

**NLWJC - Kagan**

**DPC - Box 049 - Folder-001**

**Tobacco-Settlement: New**

**Legislation-Harkin/Chafee [1]**

Tob - sec - new legis - Harkin amendment

and

**SUPPORT HARKIN AMENDMENT TO FUND  
FDA'S ON-GOING TEEN SMOKING INITIATIVE**

DRAFT

Tob - sec - FDA jurisdiction

Last fall, Congress overwhelmingly approved the Harkin-Chafco-Reed amendment to fund the on-going teen smoking initiative at FDA. The program is currently contracting with 45 states for fiscal year 1998 to ensure that children's access to tobacco products is restricted. However, at the current level of funding, states will only be able to check 20% of tobacco retailers for compliance with the law. The Committee bill only provides the FY 98 amount, \$34 million, for the FDA's on-going teen smoking initiative. This is clearly not sufficient.

The amendment that I am offering to the Agriculture Appropriations bill builds upon and strengthens the FDA's on-going teen smoking initiative. It authorizes the FDA's efforts to combat youth smoking, it fully funds the initiative, and it provides for an annual national survey of youth tobacco use.

***Authorizes FDA's Youth Anti-tobacco Initiative***

This amendment simply reaffirms the FDA's jurisdiction over the product and authorizes the FDA's on-going teen smoking initiative, including restricting children's access to tobacco, regulating tobacco advertising and labeling, setting manufacturing and performance standards, and allowing the development of reduced risk products.

***Fully Funds the Program***

The amendment fully funds the FDA's youth anti-tobacco efforts by imposing a tobacco industry assessment of \$20 per child who uses their products. This assessment would be based on an annual survey of 12-17 year olds to determine exactly which brands of tobacco children are using.

The assessment would raise approximately \$100 million for FY 99, bringing the total in the bill to \$134 million, the amount requested in the President's budget and the amount provided in S. 1415, the National Tobacco Policy and Youth Smoking Reduction Act. These funds would allow the FDA to provide increased resources for states to conduct compliance checks of tobacco retailers, increasing coverage from 20% to 60% of retailers. In addition, it would allow increased funding for education and outreach to retailers to ensure that they are aware of and comply with the ID check. Currently, FDA is only able to fund a four-week print media campaign in one media market in each state. With this amendment, they will be able to broaden the campaign to reach retailers throughout the state for a longer period of time. In addition, the amendment would provide funds for product regulation and enforcement of the advertising and marketing restrictions.

***Authorizes Annual Youth Tobacco Survey***

The amendment authorizes the Department of Health and Human Services to conduct a comprehensive, annual survey to provide more detailed accurate information on teen tobacco use, including information on teen tobacco use by brand. The survey will increase the number of young people surveyed and introduce computer assisted survey methods in order to improve the precision of the survey. The collection of precise data on youth tobacco use by brand will give parents new information and provide public health officials with new tools to address youth tobacco use. President Clinton has asked HHS to conduct such a survey.

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DRAFT

AMENDMENT NO. \_\_\_\_\_

Calendar No. \_\_\_\_\_

Purpose: To provide authority to the Food and Drug Administration with respect to tobacco.

IN THE SENATE OF THE UNITED STATES—105th Cong., 2d Sess.

**S. 2159**

Making appropriations for Agriculture, Rural Development, Food and Drug Administration, and Related Agencies programs for the fiscal year ending September 30, 1999, and for other purposes.

Referred to the Committee on \_\_\_\_\_  
and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. HARKIN

Viz:

1 At the end of the bill, add the following:

2 **TITLE \_\_\_\_\_—FOOD AND DRUG AD-**  
3 **MINISTRATION AUTHORITY**  
4 **OVER TOBACCO**

5 **SEC. \_\_\_\_01. ASSESSMENT ON MANUFACTURERS.**

6 (a) IN GENERAL.—Not later than June 1 of each fis-  
7 cal year, the Secretary of Health and Human Services (re-  
8 ferred to in this title as the "Secretary") shall assess each  
9 manufacturer of tobacco products an amount equal to \$20  
10 multiplied by the number of individuals under 18 years

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1 of age who used any tobacco product of such manufacturer  
2 in the preceding fiscal year, as determined using data  
3 gathered in the child tobacco use surveys under section  
4 \_\_\_\_02.

5 (b) DEPOSITS.—Amount collected under subsection  
6 (a) shall be deposited into the general fund of the Treas-  
7 ury.

8 (c) APPROPRIATION.—There are authorized to be ap-  
9 propriated in each fiscal year, and there are appropriated,  
10 an amount equal to the amount deposited into the Treas-  
11 ury under subsection (b) for that fiscal year, to be used  
12 by the Food and Drug Administration to carry out activi-  
13 ties relating to tobacco under the Federal Food, Drug and  
14 Cosmetic Act.

15 SEC. \_\_\_\_02. CHILD TOBACCO USE SURVEYS.

16 (a) ANNUAL PERFORMANCE SURVEY.—Not later  
17 than January 1, 1999, and annually thereafter, the Sec-  
18 retary shall conduct a survey to determine—

19 (1) the percentage of all young individuals who  
20 used a type of tobacco product within the 30-day pe-  
21 riod prior to the conduct of the survey; and

22 (2) the percentage of young individuals who  
23 identify each brand of each type of tobacco product  
24 as the usual brand smoked or used within such 30-  
25 day period.

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1 (b) YOUNG INDIVIDUALS.—For the purposes of this  
2 section, the term “young individuals” means individuals  
3 who are under 18 years of age.

4 (c) USE OF CERTAIN DATA OR METHODOLOGY.—

5 (1) IN GENERAL.—In carrying out this section,  
6 the Secretary may use the data collected through na-  
7 tional surveys of young individuals. Such surveys  
8 shall—

9 (A) be based on a nationally representative  
10 sample of at least 20,000 completed interviews  
11 of young individuals;

12 (B) be on a household-based in person sur-  
13 vey;

14 (C) measure the use of tobacco product  
15 within the past 30 days; and

16 (D) identify the usual brand of each type  
17 of tobacco product used within the past 30  
18 days.

19 (2) CONCLUSIVE ACCURATENESS.—A survey  
20 using the methodology described in paragraph (1)  
21 shall be deemed conclusively proper, correct and ac-  
22 curate for purposes of this Act. The Secretary may,  
23 by notice and comment rulemaking, subsequently  
24 adopt a different survey methodology.

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1 (3) FINAL DETERMINATION.—The determina-  
2 tion of the Secretary as to the amount and allocation  
3 of an assessment under section \_\_\_\_01 shall be final  
4 and the manufacturer shall pay such assessment  
5 within 30 days of the date on which the manufac-  
6 turer is assessed. Such payment shall be retained by  
7 the Secretary pending final judicial review of what,  
8 if any, change in the assessment is appropriate.

9 (4) REVIEW.—The amount of any assessment  
10 paid under section \_\_\_\_01 shall be subject to judi-  
11 cial review by the United States Court of Appeals  
12 for the District of Columbia Circuit, based on the  
13 arbitrary and capricious standard of section 706 of  
14 title 5, United States Code. Notwithstanding any  
15 other provision of law, no court shall have the au-  
16 thority to stay any payment due to the Secretary  
17 under section \_\_\_\_01 pending judicial review until  
18 the Secretary has made or failed to make a compli-  
19 ance determination, as described under this section,  
20 that has adversely affected the person seeking the  
21 review.

22 (5) NONAPPLICABILITY.—Chapter 35 of title  
23 44, United States Code, shall not apply to informa-  
24 tion required for the purposes of carrying out this  
25 subsection.

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1 (b) ADMINISTRATION.—

2 (1) TECHNICAL ADJUSTMENTS.—The Secretary  
3 may make technical changes in the manner in which  
4 the surveys are conducted under this section to re-  
5 flect improved methodology so long as adjustments  
6 are made to ensure that the results of the surveys  
7 are comparable from year to year.

8 (2) PARTICIPATION IN SURVEY.—Notwithstand-  
9 ing any other provision of law, the Secretary may  
10 conduct a survey under this section involving minors  
11 if the results of such survey with respect to such mi-  
12 nors are kept confidential and not disclosed.

13 (c) TOBACCO PRODUCT.—For the purposes of this  
14 title, cigarettes, cigars, little cigars, smokeless tobacco,  
15 and roll-your-own tobacco shall each be considered as a  
16 separate type of tobacco product.

17 (d) DE MINIMIS RULE.—The Secretary shall not im-  
18 pose an assessment on a manufacturer under section  
19 \_\_\_\_01 with respect to a type of tobacco product if the  
20 Secretary determines that the percentage of young individ-  
21 uals using such tobacco product (as determined using the  
22 annual surveys conducted by the Secretary under this sec-  
23 tion) is less than 0.5 percent of the total number of young  
24 individuals determined to have used tobacco products in  
25 the year involved.

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1 (e) ASSESSMENTS NONDEDUCTIBLE.—The payment  
2 of assessment under this title shall not be considered to  
3 be an ordinary and necessary expense in carrying on a  
4 trade or business for purposes of the Internal Revenue  
5 Code of 1986 and shall not be deductible.

6 (f) JUDICIAL REVIEW.—A manufacturer of tobacco  
7 products may seek judicial review of any action under this  
8 title only after the assessment involved has been paid by  
9 the manufacturer to the Department of the Treasury and  
10 only in the United States District Court for the District  
11 of Columbia.

12 **SEC. \_\_\_03. STATEMENT OF GENERAL AUTHORITY.**

13 The regulations promulgated by the Secretary in the  
14 rule dated August 28, 1996 (Vol. 61, No. 168 C.F.R.),  
15 adding part 897 to title 21, Code of Federal Regulations,  
16 shall be deemed to have been lawfully promulgated under  
17 the Food, Drug and Cosmetic Act as amended by this  
18 title. Such regulations shall apply to all tobacco products.

19 **SEC. \_\_\_04. NONAPPLICABILITY TO OTHER DRUGS OR DE-**  
20 **VICES.**

21 Nothing in this title, or an amendment made by this  
22 title, shall be construed to affect the regulation of drugs,  
23 devices, or other products that are not tobacco products  
24 by the Secretary under the Federal Food, Drug and Cos-  
25 metic Act.



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1 SEC. \_\_\_05. CONFORMING AMENDMENTS TO CONFIRM JU-  
2 RISDICTION.

3 (a) DRUG.—Section 201(g)(1) of the Federal Food,  
4 Drug, and Cosmetic Act (21 U.S.C. 321 (g)(1)) is amend-  
5 ed by striking “and (D)” and inserting “(D) nicotine in  
6 tobacco products, and (E)”.

7 (b) DEVICE.—Section 201(h) of the Federal Food,  
8 Drug, and Cosmetic Act (21 U.S.C. 321(h)) is amended—

9 (A) in paragraph (2), by striking “or” at  
10 the end;

11 (B) in paragraph (3), by striking “and” at  
12 the end and inserting “or”; and

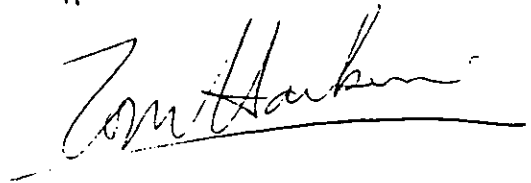
13 (C) by inserting after paragraph (3), the  
14 following:

15 “(4) nicotine-containing tobacco products, and”.

16 (c) RESTRICTED DEVICES.—Section 520(e)(1) of the  
17 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
18 321(h)) is amended by striking “or use—” and inserting  
19 “or use, including restrictions on the access to and the  
20 advertising and promotion of, tobacco products—”.

Tob - act - new legislation -  
Harkin/Chafee bill

S.L.C.



105TH CONGRESS  
1ST SESSION

**S.** \_\_\_\_\_

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IN THE SENATE OF THE UNITED STATES

Mr. HARKIN (for himself, Mr. CHAFEE, and Mr. GRAHAM) introduced the following bill; which was read twice and referred to the Committee on

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**A BILL**

To reduce tobacco use by children and others through an increase in the cost of tobacco products, the imposition of advertising and marketing limitations, assuring appropriate tobacco industry oversight, expanding the availability of tobacco use cessation programs, and implementing a strong public health prevention and education strategy that involves the private sector, schools, States, and local communities.

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

1 SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

2 (a) SHORT TITLE.—This Act may be cited as the  
3 “Kids Deserve Freedom From Tobacco Act of 1998” or  
4 the “KIDS Act”.

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

- Sec. 1. Short title; table of contents.
- Sec. 2. Findings.
- Sec. 3. Purpose.
- Sec. 4. Scope and effect.
- Sec. 5. Definitions.

TITLE I—INCENTIVES TO REDUCE YOUTH TOBACCO USE

Subtitle A—National Tobacco Trust Fund

- Sec. 101. Establishment.
- Sec. 102. Payments by tobacco product manufacturers.
- Sec. 103. Enforcement.

Subtitle B—Payments to States

- Sec. 111. Payments to States.
- Sec. 112. State bonus payments.

Subtitle C—Annual Youth Tobacco Use Reductions

- Sec. 131. Purpose.
- Sec. 132. Child tobacco use surveys.
- Sec. 133. Reduction in underage tobacco product usage.
- Sec. 134. Noncompliance.
- Sec. 135. Enforcement.

TITLE II—REGULATION OF THE TOBACCO INDUSTRY

Subtitle A—Food and Drug Administration Jurisdiction and General  
Authority

- Sec. 201. Statement of general authority.
- Sec. 202. Nonapplicability to other drugs or devices.
- Sec. 203. Conforming amendments to confirm jurisdiction.
- Sec. 204. General rule.
- Sec. 205. Safety and efficacy standard and recall authority.

Subtitle B—Regulation of Tobacco Products

- Sec. 211. Performance standards.
- Sec. 212. Application of Federal Food, Drug, and Cosmetic Act to tobacco  
products.

"SUBCHAPTER F—TOBACCO PRODUCT DEVELOPMENT, MANUFACTURING, AND ACCESS RESTRICTIONS, LICENSING, AND ANTI-SMUGGLING

"PART A—TOBACCO PRODUCT DEVELOPMENT, MANUFACTURING, AND ACCESS RESTRICTIONS

- "Sec. 570. Promulgation of regulations.
- "Sec. 571. Mail-order sales.
- "Sec. 572. Tobacco product warnings and packaging.
- "Sec. 573. General responsibilities of manufacturers, distributors and retailers.
- "Sec. 574. Disclosure and reporting of tobacco and nontobacco ingredients and constituents.
- "Sec. 575. Reduced risk products.
- "Sec. 576. Access to company information.
- "Sec. 577. Oversight of tobacco product manufacturing.
- "Sec. 578. Preservation of State and local authority.
- "Sec. 579. General responsibilities of manufacturers, distributors and retailers.

Sec. 213. Funding.

Sec. 214. Repeals.

Subtitle C—Manufacturer and Product Seller Licensing and Anti-Smuggling

- Sec. 221. Definitions.
- Sec. 222. Minimal Federal licensing and registration program.
- Sec. 223. Licensing and retailer registration.
- Sec. 224. Unlawful acts.
- Sec. 225. Penalties and compromise of liability.
- Sec. 226. General administrative provisions.
- Sec. 227. Funding.
- Sec. 228. Transitional rules.
- Sec. 229. Rules and regulations.
- Sec. 230. Severability.
- Sec. 231. Effect on State or local law.
- Sec. 232. Amendment to Contraband Cigarette Trafficking Act.

Subtitle D—Penalties

- Sec. 241. Penalties.
- Sec. 242. Application of penalties with respect to violations of certain licensing provisions.

TITLE III—PUBLIC HEALTH INITIATIVES

Subtitle A—State-Federal Anti-Tobacco Partnership

CHAPTER 1—SCHOOL- AND COMMUNITY-BASED PROGRAMS

- Sec. 301. School- and community-based programs.
- Sec. 302. National event sponsorship program.

CHAPTER 2—COUNTER-ADVERTISING PROGRAMS

- Sec. 311. Federal-State counter-advertising programs.

CHAPTER 3—NATIONAL CESSATION PROGRAM

- Sec. 321. National tobacco cessation program.
- Sec. 322. Reports, data, and audits.

Subtitle B—Health Research Program

CHAPTER 1—NATIONAL FUND FOR HEALTH RESEARCH

- Sec. 331. Establishment of National Fund for Health Research.

CHAPTER 2—TOBACCO PREVENTION RESEARCH

- Sec. 335. National Tobacco Research Task Force.
- Sec. 336. Research activities.
- Sec. 337. Tobacco prevention database and evaluation.

Subtitle C—Miscellaneous Provisions

- Sec. 341. Limitation on administrative costs.
- Sec. 342. Withholding.
- Sec. 343. Nondiscrimination.
- Sec. 344. International tobacco control.

TITLE IV—LIABILITY PROVISIONS AND CONSENT DECREES

- Sec. 400. Dismissal of and limitations on civil actions.

Subtitle A—Liability Provisions

- Sec. 401. National victims' compensation fund.
- Sec. 402. Rule of construction.
- Sec. 403. Attorney's fees and expenses.
- Sec. 404. Public disclosure of tobacco industry documents.

Subtitle B—Consent Decrees

- Sec. 411. Consent decrees.

TITLE V—TOBACCO FARM FAMILY AND COMMUNITY ASSISTANCE TRUST FUND

- Sec. 501. Tobacco farm family and community assistance trust fund.

TITLE VI—REDUCING EXPOSURE TO ENVIRONMENTAL TOBACCO SMOKE

- Sec. 601. Education and outreach.
- Sec. 602. Involuntary exposure to environmental tobacco smoke.
- Sec. 603. Coverage of Congressional buildings.

TITLE VII—MISCELLANEOUS PROVISIONS

- Sec. 701. Whistleblower protections.
- Sec. 702. Prohibition on use of funds to facilitate the exportation or promotion of tobacco.
- Sec. 703. Provisions relating to Native Americans.
- Sec. 704. Preservation of State and local authority.

1 **SEC. 2. FINDINGS.**

2 Congress makes the following findings:

3 (1) Tobacco products are the foremost prevent-  
4 able health problem facing America today. More  
5 than 400,000 individuals die each year as a result  
6 of tobacco induced illnesses and conditions.

7 (2) The use of tobacco products by the Nation's  
8 children is a pediatric disease of epic and worsening  
9 proportions that results in new generations of to-  
10 bacco-dependent children and adults.

11 (3) Virtually all new users of tobacco products  
12 are under legal age. Every day, 3,000 young people  
13 become regular smokers. Of these children, 1,000  
14 will die prematurely from a tobacco-related disease.

15 (4) Tobacco products are inherently dangerous  
16 and cause cancer, heart disease, and other serious  
17 adverse health effects.

18 (5) Tobacco advertising and marketing is often  
19 deceptive and misleading and contributes signifi-  
20 cantly to the use of nicotine-containing tobacco prod-  
21 ucts by children.

22 (6) Because past efforts to restrict the advertis-  
23 ing and marketing of tobacco products have failed to  
24 effectively curb tobacco use by children, new, more  
25 comprehensive restrictions on the sale, promotion,  
26 and distribution of such products are needed.

1           (7) Federal and State governments have lacked  
2 the resources to adequately address the public health  
3 and societal problems caused by the use of tobacco  
4 products.

5           (8) Federal and State public health officials,  
6 the public health community, Congress, and the pub-  
7 lic at large recognize that the tobacco industry  
8 should be subject to ongoing oversight.

9           (9) Under Article 1, section 8 of the Constitu-  
10 tion, Congress is vested with the responsibility for  
11 regulating interstate commerce.

12           (10) The sale, distribution, marketing, advertis-  
13 ing and use of tobacco products are activities in and  
14 substantially affecting interstate commerce. Such  
15 products are sold, marketed, advertised, and distrib-  
16 uted in interstate commerce on a nationwide basis,  
17 and have a substantial effect on the Nation's econ-  
18 omy.

19           (11) The sale, distribution, marketing, advertis-  
20 ing, and use of such products substantially affect  
21 interstate commerce through the health care and  
22 other costs attributable to the use of tobacco prod-  
23 ucts.

24           (12) Civil actions against tobacco product man-  
25 ufacturers and others are pending in Federal and

1 State courts arising from the sale, distribution, mar-  
2 keting, advertising, and use of tobacco products.  
3 Among these actions are cases brought by the attor-  
4 neys general of more than 40 States, certain cities  
5 and counties, the Commonwealth of Puerto Rico,  
6 and other parties seeking to recover monies ex-  
7 pended to treat tobacco-related diseases and for the  
8 protection of minors and consumers, as well as pen-  
9 alties and other relief for violations of antitrust,  
10 health, consumer protection, and other laws.

11 (13) Civil actions have been filed throughout  
12 the United States against tobacco product manufac-  
13 turers and their distributors, trade associations, law  
14 firms and consultants on behalf of individuals or  
15 classes of individuals claiming to be dependent upon  
16 and injured by tobacco products.

17 (14) It is in the public interest for Congress to  
18 adopt comprehensive public health legislation be-  
19 cause of tobacco's unique position in the Nation's  
20 history and economy; the need to prevent the sale,  
21 distribution, marketing, and advertising of tobacco  
22 products to persons below legal age; and the need to  
23 educate the public, especially young people, regard-  
24 ing the health effects of using tobacco products.



1           (15) The public interest requires a timely, fair,  
2 equitable, and consistent result that will serve the  
3 public interest by—

4           (A) providing that a portion of the costs of  
5 treatment for diseases and adverse health ef-  
6 fects associated with the use of tobacco prod-  
7 ucts is borne by the manufacturers of these  
8 products; and

9           (B) restricting throughout the Nation the  
10 sale, distribution, marketing, and advertising of  
11 tobacco products only to persons of legal age.

12           (16) The benefits to the Nation of enacting  
13 Federal legislation to accomplish these goals would  
14 be significant in human and economic terms.

15           (17) The Food and Drug Administration has  
16 found that reducing the use of tobacco by minors by  
17 50 percent would prevent well over 60,000 pre-  
18 mature deaths, and that the monetary value of its  
19 regulations on tobacco will save up to  
20 \$43,000,000,000 each year in reduced medical costs,  
21 improved productivity, and the avoidance of pre-  
22 mature deaths.

23           (18) The Nation's major tobacco product manu-  
24 facturers have pledged in an agreement reached with  
25 several State attorneys general that such manufac-

1       turers will comply fully with increased Federal regula-  
2       tion, substantial industry payments, and focus in-  
3       tense efforts on dramatic reductions in youth access  
4       and underage usage of tobacco products. Further,  
5       the industry has agreed to pay significant penalties  
6       for failure to meet targets for the reduction of youth  
7       use. In addition, the industry has actively sought  
8       passage of tobacco settlement legislation by Con-  
9       gress.

10       (19) As new restrictions on the sale of tobacco  
11       products are enacted, greater controls on the dis-  
12       tribution of tobacco products will be needed to en-  
13       sure that the new restriction are not evaded.

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

17 **SEC. 3. PURPOSE.**

18       It is the purpose of this Act to—

19       (1) dramatically reduce the use of tobacco prod-  
20       ucts, especially among children;

21       (2) assist individuals who are currently addicted  
22       to tobacco products in overcoming that addiction;

23       (3) affirm the authority of the Food and Drug  
24       Administration to regulate the manufacture, market-  
25       ing, distribution, and sale of tobacco products under

1 the Food, Drug and Cosmetic Act (21 U.S.C. 321  
2 et seq.);

3 (4) require that the tobacco industry fund both  
4 Federal and State oversight of the tobacco industry  
5 from on-going payments by tobacco product manu-  
6 facturers;

7 (5) require tobacco product manufacturers to  
8 provide ongoing funding to be used for an aggressive  
9 Federal, State, and local enforcement program and  
10 for a nationwide retail licensing system to prevent  
11 minors from obtaining tobacco products, while ex-  
12 pressly permitting and providing incentives to the  
13 States to adopt additional measures that further re-  
14 duce the products' use;

15 (6) impose severe financial surcharges on to-  
16 bacco product manufacturers if they do not substan-  
17 tially reduce tobacco use by children;

18 (7) authorize the Food and Drug Administra-  
19 tion to set national standards controlling the manu-  
20 facture of tobacco products and the identity, public  
21 disclosure, and amount of ingredients used in such  
22 products;

23 (8) provide new and flexible enforcement au-  
24 thority to ensure that the tobacco industry makes ef-

1       forts to develop and introduce tobacco products that  
2       are less harmful;

3           (9) ensure that the public is better informed by  
4       requiring that manufacturers of tobacco products  
5       disclose all research which has not previously been  
6       made available, as well as all research generated in  
7       the future relating to the health and dependency ef-  
8       fects or safety of tobacco products;

9           (10) require tobacco product manufacturers to  
10       provide funding for a variety of public health initia-  
11       tives;

12          (11) establish enhanced protections against en-  
13       vironmental tobacco smoke while also permitting  
14       State and local governments to enact additional and  
15       more stringent standards;

16          (12) authorize and fund from payments by to-  
17       bacco manufacturers a continuing national counter-  
18       advertising and tobacco control campaign which  
19       seeks to educate and discourage the public from be-  
20       ginning or continuing to use tobacco products;

21          (13) establish a mechanism to compensate the  
22       States in the settlement of their various claims  
23       against tobacco product manufacturers;

1           (14) authorize and fund from payments by to-  
2       bacco product manufacturers a nationwide program  
3       of smoking cessation;

4           (15) establish and fund from payments by to-  
5       bacco product manufacturers a Victims' Compensa-  
6       tion Fund; and

7           (16) continue to permit the sale of tobacco  
8       products to adults in conjunction with measures to  
9       ensure that they are not sold or accessible to under-  
10      age purchasers.

11 **SEC. 4. SCOPE AND EFFECT.**

12       (a) **INTENDED EFFECT.**—This Act is not intended by  
13 Congress to—

14           (1) establish a precedent with regard to any  
15       other industry, situation, circumstance, or legal ac-  
16       tion;

17           (2) be construed to provide civil or criminal im-  
18       munity; or

19           (3) except as provided in this Act, affect any  
20       action pending in Federal or State court, or any  
21       agreement, consent decree, or contract of any kind.

22       (b) **TAXATION.**—Notwithstanding any other provision  
23 of law, this Act (and the amendments made by this Act)  
24 shall not affect any authority of the Secretary of the  
25 Treasury (including any authority assigned to the Bureau

1 of Alcohol, Tobacco and Firearms) or of State or local gov-  
2 ernments with regard to the taxation of tobacco or tobacco  
3 products.

4 (c) FEDERAL TRADE COMMISSION AUTHORITY.—Ex-  
5 cept as expressly provided in this Act, nothing in this Act  
6 (or the amendments made by this Act) shall be construed  
7 to reduce any authority of the Federal Trade Commission  
8 over tobacco or tobacco products.

9 (d) AGRICULTURAL ACTIVITIES.—Except as other-  
10 wise provided in this Act, nothing in this Act shall be con-  
11 strued to reduce any authority under existing law of the  
12 Secretary of Agriculture regarding the growing, cultiva-  
13 tion or curing of raw tobacco.

14 **SEC. 5. DEFINITIONS.**

15 In this Act:

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

20 (2) CIGAR.—The term “cigar” means any roll  
21 of tobacco wrapped in leaf tobacco or in any sub-  
22 stance containing tobacco (other than any roll of to-  
23 bacco which is a cigarette or cigarillo within the  
24 meaning of paragraph (3) or (5)).

1           (3) CIGARETTE.—The term “cigarette” means  
2 any product that contains nicotine, is intended to be  
3 burned under ordinary conditions of use, and con-  
4 sists of—

5           (A) any roll of tobacco wrapped in paper  
6 or in any substance not containing tobacco; or

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

13           (4) CIGARETTE TOBACCO.—The term “cigarette  
14 tobacco” means any product that consists of loose  
15 tobacco that contains or delivers nicotine and is in-  
16 tended for use by consumers in a cigarette. Unless  
17 otherwise stated, the requirements of this Act for  
18 cigarettes shall also apply to cigarette tobacco.

19           (5) CIGARILLOS.—The term “cigarillos” means  
20 any roll of tobacco wrapped in leaf tobacco or any  
21 substance containing tobacco (other than any roll of  
22 tobacco which is a cigarette within the meaning of  
23 paragraph (3)) and as to which 1,000 units weigh  
24 not more than 3 pounds.

1           (6) DISTRIBUTOR.—The term “distributor”  
2 means any person who furthers the distribution of  
3 tobacco products, whether domestic or imported, at  
4 any point from the original place of manufacture to  
5 the person who sells or distributes the product to in-  
6 dividuals for personal consumption. Such term shall  
7 not include common carriers.

8           (7) LITTLE CIGAR.—The term “little cigar”  
9 means any roll of tobacco wrapped in leaf tobacco or  
10 any substance containing tobacco (other than any  
11 roll of tobacco which is a cigarette within the mean-  
12 ing of paragraph(3)) and as to which 1,000 units  
13 weigh not more than 3 pounds.

14           (8) MANUFACTURER.—The term “manufac-  
15 turer” means any person, including any repacker or  
16 relabeler, who manufactures, fabricates, assembles,  
17 processes, packs, or labels a tobacco product. Any  
18 successor or assign of a manufacturer, as well as  
19 any person affiliated with the manufacturer, shall  
20 have all of the manufacturer’s responsibilities and li-  
21 abilities as set forth in this Act.

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



1           (10) PACKAGE.—The term “package” means  
2 the innermost sealed container, irrespective of the  
3 material from which such container is made, in  
4 which a tobacco product is placed by the manufac-  
5 turer and in which such tobacco product is offered  
6 for sale to a member of the general public.

7           (11) PERSON.—The term “person” means a  
8 firm, partnership, association, corporation, legal rep-  
9 resentative, trustee, receiver or any other legally rec-  
10 ognized entity, including an individual.

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

16           (13) POINT OF SALE.—The term “point of  
17 sale” means any location at which an individual can  
18 purchase or otherwise obtain tobacco products for  
19 personal consumption.

20           (14) RETAILER.—The term “retailer” means  
21 any person who sells or distributes tobacco products  
22 at retail, or who operates a facility where vending  
23 machines or self-service displays are permitted under  
24 this Act.

1           (15) ROLL-YOUR-OWN TOBACCO.—The term  
2 “roll-your-own tobacco” means any tobacco which,  
3 because of its appearance, type, packaging, or label-  
4 ing, is suitable for use and likely to be offered to,  
5 or purchased by, consumers as tobacco for making  
6 cigarettes.

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

11           (17) SECRETARY.—The term “Secretary”  
12 means the Secretary of Health and Human Services.

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

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

1           (20) TOBACCO.—The term ‘tobacco’ means to-  
2       bacco in its unmanufactured form.

3           (21) TOBACCO PRODUCT.—The term “tobacco  
4       product” means cigarettes, cigarette tobacco, smoke-  
5       less tobacco, little cigars, roll-your-own products, ci-  
6       gars, cigarillos, pipe tobacco, roll-your-own products,  
7       and any other product made or derived from tobacco  
8       intended for human consumption.

9           **TITLE I—INCENTIVES TO**  
10       **REDUCE YOUTH TOBACCO USE**  
11       **Subtitle A—National Tobacco Trust**  
12               **Fund**

13       **SEC. 101. ESTABLISHMENT.**

14       (a) ESTABLISHMENT AND TRUSTEES.—

15           (1) IN GENERAL.—There is established in the  
16       Treasury of the United States a trust fund to be  
17       known as the “National Tobacco Trust Fund” (re-  
18       ferred to in this Act as the “Trust Fund”), consist-  
19       ing of such amounts as may be appropriated or cred-  
20       ited to the Trust Fund.

21           (2) TRUSTEES.—The trustees of the Trust  
22       Fund shall be the Secretary of the Treasury, the  
23       Secretary of Health and Human Services, and the  
24       Attorney General.

1 (b) TRANSFERS.—There are hereby appropriated and  
2 transferred to the Trust Fund an amount equal to the—

3 (1) amounts received under the annual assess-  
4 ments made under section 102;

5 (2) amounts paid as fines or penalties, includ-  
6 ing interest thereon, under section 103; and

7 (3) amounts repaid or recovered under subtitle  
8 B, including interest thereon.

9 (c) REPAYABLE ADVANCES.—

10 (1) AUTHORIZATION.—There are authorized to  
11 be appropriated to the Trust Fund, as repayable ad-  
12 vances, such sums as may from time to time be nec-  
13 essary to make the expenditures described in sub-  
14 section (d).

15 (2) REPAYMENT WITH INTEREST.—Repayable  
16 advances made to the Trust Fund shall be repaid,  
17 and interest on such advances shall be paid, to the  
18 general fund of the Treasury when the Secretary of  
19 the Treasury determines that moneys are available  
20 in the Trust Fund for such purposes.

21 (3) RATE OF INTEREST.—Interest on advances  
22 made pursuant to this subsection shall be at a rate  
23 determined by the Secretary of the Treasury (as of  
24 the close of the calendar month preceding the month  
25 in which the advance is made) to be equal to the

1 current average market yield on outstanding market-  
2 able obligations of the United States with remaining  
3 period to maturity comparable to the anticipated pe-  
4 riod during which the advance will be outstanding.

5 (d) EXPENDITURES FROM TRUST FUND.—

6 (1) APPROPRIATIONS.—

7 (A) IN GENERAL.—Amounts in the Na-  
8 tional Tobacco Trust Fund shall be appro-  
9 priated by the Committee on Appropriations of  
10 the House of Representatives and the Commit-  
11 tee on Appropriations of the Senate exclusively  
12 for the purposes authorized in this Act.  
13 Amounts appropriated for each program au-  
14 thorized under this Act shall be determined by  
15 the percentages contained in the tables in para-  
16 graph (2).

17 (B) PERMISSIBLE TRANSFERS.—Notwith-  
18 standing subparagraph (A), the Committees re-  
19 ferred to in such subparagraph may transfer  
20 funds among the programs authorized under  
21 this Act if the Committee reports and state-  
22 ment of managers that accompany any such ap-  
23 propriations Act provide an explanation of any  
24 such transfers, except that no transfers shall be  
25 made under this subparagraph—

1 (i) to the National Institutes of  
2 Health;

3 (ii) for purposes of making payments  
4 under section 111;

5 (iii) from the National Victim's Com-  
6 pensation Fund; or

7 (iv) from the amounts available for  
8 States under section 111(b)(1).

9 (2) EXPENDITURE TABLES.—For purposes of  
10 paragraph (1), amounts shall be made available in  
11 each fiscal year as follows:

12 (A) STATE REIMBURSEMENT; FOOD AND  
13 DRUG ADMINISTRATION.—

STATE SHARE ██████████  
(Percentage of amount in Trust  
Fund for fiscal year involved)

Fiscal Year	Base Pay- ment	Block Grant	Bonus Pool
1999	35.0	35.0	0.00
2000	10.0	10.0	0.00
2001	9.0	9.0	0.00
2002	10.0	10.0	2.67
2003	13.0	13.0	2.67
2004	13.0	13.0	2.67
2005	16.0	16.0	2.67
2006	16.0	16.0	2.67
2007	16.0	16.0	2.67
2008	16.0	16.0	2.67
2009	16.0	16.0	2.67
2010	16.0	16.0	2.67
2011	16.0	16.0	2.67
2012	16.0	16.0	2.67
2013	16.0	16.0	2.67
2014	16.0	16.0	2.67
2015-2024	16.0	16.0	2.67

14

(B) PUBLIC HEALTH PROGRAMS.—

## PUBLIC HEALTH

(Percentage of amount in Trust Fund for fiscal year involved)

Fiscal Year	Smoking Cessation	Counter-advertising	Community-Based Prevention	School-Based Prevention	Event Sponsorship	Youth Database
1999	1.3333	2.6667	2.6667	1.3333	0.0	2.6667
2000	6.6667	4.0000	3.3333	1.1667	0.5	1.1667
2001	5.3333	3.2000	3.4667	1.0667	0.4	0.9333
2002	5.3333	2.6667	3.3333	1.0667	0.4	0.9333
2003	5.3333	2.9333	4.2667	1.2000	0.4	0.9333
2004	5.3333	2.9333	5.0667	1.3333	0.4	0.9333
2005	5.3333	2.9333	5.0667	1.4667	0.4	0.9333
2006	8.0000	2.6667	5.0667	1.4667	0.4	0.9333
2007	8.0000	2.6667	5.0667	1.4667	0.4	0.9333
2008	8.0000	2.6667	5.0667	1.4667	0.4	0.9333
2009	8.0000	2.6667	5.0667	1.4667	0.4	0.9333
2010	8.0000	2.6667	5.0667	1.6000	0.0	0.9333
2011	8.0000	2.6667	5.0667	1.6000	0.0	0.9333
2012	8.0000	2.6667	5.0667	1.6000	0.0	0.9333
2013	8.0000	2.6667	5.0667	1.6000	0.0	0.9333
2014	8.0000	2.6667	5.0667	1.6000	0.0	0.9333
2015-2024	8.0000	2.9333	5.3333	1.6000	0.0	0.9333

1

## (C) RESEARCH.—

## RESEARCH / FDA

(Percentage of amount in Trust Fund for fiscal year involved)

Fiscal Year	Health Research	Tobacco Prevention	FDA
1999	2.67	0.0	2.667
2000	21.5	4.0	2.0
2001	17.2	3.2	1.6
2002	17.2	3.2	1.6
2003	17.2	3.2	1.6
2004	17.2	3.2	1.6
2005	17.2	3.2	1.6
2006	17.2	3.2	1.6
2007	17.2	3.2	1.6
2008	17.2	3.2	1.6
2009	17.2	3.2	1.6
2010	17.2	3.2	1.6
2011	17.2	3.2	1.6
2012	17.2	3.2	1.6
2013	17.2	3.2	1.6
2014	17.2	3.2	1.6
2015-2024	17.2	3.2	1.6

2

## (D) MISCELLANEOUS PROGRAMS AND AC-

3

TIVITIES.—

## MISCELLANEOUS

(Percentage of amount in Trust Fund for fiscal year involved)

Fiscal Year	Agri- culture	Victims' Com- pensation	ETS	Native Americans	Inter- national Education	Anti- Smuggling
1999	0.0000	0.0000	0.0000	0.3333	0.3333	1.3333
2000	4.5000	26.665	1.3333	1.3333	0.6667	0.6667
2001	21.0667	21.332	1.0667	1.0667	0.5333	0.5333
2002	17.0667	21.332	1.0667	1.0667	0.5333	0.5333
2003	9.7333	21.332	1.0667	1.0667	0.5333	0.5333
2004	8.8000	21.332	1.0667	1.0667	0.5333	0.5333
2005	2.6667	21.332	1.0667	1.0667	0.5333	0.5333
2006	0.2667	21.332	1.0667	1.0667	0.5333	0.5333
2007	0.2667	21.332	1.0667	1.0667	0.5333	0.5333
2008	0.2667	21.332	1.0667	1.0667	0.5333	0.5333
2009	0.2667	21.332	1.0667	1.0667	0.5333	0.5333
2010	0.5333	21.332	1.0667	1.0667	0.5333	0.5333
2011	0.5333	21.332	1.0667	1.0667	0.5333	0.5333
2012	0.5333	21.332	1.0667	1.0667	0.5333	0.5333
2013	0.5333	21.332	1.0667	1.0667	0.5333	0.5333
2014	0.5333	21.332	1.0667	1.0667	0.5333	0.5333
2015-2024	0.0000	21.332	1.0667	1.0667	0.5333	0.5333

1           (3) BUDGETARY IMPACT.—Amounts appro-  
2           priated under paragraph (1) and outlays flowing  
3           from such appropriations shall not be taken into ac-  
4           count for purposes of any budget enforcement proce-  
5           dures under the Congressional Budget of 1974 and  
6           the Balanced Budget and Emergency Deficit Control  
7           Act of 1985.

8           (3) DEFINITIONS AND USE OF FUNDS.—With  
9           respect to the tables in paragraph (2)—

10           (A) the term “base payment” as used in  
11           the table under subparagraph (A) means the  
12           amounts for payments to States under section  
13           111(b)(1);

14           (B) the term “block grant” as used in the  
15           table under subparagraph (A) means the



1 amount for payments to States under section  
2 111(b)(2);

3 (C) the term "bonus pool" as used in the  
4 table under subparagraph (A) means the  
5 amounts for payments to States under section  
6 112;

7 (D) the term "smoking cessation" as used  
8 in the table under subparagraph (B) means the  
9 amounts to carry out section 321;

10 (E) the term "counter-advertising" as used  
11 in the table under subparagraph (B) means the  
12 amounts to carry out section 311;

13 (F) the term "community-based preven-  
14 tion" as used in the table under subparagraph  
15 (B) means the amounts to carry out section  
16 301;

17 (G) the term "school-based prevention" as  
18 used in the table under subparagraph (B)  
19 means the amounts to carry out section 301;

20 (H) the term "event sponsorship" as used  
21 in the table under subparagraph (B) means the  
22 amounts to carry out section 302;

23 (I) the term "youth database" as used in  
24 the table under subparagraph (B) means the  
25 amounts to carry out section 337;

1           (J) the term “biomedical research” as used  
2           in the table under subparagraph (C) means the  
3           amounts to carry out section 331;

4           (K) the term “applied research” as used in  
5           the table under subparagraph (C) means the  
6           amounts to carry out section 336;

7           (L) the term “FDA” as used in the table  
8           under subparagraph (C) means the amounts for  
9           the Food and Drug Administration to carry out  
10          title II (and the amendments made by such  
11          title);

12          (M) the term “agriculture” as used in the  
13          table under subparagraph (D) means the  
14          amounts to carry out title V;

15          (N) the term “victims’ compensation” as  
16          used in the table under subparagraph (D)  
17          means the amounts to carry out section 401;

18          (O) the term “ETS” as used in the table  
19          under subparagraph (D) means the amounts to  
20          carry out title VI;

21          (P) the term “Native Americans” as used  
22          in the table under subparagraph (D) means the  
23          amounts to carry out section 703;

24          (Q) the term “international education” as  
25          used in the table under subparagraph (D)

1 means the amounts to carry out section 344;  
2 and

3 (R) the term "anti-smuggling" as used in  
4 the table under subparagraph (D) means the  
5 amounts to carry out section 226.

6 (e) PROHIBITION ON TREATMENT AS OVERPAY-  
7 MENT.—

8 (1) IN GENERAL.—Section 1903(d)(3) of the  
9 Social Security Act (42 U.S.C. 1396b(d)(3)) is  
10 amended—

11 (A) by inserting "(A)" before "The"; and

12 (B) by adding at the end the following:

13 "(B) Subparagraph (A) and paragraph (2)(B) shall  
14 not apply to any amount recovered or paid to a State as  
15 part of a settlement or judgment reached in litigation initi-  
16 ated or pursued by a State against one or more manufac-  
17 turers of tobacco products, as defined in section 5702(d)  
18 of the Internal Revenue Code of 1986."

19 (2) EFFECTIVE DATE.—The amendment made  
20 by subsection (a) applies to amounts recovered or  
21 paid to a State before, on, or after the date of enact-  
22 ment of this Act.

23 (f) BUDGETARY EFFECT.—

24 (1) IN GENERAL.—The Director of the Office of  
25 Management and Budget shall annually determine

1           whether the payments made under section 102 have  
2           resulted in a decrease in the amount of revenues col-  
3           lected under the excise tax provisions of chapter 52  
4           of the Internal Revenue Code of 1986.

5           (2) NOTICE.—The Director shall notify the  
6           trustees in any year in which the Director deter-  
7           mines that a shortfall described in paragraph (1) ex-  
8           ists. Upon such a notification, the trustees shall  
9           transfer from the Trust Fund to the General Fund  
10          of the Treasury an amount necessary to make up  
11          such shortfall.

12          (g) INCREASE IN AMOUNTS.—The amounts described  
13          in the tables under subsection (d)(2) shall be adjusted by  
14          the Trustees to account for any adjustments made under  
15          section 102(b) relating to inflationary adjustments or sec-  
16          tion 102(e)(1) relating to the deductibility of payments by  
17          manufacturers.

18          **SEC. 102. PAYMENTS BY TOBACCO PRODUCT MANUFACTUR-**  
19                                   **ERS.**

20          (a) PAYMENTS.—

21           (1) INITIAL PAYMENT.—Not later than 90 days  
22          after the date of enactment of this Act, each manu-  
23          facturer shall pay to the Trust Fund an amount  
24          that bears the same ratio to \$10,000,000,000 as the  
25          tobacco product market share of the manufacturer

1 bears to the tobacco market share of all tobacco  
2 manufacturers for the year preceding the year in  
3 which the determination is being made.

4 (2) SUBSEQUENT PAYMENT.—Not later than  
5 October 1, 1999, each manufacturer shall pay to the  
6 Trust Fund an amount that bears the same ratio to  
7 \$20,000,000,000 as the tobacco product market  
8 share of the manufacturer bears to the tobacco mar-  
9 ket share of all tobacco manufacturers for the year  
10 preceding the year in which the determination is  
11 being made.

12 (3) ANNUAL PAYMENTS AND COLLECTION.—  
13 Not later than October 1, 2000, and each October  
14 1 thereafter, each manufacturer shall pay to the  
15 Trust Fund an amount that bears the same ratio to  
16 \$25,000,000,000 as the tobacco product market  
17 share of the manufacturer bears to the tobacco mar-  
18 ket share of all tobacco manufacturers for the year  
19 preceding the year in which the determination is  
20 being made.

21 (4) PAYMENTS APPLICABLE TO CIGARS.—Prior  
22 to the date of the completion of the first annual per-  
23 formance survey under section 132(a), the Secretary  
24 shall not consider the manufacture of cigars for pur-

1       poses of determining the amount that a manufac-  
2       turer shall be assessed under this subsection.

3           (5) NO REQUIREMENT FOR PAYMENT.—The  
4       Secretary shall not require that a manufacturer  
5       make a payment under this subsection for any to-  
6       bacco product for any fiscal year if the Secretary de-  
7       termines that the tobacco product involved as manu-  
8       factured by the manufacturer is used by less than  
9       0.5 percent of the total number of children deter-  
10      mined to have used any tobacco product as manufac-  
11      tured by all manufacturers for the year involved.

12          (6) APPLICATION TO CERTAIN MANUFACTUR-  
13      ERS.—The provisions of this subsection shall apply  
14      to a manufacturer that begins manufacturing to-  
15      bacco products after the date of enactment of this  
16      Act, except that if such a manufacturer fails to  
17      make payments as provided for in this subsection,  
18      such manufacturer shall pay to the Trust Fund an  
19      amount equal to 150 percent of the amount that  
20      such manufacturer would have paid under this sub-  
21      section.

22          (7) NONAPPLICATION TO CERTAIN MANUFAC-  
23      TURERS.—

24            (A) EXEMPTION.—A manufacturer de-  
25      scribed in subparagraph (B) shall be exempt

1 from the requirements of this section relating  
2 to—

3 (i) the payment of an initial payment  
4 under subsection (a)(1); and

5 (ii) the payment of an amount equal  
6 to 40 percent of the annual assessments  
7 under this section otherwise applicable to  
8 such manufacturer.

9 (B) MANUFACTURER.—A manufacturer  
10 described in this subparagraph is a manufac-  
11 turer that—

12 (i) has resolved tobacco-related civil  
13 actions with more than 25 States prior to  
14 January 1, 1998 through written settle-  
15 ment agreements signed by the attorneys  
16 general of such States; and

17 (ii) not later than December 31,  
18 1998, provides to all other States the op-  
19 portunity to enter into written settlement  
20 agreements that are substantially similar  
21 to the agreements described in clause (i)  
22 and provides such other States with the  
23 most favorable annual payment terms pro-  
24 vided in the settlement agreements de-  
25 scribed in clause (i).

1                   (C) LIMITATION.—The provisions of sub-  
2                   paragraph (A)(ii) shall apply only to assess-  
3                   ments on cigarettes to the extent that such  
4                   cigarettes constitute less than 3 percent of all  
5                   cigarettes manufactured and distributed for  
6                   consumers in any year.

7                   (b) INFLATION ADJUSTMENT.—

8                   (1) IN GENERAL.—Except with respect to the  
9                   amount relating to the National Victims' Compensa-  
10                  tion Fund under section 401 as described in the  
11                  table under section 101(d)(2), the amount described  
12                  in subsection (a)(3) shall be increased by 3 percent  
13                  each year, or adjusted each year to reflect the in-  
14                  crease in the Consumer Price Index for all urban  
15                  consumers (as published by the Bureau of Labor  
16                  Statistics) from the year previous to the year for  
17                  which the adjustment is being applied, whichever is  
18                  greater.

19                  (2) NATIONAL VICTIMS' COMPENSATION  
20                  FUND.—The amount described in subsection (a)(3)  
21                  relating to the National Victims' Compensation  
22                  Fund under section 401 as described in the table  
23                  under section 101(d)(2), shall be increased by 3 per-  
24                  cent each year, or adjusted each year to reflect the  
25                  increase in the Medical Consumer Price Index (as



1 published by the Bureau of Labor Statistics) from  
2 the year previous to the year for which the adjust-  
3 ment is being applied, whichever is greater.

4 (c) **REQUIRED PASS THROUGH.**—The trustees shall  
5 certify that, with respect to an assessment paid by a man-  
6 ufacturer under this section under paragraphs (1) and (2)  
7 of subsection (a), the manufacturer shall increase the price  
8 of its tobacco products so as to reflect the amount of the  
9 assessment, but in no case shall such increase be less  
10 than—

11 (1) in the case of cigarettes, \$1.00 with respect  
12 to the assessment under subsection (a)(2), and an  
13 additional \$.50 cents with respect to the assessment  
14 under subsection (a)(3); and

15 (2) in the case of other tobacco products, an  
16 amount comparable to the amount of the increase  
17 under paragraph (1).

18 (d) **FAILURE TO MAKE PAYMENT.**—Upon a deter-  
19 mination that a manufacturer has failed to pay an assess-  
20 ment as required under this section—

21 (1) the provisions of subtitle A of title IV shall  
22 not apply with respect to such manufacturer;

23 (2) the Secretary shall impose penalties on the  
24 manufacturer as provided for under section 103;  
25 and.

1           (3) in full within 90 days of the date on which  
2 such payment is due, the Secretary shall revoke the  
3 tobacco license of such manufacturer under section  
4 222 until such time as such assessment is fully paid.

5 (e) NO TAX BENEFIT.—

6           (1) IN GENERAL.—With respect to a payment  
7 under subsection (a), an amount equal to 25 percent  
8 of such payment shall not be considered to be an or-  
9 dinary and necessary expense in carrying on a trade  
10 or business for purposes of the Internal Revenue  
11 Code of 1986 and shall not be tax deductible.

12           (2) LOOK-BACK PENALTIES.—The payment of  
13 penalties under subtitle B shall not be considered to  
14 be an ordinary and necessary expense in carrying on  
15 a trade or business for purposes of the Internal Rev-  
16 enue Code of 1986 and shall not be deductible.

17 (f) EFFECT OF BANKRUPTCY.—Section 507(a)(8) of  
18 title 11, United States Code, is amended—

19           (1) in subparagraph (F)(iii), by striking “or” at  
20 the end;

21           (2) in subparagraph (G), by striking the period  
22 and inserting “; or”; and

23           (3) by adding at the end the following:

24                   “(H) a payment, an assessment, or a pen-  
25 alty to be paid into the National Tobacco Trust

1 Fund under section 102 (or any other section)  
2 of the KIDS Act.”.

3 **SEC. 103. ENFORCEMENT.**

4 (a) **IN GENERAL.**—The Secretary of the Treasury, in  
5 consultation with the Secretary of Health and Human  
6 Services, shall enforce the provisions of section 102 with  
7 respect to the manufacturer that fails to pay any amount  
8 assessed under section 102.

9 (b) **AMOUNT OF PENALTY.**—The amount of the pen-  
10 alty imposed by subsection (a) on any failure with respect  
11 to a manufacturer shall be established by the Secretary  
12 of the Treasury for each day during the noncompliance  
13 period, except that no such penalty shall be less than the  
14 greater of—

15 (1) \$100,000 plus interest; or

16 (2) an amount equal to 2 percent of the amount  
17 of the annual payment involved with respect to the  
18 manufacturer.

19 (c) **NONCOMPLIANCE PERIOD.**—For purposes of this  
20 section, the term “noncompliance period” means, with re-  
21 spect to any failure to pay an assessment under section  
22 102, the period—

23 (1) beginning on the due date for such pay-  
24 ment; and

1 (2) ending on the date on which such payment  
2 is paid in full.

3 (d) FINANCIAL OBLIGATIONS NOT DISCHARGE-  
4 ABLE.—No financial responsibility or liability of any per-  
5 son under this Act shall be extinguished, reduced, or modi-  
6 fied as the result of any proceeding in bankruptcy by or  
7 on behalf of a person or the person’s successor or assign.

8 **Subtitle B—Payments to States**

9 **SEC. 111. PAYMENTS TO STATES.**

10 (a) PAYMENTS.—

11 (1) IN GENERAL.—There are authorized to be  
12 appropriated amounts provided for under section  
13 101(d)(2)(A) in each fiscal year to provide funds to  
14 each State to reimburse such State for amounts ex-  
15 pended by the State for the treatment of individuals  
16 with tobacco-related illnesses or conditions.

17 (2) AMOUNT.—From the amount made avail-  
18 able under section 101(d)(2)(A) for any fiscal year,  
19 each State shall receive the applicable percentage of  
20 such amount in accordance with the following table:

State	Applicable Percentage
Alabama .....	1.400
Alaska .....	0.400
Arizona .....	1.334
Arkansas .....	0.800
California .....	9.696
Colorado .....	1.204
Connecticut .....	1.612
Delaware .....	0.400
District of Columbia .....	0.600
Florida .....	4.977
Georgia .....	2.174

Hawaii .....	0.600
Idaho .....	0.400
Illinois .....	4.241
Indiana .....	1.780
Iowa .....	0.802
Kansas .....	0.800
Kentucky .....	1.575
Louisiana .....	1.734
Maine .....	0.800
Maryland .....	2.065
Massachusetts .....	3.571
Michigan .....	3.917
Minnesota .....	2.138
Mississippi .....	0.800
Missouri .....	1.930
Montana .....	0.400
Nebraska .....	0.600
Nevada .....	0.600
New Hampshire .....	0.600
New Jersey .....	3.193
New Mexico .....	0.600
New York .....	10.899
North Carolina .....	2.143
North Dakota .....	0.400
Ohio .....	4.463
Oklahoma .....	0.943
Oregon .....	1.076
Pennsylvania .....	5.202
Rhode Island .....	0.800
South Carolina .....	0.961
South Dakota .....	0.400
Tennessee .....	2.230
Texas .....	4.905
Utah .....	0.400
Vermont .....	0.400
Virginia .....	1.827
Washington .....	1.323
West Virginia .....	0.818
Wisconsin .....	1.919
Wyoming .....	0.200
American Samoa .....	0.009
N. Mariana Islands .....	0.002
Guam .....	0.007
U.S. Virgin Islands .....	0.005
Puerto Rico .....	0.428

1 (b) USE OF FUNDS.—

2 (1) DISCRETIONARY AMOUNTS.—A State may  
 3 use not to exceed 50 percent of the amount received

1 under this section in a fiscal year for any activities  
2 determined appropriate by the State.

3 (2) MANDATORY EXPENDITURES.—A State  
4 shall use not less than 50 percent of the amount re-  
5 ceived under this section in a fiscal year

6 (A) to carry out additional activities or  
7 provide additional services under—

8 (i) subject to subsection (d), the State  
9 program under title XIX of the Social Se-  
10 curity Act (42 U.S.C. 1396 et seq.);

11 (ii) the State program under title XXI  
12 of the Social Security Act (42 U.S.C.  
13 1397aa et seq.);

14 (iii) the State program under the ma-  
15 ternal and child health services block grant  
16 under title V of the Social Security Act (42  
17 U.S.C. 701 et seq.);

18 (iv) the community health center pro-  
19 gram under section 330 of the Public  
20 Health Service Act (42 U.S.C. 254b);

21 (v) programs administered within the  
22 State under the authority of the Substance  
23 Abuse and Mental Health Services Admin-  
24 istration;

1 (vi) the State program under the pre-  
2 ventive health services block grant under  
3 part A of title XIX of the Public Health  
4 Service Act (42 U.S.C. 300w et seq.);

5 (vii) the State program for temporary  
6 assistance to needy families funded under  
7 part A of title IV of the Social Security  
8 (42 U.S.C. 601 et seq.);

9 (viii) federally funded child welfare  
10 and abuse programs;

11 (ix) federally funded child care pro-  
12 grams operating in the State;

13 (x) programs to aid disabled children;

14 (xi) the State program under section  
15 17 of the Child Nutrition Act of 1966 (42  
16 U.S.C. 1786 et seq.);

17 (xii) federally funded child abuse pro-  
18 grams;

19 (xiii) the Head Start Act (42 U.S.C.  
20 9831 et seq.);

21 (xiv) the even start family literacy  
22 program carried out under part B of title  
23 I of the Elementary and Secondary Edu-  
24 cation Act of 1965 (20 U.S.C. 6361 et  
25 seq.);

1 (xv) the State program under part B  
2 of the Individuals With Disabilities Edu-  
3 cation Act (20 U.S.C. 1411 et seq.);

4 (xvi) the State program under the so-  
5 cial services block grant under title XX of  
6 Social Security Act (42 U.S.C. 1397 et  
7 seq.);

8 (xvii) the State program under the  
9 Community Services Block Grant Act (42  
10 U.S.C. 9901 et seq.);

11 (xviii) the State program under the  
12 Food Stamp Act of 1977 (7 U.S.C. 2011  
13 et seq.);

14 (xix) the State program under Low-  
15 Income Home Energy Assistance Act of  
16 1981 (42 U.S.C. 8621 et seq.); and

17 (xx) federally funded programs pro-  
18 viding assistance for general public edu-  
19 cation from kindergarten through 12th  
20 grade; and

21 (B) to carry out any other anti-tobacco or  
22 health activities determined appropriate by the  
23 Secretary.

24 (c) SUPPLEMENT NOT SUPPLANT.—Amounts re-  
25 ferred to in subsection (b)(2) shall be used to supplement



1 and not supplant other Federal, State and local funds pro-  
2 vided for any of the programs described in subparagraphs  
3 (A) and (B) of such subsection. Amounts provided to the  
4 State under any of the provisions of law referred to in  
5 such subparagraph shall not be reduced solely as a result  
6 of the availability of funds under this section.

7 (d) NO INCLUSION OF FUNDS FOR PURPOSES OF  
8 MEDICAID MATCH.—Amounts received under this section  
9 and expended by a State under a program described in  
10 subsection (b) may not be used for purposes of claiming  
11 a State expenditure under title XIX (42 U.S.C. 1396 et  
12 seq.) including expenditures for which an enhanced FMAP  
13 is made under the fourth sentence of section 1905(b) of  
14 such Act.

15 **SEC. 112. STATE BONUS PAYMENTS.**

16 (a) IN GENERAL.—The Secretary shall make a grant  
17 pursuant to this section to each State for each year for  
18 which the State is a high performing State.

19 (b) AMOUNT OF GRANT.—

20 (1) IN GENERAL.—Subject to paragraph (2),  
21 the Secretary shall determine the amount of the  
22 grant payable under this section to a high perform-  
23 ing State for a year, which shall be based on the  
24 score assigned to the State under subsection (d) for

1 the fiscal year that immediately precedes the year  
2 for which the bonus is being given.

3 (2) LIMITATION.—The amount payable to a  
4 State under this section for a year shall not exceed  
5 10 percent of the amount made available for pur-  
6 poses of this section under the table under section  
7 101(d)(2).

8 (c) FORMULA FOR MEASURING STATE PERFORM-  
9 ANCE.—Not later than 1 year after the date of the enact-  
10 ment of this Act, the Secretary shall develop a formula  
11 for measuring State performance in achieving the under-  
12 age reduction goals described in section 133(b) with re-  
13 spect to the State in the year involved. Such formula shall  
14 include the development and utilization of State-specific  
15 underage use baselines and targets under a standardized  
16 methodology developed by the Centers for Disease Control  
17 and Prevention.

18 (d) SCORING OF STATE PERFORMANCE; SETTING OF  
19 PERFORMANCE THRESHOLDS.—For each year, the Sec-  
20 retary shall use the formula developed under subsection  
21 (c) to assign a score to each eligible State for the fiscal  
22 year that immediately precedes the year for which the eli-  
23 gibility for the bonus is being determined.

24 (e) HIGH PERFORMING STATE.—The term “high  
25 performing State” means, with respect to a year, a State

1 whose score assigned pursuant to subsection (d) for the  
2 year immediately preceding the year for which eligibility  
3 for the bonus is being determined equals or exceeds the  
4 performance threshold prescribed under such subsection  
5 for such preceding year.

6 (f) AMOUNT OF AWARDS.—In determining the  
7 amount of an award under this section for any year for  
8 a high performing State, the Secretary shall award 20 per-  
9 cent of the funds available for such fiscal year to States  
10 that have adopted any or all of the following policies to  
11 help meet their annual youth reduction targets:

12 (1) Further increasing the price of cigarettes  
13 and other tobacco products.

14 (2) Exceeding Federal minors' access restric-  
15 tions (including penalties for employees who sell to  
16 minors, penalties for minors who purchase, and in-  
17 creasing the legal purchase age).

18 (3) Increased State investments in anti-tobacco  
19 programs (including counter-advertising, school and  
20 community-based activities, and event sponsorship).

21 (4) Enactment of more stringent policies to re-  
22 duce or eliminate exposures to environmental to-  
23 bacco smoke (including bars, restaurants, bowling  
24 alleys, bingo parlors, public transportation, public  
25 arenas and stadia).

1           (5) Other activities or actions that the Sec-  
2           retary may deem appropriate.

3           (g) FUNDING.—The Secretary shall use amounts  
4 made available for each fiscal year under section  
5 101(d)(2)(A) to carry out this section. Amounts remaining  
6 available under this section at the end of the fiscal year  
7 involved shall be used in subsequent fiscal years to carry  
8 out this section.

9           **Subtitle C—Annual Youth Tobacco**  
10           **Use Reductions**

11       **SEC. 131. PURPOSE.**

12           It is the purpose of this subtitle to achieve reductions  
13 in the proportion of underage consumers of tobacco prod-  
14 ucts through the imposition of financial deterrents relating  
15 to the use of tobacco products if certain underage tobacco-  
16 use reduction targets are not met.

17       **SEC. 132. CHILD TOBACCO USE SURVEYS.**

18           (a) ANNUAL PERFORMANCE SURVEY.—Not later  
19 than October 1, 1999, and annually thereafter, the Sec-  
20 retary shall conduct a survey to determine—

21           (1) the percentage of all young individuals who  
22           used a type of tobacco product within the 30-day pe-  
23           riod prior to the conduct of the survey; and

24           (2) the percentage of young individuals who  
25           identify each brand of each type of tobacco product

1 as the usual brand smoked or used within such 30-  
2 day period.

3 (b) YOUNG INDIVIDUALS.—For the purposes of this  
4 subtitle, the term “young individuals” means individuals  
5 who are under 18 years of age.

6 (c) BASELINE LEVEL.—

7 (1) IN GENERAL.—For the purposes of this  
8 subtitle, the term “baseline level” means, with re-  
9 spect to each type of tobacco product, the percentage  
10 of young individuals determined to have used such  
11 tobacco products in the annual performance survey  
12 described in subsection (a) completed by October 1,  
13 1999.

14 (2) MANUFACTURER’S BASELINE LEVEL.—For  
15 the purposes of this subtitle, the term “manufactur-  
16 er’s baseline level” means, with respect to each type  
17 of tobacco product, the percentage of young individ-  
18 uals determined to have identified a brand of each  
19 such tobacco product of such manufacturer as the  
20 usual brand smoked or used in the annual perform-  
21 ance survey described in subsection (a) completed by  
22 October 1, 1999.

23 (3) USE OF CERTAIN DATA OR METHODOL-  
24 OGY.—

1 (A) IN GENERAL.—For purposes of deter-  
2 mining the percentages under paragraphs (1)  
3 and (2), the Secretary may use the data col-  
4 lected through national surveys of young indi-  
5 viduals. Such surveys shall—

6 (i) be based on a nationally represent-  
7 ative sample of at least 20,000 completed  
8 interviews of young individuals;

9 (ii) be on a household-based in person  
10 survey;

11 (iii) measure the use of tobacco prod-  
12 uct within the past 30 days;

13 (iv) identify the usual brand of each  
14 type of tobacco product used within the  
15 past 30 days; and

16 (v) calculate the actual percentage re-  
17 ductions in underage the use of a type of  
18 tobacco product (or, in the case of the  
19 manufacturer-specific surcharge, the use of  
20 a type of tobacco product of a manufac-  
21 turer) based on the point estimates from  
22 the annual performance survey.

23 For purposes of clause (iv), point estimates  
24 shall be deemed acceptable for measuring com-  
25 pliance with percent reduction targets and for

1 calculating surcharges if the precision of esti-  
2 mates of the proportion of young individuals re-  
3 porting the use of a type of tobacco product (or,  
4 in the case of the manufacturer-specific sur-  
5 charge, the use of a type of tobacco product of  
6 a manufacturer) for the purpose of measuring  
7 compliance with percentage reduction targets  
8 and calculating surcharges without regard to  
9 the 95 percent confidence interval around such  
10 point estimates if the precision of estimates of  
11 the percentage of young individuals reporting  
12 use of a type of tobacco product (or, in the case  
13 of the manufacturer-specific surcharge, the use  
14 of a type of tobacco product of a manufacturer)  
15 is such that the 95 percent confidence interval  
16 around such point estimates is no more than  
17 plus or minus 1 percent.

18 (B) CONCLUSIVE ACCURATENESS.—A sur-  
19 vey using the methodology described in sub-  
20 paragraph (A) shall be deemed conclusively  
21 proper, correct and accurate for purposes of  
22 this Act. The Secretary may, by notice and  
23 comment rulemaking, subsequently adopt a dif-  
24 ferent survey methodology.

1           (C) FINAL DETERMINATION.—The deter-  
2           mination of the Secretary as to the amount and  
3           allocation of the surcharge under this subtitle  
4           shall be final and the manufacturer shall pay  
5           such surcharge within 30 days of the date on  
6           which the manufacturer is assessed. Such pay-  
7           ment shall be retained by the Secretary pending  
8           final judicial review of what, if any, change in  
9           the surcharge is appropriate.

10           (D) REVIEW.—The amount of any sur-  
11           charge paid under this subtitle shall be subject  
12           to judicial review by the United States Court of  
13           Appeals for the District of Columbia Circuit,  
14           based on the arbitrary and capricious standard  
15           of section 706 of title 5, United States Code.  
16           Notwithstanding any other provision of law, no  
17           court shall have the authority to stay any sur-  
18           charge payment due to the Secretary under this  
19           subtitle pending judicial review until the Sec-  
20           retary has made or failed to make a compliance  
21           determination, as described under this subtitle,  
22           that has adversely affected the person seeking  
23           the review.

24           (E) NONAPPLICABILITY.—Chapter 35 of  
25           title 44, United States Code, shall not apply to



1 information required for the purposes of carry-  
2 ing out this subsection.

3 (F) AMENDMENT TO PUBLIC HEALTH  
4 SERVICE ACT.—Section 308(d) of the Public  
5 Health Service Act (42 U.S.C. 242m(d)) is  
6 amended—

7 (i) by inserting after “or 307” the fol-  
8 lowing: “, or a survey conducted under sec-  
9 tion 132 of the KIDS Act,”; and

10 (ii) by inserting after “or 306” the  
11 following: “, or in the course of a survey  
12 conducted under section 132 of the KIDS  
13 Act,”

14 (d) ADMINISTRATION.—

15 (1) TECHNICAL ADJUSTMENTS.—The Secretary  
16 may make technical changes in the manner in which  
17 the surveys are conducted under this section to re-  
18 flect improved methodology so long as adjustments  
19 are made to ensure that the results of the surveys  
20 are comparable from year to year.

21 (2) PARTICIPATION IN SURVEY.—Notwithstand-  
22 ing any other provision of law, the Secretary may  
23 conduct a survey under this section involving minors  
24 if the results of such survey with respect to such mi-  
25 nors are kept confidential and not disclosed.

1 (e) TOBACCO PRODUCT.—For the purposes of this  
2 subtitle, cigarettes, cigars, little cigars, smokeless tobacco,  
3 and roll-your-own tobacco shall each be considered as a  
4 separate type of tobacco product.

5 **SEC. 133. REDUCTION IN UNDERAGE TOBACCO PRODUCT**  
6 **USAGE.**

7 (a) ANNUAL DETERMINATION.—The Secretary shall  
8 annually determine, based on the annual performance sur-  
9 veys under section 132, whether the required percentage  
10 reductions in underage use of tobacco products (as de-  
11 scribed in subsection (b)) for a year has been achieved  
12 for the year involved. Such determination shall be based  
13 on the average annual percentage prevalence of the use  
14 of tobacco products by young individuals (as determined  
15 using the annual surveys conducted by the Secretary  
16 under section 132) for the year involved as compared to  
17 the baseline level.

18 (b) REQUIRED PERCENTAGE REDUCTION IN UNDER-  
19 AGE USE OF TOBACCO PRODUCTS.—For purposes of this  
20 section, the required percentage reduction from the base-  
21 line level in the percentage of underage use of tobacco  
22 products with respect to each tobacco product shall be as  
23 follows:

24 (1) With respect to calendar year 2000, at least  
25 15 percent.

1           (2) With respect to calender year 2001, at least  
2       20 percent.

3           (3) With respect to calender year 2002, at least  
4       25 percent.

5           (4) With respect to calender year 2003, at least  
6       30 percent.

7           (5) With respect to calender year 2004, at least  
8       40 percent.

9           (6) With respect to calender year 2005, at least  
10      50 percent.

11          (7) With respect to calender year 2006, at least  
12      55 percent.

13          (8) With respect to calender year 2007, at least  
14      60 percent.

15          (9) With respect to calender year 2008, and  
16      each subsequent calendar year, at least 65 percent.

17      (c) **REQUIRED REDUCTION FOR MANUFACTURERS.**—  
18      With respect to the average percentage prevalence of the  
19      use of each manufacturer's brands of tobacco products by  
20      young individuals (as determined on the basis of the an-  
21      nual performance surveys conducted by the Secretary  
22      under section 132) for a year—

23           (1) each manufacturer which manufactured a  
24      brand or brands of tobacco product on or before the  
25      date of the enactment of this Act shall reduce the

1 percentage of young individuals who use such manu-  
2 facturer's brand or brands as their usual brand in  
3 accordance with the percentage reductions described  
4 under subsection (b); and

5 (2) each manufacturer which manufactures a  
6 new brand or brands of tobacco products (a brand  
7 of tobacco product that was not manufactured prior  
8 to the date of enactment of this Act) after the date  
9 of the enactment of this Act shall ensure that the  
10 percentage prevalence of young individuals who use  
11 such manufacturer's brand or brands as their usual  
12 brand is equal to or less than the de minimis level  
13 described in section 134(b).

14 **SEC. 134. NONCOMPLIANCE.**

15 (a) **INDUSTRY-WIDE PENALTY.—**

16 (1) **IN GENERAL.—**If, with respect to a year,  
17 the Secretary determines that the required percent-  
18 age reduction in underage use of a tobacco product  
19 has not been achieved as required under section  
20 133(b), the Secretary shall impose an industry-wide  
21 penalty on the manufacturers of such product in an  
22 amount that is equal to the product of—

23 (A) the amount applicable under para-  
24 graph (2) for each unit of the tobacco product  
25 involved that is sold for consumer use by such

1 manufacturers in the year following the year in  
2 which the noncompliance occurs; and

3 (B) the number of percentage points by  
4 which the required percentage reduction in un-  
5 derage use of tobacco products under section  
6 133(b) for the year exceeds the actual reduction  
7 in the use of such products for the year (as de-  
8 termined under subsection (c)).

9 (2) APPLICABLE AMOUNT.—The amount appli-  
10 cable for purposes of paragraph (1)(A) for a year  
11 shall equal—

12 (A) for the first 10 percentage points by  
13 which the required percentage reduction in un-  
14 derage use of tobacco products under section  
15 133(b) for the year exceeds the actual reduction  
16 in the use of such products for the year (as de-  
17 termined under subsection (c)), \$.01 cent for  
18 each such excess percentage point;

19 (B) for each percentage point in excess of  
20 11 and less than 21 by which the required per-  
21 centage reduction in underage use of tobacco  
22 products under section 133(b) for the year ex-  
23 ceeds the actual reduction in the use of such  
24 products for the year (as determined under sub-

1 section (c)), \$.02 cents for each such excess  
2 percentage point; and

3 (C) for each percentage point in excess of  
4 20 by which the required percentage reduction  
5 in underage use of tobacco products under sec-  
6 tion 133(b) for the year exceeds the actual re-  
7 duction in the use of such products for the year  
8 (as determined under subsection (c)), \$.03  
9 cents for each such excess percentage point.

10 (3) INCREASED PENALTY FOR CONSECUTIVE  
11 FAILURES.—If the Secretary determines that the re-  
12 quired percentage reduction in underage use of a  
13 type of tobacco product has not been achieved as re-  
14 quired under section 133(b) in 3 or more consecutive  
15 years, the amount described in paragraph (2) shall  
16 be increased by a factor of 2.

17 (4) DE MINIMIS RULE.—The Secretary shall  
18 not impose a penalty on a manufacturer under para-  
19 graph (1) with respect to a type of tobacco product  
20 if the Secretary determines that the percentage of  
21 young individuals using such tobacco product (as de-  
22 termined using the annual surveys conducted by the  
23 Secretary under section 132) is less than 0.5 percent  
24 of the total number of young individuals determined  
25 to have used tobacco products in the year involved.

1           (5) PAYMENT.—An industry-wide penalty im-  
2 posed under this subsection for a tobacco product  
3 shall be paid by each manufacturer based on each  
4 such manufacturers market share for the type of to-  
5 bacco product involved.

6 (b) MANUFACTURER-SPECIFIC PENALTY.—

7           (1) IN GENERAL.—With respect to each manu-  
8 facturer for a year, if the Secretary determines that  
9 the required percentage reduction in underage use of  
10 a type of tobacco product has not been achieved by  
11 such manufacturer as required under section 134,  
12 the Secretary shall impose a penalty on the tobacco  
13 products of such type of such manufacturer in an  
14 amount that is equal to the product of—

15           (A) the amount applicable under para-  
16 graph (2) for each unit of the tobacco product  
17 involved that is sold for consumer use by such  
18 manufacturer in the year following the year in  
19 which the noncompliance occurs; and

20           (B) the number of percentage points by  
21 which the required percentage reduction in un-  
22 derage use of the type of tobacco product of  
23 such manufacturer under section 133(b) for the  
24 year exceeds the actual reduction in the use of

1           such product of such manufacturer for the year  
2           (as determined under subsection (c)).

3           (2) APPLICABLE AMOUNT.—The amount appli-  
4           cable for purposes of paragraph (1)(A) for a year  
5           shall equal—

6                   (A) for the first 10 percentage points by  
7                   which the required percentage reduction in un-  
8                   derage use of tobacco products under section  
9                   133(b) for the year exceeds the actual reduction  
10                   in the use of such products for the year (as de-  
11                   termined under subsection (c)), \$.01 cent for  
12                   each such excess percentage point;

13                   (B) for each percentage point in excess of  
14                   11 and less than 21 by which the required per-  
15                   centage reduction in underage use of tobacco  
16                   products under section 133(b) for the year ex-  
17                   ceeds the actual reduction in the use of such  
18                   products for the year (as determined under sub-  
19                   section (c)), \$.02 cents for each such excess  
20                   percentage point; and

21                   (C) for each percentage point in excess of  
22                   20 by which the required percentage reduction  
23                   in underage use of tobacco products under sec-  
24                   tion 133(b) for the year exceeds the actual re-  
25                   duction in the use of such products for the year



1 (as determined under subsection (c)), \$.03  
2 cents for each such excess percentage point.

3 (3) INCREASED PENALTY FOR CONSECUTIVE  
4 FAILURES.—If the Secretary determines that a par-  
5 ticular manufacturer has failed to meet the required  
6 percentage reduction in underage use of a type of to-  
7 bacco product (under section 133(b)) by at least 30  
8 percentage points for a period of at least 3 consecu-  
9 tive years, the amount applicable under paragraph  
10 (2) shall be, for each percentage point in excess of  
11 30 by which the required percentage reduction in  
12 underage use of tobacco products exceeds the actual  
13 reduction in the use of such products for the year  
14 (as determined under subsection (c)), \$.06 cents for  
15 each such excess percentage point.

16 (4) DE MINIMIS RULE.—The Secretary shall  
17 not impose a penalty on a manufacturer under this  
18 subsection for a type of tobacco product for a year  
19 if the Secretary determines that the percentage of  
20 young individuals identifying a brand of such to-  
21 bacco product of such manufacturer as the usual  
22 brand smoked or used for such year (as determined  
23 using the annual surveys conducted by the Secretary  
24 under section 132) is less than 0.5 percent of the

1 total number of young individuals determined to  
2 have used such tobacco products in such year.

3 (5) PAYMENT.—Penalties under this section  
4 shall be paid within 30 days of the date on which  
5 an assessment is made by the Secretary.

6 (c) ACTUAL PERCENTAGE REDUCTION IN UNDERAGE  
7 USE OF TOBACCO PRODUCTS.—For purposes of this sec-  
8 tion, the term “actual percentage reduction in underage  
9 use of tobacco products” means, with respect to a type  
10 of tobacco product involved for a year, the percentage re-  
11 duction, as determined by the Secretary using the annual  
12 performance surveys under section 132, in the use of such  
13 tobacco product by young individuals as compared to the  
14 baseline for such tobacco product under section 132(c).

15 (d) PROCEDURES.—In assessing penalties under this  
16 section, the Secretary may apply such statistical methods,  
17 including sampling, as may be appropriate to increase the  
18 accuracy of the estimates from the annual performance  
19 survey. In determining the industry-wide and manufac-  
20 turer-specific penalties under this section, the Secretary  
21 shall determine what confidence interval to use from the  
22 survey information made available from the annual per-  
23 formance survey under section 132.

24 (e) ADJUSTMENTS.—If for any calendar year the Sec-  
25 retary determines that the average annual percentage

1 prevalence of the use of tobacco products by young individ-  
2 uals (as determined using the annual surveys conducted  
3 by the Secretary under section 132) for the year involved  
4 is greater than the baseline level for such products (as  
5 determined under section 132(b)), the amount determined  
6 under subsections (a)(1) and (b)(1) shall be adjusted to  
7 reflect the—

8           (1) the percentage point amount applicable  
9           under section 133(b); and

10           (2) the percentage increase in the average an-  
11           nual percentage prevalence of the use of the tobacco  
12           products involved by individuals who are under 18  
13           years of age for the year (as determined under sec-  
14           tion 132) compared to the baseline level for such  
15           products (as determined under section 132(b)).

16           (f) **PENALTIES NONDEDUCTIBLE.**—The payment of  
17 penalties under this subtitle shall not be considered to be  
18 an ordinary and necessary expense in carrying on a trade  
19 or business for purposes of the Internal Revenue Code of  
20 1986 and shall not be deductible.

21           (g) **USE OF AMOUNTS.**—With respect to amounts  
22 paid by manufacturers under this section or section 135,  
23 the Secretary shall use such amounts as follows:

1           (1)  $\frac{1}{3}$  of such amounts shall be used for smok-  
2           ing cessation programs under chapter 2 of subtitle  
3           B of title III.

4           (2)  $\frac{1}{3}$  of such amounts shall be used for com-  
5           munity and school-based prevention programs under  
6           subtitle A, and counter advertising under chapter 1  
7           of subtitle B, of title III.

8           (3)  $\frac{1}{3}$  of such amounts shall be used for bio-  
9           medical and applied research under subtitle C of  
10          title III.

11          (h) JUDICIAL REVIEW.—A manufacturer of tobacco  
12          products may seek judicial review of any action under this  
13          subtitle only after the assessment involved has been paid  
14          by the manufacturer to the Department of the Treasury  
15          and only in the United States District Court for the Dis-  
16          trict of Columbia.

17          (i) LIMITATION ON PENALTIES FOR NONCOMPLI-  
18          ANCE.—With respect to penalties applicable for a year  
19          under this section, the sum of the penalties imposed shall  
20          not exceed \$10,000,000,000 per year, increased by the in-  
21          crease in the Consumer Price Index for the year involved.  
22          In complying with this subsection, the Secretary shall  
23          apply penalties under subsection (b) prior to the applica-  
24          tion of penalties under subsection (a).

1 **SEC. 135. ENFORCEMENT.**

2 (a) **INITIAL PENALTY.**—There is hereby imposed an  
3 initial penalty on the failure of any manufacturer to make  
4 any payment required under this subtitle within 30 days  
5 after the date on which such payment is due.

6 (b) **AMOUNT OF PENALTY.**—The amount of the pen-  
7 alty imposed by subsection (a) on any failure with respect  
8 to a manufacturer shall be the greater of \$100,000 or an  
9 amount equal to 2 percent of the penalty owed under sec-  
10 tion 134 for each day during the noncompliance period.

11 (c) **NONCOMPLIANCE PERIOD.**—For purposes of this  
12 section, the term “noncompliance period” means, with re-  
13 spect to any failure to make the surcharge payment re-  
14 quired under this subtitle, the period—

15 (1) beginning on the due date for such pay-  
16 ment; and

17 (2) ending on the date on which such payment  
18 is paid in full.

19 (d) **LIMITATIONS.**—No penalty shall be imposed by  
20 subsection (a) on any failure to make a surcharge payment  
21 under this subtitle during any period for which it is estab-  
22 lished to the satisfaction of the Secretary that none of the  
23 persons responsible for such failure knew or, exercising  
24 reasonable diligence, would have known, that such failure  
25 existed.

1 **TITLE II—REGULATION OF THE**  
2 **TOBACCO INDUSTRY**  
3 **Subtitle A—Food and Drug Admin-**  
4 **istration Jurisdiction and Gen-**  
5 **eral Authority**

6 **SEC. 201. STATEMENT OF GENERAL AUTHORITY.**

7 The regulations promulgated by the Secretary in the  
8 rule dated August 28, 1996 (Vol. 61, No. 168 C.F.R.),  
9 adding part 897 to title 21, Code of Federal Regulations,  
10 shall be deemed to have been lawfully promulgated under  
11 the Food, Drug and Cosmetic Act as amended by this  
12 title. Such regulations shall apply to all tobacco products.

13 **SEC. 202. NONAPPLICABILITY TO OTHER DRUGS OR DE-**  
14 **VICES.**

15 Nothing in this Act, or an amendment made by this  
16 title, shall be construed to affect the regulation of drugs  
17 and devices that are not tobacco products by the Secretary  
18 under the Federal Food, Drug and Cosmetic Act.

19 **SEC. 203. CONFORMING AMENDMENTS TO CONFIRM JURIS-**  
20 **DICTION.**

21 (a) **DEFINITIONS.—**

22 (1) **DRUG.**—Section 201(g)(1) of the Federal  
23 Food, Drug, and Cosmetic Act (21 U.S.C. 321  
24 (g)(1)) is amended by striking “and (D)” and in-  
25 serting “(D) nicotine in tobacco products, and (E)”.

1           (2) DEVICE.—Section 201(h) of the Federal  
2 Food, Drug, and Cosmetic Act (21 U.S.C. 321(h))  
3 is amended—

4           (A) in paragraph (2), by striking “or” at  
5 the end;

6           (B) in paragraph (3), by striking “and” at  
7 the end and inserting “or”; and

8           (C) by inserting after paragraph (3), the  
9 following:

10           “(4) nicotine-containing tobacco products, and”.

11           (3) ADDITIONAL DEFINITIONS.—Section 201 of  
12 the Federal Food, Drug and Cosmetic Act (21  
13 U.S.C. 321) is amended by adding at the end the  
14 following:

15           “(kk) The term ‘cigarette’ means any product that  
16 contains nicotine, is intended to be burned under ordinary  
17 conditions of use, and consists of—

18           “(1) any roll of tobacco wrapped in paper or in  
19 any substance not containing tobacco; or

20           “(2) any roll of tobacco wrapped in any sub-  
21 stance containing tobacco which, because of its ap-  
22 pearance, the type of tobacco used in the filler, or  
23 its packaging and labeling, is likely to be offered to,  
24 or purchased by, consumers as a cigarette described  
25 in paragraph (1).

1           “(ll) The term ‘cigarette tobacco’ means any product  
2 that consists of loose tobacco that contains or delivers nic-  
3 otine and is intended for use by consumers in a cigarette.  
4 Unless otherwise stated, the requirements for cigarettes  
5 shall also apply to cigarette tobacco.

6           “(mm) The term ‘cigar’ means any roll of tobacco  
7 wrapped in leaf tobacco or in any substance containing  
8 tobacco (other than any roll of tobacco that is a cigarette  
9 or little cigar with the meaning of paragraph (kk) or (oo).

10          “(nn) The term ‘distributor’ with respect to a tobacco  
11 product means any person who furthers the distribution  
12 of cigarette or smokeless tobacco, whether domestic or im-  
13 ported, at any point from the original place of manufac-  
14 ture to the person who sells or distributes the product to  
15 individuals for personal consumption. Common carriers  
16 shall not be considered distributors for purposes of this  
17 Act.

18          “(oo) The term ‘little cigar’ means any roll of tobacco  
19 wrapped in leaf tobacco or any substance containing to-  
20 bacco (other than any roll of tobacco which is a cigarette)  
21 and as to which 1,000 units weigh not more than 3  
22 pounds.

23          “(pp) The term ‘manufacturer’ means any person, in-  
24 cluding any repacker or relabeler, who manufactures, fab-  
25 ricates, assembles, processes, packs, or labels a tobacco



1 product. Any successor or assign of a manufacturer, as  
2 well as any person affiliated with the manufacturer, shall  
3 have all of the manufacturer's responsibilities and liabil-  
4 ities under this Act.

5       “(qq) The term ‘nicotine’ means the chemical sub-  
6 stance named 3-(1-Methyl-2-pyrrolidinyl)pyridine or  
7  $C_{10}H_{14}N_2$ , including any salt or complex of nicotine.

8       “(rr) The term ‘package’ means the innermost sealed  
9 contained, irrespective of the material from which such  
10 container is made, in which a tobacco product is placed  
11 by the manufacturer and in which such tobacco product  
12 is offered for sale to a member of the general public.

13       “(ss) The term ‘person’ means a firm, partnership,  
14 association, corporation, legal representative, trustee, re-  
15 ceiver or any other legally recognized entity.

16       “(tt) The term ‘pipe tobacco’ means any loose tobacco  
17 that, because of its appearance, type, packaging, or label-  
18 ing is likely to be offered to or purchased by, consumers  
19 as a tobacco product to be smoked in a pipe.

20       “(uu) The term ‘point-of-sale’ means any location at  
21 which a consumer can purchase or otherwise obtain to-  
22 bacco products for personal consumption.

23       “(vv) The term ‘retailer’ means any person who sells  
24 tobacco products to individuals for personal consumption

1 or who operates a facility where vending machines or self-  
2 service displays are permitted under this Act.

3       “(ww) The term ‘roll-your-own’ means any tobacco  
4 which, because of its appearance, type, packaging, or la-  
5 beling, is suitable for use and likely to be offered to, or  
6 purchased by, consumers as tobacco for making cigarettes.

7       “(xx) The term ‘smokeless tobacco’ means any prod-  
8 uct that consists of cut, ground, powdered or leaf tobacco  
9 that contains nicotine and that is intended to be placed  
10 in the oral or nasal cavity.

11       “(yy) The term ‘tobacco product’ means any product  
12 made of or derived from tobacco leaf for human consump-  
13 tion, including, but not limited to, cigarettes, cigarillos,  
14 cigarette tobacco, cigars, little cigars, pipe tobacco, smoke-  
15 less tobacco, and roll-your-own tobacco.”.

16       (4) COMBINATION OF PRODUCTS.—Section  
17 503(g) of the Federal Food, Drug, and Cosmetic Act  
18 (21 U.S.C. 353(g)) is amended by inserting “(in-  
19 cluding any tobacco product)” after “products” the  
20 first place that such appears.

21       (b) PROHIBITED ACTS.—Section 301 of the Federal  
22 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-  
23 ed by adding at the end the following:

1       “(x) The manufacture, labeling, distribution, adver-  
2       tising and sale of any adulterated or misbranded tobacco  
3       product in violation of—

4               “(1) regulations issued under this Act; or

5               “(2) the KIDS Act, or regulations issued under  
6       such Act.”.

7       (c) ADULTERATED DRUGS AND DEVICES.—

8               (1) IN GENERAL.—Section 501 of the Federal  
9       Food, Drug, and Cosmetic Act (21 U.S.C. 351) is  
10       amended by adding at the end the following:

11              “(j) If it is a tobacco product and it does not comply  
12       with the provisions of subchapter D of this chapter or the  
13       KIDS Act.”.

14              (2) MISBRANDING.—Section 502(q) of the Fed-  
15       eral Food, Drug, and Cosmetic Act (21 U.S.C.  
16       352(q)) is amended—

17                      (A) by striking “or (2)” and inserting in  
18       lieu thereof “(2)”; and

19                      (B) by inserting before the period the fol-  
20       lowing: “, or (3) in the case of a tobacco prod-  
21       uct, it is sold, distributed, advertised, labeled,  
22       or used in violation of this Act or the KIDS  
23       Act, or regulations prescribed under such  
24       Acts”.

1 (d) RESTRICTED DEVICE.—Section 520(e) of the  
2 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
3 360j(e)) is amended—

4 (1) in paragraph (1), by striking “or use—”  
5 and inserting “or use, including restrictions on the  
6 access to, and the advertising and promotion of, to-  
7 bacco products—”; and

8 (2) by adding at the end the following:

9 “(3) Tobacco products are a restricted device under  
10 this paragraph.”.

11 (e) REGULATORY AUTHORITY.—Section 503(g) (21  
12 U.S.C. 353(g)) is amended by adding at the end the fol-  
13 lowing:

14 “(5) The Secretary may regulate any tobacco product  
15 as a drug, device, or both, and may designate the office  
16 of the Administration that shall be responsible for regulat-  
17 ing such products.”.

18 **SEC. 204. GENERAL RULE.**

19 Section 513(a)(1)(B) of the Federal Food, Drug and  
20 Cosmetic Act (21 U.S.C. 360e(a)(1)(B)) is amended by  
21 adding at the end the following: “The sale of tobacco prod-  
22 ucts to adults that comply with performance standards es-  
23 tablished for these products under section 514 and other  
24 provisions of this Act and any regulations prescribed

1 under this Act shall not be prohibited by the Secretary,  
2 notwithstanding sections 502(j), 516, and 518.”

3 **SEC. 205. SAFETY AND EFFICACY STANDARD AND RECALL**

4 **AUTHORITY.**

5 (a) SAFETY AND EFFICACY STANDARD.—Section  
6 513(a) (21 U.S.C. 360c(a)) is amended—

7 (1) in paragraph (1)(B), by inserting after the  
8 first sentence the following: “For a device which is  
9 a tobacco product, the assurance in the previous sen-  
10 tence need not be found if the Secretary finds that  
11 special controls achieve the best public health re-  
12 sult.”; and

13 (2) in paragraph (2)—

14 (A) by redesignating subparagraphs (A),  
15 (B) and (C) as clauses (i), (ii) and (iii), respec-  
16 tively;

17 (B) by striking “(2) For” and inserting  
18 “(2)(A) For”; and

19 (C) by adding at the end the following:

20 “(B) For purposes of paragraph (1)(B), subsections  
21 (c)(2)(C), (d)(2)(B), (e)(2)(A), (f)(3)(B)(i), and  
22 (f)(3)(C)(i), and sections 514, 519(a), 520(e), and 520(f),  
23 the safety and effectiveness of a device that is a tobacco  
24 product need not be found if the Secretary finds that the  
25 action to be taken under any such provision would achieve

1 the best public health result. The finding as to whether  
2 the best public health result has been achieved shall be  
3 determined with respect to the risks and benefits to the  
4 population as a whole, including users and non-users of  
5 the tobacco product, and taking into account—

6 “(i) the increased or decreased likelihood that  
7 existing consumers of tobacco products will stop  
8 using such products; and

9 “(ii) the increased or decreased likelihood that  
10 those who do not use tobacco products will start  
11 using such products.”.

12 (b) RECALL AUTHORITY.—Section 518(e)(1) (21  
13 U.S.C. 360h(e)(1)) is amended by inserting after “adverse  
14 health consequences or death,” the following: “and for to-  
15 bacco products that the best public health result would  
16 be achieved,”.

## 17 **Subtitle B—Regulation of Tobacco** 18 **Products**

### 19 **SEC. 211. PERFORMANCE STANDARDS.**

20 Section 514(a) of the Federal Food, Drug, and Cos-  
21 metic Act (21 U.S.C. 60d(a)) is amended—

22 (1) in paragraph (2), by striking “device” and  
23 inserting “nontobacco product device”;

24 (2) by redesignating paragraphs (3) and (4) as  
25 paragraphs (6) and (7), respectively; and

1           (3) by inserting after paragraph (2) the follow-  
2           ing:

3           “(3) The Secretary may adopt a performance stand-  
4           ard under section 514(a)(2) for a tobacco product regard-  
5           less of whether the product has been classified under sec-  
6           tion 513. Such standard may—

7           “(A) include provisions to achieve the best pub-  
8           lic health result;

9           “(B) where necessary to achieve the best public  
10          health result, include—

11           “(i) provisions respecting the construction,  
12           components, constituents, ingredients, and  
13           properties of the tobacco product device, includ-  
14           ing the reduction or elimination (or both) of  
15           nicotine and the other components, ingredients,  
16           and constituents of the tobacco product, its  
17           components and its by-products, based upon the  
18           best available technology;

19           “(ii) provisions for the testing (on a sam-  
20           ple basis or, if necessary, on an individual  
21           basis) of the tobacco product device or, if it is  
22           determined that no other more practicable  
23           means are available to the Secretary to assure  
24           the conformity of the tobacco product device to  
25           such standard, provisions for the testing (on a

1 sample basis or, if necessary, on an individual  
2 basis) by the Secretary or by another person at  
3 the direction of the Secretary;

4 “(iii) provisions for the measurement of  
5 the performance characteristics of the tobacco  
6 product device;

7 “(iv) provisions requiring that the results  
8 of each test or of certain tests of the tobacco  
9 product device required to be made under  
10 clause (ii) demonstrate that the tobacco product  
11 device is in conformity with the portions of the  
12 standard for which the test or tests were re-  
13 quired; and

14 “(v) a provision that the sale and dis-  
15 tribution of the tobacco product device be  
16 restricted but only to the extent that the  
17 sale, ~~advertising,~~ and distribution of a to-  
18 bacco product device may otherwise be re-  
19 stricted under this Act; and

20 “(C) where appropriate, require the use and  
21 prescribe the form and content of labeling for the  
22 use of the tobacco product device.

23 “(4) Not later than 1 year after the date of enact-  
24 ment of this paragraph, the Secretary (acting through the  
25 Commissioner of Food and Drugs) shall establish a Sci-



1 entific Advisory Committee to evaluate whether a level or  
2 range of levels exists at which nicotine yields do not  
3 produce drug-dependence. The Advisory Committee shall  
4 also review any other safety, dependence or health issue  
5 assigned to it by the Secretary. The Secretary need not  
6 promulgate regulations to establish the Committee.”.

7 **SEC. 212. APPLICATION OF FEDERAL FOOD, DRUG, AND**  
8 **COSMETIC ACT TO TOBACCO PRODUCTS.**

9 (a) TOBACCO PRODUCTS REGULATION.—Chapter V  
10 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
11 351 et seq.) is amended by adding at the end the follow-  
12 ing:

13 “SUBCHAPTER F—TOBACCO PRODUCT DEVEL-  
14 OPMENT, MANUFACTURING, AND ACCESS  
15 RESTRICTIONS, LICENSING, AND ANTI-  
16 SMUGGLING

17 **“Part A—Tobacco Product Development,**  
18 **Manufacturing, and Access Restrictions**

19 **“SEC. 570. PROMULGATION OF REGULATIONS.**

20 “Any regulations necessary to implement this sub-  
21 chapter shall be promulgated not later than 12 months  
22 after the date of enactment of this subchapter using notice  
23 and comment rulemaking (in accordance with chapter 5  
24 of title 5, United States Code). Such regulations may be

1 revised thereafter as determined necessary by the Sec-  
2 retary.

3 **"SEC. 571. MAIL-ORDER SALES.**

4       “(a) IN GENERAL.—Not later than 2 years after the  
5 date of enactment of this subchapter, the Secretary shall  
6 review and determine whether persons under the age of  
7 18 years are obtaining tobacco products by means of the  
8 mail.

9       “(b) RESTRICTIONS.—Based solely upon the review  
10 conducted under subsection (a), the Secretary may take  
11 regulatory and administrative action to restrict or elimi-  
12 nate mail order sales of tobacco products.

13 **"SEC. 572. TOBACCO PRODUCT WARNINGS AND PACKAG-**  
14 **ING.**

15       “(a) CIGARETTE WARNINGS.—

16               “(1) IN GENERAL.—

17                       “(A) PACKAGING.—It shall be unlawful for  
18 any person to manufacture, package, or import  
19 for sale or distribution any cigarettes the pack-  
20 age of which fails to bear, in accordance with  
21 the requirements of this subsection, one of the  
22 following labels:

23                               “WARNING: Cigarettes Are Addictive.

24                               “WARNING: Tobacco Smoke Can Harm  
25 Your Children.

1                   “WARNING: Cigarettes Cause Fatal Lung  
2                   Disease.

3                   “WARNING: Cigarettes Cause Cancer.

4                   “WARNING: Cigarettes Cause Strokes  
5                   And Heart Disease.

6                   “WARNING: Smoking During Pregnancy  
7                   Can Harm Your Baby.

8                   “WARNING: Smoking Can Kill You.

9                   “WARNING: Tobacco Smoke Causes  
10                  Fatal Lung Disease In Nonsmokers.

11                  “WARNING: Quitting Smoking Now  
12                  Greatly Reduces Serious Risks To Your  
13                  Health.

14                  “(B) ADVERTISING.—It shall be unlawful  
15                  for any manufacturer, importer, distributor or  
16                  retailer of cigarettes to advertise or cause to be  
17                  advertised any cigarette unless the advertising  
18                  bears, in accordance with the requirements of  
19                  this subsection, one of the following labels:

20                  “WARNING: Cigarettes Are Addictive.

21                  “WARNING: Tobacco Smoke Can Harm  
22                  Your Children.

23                  “WARNING: Cigarettes Cause Fatal Lung  
24                  Disease.

25                  “WARNING: Cigarettes Cause Cancer.

1           “WARNING: Cigarettes Cause Strokes  
2           And Heart Disease.

3           “WARNING: Smoking During Pregnancy  
4           Can Harm Your Baby.

5           “WARNING: Smoking Can Kill You.

6           “WARNING: Tobacco Smoke Causes  
7           Fatal Lung Disease In Nonsmokers.

8           “WARNING: Quitting Smoking Now  
9           Greatly Reduces Serious Risks To Your  
10          Health.

11          “(C) ADDITIONAL WARNINGS.—Beginning  
12          on the date that is 18 months after the date of  
13          enactment of this subchapter, the Secretary  
14          may substitute for, or require warnings in addi-  
15          tion to, those otherwise required under subpara-  
16          graphs (A) and (B) if the Secretary determines  
17          that such warnings would be more effective in  
18          detering the use of cigarettes.

19          “(2) REQUIREMENTS FOR LABELING.—

20                 “(A) LOCATION.—Each label statement re-  
21                 quired by subparagraph (A) of paragraph (1)  
22                 shall be located on the upper portion of the  
23                 front and rear panels of the cigarette package  
24                 (or carton) directly on the package underneath

1 the cellophane or other clear wrapping and oc-  
2 cupy not less than 25 percent of such panels.

3 “(B) TYPE AND COLOR.—With respect to  
4 each label statement required by subparagraph  
5 (A) of paragraph (1), the phrase ‘WARNING’  
6 shall appear in capital letters and the label  
7 statement shall be printed in 17 point type with  
8 adjustments as determined appropriate by the  
9 Secretary to reflect the length of the required  
10 statement. All the letters in the label shall ap-  
11 pear in conspicuous and legible type, in contrast  
12 by typography, layout, or color with all other  
13 printed material on the package, and be printed  
14 in an alternating black-on-white and white-on-  
15 black format as determined appropriate by the  
16 Secretary.

17 “(C) EXCEPTION.—With respect to ciga-  
18 rettes manufactured and distributed prior to  
19 January 1, 2000, the provisions of subpara-  
20 graph (A) shall not apply with respect to the  
21 front panel in the case of a flip-top cigarette  
22 package (offered for sale prior to or on June 1,  
23 1997) where the front portion of the flip-top  
24 does not comprise at least 25 percent of the  
25 front panel. In the case of such a package, the

1 label statement required by subparagraph (A)  
2 of paragraph (1) shall occupy the entire front  
3 portion of the flip-top.

4 “(3) REQUIREMENTS FOR ADVERTISING.—

5 “(A) LOCATION.—Each label statement re-  
6 quired by subparagraph (B) of paragraph (1)  
7 shall appear in a conspicuous and prominent  
8 format and location at the top of each adver-  
9 tisement within the trim area and shall occupy  
10 not less than 20 percent of the area of the ad-  
11 vertisement involved.

12 “(B) TYPE, COLOR AND FORMAT.—

13 “(i) TYPE.—With respect to each  
14 label statement required by subparagraph  
15 (B) of paragraph (1), the phrase ‘WARN-  
16 ING’ shall appear in capital letters and the  
17 label statement shall be printed in the fol-  
18 lowing types:

19 “(I) With respect to whole page  
20 advertisements on broadsheet news-  
21 paper—45 point type.

22 “(II) With respect to half page  
23 advertisements on broadsheet news-  
24 paper—39 point type.

1                   “(III) With respect to whole page  
2                   advertisements on tabloid news-  
3                   paper—39 point type.

4                   “(IV) With respect to half page  
5                   advertisements on tabloid news-  
6                   paper—27 point type.

7                   “(V) With respect to DPS maga-  
8                   zine advertisements—31.5 point type.

9                   “(VI) With respect to whole page  
10                  magazine advertisements—31.5 point  
11                  type.

12                  “(VII) With respect to 28cm x 3  
13                  column advertisements—22.5 point  
14                  type.

15                  “(VIII) With respect to 20cm x 2  
16                  column advertisements—15 point  
17                  type.

18                  Within the 20 percent requirement de-  
19                  scribed in subparagraph (A), the Secretary  
20                  may revise the required type sizes if the  
21                  Secretary determines that such revisions  
22                  will enhance public health protections.

23                  “(ii) COLOR.—All the letters in the  
24                  label under this subparagraph shall appear  
25                  in conspicuous and legible type, in contrast

1 by typography, layout, or color with all  
2 other printed material on the package, and  
3 be printed in an alternating black-on-white  
4 and white-on-black format as determined  
5 appropriate by the Secretary.

6 “(iii) FORMAT.—The label statements  
7 under subparagraph (B) of paragraph (1)  
8 shall be black when the background is  
9 white and white when the background is  
10 black, and shall be in the point size re-  
11 quired under this subparagraph. The label  
12 statements shall be enclosed by a rectangu-  
13 lar border that is the same color as the let-  
14 ters of the statements and that is the  
15 width of the first down stroke of the cap-  
16 ital ‘W’ of the word ‘WARNING’ in the  
17 label statements.

18 “(C) LANGUAGE REQUIREMENT.—The  
19 label statements required under paragraph  
20 (1)(B) shall be in English, except that—

21 “(i) in the case of an advertisement  
22 that appears in a newspaper, magazine, pe-  
23 riodical or other publication that is not in  
24 English, such statements shall appear in



1 the predominant language of the publica-  
2 tion; or

3 “(ii) in the case of any other adver-  
4 tisement that is not in English, such state-  
5 ments shall appear in the same language  
6 as that principally used in the advertise-  
7 ment.

8 “(4) ROTATION OF LABEL STATEMENTS.—

9 “(A) LABELING.—The label statements  
10 specified in subparagraph (A) of paragraph (1)  
11 shall be randomly displayed in each 12 month  
12 period, in as equal a number of times as is pos-  
13 sible on each brand of the product and be ran-  
14 domly distributed in all areas of the United  
15 States in which such product is marketed in ac-  
16 cordance with a plan submitted by the manu-  
17 facturer, importer, distributor or retailer and  
18 approved by the Secretary.

19 “(B) ADVERTISING.—The label statements  
20 specified in subparagraph (B) of paragraph (1)  
21 shall be rotated quarterly in alternating se-  
22 quence in advertisements for each such brand  
23 of cigarettes in accordance with a plan submit-  
24 ted by the manufacturer, importer, distributor  
25 or retailer and approved by the Secretary.

1           “(C) APPROVAL OF PLANS.—The Sec-  
2           retary shall review each plan submitted by a  
3           manufacturer, importer, distributor or retailer  
4           of cigarettes under this paragraph and approve  
5           such plan if the plan will provide for the equal  
6           distribution and display on packaging and the  
7           rotation required in advertising under this para-  
8           graph and if such plan assures that all of the  
9           labels required under subparagraphs (A) and  
10          (B) will be displayed by the manufacturer, im-  
11          porter, distributor or retailer at the same time.

12          “(b) SMOKELESS TOBACCO PRODUCTS.—

13           “(1) IN GENERAL.—

14           “(A) PACKAGING.—It shall be unlawful for  
15           any person to manufacture, package, or import  
16           for sale or distribution any smokeless tobacco  
17           product the package of which fails to bear, in  
18           accordance with the requirements of this sub-  
19           section, one of the following labels:

20           “WARNING: This Product Can Cause  
21           Mouth Cancer.

22           “WARNING: This Product Can Kill You.

23           “WARNING: This Product Can Cause  
24           Gum Disease And Tooth Loss.

1                   “WARNING: This Product Is Not A Safe  
2                   Alternative To Cigarettes.

3                   “WARNING: This Product Contains Can-  
4                   cer-Causing Chemicals.

5                   “WARNING: Smokeless Tobacco Is Ad-  
6                   dictive.

7                   “(B) ADVERTISING.—It shall be unlawful  
8                   for any manufacturer, importer, distributor or  
9                   retailer of smokeless tobacco products to adver-  
10                  tise or cause to be advertised any smokeless to-  
11                  bacco product unless the advertising bears, in  
12                  accordance with the requirements of this sub-  
13                  section, one of the following labels:

14                  “WARNING: This Product Can Cause  
15                  Mouth Cancer.

16                  “WARNING: This Product Can Kill You.

17                  “WARNING: This Product Can Cause  
18                  Gum Disease And Tooth Loss.

19                  “WARNING: This Product Is Not A Safe  
20                  Alternative To Cigarettes.

21                  “WARNING: This Product Contains Can-  
22                  cer-Causing Chemicals.

23                  “WARNING: Smokeless Tobacco Is Ad-  
24                  dictive.

1           “(C) ADDITIONAL WARNINGS.—Beginning  
2           on the date that is 18 months after the date of  
3           enactment of this subchapter, the Secretary  
4           may substitute for, or require warnings in addi-  
5           tion to, those otherwise required under subpara-  
6           graphs (A) and (B) if the Secretary determines  
7           that such warnings would be more effective in  
8           detering the use of smokeless tobacco products.

9           “(2) REQUIREMENTS FOR LABELING.—

10           “(A) LOCATION.—Each label statement re-  
11           quired by subparagraph (A) of paragraph (1)  
12           shall be located on the 2 most prominent dis-  
13           play panels of the product and occupy not less  
14           than 25 percent of such panels.

15           “(B) TYPE AND COLOR.—With respect to  
16           each label statement required by subparagraph  
17           (A) of paragraph (1), the phrase ‘WARNING’  
18           shall appear in capital letters and the label  
19           statement shall be printed in 17 point type with  
20           adjustments as determined appropriate by the  
21           Secretary to reflect the length of the required  
22           statement and the size of the package. All the  
23           letters in the label shall appear in conspicuous  
24           and legible type in contrast by typography, lay-  
25           out, or color with all other printed material on

1           the package and be printed in an alternating  
2           black-on-white and white-on-black format as de-  
3           termined appropriate by the Secretary.

4           “(3) ADVERTISING AND ROTATION.—The provi-  
5           sions of paragraph (3) and (4) of subsection (a)  
6           shall apply to advertisements for smokeless tobacco  
7           products and the rotation of the label statements re-  
8           quired under paragraph (1)(A) on such products.

9           “(c) OTHER TOBACCO PRODUCTS.—The Secretary  
10          shall prescribe such regulations as may be necessary to  
11          establish warning labels for other tobacco product packag-  
12          ing, labeling and advertising.

13          “(d) RULES OF CONSTRUCTION.—

14                 “(1) IN GENERAL.—Nothing in this section  
15                 shall be construed to limit the ability of the Sec-  
16                 retary to change the text or layout of any of the  
17                 warning statements, or any of the labeling provi-  
18                 sions, under subsections (a) and (b) and other provi-  
19                 sions of this Act, if determined necessary by the Sec-  
20                 retary in order to make such statements or labels  
21                 larger, more prominent, more conspicuous, or more  
22                 effective.

23                 “(2) UNFAIR ACTS.—Nothing in this section  
24                 (other than the requirements of subsections (a), (b)  
25                 and (c)) shall be construed to limit or restrict the

1 authority of the Federal Trade Commission with re-  
2 spect to unfair or deceptive acts or practices in the  
3 advertising of tobacco products.

4 “(e) LIMITED PREEMPTION.—

5 “(1) STATE AND LOCAL ACTION.—No warning  
6 label with respect to tobacco products, or any other  
7 tobacco product for which warning labels have been  
8 required under this section, other than the warning  
9 labels required under this Act, shall be required by  
10 any State or local statute or regulation to be in-  
11 cluded on any package of a tobacco product.

12 “(2) EFFECT ON LIABILITY LAW.—Nothing in  
13 this section shall relieve any person from liability at  
14 common law or under State statutory law to any  
15 other person.

16 “(f) VIOLATION OF SECTION.—Any tobacco product  
17 that is in violation of this section shall be deemed to be  
18 misbranded.

19 **“SEC. 573. GENERAL RESPONSIBILITIES OF MANUFACTUR-**  
20 **ERS, DISTRIBUTORS AND RETAILERS.**

21 “Each manufacturer, distributor, and retailer shall  
22 ensure that the tobacco products it manufactures, labels,  
23 advertises, packages, distributes, sells, or otherwise holds  
24 for sale comply with all applicable requirements of this  
25 Act.

1 "SEC. 574. DISCLOSURE AND REPORTING OF TOBACCO AND  
2 NONTOBACCO INGREDIENTS AND CONSTITU-  
3 ENTS.

4 "(a) DISCLOSURE OF ALL INGREDIENTS.—

5 "(1) IMMEDIATE AND ANNUAL DISCLOSURE.—

6 Not later than 30 days after the date of enactment  
7 of this subchapter, and annually thereafter, each  
8 manufacturer of a tobacco product shall submit to  
9 the Secretary an ingredient list for each brand of to-  
10 bacco product it manufactures that contains the in-  
11 formation described in paragraph (2).

12 "(2) REQUIREMENTS.—The list described in  
13 paragraph (1) shall, with respect to each brand or  
14 variety of tobacco product of a manufacturer, in-  
15 clude—

16 "(A) a list of all ingredients, constituents,  
17 substances, and compounds that are found in or  
18 added to the tobacco or tobacco product (in-  
19 cluding the paper, filter, or packaging of the  
20 product if applicable) in the manufacture of the  
21 tobacco product, for each brand or variety of to-  
22 bacco product so manufactured, including, if  
23 determined necessary by the Secretary, any ma-  
24 terial added to the tobacco used in the product  
25 prior to harvesting;

1           “(B) the quantity of the ingredients, con-  
2           stituents, substances, and compounds that are  
3           listed under subparagraph (A) in each brand or  
4           variety of tobacco product;

5           “(C) the nicotine content of the product,  
6           measured in milligrams of nicotine;

7           “(D) for each brand or variety of ciga-  
8           rettes—

9                   “(i) the filter ventilation percentage  
10                   (the level of air dilution in the cigarette as  
11                   provided by the ventilation holes in the fil-  
12                   ter, described as a percentage);

13                   “(ii) the pH level of the smoke of the  
14                   cigarette; and

15                   “(iii) the tar, unionized (free) nico-  
16                   tine, and carbon monoxide delivery level  
17                   and any other smoking conditions estab-  
18                   lished by the Secretary, reported in milli-  
19                   grams of tar, nicotine, and carbon mon-  
20                   oxide per cigarette;

21           “(E) for each brand or variety of smoke-  
22           less tobacco products—

23                   “(i) the pH level of the tobacco;



1                   “(ii) the moisture content of the to-  
2                   bacco expressed as a percentage of the  
3                   weight of the tobacco; and

4                   “(iii) the nicotine content—

5                   “(I) for each gram of the prod-  
6                   uct, measured in milligrams of nico-  
7                   tine;

8                   “(II) expressed as a percentage  
9                   of the dry weight of the tobacco; and

10                  “(III) with respect to unionized  
11                  (free) nicotine, expressed as a percent-  
12                  age per gram of the tobacco and ex-  
13                  pressed in milligrams per gram of the  
14                  tobacco; and

15                  “(F) any other information determined ap-  
16                  propriate by the Secretary.

17                  “(3) METHODS.—The Secretary shall have the  
18                  authority to promulgate regulations to establish the  
19                  methods to be used by manufacturers in making the  
20                  determinations required under paragraph (2).

21                  “(4) OTHER TOBACCO PRODUCTS.—The Sec-  
22                  retary shall prescribe such regulations as may be  
23                  necessary to establish information disclosure proce-  
24                  dures for other tobacco products.

25                  “(b) SAFETY ASSESSMENTS.—

1           “(1) APPLICATION TO NEW INGREDIENTS.—

2           “(A) IN GENERAL.—Not later than 1 year  
3 after the date of enactment of this subchapter,  
4 and annually thereafter, each manufacturer  
5 shall submit to the Secretary a safety assess-  
6 ment for each new ingredient, constituent, sub-  
7 stance, or compound that such manufacturer  
8 desires to make a part of a tobacco product.  
9 Such new ingredient, constituent, substance, or  
10 compound shall not be included in a tobacco  
11 product prior to approval by the Secretary of  
12 such a safety assessment.

13           “(B) METHOD OF FILING.—A safety as-  
14 sessment submitted under subparagraph (A)  
15 shall be signed by an officer of the manufac-  
16 turer who is acting on behalf of the manufac-  
17 turer and who has the authority to bind the  
18 manufacturer, and contain a statement that en-  
19 sures that the information contained in the as-  
20 sessment is true, complete and accurate.

21           “(C) DEFINITION OF NEW INGREDIENT.—  
22 For purposes of subparagraph (A), the term  
23 ‘new ingredient, constituent, substance, or  
24 compound’ means an ingredient, constituent,  
25 substance, or compound listed under subsection

1 (a)(1) that was not used in the brand or variety  
2 of tobacco product involved prior to January 1,  
3 1998.

4 “(2) APPLICATION TO OTHER INGREDIENTS.—  
5 With respect to the application of this section to in-  
6 gredients, constituents substances, or compounds  
7 listed under subsection (a) to which paragraph (1)  
8 does not apply, all such ingredients, constituents,  
9 substances, or compounds shall be reviewed through  
10 the safety assessment process within the 5-year pe-  
11 riod beginning on the date of enactment of this sub-  
12 chapter. The Secretary shall develop a procedure for  
13 the submission of safety assessments of such ingre-  
14 dients, constituents, substances, or compounds that  
15 staggers such safety assessments within the 5-year  
16 period.

17 “(3) BASIS OF ASSESSMENT.—The safety as-  
18 sessment of an ingredient, constituent, substance, or  
19 compound described in paragraphs (1) and (2)  
20 shall—

21 “(A) be based on the best scientific evi-  
22 dence available at the time of the submission of  
23 the assessment; and

24 “(B) demonstrate that there is a reason-  
25 able certainty among experts qualified by sci-

1           entific training and experience who are con-  
2           sulted, that the ingredient, constituent, sub-  
3           stance, or compound will not present any risk  
4           to consumers or the public in the quantities  
5           used under the intended conditions of use.

6           “(c) PROHIBITION.—

7           “(1) REGULATIONS.—Not later than 12 months  
8           after the date of enactment of this subchapter, the  
9           Secretary shall promulgate regulations to prohibit  
10          the use of any ingredient, constituent, substance, or  
11          compound in the tobacco product of a manufac-  
12          turer—

13                 “(A) if no safety assessment has been sub-  
14                 mitted by the manufacturer for the ingredient,  
15                 constituent, substance, or compound as other-  
16                 wise required under this section; or

17                 “(B) if the Secretary finds that the manu-  
18                 facturer has failed to demonstrate the safety of  
19                 the ingredient, constituent, substance, or  
20                 compound that was the subject of the assess-  
21                 ment under paragraph (2).

22           “(2) REVIEW OF ASSESSMENTS.—

23                 “(A) GENERAL REVIEW.—Not later than  
24                 180 days after the receipt of a safety assess-  
25                 ment under subsection (b), the Secretary shall

1 review the findings contained in such assess-  
2 ment and approve or disapprove of the safety of  
3 the ingredient, constituent, substance, or  
4 compound that was the subject of the assess-  
5 ment. The Secretary may, for good cause, ex-  
6 tend the period for such review. The Secretary  
7 shall provide notice to the manufacturer of an  
8 action under this subparagraph.

9 “(B) INACTION BY SECRETARY.—If the  
10 Secretary fails to act with respect to an assess-  
11 ment of an existing ingredient, constituent, sub-  
12 stance, or additive during the period referred to  
13 in subparagraph (A), the manufacturer of the  
14 tobacco product involved may continue to use  
15 the ingredient, constituent, substance, or  
16 compound involved until such time as the Sec-  
17 retary makes a determination with respect to  
18 the assessment.

19 “(d) RIGHT TO KNOW; FULL DISCLOSURE OF INGRE-  
20 DIENTS TO THE PUBLIC.—

21 “(1) IN GENERAL.—Except as provided in para-  
22 graph (3), a package of a tobacco product shall dis-  
23 close all ingredients, constituents, substances, or  
24 compounds contained in the product in accordance

1 with regulations promulgated under section 701(a)  
2 by the Secretary.

3 “(2) DISCLOSURE OF PERCENTAGE OF DOMES-  
4 TIC AND FOREIGN TOBACCO.—The regulations re-  
5 ferred to in paragraph (1) shall require that the  
6 package of a tobacco product disclose, with respect  
7 to the tobacco contained in the product—

8 “(A) the percentage that is domestic to-  
9 bacco; and

10 “(B) the percentage that is foreign to-  
11 bacco.

12 “(3) HEALTH DISCLOSURE.—Notwithstanding  
13 section 301(j), the Secretary may require the public  
14 disclosure of any ingredient, constituent, substance,  
15 or compound contained in a tobacco product that re-  
16 lates to a trade secret or other matter referred to in  
17 section 1905 of title 18, United States Code, if the  
18 Secretary determines that such disclosure will pro-  
19 mote the public health.

20 **“SEC. 575. REDUCED RISK PRODUCTS.**

21 “(a) PROHIBITION.—

22 “(1) IN GENERAL.—No manufacturer, distribu-  
23 tor or retailer of tobacco products may make any di-  
24 rect or implied statement in advertising or on a  
25 product package that could reasonably be inter-

1        preted to state or imply a reduced health risk associ-  
2        ated with a tobacco product unless the manufacturer  
3        demonstrates to the Secretary, in such form as the  
4        Secretary may require, that based on the best avail-  
5        able scientific evidence the product significantly re-  
6        duces the overall health risk to the public when com-  
7        pared to other tobacco products.

8           “(2) SUBMISSION TO SECRETARY.—Prior to  
9        making any statement described in paragraph (1), a  
10       manufacturer, distributor or retailer shall submit  
11       such statement to the Secretary, who shall review  
12       such statement to ensure its accuracy and, in the  
13       case of advertising, to prevent such statement from  
14       increasing, or preventing the contraction of, the size  
15       of the overall market for tobacco products.

16       “(b) DETERMINATION BY SECRETARY.—If the Sec-  
17       retary determines that a statement described in subsection  
18       (a)(2) is permissible because the tobacco product does  
19       present a significantly reduced overall health risk to the  
20       public, the Secretary may permit such statement to be  
21       made.

22       “(c) DEVELOPMENT OR ACQUISITION OF REDUCED  
23       RISK TECHNOLOGY.—

24           “(1) IN GENERAL.—Any manufacturer that de-  
25       velops or acquires any technology that the manufac-

1 turer reasonably believes will reduce the risk from  
2 tobacco products shall notify the Secretary of the de-  
3 velopment or acquisition of the technology. Such no-  
4 tice shall be in such form and within such time as  
5 the Secretary shall require.

6 “(2) CONFIDENTIALITY.—With respect to any  
7 technology described in paragraph (1) that is in the  
8 early stages of development (as determined by the  
9 Secretary), the Secretary shall establish protections  
10 to ensure the confidentiality of any proprietary in-  
11 formation submitted to the Secretary under this sub-  
12 section during such development.

13 **“SEC. 576. ACCESS TO COMPANY INFORMATION.**

14 “(a) COMPLIANCE PROCEDURES.—Each manufac-  
15 turer of tobacco products shall establish procedures to en-  
16 sure compliance with this Act.

17 “(b) REQUIREMENT.—In addition to any other dis-  
18 closure obligations under this Act, the KIDS Act, or any  
19 other law, each manufacturer of tobacco products shall,  
20 not later than 90 days after the date of the enactment  
21 of the KIDS Act and thereafter as required by the Sec-  
22 retary, disclose to the Secretary all nonpublic information  
23 and research in its possession or control relating to the  
24 addiction or dependency, or the health or safety of tobacco  
25 products, including (without limitation) all research relat-



1 ing to processes to make tobacco products less hazardous  
2 to consumers and the research and documents described  
3 in subsection (c).

4 “(c) RESEARCH AND DOCUMENTS.—The documents  
5 described in this section include any documents concerning  
6 tobacco product research relating to—

7 “(1) nicotine, including—

8 “(A) the interaction between nicotine and  
9 other components in tobacco products including  
10 ingredients in the tobacco and smoke compo-  
11 nents;

12 “(B) the role of nicotine in product design  
13 and manufacture, including product charters,  
14 and parameters in product development, the to-  
15 bacco blend, filter technology, and paper;

16 “(C) the role of nicotine in tobacco leaf  
17 purchasing;

18 “(D) reverse engineering activities involv-  
19 ing nicotine (such as analyzing the products of  
20 other companies);

21 “(E) an analysis of nicotine delivery; and

22 “(F) the biology, psychopharmacology and  
23 any other health effects of nicotine;

24 “(2) other ingredients, including—

1           “(A) the identification of ingredients in to-  
2           bacco products and constituents in smoke, in-  
3           cluding additives used in product components  
4           such as paper, filter, and wrapper;

5           “(B) any research on the health effects of  
6           ingredients; and

7           “(C) any research or other information ex-  
8           plaining what happens to ingredients when they  
9           are heated and burned;

10          “(3) less hazardous or safer products, including  
11          any research or product development information on  
12          activities involving reduced risk, less hazardous, low-  
13          tar or reduced-tar, low-nicotine or reduced-nicotine  
14          or nicotine-free products; and

15          “(4) tobacco product advertising, marketing  
16          and promotion, including—

17                 “(A) documents related to the design of  
18                 advertising campaigns, including the desired de-  
19                 mographics for individual products on the mar-  
20                 ket or being tested;

21                 “(B) documents concerning the age of ini-  
22                 tiation of tobacco use, general tobacco use be-  
23                 havior, beginning smokers, pre-smokers, and  
24                 new smokers;

1                   “(C) documents concerning the effects of  
2                   advertising; and

3                   “(D) documents concerning future market-  
4                   ing options or plans in light of the requirements  
5                   and regulations to be imposed under this sub-  
6                   chapter or the KIDS Act.

7                   “(d) AUTHORITY OF SECRETARY.—With respect to  
8                   tobacco product manufacturers, the Secretary shall have  
9                   the same access to records and information and inspection  
10                  authority as is available with respect to manufacturers of  
11                  other medical devices.

12                  **“SEC. 577. OVERSIGHT OF TOBACCO PRODUCT MANUFAC-**  
13                  **TURING.**

14                  “The Secretary shall by regulation prescribe good  
15                  manufacturing practice standards for tobacco products.  
16                  Such regulations shall be modeled after good manufactur-  
17                  ing practice regulations for medical devices, food, and  
18                  other items under section 520(f). Such standards shall be  
19                  directed specifically toward tobacco products, and shall in-  
20                  clude—

21                         “(1) a quality control system, to ensure that to-  
22                         bacco products comply with such standards;

23                         “(2) a system for inspecting tobacco product  
24                         materials to ensure their compliance with such  
25                         standards;

1           “(3) requirements for the proper handling of  
2 finished tobacco products;

3           “(4) strict tolerances for pesticide chemical resi-  
4 dues in or on tobacco or tobacco product commod-  
5 ities in the possession of the manufacturer, except  
6 that nothing in this paragraph shall be construed to  
7 affect any authority of the Environmental Protection  
8 Agency;

9           “(5) authority for officers or employees of the  
10 Secretary to inspect any factory, warehouse, or other  
11 establishment of any tobacco product manufacturer,  
12 and to have access to records, files, papers, proc-  
13 esses, controls and facilities related to tobacco prod-  
14 uct manufacturing, in accordance with appropriate  
15 authority and rules promulgated under this Act; and

16           “(6) a requirement that the tobacco product  
17 manufacturer maintain such files and records as the  
18 Secretary may specify, as well as that the manufac-  
19 turer report to the Secretary such information as  
20 the Secretary shall require, in accordance with sec-  
21 tion 519.

22 **“SEC. 578. PRESERVATION OF STATE AND LOCAL AUTHOR-**  
23 **ITY.**

24           “Notwithstanding section 521 and except as other-  
25 wise provided for in section 572(e), nothing in this sub-

1 chapter shall be construed as prohibiting a State or local-  
2 ity from imposing requirements, prohibitions, penalties or  
3 other measures to further the purposes of this subchapter  
4 that are in addition to the requirements, prohibitions, or  
5 penalties required under this subchapter. State and local  
6 governments may impose additional tobacco product con-  
7 trol measures to further restrict or limit the use of such  
8 products.”.

9 **SEC. 213. FUNDING.**

10 (a) **AUTHORIZATION OF APPROPRIATIONS.**—There  
11 are authorized to be appropriated amounts provided under  
12 section 101(d)(2)(C) to carry out this subtitle (and the  
13 amendments made by this subtitle).

14 (b) **TRIGGER.**—No expenditures shall be made under  
15 this subtitle (or the amendments made by this subtitle)  
16 during any fiscal year in which the annual amount appro-  
17 priated for the Food and Drug Administration is less than  
18 the amount so appropriated for the prior fiscal year.

19 **SEC. 214. REPEALS.**

20 The following provisions of law shall be repealed:

21 (1) The Federal Cigarette Labeling and Adver-  
22 tising Act (15 U.S.C. 1331 et seq.), except for sec-  
23 tions 5(d)(1) and (2) and 6.

1           (2) The Comprehensive Smokeless Tobacco  
 2 Health Education Act of 1986 (15 U.S.C. 4401 et  
 3 seq.), except for sections 3(f) and 3(a) and (b).

4           (3) The Comprehensive Smoking Education Act  
 5 of 1964 (Public law 98-474).

6 **Subtitle C—Manufacturer and**  
 7 **Product Seller Licensing and**  
 8 **Anti-Smuggling**

9 **SEC. 221. DEFINITIONS.**

10 In this subtitle:

11           (1) **CONTRABAND TOBACCO PRODUCT.**—The  
 12 term “contraband tobacco product” means any to-  
 13 bacco product that is manufactured, sold or offered  
 14 for sale, shipped, delivered, transferred, or possessed  
 15 in violation of this subtitle, chapter 52 of the Inter-  
 16 nal Revenue Code of 1986, or Chapter 114 of Title  
 17 18, United States Code, or any regulations issued  
 18 under any such provision.

19           (2) **DEALER.**—The term “dealer” means any  
 20 person lawfully engaged in the business of selling to-  
 21 bacco products.

22           (3) **ENGAGED IN THE BUSINESS.**—The term  
 23 “engaged in the business” means—

24                   (A) as applied to a manufacturer of to-  
 25 bacco products, any person who devotes time,

1 attention, and labor to manufacturing tobacco  
2 products for sale or distribution;

3 (B) as applied to an importer of tobacco  
4 products, any person who devotes time, atten-  
5 tion, and labor to importing tobacco products  
6 into the United States from a place outside of  
7 the United States for sale or distribution;

8 (C) as applied to an exporter of tobacco  
9 products, any person who devotes time, atten-  
10 tion, and labor to exporting tobacco products  
11 for sale or distribution outside of the United  
12 States;

13 (D) as applied to a wholesaler in tobacco  
14 products, any person who devotes time, atten-  
15 tion, and labor to the sale or distribution of to-  
16 bacco products at wholesale; and

17 (E) as applied to a retailer in tobacco  
18 products, any person who devotes time, atten-  
19 tion, and labor to the sale or distribution of to-  
20 bacco products to consumers.

21 (4) EXPORTER.—The term “exporter” means  
22 any person engaged in the business of exporting to-  
23 bacco products from the United States for purposes  
24 of sale or distribution. The term “licensed exporter”

1 means any such person licensed under the provisions  
2 of this subtitle.

3 (5) IMPORTER.—The term “importer” means  
4 any person engaged in the business of importing to-  
5 bacco products into the United States for purposes  
6 of sale or distribution. The term “licensed importer”  
7 means any such person licensed under the provisions  
8 of this subtitle.

9 (6) INTENTIONALLY.—The term “intentionally”  
10 means doing an act, or omitting to do an act, delib-  
11 erately, and not due to accident, inadvertence, or  
12 mistake. An intentional act does not require that a  
13 person knew that such person’s act constituted an  
14 offense.

15 (7) MANUFACTURER.—The term “manufac-  
16 turer” means any person engaged in the business of  
17 manufacturing a tobacco product for purposes of  
18 sale or distribution. The term “licensed manufac-  
19 turer” means any such person licensed under the  
20 provisions of this subtitle, except that such term  
21 shall not include a person who produces cigars, ciga-  
22 rettes, smokeless tobacco, or pipe tobacco solely for  
23 his own personal consumption or use.



1           (8) PERSON.—The term “person” includes any  
2 individual, corporation, company, association, firm,  
3 partnership, society, or joint stock company.

4           (9) SECRETARY.—The term “Secretary” means  
5 the Secretary of the Treasury.

6           (10) UNITED STATES.—The term “United  
7 States” means the several States, the District of Co-  
8 lumbia, the Commonwealth of Puerto Rico, and the  
9 possessions of the United States.

10          (11) WHOLESALER.—The term “wholesaler”  
11 means any person engaged in the business of pur-  
12 chasing tobacco products for resale at wholesale, or  
13 any person acting as an agent or broker for any per-  
14 son engaged in the business of purchasing tobacco  
15 products for resale at wholesale.

16 **SEC. 222. MINIMAL FEDERAL LICENSING AND REGISTRA-**  
17 **TION PROGRAM.**

18          (a) ESTABLISHMENT.—The Secretary shall establish  
19 a minimum Federal licensing and registration program  
20 that provides for a comprehensive system to support State  
21 efforts to collect State tobacco excise taxes and to prevent  
22 tobacco contraband activities.

23          (b) FUNDING.—The Secretary shall use amounts  
24 made available under section 101(d)(2)(D) to carry out  
25 this section.

1 **SEC. 223. LICENSING AND RETAILER REGISTRATION.**

2 (a) **LICENSING.**—

3 (1) **REQUIREMENT.**—No person shall engage in  
4 the business as a manufacturer, importer, exporter,  
5 or wholesaler of tobacco products until such person  
6 has been licensed to do so by the Secretary.

7 (2) **APPLICATION.**—To be licensed under this  
8 section, a manufacturer, importer, exporter or  
9 wholesaler shall prepare and submit to the Secretary  
10 an application at such time, in such manner and  
11 containing such information as the Secretary deter-  
12 mines necessary to determine the eligibility of the  
13 applicant to be licensed under this section. The Sec-  
14 retary may promulgate regulations to prescribe ap-  
15 plication requirements under this paragraph.

16 (3) **FEE.**—Each applicant under paragraph (2)  
17 shall pay an annual fee to the Secretary for obtain-  
18 ing and maintaining a license under this section. A  
19 separate license and fee shall be required for each  
20 place in which the applicant is to do business. Fail-  
21 ure to pay an annual fee will result in the automatic  
22 termination of the license.

23 (4) **ELIGIBILITY.**—A person shall be entitled to  
24 a license under this section unless the Secretary  
25 finds—

1 (A) that such person has been previously  
2 convicted of a Federal crime relating to to-  
3 bacco, including the taxation thereof;

4 (B) that such person has, during the 5-  
5 year period prior to the date on which the ap-  
6 plication is submitted, been convicted of any fel-  
7 ony under Federal or State law; or

8 (C) that such person is, by virtue of that  
9 person's business experience, financial standing,  
10 or trade connections, not likely to maintain  
11 such operations in conformity with Federal law.

12 (5) ISSUANCE OF LICENSE.—Upon the filing of  
13 a proper application under paragraph (2), the pay-  
14 ment of the prescribed annual fee under paragraph  
15 (3), and a finding by the Secretary that the person  
16 is entitled to a license under paragraph (4), the Sec-  
17 retary shall issue to the applicant the appropriate li-  
18 cense and such license shall entitle the licensee to  
19 engage in the business of manufacturing, importing,  
20 exporting, or wholesaling in tobacco products as the  
21 case may be, subject to the provisions of this subtitle  
22 and other applicable provisions of law.

23 (6) DURATION.—A license issued under this  
24 subtitle shall continue in effect until revoked, sus-

1        pended, or annulled as provided for in this subtitle,  
2        or until voluntarily surrendered, except that—

3                (A) if leased, sold, or otherwise trans-  
4                ferred, the license shall be automatically termi-  
5                nated; and

6                (B) if transferred by operation of law or if  
7                actual or legal control of the licensee is ac-  
8                quired, directly or indirectly, whether by stock-  
9                ownership or in any other manner, by any per-  
10              son, then such license shall be terminated after  
11              30 days.

12        If within the 30-day period described in subpara-  
13        graph (B), an application is made for a new license,  
14        the outstanding license to which such subparagraph  
15        applies shall continue in effect until such application  
16        is finally acted upon by the Secretary.

17              (7) CONDITIONS.—All licenses issued under this  
18        subtitle shall be conditioned upon compliance with  
19        the provisions of this subtitle, all Federal laws relat-  
20        ing to the taxation of tobacco products, chapter 114  
21        of title 18, United States Code, the Jenkins Act (15  
22        U.S.C. 375, et seq.) and any regulations issued pur-  
23        suant to such provisions.

24        (b) RETAILER REGISTRATION.—

1           (1) REQUIREMENT.—No person shall engage in  
2 the business as a retailer of tobacco products until  
3 such person has registered with the Secretary and  
4 paid a fee for obtaining such registration. A sepa-  
5 rate registration and fee shall be required for each  
6 place in which the retailer is to do business. Such  
7 fee shall be paid in such form, manner, and at such  
8 time as the Secretary by regulation shall prescribe.  
9 No fee shall be pro-rated if a retailer commences op-  
10 erations any time after the first of the year.

11           (2) FORM AND CONTENT.—A registration under  
12 this subsection shall be in such form and contain  
13 such information as determined to be necessary by  
14 the Secretary. The Secretary may promulgate regu-  
15 lations to prescribe registration requirements under  
16 this paragraph.

17           (3) DURATION.—

18           (A) IN GENERAL.—A registration issued  
19 under this subsection shall continue in effect for  
20 a period of 1 year from the date of issuance.

21           (B) LIMITATION.—A registration issued  
22 under this subsection may not be leased, sold,  
23 or transferred, by operation of law or otherwise.  
24 Any registration issued under this subsection  
25 shall terminate upon the lease, sale, or transfer,

1           by operation of law, or otherwise, of such reg-  
2           istration to another person.

3           (4) ISSUANCE OF REGISTRATION.—Upon the  
4           filing of a proper registration and payment of the  
5           prescribed fee under paragraph (1), the Secretary  
6           shall register a qualified retailer that, subject to the  
7           provisions of this subtitle and other applicable provi-  
8           sions of law, shall entitle the retailer to engage in  
9           the business as a retailer in tobacco products, unless  
10          the Secretary finds that the person submitting a reg-  
11          istration has previously had a registration under this  
12          subtitle revoked.

13          (5) CONDITIONS.—A retailer registration under  
14          this subtitle shall be conditioned upon compliance  
15          with this subtitle, all Federal laws relating to the  
16          taxation of tobacco products, chapter 114 of title 18,  
17          United States Code, and any regulations issued pur-  
18          suant to such provisions.

19          (c) PROCEDURES.—

20               (1) ANNULMENT.—The Secretary may, after  
21               providing notice, annul any license or registration is-  
22               sued under this subtitle if the Secretary finds that  
23               the license or registration was procured through  
24               fraud, misrepresentation, or concealment of material  
25               fact. If the Secretary annuls a license or registration

1 under this paragraph, the Secretary shall, upon a re-  
2 quest by the aggrieved party, promptly hold a hear-  
3 ing to review the annulment of such license or reg-  
4 istration.

5 (2) DENIAL.—The Secretary may, after provid-  
6 ing notice, deny any application for a license or re-  
7 ject any registration submitted under this subtitle by  
8 a person the Secretary has reason to believe is not  
9 entitled to receive such license or registration. If the  
10 Secretary denies an application for a license or re-  
11 jects a registration, the Secretary shall, upon a re-  
12 quest by the aggrieved party, promptly hold a hear-  
13 ing to review the denial, revocation, or suspension of  
14 such license or registration.

15 (3) REVOCATION OR SUSPENSION.—The Sec-  
16 retary may, after providing notice, revoke, or sus-  
17 pend any license or registration issued under this  
18 subtitle if the Secretary finds the person holding the  
19 license or registration has violated the conditions of  
20 licensing or registration. If the Secretary revokes or  
21 suspends a license or registration, the Secretary  
22 shall, upon request by the aggrieved party, promptly  
23 hold a hearing to review the revocation or suspen-  
24 sion of such license or registration.

1           (4) VIOLATION OF YOUTH ACCESS RESTRIC-  
2           TIONS.—

3           (A) IN GENERAL.—Upon the issuance of a  
4           final order by the Secretary of Health and  
5           Human Services pursuant to the Federal Food,  
6           Drug and Cosmetic Act (21 U.S.C. 321 et seq.)  
7           that a registered retailer has violated section  
8           520(e) of the Federal Food, Drug and Cosmetic  
9           Act (21 U.S.C. 360j(e)), or the regulations is-  
10          sued thereunder, and upon proper referral of  
11          such final order to the Secretary, a registration  
12          issued under this subtitle shall be automatically  
13          suspended or revoked in accordance with the  
14          final order of the Secretary of Health and  
15          Human Services. Upon receipt of such order,  
16          the Secretary shall, within 30 days, provide no-  
17          tice to the registrant that the registration in-  
18          volved is suspended or revoked.

19          (B) NONAPPLICATION OF CERTAIN PROVI-  
20          SIONS.—The provisions of subsections (d) and  
21          (e) shall not apply with respect to the revoca-  
22          tion or suspension of any registration issued  
23          under this subtitle resulting from a final order  
24          from the Secretary of Health and Human Serv-  
25          ices under subparagraph (A).



1           (5) VIOLATION OF KIDS ACT PROVISIONS.—

2           Upon a certification by the Secretary of Health and  
3           Human Services that a licensed or registered entity  
4           under this section has violated a provision of this  
5           Act (or an amendment made by this Act) the Sec-  
6           retary of the Treasury may, after providing notice,  
7           revoke, or suspend any license or registration. If the  
8           Secretary revokes or suspends a license or registra-  
9           tion, the Secretary shall, upon a request by the ag-  
10          grieved party, promptly hold a hearing to review the  
11          revocation, or suspension of such license or registra-  
12          tion.

13          (d) PROCESS.—

14               (1) IN GENERAL.—Any person whose applica-  
15               tion for a license is denied or application for reg-  
16               istration is rejected, or any holder of a license or  
17               registration that is revoked, suspended, or annulled  
18               shall receive a written notice from the Secretary  
19               stating specifically the grounds upon which the ap-  
20               plication was denied or upon which the license or  
21               registration was revoked, suspended, or annulled.  
22               Notice of a revocation or suspension of a license or  
23               registration shall be given to the holder of such li-  
24               cense or registration prior to the effective date of  
25               the revocation or suspension.

1           (2) NOTICE.—Written notice of any denial of  
2 application, rejection of registration, suspension, rev-  
3 ocation, annulment, or other proceedings, shall be  
4 served—

5           (A) in person by any officer or employee of  
6 the Secretary authorized for such purpose; or

7           (B) by mailing the order certified mail, ad-  
8 dressed to the applicant or respondent at the  
9 last known address in the records of the Sec-  
10 retary.

11 (e) APPEAL.—

12           (1) IN GENERAL.—An applicant, registrant, or  
13 licensee may appeal any final order of the Secretary  
14 denying an application for a license, rejecting a reg-  
15 istration, or suspending, revoking, or annulling, a li-  
16 cense or registration.

17           (2) FILING.—An aggrieved party may, at any  
18 time within 60 days after the date on which a notice  
19 of a final order described in paragraph (1) was re-  
20 ceived, file a petition in the circuit court of appeals  
21 of the United States within any circuit in which such  
22 person resides or has as a principal place of busi-  
23 ness, or in the United States Court of Appeals for  
24 the District of Columbia, asking that the order of

1 the Secretary be modified or set aside in whole or  
2 in part.

3 (3) REQUIREMENT.—With respect to a filing  
4 under paragraph (2), a copy of the petition shall be  
5 transmitted by the clerk of the court to the Sec-  
6 retary, or any officer designated by the Secretary for  
7 that purpose, and thereupon the Secretary shall file  
8 in the court the record upon which the order com-  
9 plained of was entered, as provided for in section  
10 2112 of title 28, United States Code.

11 (4) JURISDICTION.—Upon the filing of a peti-  
12 tion with the court under this subsection, the court  
13 shall have exclusive jurisdiction to affirm, modify, or  
14 set aside such order, in whole or in part.

15 (5) PROCEDURE.—

16 (A) OBJECTION.—No objection to the  
17 order of the Secretary shall be considered by  
18 the court under this subsection unless such ob-  
19 jection shall have been urged before the Sec-  
20 retary or unless there were reasonable grounds  
21 for failure to do so.

22 (B) FINDINGS.—The findings of the Sec-  
23 retary as to the facts, if supported by substan-  
24 tial evidence, shall be conclusive in any action  
25 under this subsection.

1           (C) ADDITIONAL EVIDENCE.—If any party  
2           in an action under this subsection applies to the  
3           court for leave to adduce additional evidence,  
4           and demonstrated to the satisfaction of the  
5           court that such additional evidence is material  
6           and there were reasonable grounds for failure  
7           to adduce such evidence on the proceeding be-  
8           fore the Secretary, the court may order such  
9           additional evidence to be taken before the Sec-  
10          retary and to be adduced upon the hearing in  
11          such manner and upon such terms and condi-  
12          tions as the court may deem proper.

13          (D) MODIFICATION OF FINDINGS.—The  
14          Secretary may modify findings to which this  
15          subsection applies as to the facts by reason of  
16          additional evidence taken under subparagraph  
17          (C), and the Secretary shall file with the court  
18          such new or modified findings, which, if sup-  
19          ported by substantial evidence, shall be conclu-  
20          sive. The recommendations of the Secretary, if  
21          any, for the modification or setting aside of the  
22          original order shall be conclusive.

23          (6) ORDER OF COURT.—The judgment or de-  
24          cree of the court affirming, modifying, or setting  
25          aside, in whole or in part, any order of the Secretary

1 under this section shall be final, subject to review by  
2 the Supreme Court of the United States upon certio-  
3 rari or certification as provided for in section 1254  
4 of title 28, United States Code.

5 (7) STAY.—The commencement of proceedings  
6 under this subsection shall, unless specifically or-  
7 dered by the court to the contrary, operate as a stay  
8 of the Secretary's order.

9 **SEC. 224. UNLAWFUL ACTS.**

10 (a) IN GENERAL.—It shall be unlawful for any per-  
11 son—

12 (1) except a licensed manufacturer, licensed ex-  
13 porter, licensed importer, or licensed wholesaler to  
14 engage intentionally in the business of manufactur-  
15 ing, exporting, importing or wholesaling any tobacco  
16 product; or

17 (2) except a registered retailer to engage inten-  
18 tionally in the business of selling or offering for sale  
19 tobacco products at retail.

20 (b) SHIPMENT TO OTHER THAN LICENSED OR REG-  
21 ISTERED ENTITY.—It shall be unlawful for any licensed  
22 importer, licensed manufacturer, licensed wholesaler in-  
23 tentiously to ship, transport, deliver or receive any to-  
24 bacco products from or to any person other than a person  
25 licensed or registered under this subtitle.

1 (c) RETAILERS.—It shall be unlawful for any retailer  
2 registered under this subtitle intentionally—

3 (1) to receive tobacco products from any person  
4 other than a licensed manufacturer, licensed im-  
5 porter, or licensed wholesaler; or

6 (2) to sell or offer for sale to any person in a  
7 single transaction any tobacco products in quantities  
8 of more than 50 packages, other than a direct re-  
9 turn to a licensee for credit.

10 (d) EXPORTERS.—

11 (1) IN GENERAL.—It shall be unlawful for any  
12 licensed exporter intentionally—

13 (A) to ship, transport, sell or deliver for  
14 sale any tobacco products to any person other  
15 than a licensed manufacturer, licensed im-  
16 porter, licensed wholesaler, or foreign pur-  
17 chaser;

18 (B) to receive any tobacco products from  
19 any person other than a licensed manufacturer,  
20 licensed importer, or licensed wholesaler; or

21 (C) to ship, transport, sell, deliver or oth-  
22 erwise transfer any tobacco product intended  
23 for export unless the package containing the to-  
24 bacco product is marked “FOR EXPORT  
25 ONLY FROM THE UNITED STATES”.

1           (2) LIMITATION.—It shall be unlawful for any  
2           person other than a licensed exporter intentionally to  
3           ship, transport, receive or possess, for purposes of  
4           resale, any tobacco product in packages marked  
5           “FOR EXPORT ONLY FROM THE UNITED  
6           STATES,” other than for direct return to the man-  
7           ufacturer or exporter for re-packing or for re-expor-  
8           tation.

9           (e) FALSE RECORDS.—It shall be unlawful for any  
10          licensed manufacturer, licensed exporter, licensed im-  
11          porter, licensed wholesaler, or retailer to make inten-  
12          tionally any false entry in, to fail willfully to make appro-  
13          priate entry in, or to fail willfully to maintain properly  
14          any record or report that such person is required to keep  
15          as required by this subtitle or the regulations promulgated  
16          thereunder.

17          (f) CONTRABAND PRODUCTS.—It shall be unlawful  
18          for any person intentionally to ship, transport, receive,  
19          possess, sell, offer for sale, distribute, or purchase contra-  
20          band tobacco products in or affecting interstate commerce.

21   **SEC. 225. PENALTIES AND COMPROMISE OF LIABILITY.**

22          (a) CRIMINAL PENALTIES.—Any person violating any  
23          of the provisions of section 224 shall upon conviction be  
24          fined as provided for in section 3571 of title 18, United

1 States Code, imprisoned for not more than 5 years, or  
2 both.

3 (b) CIVIL PENALTIES.—The Secretary may, in lieu  
4 of referring violations of this section for criminal prosecu-  
5 tion, impose a civil penalty of not more than \$10,000 for  
6 each offense.

7 (c) COMPROMISE OF LIABILITY.—The Secretary is  
8 authorized, with respect to any violation of this subtitle  
9 or any regulation issued thereunder, to compromise the  
10 liability arising with respect to such violation upon pay-  
11 ment of a sum for each offense prior to referral to the  
12 Department of Justice for prosecution or defense. The At-  
13 torney General may compromise any such case after refer-  
14 ral to the Department of Justice for prosecution or de-  
15 fense.

16 (d) FORFEITURE.—

17 (1) IN GENERAL.—The Secretary shall seize  
18 and forfeit, in accordance with section 9703(o) of  
19 title 31, United States Code, any conveyance, to-  
20 bacco products, or monetary instrument (as defined  
21 in section 5312 of title 31, United States Code) in-  
22 volved in a violation of this subtitle or any property,  
23 real or personal, which constitutes or is derived from  
24 proceeds traceable to a violation of this subtitle.



1           (2) SENTENCING.—The court, in imposing sen-  
2           tence on a person convicted of violating this subtitle,  
3           shall order that person to forfeit to the United  
4           States any property described in paragraph (1) in-  
5           volved in such violation. The seizure and forfeiture  
6           of such property shall be governed by subsections  
7           (b), (c) and (e) through (p) of section 853 of title  
8           21, United States Code.

9 **SEC. 226. GENERAL ADMINISTRATIVE PROVISIONS.**

10          (a) RECORDS.—

11           (1) IN GENERAL.—Every manufacturer, im-  
12           porter, wholesaler, or exporter shall maintain records  
13           in such manner as the Secretary shall by regulation  
14           prescribe.

15           (2) RETAILER.—Every retailer of tobacco prod-  
16           ucts shall maintain records in a manner as the Sec-  
17           retary shall by regulation prescribe, including  
18           records of tobacco products received, and the person  
19           from whom such tobacco products were received.

20           (3) REQUIREMENT.—The records required by  
21           this subsection shall be maintained for a period of  
22           not less than 5 years and the Secretary may, by giv-  
23           ing written notice to the manufacturer, importer,  
24           wholesaler, exporter, or retailer require the retention  
25           for an additional period of not more than 2 years.

1 (b) PRESERVATION AND INSPECTION OF RECORDS.—

2 Any records or documents required to be maintained  
3 under subsection (a) or any regulations issued pursuant  
4 thereto shall be preserved by the person required to keep  
5 such records or documents available for inspection by the  
6 Secretary during business hours.

7 (c) ENTRY OF PREMISES FOR INSPECTION.—The

8 Secretary may enter, during business hours, the premises  
9 (including places of storage) of any manufacturer, im-  
10 porter, wholesaler, exporter, or retailer for the purposes  
11 of inspecting such premises and for the examination of  
12 any required record or inventory of tobacco products kept  
13 or stored by such person on the business premises.

14 (d) EXAMINATION AND SUMMONS.—

15 (1) IN GENERAL.—For the purpose of deter-  
16 mining whether any manufacturer, importer, whole-  
17 saler, exporter, retailer, or any other person is in  
18 compliance with the provisions of this subtitle, the  
19 Secretary is authorized, at all reasonable times, to  
20 examine and copy any books, paper, records, or  
21 other data that may be relevant or material to such  
22 inquiry.

23 (2) SUMMONS.—In order to conduct an inspec-  
24 tion, investigation, or maintain an enforcement ac-  
25 tion under this section, the Secretary may summon

1 any person having information on the compliance of  
2 the provisions of this subtitle by any manufacturer,  
3 importer, wholesaler, exporter, retailer, or any other  
4 person to appear before the Secretary at a time and  
5 place named in the summons and to give testimony  
6 under oath or produce such books, papers, records,  
7 or other data as may be relevant or material to such  
8 inquiry.

9 (3) SERVICE.—A summons shall be served by  
10 the Secretary, by an attested copy delivered in hand  
11 to the person to whom it is directed, or left at such  
12 person's last place of business or abode. The certifi-  
13 cate of service signed by the person serving the sum-  
14 mons shall be evidence of the facts it states on the  
15 hearing of an application for the enforcement of the  
16 summons. When the summons requires the produc-  
17 tion of books, papers, records, or other data, it shall  
18 be sufficient if such books, papers, records, or other  
19 data are described with reasonable certainty.

20 (4) JURISDICTION.—Any of the district courts  
21 of the United States within the jurisdiction of which  
22 such inquiry is carried on may, in case of contumacy  
23 or refusal to obey a summons, issue to a person an  
24 order requiring such person to appear before the  
25 Secretary and give such testimony or produce such

1 books, papers, records, or other data relating to the  
2 inquiry. Any failure to obey such order of the court  
3 may be punished by such court as a contempt there-  
4 of.

5 (e) INDUSTRY COMPLIANCE PROGRAM.—The Sec-  
6 retary shall prescribe regulations necessary to ensure each  
7 licensee establishes and maintains a compliance program.  
8 Such program shall be designed to ensure that retailers  
9 comply with Federal laws and regulations relating to the  
10 distribution of tobacco products to consumers.

11 (f) REPORTS TO THE SECRETARY.—

12 (1) IN GENERAL.—The Secretary is authorized  
13 to require, in such manner and form as shall be pre-  
14 scribed in regulations, such reports as are necessary  
15 to carry out the powers and duties under this sub-  
16 title including any reports deemed necessary to en-  
17 sure the proper accounting of materials necessary to  
18 manufacture tobacco products. Such reports will in-  
19 clude detailed descriptions of licensee compliance  
20 programs that have been developed by the licensees  
21 to ensure that retailers comply with the Federal laws  
22 and regulations relating to the distribution of to-  
23 bacco products to consumers.

24 (2) REPORTS TO CONGRESS.—The Secretary  
25 shall biennially prepare and submit to the appro-

1        piate committees of Congress a report concerning  
2        the activities of the Secretary under this subtitle.

3        (g) UTILIZATION OF OTHER GOVERNMENT AGEN-  
4        CIES.—The Secretary may, with the consent of the depart-  
5        ment or agency affected, utilize the services of any depart-  
6        ment or other agency of the Federal Government to the  
7        extent necessary to carry out the powers and duties under  
8        this subtitle and authorize officers and employees thereof  
9        to act as agents of the Secretary. The Secretary may pro-  
10       vide funds to State and local enforcement entities to be  
11       used to support training and technical assistance. Such  
12       activities shall be coordinated with the Secretary of Health  
13       and Human Services in the conduct of State-based en-  
14       forcement of requirements relating to restriction on mi-  
15       nors' access to tobacco products.

16       (h) MARKINGS, BRANDING, IDENTIFICATION.—To-  
17       bacco products shall be marked, branded, packaged, or  
18       identified in such a manner as the Secretary shall by regu-  
19       lation prescribe.

20       (i) PROCEEDS OF INVESTIGATIVE OPERATIONS.—  
21       With respect to any undercover investigative operation of  
22       the Bureau of Alcohol, Tobacco and Firearms (referred  
23       to in this subtitle as "ATF") that is necessary for the  
24       detection and prosecution of offenses against the United

1 States under this subtitle, and notwithstanding any other  
2 provision of law—

3 (1) amounts collected under section 227 and  
4 the proceeds from such operation may be deposited  
5 in banks or other financial institutions;

6 (2) the proceeds from such operation may be  
7 used to offset necessary and reasonable expenses in-  
8 curred in such operation;

9 (3) amounts collected under section 227 may be  
10 used to purchase property, building, and other facili-  
11 ties, and to lease space within the United States, the  
12 District of Columbia, and the territories and posses-  
13 sions of the United States, and to establish or ac-  
14 quire proprietary corporations or business entities on  
15 a commercial basis; and

16 (4) ATF shall comply with liquidation, deposit,  
17 audit, and reporting provisions in sections 2081(b)  
18 through (d) of title 19, United States Code, to the  
19 extent applicable and not inconsistent with this sub-  
20 section;

21 if, with respect to paragraphs (1), (2) and (3), the Direc-  
22 tor has certified in writing that the actions authorized by  
23 paragraphs (1), (2), and (3) are necessary for the conduct  
24 of such operation.

1           (j) AUTHORIZATION OF APPROPRIATIONS AND  
2 TRACKING SYSTEM.—

3           (1) AUTHORIZATION OF APPROPRIATIONS.—

4           There are authorized to be appropriated amounts  
5           provided under section 101(d)(2)(D) to enable the  
6           Department of the Treasury to carry out activities  
7           under this subtitle relating to—

8                   (A) training of Federal, State, and foreign  
9                   tobacco administrators and enforcement offi-  
10                   cials;

11                   (B) training for smuggling and diversion  
12                   interdiction;

13                   (C) educational outreach for tobacco indus-  
14                   try members on the objectives of this Act and  
15                   the responsibilities of such individuals under  
16                   this Act;

17                   (D) research by the Customs Services and  
18                   the Bureau relating to tracking technologies;  
19                   and

20                   (E) other activities relating to the purposes  
21                   of this subtitle.

22           (2) TRACKING SYSTEM.—In establishing a con-  
23           trolled commodity tracking system for tobacco prod-  
24           ucts, the Secretary shall evaluate the deployment of  
25           an innovative anti-diversion system that can be im-

1       plemented at the manufacturing level to track prod-  
2       ucts through the stream of commerce to the point of  
3       retail sale.

4 **SEC. 227. FUNDING.**

5       (a) **LICENSING AND REGISTRATION FEES.**—The Sec-  
6       retary may, in the Secretary's sole discretion, set the li-  
7       censing and registration fees required by this subtitle, in  
8       such amounts as are necessary to recover the costs of ad-  
9       ministering the provisions of this subtitle, including pre-  
10      venting trafficking in contraband tobacco products.

11      (b) **DISPOSITION OF FEES.**—

12           (1) **ACCOUNT.**—Fees collected by the Secretary  
13      under this subtitle shall be deposited in an account  
14      within the Treasury of the United States that is spe-  
15      cially designated for paying the costs associated with  
16      the administration or enforcement of this subtitle or  
17      any other Federal law relating to the unlawful traf-  
18      ficking of tobacco products.

19           (2) **PAYMENTS.**—The Secretary is authorized  
20      and directed to pay out of any funds in the account  
21      referred to in paragraph (1) any expenses incurred  
22      by the Federal Government in administering and en-  
23      forcing this subtitle or any other Federal law relat-  
24      ing to the unlawful trafficking in tobacco products  
25      (including expenses incurred for the salaries and ex-



1       penses of individuals employed to provide such serv-  
2       ices).

3               (3) **LIMITATION.**—None of the funds deposited  
4       into the account referred to in paragraph (1) shall  
5       be made available for any purpose other than mak-  
6       ing payments authorized under the preceding sen-  
7       tence.

8               (c) **SUPPLEMENT NOT SUPPLANT.**—Amounts pro-  
9       vided under this subtitle for the Department of the Treas-  
10       ury shall be in addition to any other amounts appropriated  
11       for such Department. Amounts otherwise appropriated for  
12       such Department shall not be reduced below the amounts  
13       so appropriated for fiscal year 1998, as a result of the  
14       amounts made available under this subtitle.

15       **SEC. 228. TRANSITIONAL RULES.**

16               (a) **MANUFACTURERS OR EXPORTERS.**—Any manu-  
17       facturer or export warehouse proprietor, who, on the date  
18       of enactment of this Act, is a permittee under chapter 52  
19       of the Internal Revenue Code of 1986, and who submits  
20       an application pursuant to the provisions of this subtitle  
21       not later than 90 days after the date of enactment of this  
22       Act, may continue to engage in such business pending  
23       final action on such application.

24               (b) **IMPORTERS, EXPORTERS, WHOLESALERS AND**  
25       **RETAILERS.**—Any person engaged in the business of im-

1 porting, exporting, wholesaling, or retailing tobacco prod-  
2 ucts on the date of enactment of this Act, who submits  
3 an application pursuant to the provisions of this subtitle  
4 not later than 90 days after the date of enactment of this  
5 Act, may continue to engage in such business pending  
6 final action on such application.

7 **SEC. 229. RULES AND REGULATIONS.**

8 The Secretary shall prescribe rules and regulations  
9 for the enforcement of this subtitle, including all rules and  
10 regulations that are necessary to ensure the lawful dis-  
11 tribution of tobacco products in interstate or foreign com-  
12 merce.

13 **SEC. 230. SEVERABILITY.**

14 If any provision of this subtitle or the application  
15 thereof to any person or circumstance is held invalid, the  
16 validity of the remainder of this subtitle and of the appli-  
17 cation of such provision to other persons and cir-  
18 cumstances shall not be affected thereby.

19 **SEC. 231. EFFECT ON STATE OR LOCAL LAW.**

20 No provision of this subtitle shall be construed to oc-  
21 cupy the field in which such provision operates to the ex-  
22 clusion of the law of any State or political subdivision  
23 thereof on the same subject matter, unless there is a direct  
24 and positive conflict between such provision and the law

1 of the State or political subdivision thereof so that the two  
2 cannot be reconciled or consistently stand together.

3 **SEC. 232. AMENDMENT TO CONTRABAND CIGARETTE TRAF-**  
4 **FICKING ACT.**

5 Chapter 114 of title 18, United States Code, is  
6 amended—

7 (1) in section 2341—

8 (A) in paragraph (2)—

9 (i) by striking “60,000” and inserting  
10 “30,000”; and

11 (ii) by striking “if such State” and all  
12 that follows through “payment of cigarette  
13 taxes”;

14 (B) in paragraph (4), by striking “and” at  
15 the end;

16 (C) in paragraph (5), by striking the pe-  
17 riod and inserting “; and”; and

18 (D) by adding at the end the following:

19 “(6) the term ‘tobacco product’ means ciga-  
20 rettes, cigarette tobacco, smokeless tobacco, little ci-  
21 gars, roll-your-own products, cigars, cigarillos, pipe  
22 tobacco, roll-your-own products, (as such terms are  
23 defined in section 5 of the KIDS Act) and any other  
24 product made or derived from tobacco intended for  
25 human consumption.”;

1 (2) in section 2342(b), by striking “60,000”  
2 and inserting “30,000”;

3 (3) in sections 2343, by striking “60,000” each  
4 place that such term appears and inserting  
5 “30,000”.

6 (4) by striking “cigarette” each place that such  
7 term appears, other than in paragraphs (1) and (6)  
8 of section 2341, and inserting “tobacco product”;  
9 and

10 (5) by striking “cigarettes” each place that  
11 such term appears and inserting “tobacco products”.

## 12 **Subtitle D—Penalties**

### 13 **SEC. 241. PENALTIES.**

14 Section 307 of the Federal Food, Drug, and Cosmetic  
15 Act (21 U.S.C. 335b) is amended by adding at the end  
16 the following:

17 “(f) PENALTIES RELATING TO TOBACCO PROD-  
18 UCTS.—

19 “(1) COMPLIANCE AND DISCLOSURE.—

20 “(A) IN GENERAL.—Any tobacco manufac-  
21 turer, or employee or agent of any tobacco man-  
22 ufacturer which violates this Act or the KIDS  
23 Act shall be subject to a civil penalty of  
24 \$25,000 per day of violation. In addition, the  
25 Secretary may require any such manufacturer

1 to include in its advertising for the relevant to-  
2 bacco product a statement of such violation.

3 “(B) DISCLOSURE.—Any tobacco product  
4 manufacturer or employee or agent of any to-  
5 bacco product manufacturer who fails to dis-  
6 close to the Secretary research documents or in-  
7 formation required to be disclosed by this Act  
8 or the KIDS Act or any other provision of law  
9 relating to the health effects or toxicity of to-  
10 bacco products, nontobacco ingredients and to-  
11 bacco product constituents shall be subject to a  
12 civil penalty of not more than \$10,000,000 for  
13 each such violation. Such civil penalty shall be  
14 in addition to any other criminal, civil or ad-  
15 ministrative penalty prescribed by law.

16 “(2) CIVIL ACTIONS TO RECOVER PENALTIES.—  
17 The Secretary may commence a civil action to assess  
18 and recover any civil penalty under paragraph (1) in  
19 the district court of the United States for the dis-  
20 trict in which the violation is alleged to have oc-  
21 curred or in which the defendant resides or has its  
22 principal place of business. The court shall have ju-  
23 risdiction to assess a civil penalty in such an action.  
24 In determining the amount of any civil penalty to be

1       assessed under this subsection, the court shall take  
2       into account—

3               “(A) the gravity of the violation;

4               “(B) the economic benefit or savings (if  
5       any) resulting from the violation;

6               “(C) the size of the violator’s business;

7               “(D) the violator’s history of compliance  
8       with this Act;

9               “(E) action taken to remedy the violation;

10              “(F) the effect of the penalty on the viola-  
11       tor’s ability to continue business operations;  
12       and

13              “(G) such other matters as justice may re-  
14       quire.

15       In any such action, subpoenas for witnesses who are  
16       required to attend a district court in any district  
17       may run into any other district.”.

18       **SEC. 242. APPLICATION OF PENALTIES WITH RESPECT TO**  
19                               **VIOLATIONS OF CERTAIN LICENSING PROVI-**  
20                               **SIONS.**

21       (a) IN GENERAL.—A manufacturer, exporter, im-  
22       porter, wholesaler or retailer who violates any provision  
23       of this Act (or an amendment made by this Act) or regula-  
24       tions issued thereunder with respect to tobacco products  
25       shall, in addition to any applicable penalties otherwise pro-

1 vided for in this Act (or amendments), be liable to an  
2 order of the Secretary suspending or revoking a license  
3 or registration issued pursuant to section 223(b). Such  
4 revocation or suspension shall be adjudicated in accord-  
5 ance with the procedures provided for in subsection 303(f)  
6 (3)(A) and (4) of the Federal Food, Drug and Cosmetic  
7 Act (21 U.S.C. 333(f)(3)(A) and (4)). If civil penalties  
8 pursuant to such section 303(f)(1)(A) are being sought  
9 for the same violation or violations, such violation will be  
10 adjudicated in a single proceeding for purposes of such  
11 subsection.

12 (b) NOTIFICATION.—Upon receiving a final order is-  
13 sued by the Secretary suspending or revoking a license or  
14 registration issued under section 223(c), the Secretary of  
15 the Treasury shall notify the licensee or registrant that  
16 such license or registration has been suspended or revoked  
17 in accordance with this section.