretary can
6 make a significant contribution.

7 “(e) PROCEDURES.—

8 “(1) IN GENERAL.—The Secretary shall publish
9 in the Federal Register a notice of proposed rule-
10 making for the establishment, amendment, or rev-
11 ocation of any performance standard under this sec-
12 tion.

13 “(2) NOTICE REQUIREMENTS.—A notice of pro-
14 posed rulemaking for the establishment or amend-
15 ment of a performance standard under this section
16 shall—

17 “(A) set forth a finding with supporting
18 justification that the performance standard is
19 appropriate under subsection (b)(1) with re-
20 spect to the product; and

21 “(B) invite interested persons to submit an
22 existing performance standard for the product,
23 including a draft or proposed performance
24 standard, for consideration by the Secretary.

1 “(3) COMMENT PERIOD.—The Secretary shall
2 provide for a comment period of not less than 60
3 days.

4 “(4) APPLICABILITY OF SECTION 514.—The
5 provisions of paragraphs (3) and (4) of section
6 514(b) shall apply to the establishment, amendment,
7 or revocation of any performance standard under
8 this section, except that any reference to an advisory
9 committee shall be deemed to be a reference the Sci-
10 entific Advisory Committee established under section
11 906.

12 “(f) NICOTINE.—Except as provided in section 907,
13 a performance standard established under this section
14 may not require the elimination of nicotine from tobacco
15 products.

16 “(g) LIMITATION.—The Commissioner may not es-
17 tablish a performance standard under this section that has
18 the effect of prohibiting the sale and distribution, to indi-
19 viduals who are at least 18 years of age, of traditional
20 tobacco products in the basic form of the particular prod-
21 uct as described in the definition of the particular product
22 under section 100 of the
23 _____ Act. [Is this correct
24 policy?]

1 "SEC. 906. SCIENTIFIC ADVISORY COMMITTEE.

2 "(a) ESTABLISHMENT.—Not later than 1 year after
3 the date of enactment of the
4 _____ Act, the Sec-
5 retary shall establish an advisory committee, to be known
6 as the 'Scientific Advisory Committee', to assist the Sec-
7 retary in establishing, amending, or revoking a perform-
8 ance standard under section 905.

9 "(b) MEMBERSHIP.—The Secretary shall appoint as
10 members of the Scientific Advisory Committee any individ-
11 uals with expertise in the medical, scientific, or other tech-
12 nological data involving the manufacture and use of to-
13 bacco products, and of appropriately diversified profes-
14 sional backgrounds. The Secretary may not appoint to the
15 Committee any individual who is in the regular full-time
16 employ of the Federal Government. The Secretary shall
17 designate one of the members of each advisory committee
18 to serve as chairperson of the Committee. [The Commit-
19 tee shall include as nonvoting members a representative
20 of consumer interests and a representative of interests of
21 the device manufacturing industry.]

22 "(c) COMPENSATION AND EXPENSES.—

23 "(1) COMPENSATION.—Members of the Sci-
24 entific Advisory Committee who are not officers or
25 employees of the United States, while attending con-
26 ferences or meetings of the Committee or otherwise

1 serving at the request of the Secretary, shall be enti-
2 tled to receive compensation at rates to be fixed by
3 the Secretary, which rates may not exceed the daily
4 equivalent of the rate of pay for level 4 of the Senior
5 Executive Schedule under section 5382 of title 5,
6 United States Code, for each day (including travel-
7 time) they are so engaged.

8 “(2) EXPENSES.—While conducting the busi-
9 ness of the Scientific Advisory Committee away from
10 their homes or regular places of business, each mem-
11 ber may be allowed travel expenses, including per
12 diem in lieu of subsistence, as authorized by section
13 5703 of title 5 of the United States Code for per-
14 sons in the Government service employed intermit-
15 tently.

16 “(d) DUTIES.—The Scientific Advisory Committee
17 shall—

18 “(1) assist the Secretary in establishing,
19 amending, or revoking performance standards under
20 section 905;

21 “(2) examine and determine the effects of the
22 alteration of the nicotine yield levels in tobacco prod-
23 ucts;

24 “(3) examine and determine whether there is a
25 threshold level below which nicotine yields do not

1 produce dependence on the tobacco product involved,
2 and, if so, determine what that level is; and

3 “(4) review other safety, dependence or health
4 issues relating to tobacco products as determined ap-
5 propriate by the Secretary.

6 **“SEC. 907. REQUIREMENTS RELATING TO NICOTINE AND**
7 **OTHER CONSTITUENTS.**

8 “(a) GENERAL RULE.—Except as provided in sub-
9 section (d), the Secretary, based on a finding under sub-
10 section (b), may adopt a performance standard under sec-
11 tion 905 that requires the modification of a tobacco prod-
12 uct in a manner that involves—

13 “(1) the gradual reduction of nicotine yields of
14 the product; or

15 “(2) the reduction or elimination of other con-
16 stituents or harmful components of the product.

17 “(b) REQUIRED FINDING.—

18 “(1) IN GENERAL.—A modification described in
19 subsection (a) shall not be adopted unless the Sec-
20 retary determines that the modification—

21 “(A) will result in a significant reduction
22 in the health risks associated with the use of
23 the tobacco product involved;

24 “(B) is technologically feasible; and

1 “(C) will not result in the creation of a sig-
2 nificant demand for contraband products or
3 other tobacco products that do not meet the
4 performance standard that requires the modi-
5 fication.

6 “(2) CONTRABAND PRODUCTS.—For purposes
7 of paragraph (1)(C), the Secretary, in determining
8 whether a significant demand for contraband prod-
9 ucts will be created, shall take in account—

10 “(A) the estimated number of dependent
11 tobacco product users residing in the United
12 States on the date on which the proposed modi-
13 fication is being considered;

14 “(B) the availability to such users, or lack
15 thereof, of alternative products; and

16 “(C) any other factors determined appro-
17 priate by the Secretary.

18 “(3) SUBSTANTIAL EVIDENCE.—A determina-
19 tion under paragraph (2) shall be based upon sub-
20 stantial evidence as demonstrated through an admin-
21 istrative record developed through formal rule-
22 making procedures as required under title 5, United
23 States Code. Any such determination, and any deter-
24 mination by the Secretary with respect to a petition
25 filed for an administrative review of the modifica-

1 tion, shall be subject to judicial review in the United
2 States District Court for the District of Columbia.

3 **【Should provisions of section 517 of FDCA apply?】**

4 “(c) LIMITATION.—Effective on the date that is 3
5 years after the date of enactment of the
6 _____ Act, and notwithstand-
7 ing any performance standard established under this chap-
8 ter, no **【cigarette/tobacco product】** shall be sold or other-
9 wise distributed in the United States that exceeds a 12
10 milligram tar yield, as determined using the testing meth-
11 odology used by the Federal Trade Commission on such
12 date of enactment.

13 “(d) 12-YEAR PROHIBITION.—During the 12-year
14 period beginning on the date of enactment of the
15 _____ Act, the Sec-
16 retary shall not adopt any performance standard under
17 section 905 that requires the complete elimination of nico-
18 tine yields in a tobacco product.

19 “(e) ACTION AFTER PROHIBITION.—

20 “(1) IN GENERAL.—After the expiration of the
21 12-year period referred to in subsection (d), the Sec-
22 retary may establish or amend any performance
23 standard to completely eliminate nicotine yields in a
24 tobacco product.

1 “(2) DETERMINATION.—Any performance
2 standard described in paragraph (1) shall not be
3 adopted unless the Secretary determines that the
4 standard—

5 “(A) will result in a significant overall re-
6 duction in the health risks associated with the
7 use of the tobacco product involved by consum-
8 ers, including individuals who continue to use
9 tobacco products but use such products less
10 often and individuals who stop using such prod-
11 ucts;

12 “(B) is technologically feasible; and

13 “(C) will not result in the creation of a sig-
14 nificant demand for contraband products or
15 other tobacco products that do not meet the
16 performance standard.

17 “(3) HEALTH BENEFITS.—In making a deter-
18 mination with respect to health risks under para-
19 graph (2)(A), the Secretary shall consider—

20 “(A) the number of dependent tobacco
21 users residing in the United States on the date
22 on which the proposed performance standard is
23 being considered;

24 “(B) the availability and demonstrated
25 market acceptance of alternative products;