

111TH CONGRESS
1ST SESSION

H. R. 1261

To protect the public health by establishing the Tobacco Harm Reduction Center within the Department of Health and Human Services with certain authority to regulate tobacco products, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 3, 2009

Mr. BUYER (for himself, Mr. McINTYRE, Mr. DEAL of Georgia, Mr. WILSON of South Carolina, Mr. COBLE, Mr. BURGESS, Mr. GINGREY of Georgia, Mrs. MYRICK, Mr. SHADEGG, and Mr. SHULER) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To protect the public health by establishing the Tobacco Harm Reduction Center within the Department of Health and Human Services with certain authority to regulate tobacco products, and for other purposes.

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

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

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Youth Prevention and Tobacco Harm Reduction Act”.

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

- Sec. 1. Short title; table of contents.
- Sec. 2. Findings.
- Sec. 3. Purpose.
- Sec. 4. Scope and effect.
- Sec. 5. Severability.
- Sec. 6. Effective date.

TITLE I—AUTHORITY OF THE TOBACCO HARM REDUCTION CENTER

- Sec. 100. Definitions.
- Sec. 101. Center authority over tobacco products.
- Sec. 102. Exclusion of other regulatory programs.
- Sec. 103. Existing Federal statutes maintained.
- Sec. 104. Proceedings in the name of the United States; subpoenas; preemption of State and local law; no private right of action.
- Sec. 105. Illicit trade.
- Sec. 106. Adulterated tobacco products.
- Sec. 107. Misbranded tobacco products.
- Sec. 108. Submission of health information to the Administrator.
- Sec. 109. Registration and listing.
- Sec. 110. General provisions respecting control of tobacco products.
- Sec. 111. Smoking article standards.
- Sec. 112. Notification and other remedies.
- Sec. 113. Records and reports on tobacco products.
- Sec. 114. Application for review of certain smoking articles.
- Sec. 115. Modified risk tobacco products.
- Sec. 116. Judicial review.
- Sec. 117. Jurisdiction of and coordination with the Federal Trade Commission.
- Sec. 118. Regulation requirement.
- Sec. 119. Preservation of State and local authority.
- Sec. 120. Tobacco Products Scientific Advisory Committee.
- Sec. 121. Drug products used to treat tobacco dependence.
- Sec. 122. Advertising and marketing of tobacco products.

TITLE II—TOBACCO PRODUCTS WARNINGS; CONSTITUENT AND SMOKE CONSTITUENT DISCLOSURE

- Sec. 201. Cigarette label and advertising warnings.
- Sec. 202. Smokeless tobacco labels and advertising warnings.

TITLE III—PUBLIC DISCLOSURES BY TOBACCO PRODUCTS MANUFACTURERS

- Sec. 301. Disclosures on packages of tobacco products.
- Sec. 302. Disclosures on packages of smokeless tobacco.
- Sec. 303. Public disclosure of ingredients.

TITLE IV—PREVENTION OF ILLICIT TRADE IN TOBACCO PRODUCTS

- Sec. 401. Study and report on illicit trade.
- Sec. 402. Amendment to section 1926 of the Public Health Service Act.
- Sec. 403. Establishment of rankings.

TITLE V—ENFORCEMENT PROVISIONS

- Sec. 501. Prohibited acts.
- Sec. 502. Injunction proceedings.
- Sec. 503. Penalties.
- Sec. 504. Seizure.
- Sec. 505. Report of minor violations.
- Sec. 506. Inspection.
- Sec. 507. Effect of compliance.
- Sec. 508. Imports.
- Sec. 509. Tobacco products for export.

TITLE VI—MISCELLANEOUS PROVISIONS

- Sec. 601. Use of payments under the master settlement agreement and individual State settlement agreements.
- Sec. 602. Preemption of State Laws Implementing Fire Safety Standard for Cigarettes.
- Sec. 603. Inspection by the alcohol and tobacco tax trade bureau of records of certain cigarette and smokeless tobacco sellers.
- Sec. 604. Severability.

TITLE VII—TOBACCO GROWER PROTECTION

- Sec. 701. Tobacco grower protection.

1 **SEC. 2. FINDINGS.**

2 The Congress finds the following:

3 (1) Cigarette smoking is a leading cause of pre-
4 ventable deaths in the United States. Cigarette
5 smoking significantly increases the risk of developing
6 lung cancer, heart disease, chronic bronchitis, em-
7 physema and other serious diseases with adverse
8 health conditions.

9 (2) The risk for serious diseases is significantly
10 affected by the type of tobacco product and the fre-
11 quency, duration and manner of use.

12 (3) No tobacco product has been shown to be
13 safe and without risks. The health risks associated
14 with cigarettes are significantly greater than those

1 associated with the use of smoke-free tobacco and
2 nicotine products.

3 (4) Nicotine in tobacco products is addictive but
4 is not considered a significant threat to health.

5 (5) It is the smoke inhaled from burning to-
6 bacco which poses the most significant risk of seri-
7 ous diseases.

8 (6) Quitting cigarette smoking significantly re-
9 duces the risk for serious diseases.

10 (7) Adult tobacco consumers have a right to be
11 fully and accurately informed about the risks of seri-
12 ous diseases, the significant differences in the com-
13 parative risks of different tobacco and nicotine-based
14 products, and the benefits of quitting. This informa-
15 tion should be based on sound science.

16 (8) Governments, public health officials, tobacco
17 manufacturers and others share a responsibility to
18 provide adult tobacco consumers with accurate infor-
19 mation about the various health risks and compara-
20 tive risks associated with the use of different tobacco
21 and nicotine products.

22 (9) Tobacco products should be regulated in a
23 manner that is designed to achieve significant and
24 measurable reductions in the morbidity and mor-
25 tality associated with tobacco use. Regulations

1 should enhance the information available to adult
2 consumers to permit them to make informed choices,
3 and encourage the development of tobacco and nico-
4 tine products with lower risks than cigarettes cur-
5 rently sold in the United States.

6 (10) The form of regulation should be based on
7 the risks and comparative risks of tobacco and nico-
8 tine products and their respective product categories.

9 (11) The regulation of marketing of tobacco
10 products should be consistent with constitutional
11 protections and enhance an adult consumer's ability
12 to make an informed choice by providing accurate
13 information on the risks and comparative risks of to-
14 bacco products.

15 (12) Reducing the diseases and deaths associ-
16 ated with the use of cigarettes serves public health
17 goals and is in the best interest of consumers and
18 society. Harm reduction should be the critical ele-
19 ment of any comprehensive public policy surrounding
20 the health consequences of tobacco use.

21 (13) Significant reductions in the harm associ-
22 ated with the use of cigarettes can be achieved by
23 providing accurate information regarding the com-
24 parative risks of tobacco products to adult tobacco
25 consumers, thereby encouraging smokers to migrate

1 to the use of smoke-free tobacco and nicotine prod-
2 ucts, and by developing new smoke-free tobacco and
3 nicotine products and other actions.

4 (14) Governments, public health officials, man-
5 ufacturers, tobacco producers and consumers should
6 support the development, production, and commer-
7 cial introduction of tobacco leaf, and tobacco and
8 nicotine-based products that are scientifically shown
9 to reduce the risks associated with the use of exist-
10 ing tobacco products, particularly cigarettes.

11 (15) Adult tobacco consumers should have ac-
12 cess to a range of commercially viable tobacco and
13 nicotine-based products.

14 (16) There is substantial scientific evidence
15 that selected smokeless tobacco products can satisfy
16 the nicotine addiction of inveterate smokers while
17 eliminating most, if not all, risk of pulmonary and
18 cardiovascular complications of smoking and while
19 reducing the risk of cancer by more than 95 percent.

20 (17) Transitioning smokers to selected smoke-
21 less tobacco products will eliminate environmental
22 tobacco smoke and fire-related hazards.

23 (18) Current “abstain, quit, or die” tobacco
24 control policies in the United States may have
25 reached their maximum possible public health ben-

1 efit because of the large number of cigarette smok-
2 ers either unwilling or unable to discontinue their
3 addiction to nicotine.

4 (19) There is evidence that harm reduction
5 works and can be accomplished in a way that will
6 not increase initiation or impede smoking cessation.

7 (20) Health-related agencies and organizations,
8 both within the United States and abroad have al-
9 ready gone on record endorsing Harm Reduction as
10 an approach to further reducing tobacco related ill-
11 ness and death.

12 (21) Current Federal policy requires tobacco
13 product labeling that leaves the incorrect impression
14 that all tobacco product present equal risk.

15 **SEC. 3. PURPOSE.**

16 The purposes of this Act are—

17 (1) to provide authority to the Tobacco Harm
18 Reduction Center by recognizing it as the primary
19 Federal regulatory authority with respect to tobacco
20 products as provided for in this Act;

21 (2) to ensure that the Center has the authority
22 to address issues of particular concern to public
23 health officials, especially the use of tobacco by
24 young people and dependence on tobacco;

1 (3) to authorize the Center to set national
2 standards controlling the manufacture of tobacco
3 products and the identity, public disclosure, and
4 amount of ingredients used in such products;

5 (4) to provide new and flexible enforcement au-
6 thority to ensure that there is effective oversight of
7 the tobacco industry's efforts to develop, introduce,
8 and promote less harmful tobacco products;

9 (5) to vest the Center with the authority to reg-
10 ulate the levels of tar, nicotine, and other harmful
11 components of tobacco products;

12 (6) to ensure that consumers are better in-
13 formed regarding the relative risks for death and
14 disease between categories of tobacco products;

15 (7) to continue to allow the sale of tobacco
16 products to adults in conjunction with measures to
17 ensure that they are not sold or accessible to under-
18 age purchasers;

19 (8) to impose appropriate regulatory controls on
20 the tobacco industry;

21 (9) to promote prevention, cessation, and harm
22 reduction policies and regulations to reduce disease
23 risk and the social costs associated with tobacco-re-
24 lated diseases;

1 (10) to provide authority to the Department of
2 Health and Human Services to regulate tobacco
3 products;

4 (11) to establish national policies that effec-
5 tively reduce disease and death associated with ciga-
6 rette smoking and other tobacco use;

7 (12) to establish national policies that encour-
8 age prevention, cessation, and harm reduction meas-
9 ures regarding the use of tobacco products;

10 (13) to encourage current cigarette smokers
11 who will not quit to use noncombustible tobacco or
12 nicotine products that have significantly less risk
13 than cigarettes;

14 (14) to establish national policies that accu-
15 rately and consistently inform adult tobacco con-
16 sumers of significant differences in risk between re-
17 spective tobacco products;

18 (15) to establish national policies that encour-
19 age and assist the development and awareness of
20 noncombustible tobacco and nicotine products;

21 (16) to coordinate national and State preven-
22 tion, cessation, and harm reduction programs;

23 (17) to impose measures to ensure tobacco
24 products are not sold or accessible to underage pur-
25 chasers; and

1 (18) to strengthen Federal and State legislation
2 to prevent illicit trade in tobacco products.

3 **SEC. 4. SCOPE AND EFFECT.**

4 (a) INTENDED EFFECT.—Nothing in this Act (or an
5 amendment made by this Act) shall be construed to—

6 (1) establish a precedent with regard to any
7 other industry, situation, circumstance, or legal ac-
8 tion;

9 (2) affect any action pending in Federal, State,
10 or Tribal court, or any agreement, consent decree, or
11 contract of any kind; or

12 (3) be applicable to tobacco products or compo-
13 nent parts manufactured in the United States for
14 export.

15 (b) AGRICULTURAL ACTIVITIES.—The provisions of
16 this Act (or an amendment made by this Act) which au-
17 thorize the Administrator to take certain actions with re-
18 gard to tobacco and tobacco products shall not be con-
19 strued to affect any authority of the Secretary of Agri-
20 culture under existing law regarding the growing, cultiva-
21 tion, or curing of raw tobacco.

22 (c) REVENUE ACTIVITIES.—The provisions of this
23 Act (or an amendment made by this Act) which authorize
24 the Administrator to take certain actions with regard to
25 tobacco products shall not be construed to affect any au-

1 thority of the Secretary of the Treasury under chapter 52
2 of the Internal Revenue Code of 1986.

3 **SEC. 5. SEVERABILITY.**

4 If any provision of this Act, the amendments made
5 by this Act, or the application of any provision of this Act
6 to any person or circumstance is held to be invalid, the
7 remainder of this Act, the amendments made by this Act,
8 and the application of the provisions of this Act to any
9 other person or circumstance shall not be affected and
10 shall continue to be enforced to the fullest extent possible.

11 **SEC. 6. EFFECTIVE DATE.**

12 Except as otherwise specifically provided, the effec-
13 tive date of this Act shall be the date of its enactment.

14 **TITLE I—AUTHORITY OF THE TO-**
15 **BACCO HARM REDUCTION**
16 **CENTER**

17 **SEC. 100. DEFINITIONS.**

18 In this Act:

19 (1) The term “Administrator” means the chief
20 executive of the Tobacco Harm Reduction Center.

21 (2) The term “adult” means any individual who
22 has attained the minimum age under applicable
23 State law to be an individual to whom tobacco prod-
24 ucts may lawfully be sold.

1 (3) The term “adult-only facility” means a fa-
2 cility or restricted area, whether open-air or en-
3 closed, where the operator ensures, or has a reason-
4 able basis to believe, that no youth is present. A fa-
5 cility or restricted area need not be permanently re-
6 stricted to adults in order to constitute an adult-only
7 facility, if the operator ensures, or has a reasonable
8 basis to believe, that no youth is present during any
9 period of operation as an adult-only facility.

10 (4) The term “affiliate” means a person that
11 directly or indirectly owns or controls, is owned or
12 controlled by, or is under common ownership or con-
13 trol with, another person. The terms “owns,” “is
14 owned”, and “ownership” refer to ownership of an
15 equity interest, or the equivalent thereof, of 50 per-
16 cent or more.

17 (5) The term “annual report” means a tobacco
18 product manufacturer’s annual report to the Center,
19 which provides ingredient information and nicotine
20 yield ratings for each brand style that tobacco prod-
21 uct manufacturer manufactures for commercial dis-
22 tribution domestically.

23 (6) The term “brand name” means a brand
24 name of a tobacco product distributed or sold do-
25 mestically, alone, or in conjunction with any other

1 word, trademark, logo, symbol, motto, selling mes-
2 sage, recognizable pattern of colors, or any other in-
3 dicial of product identification identical or similar
4 to, or identifiable with, those used for any domestic
5 brand of tobacco product. The term shall not include
6 the corporate name of any tobacco product manufac-
7 turer that does not, after the effective date of this
8 Act, sell a brand style of tobacco product in the
9 United States that includes such corporate name.

10 (7) The term “brand style” means a tobacco
11 product having a brand name, and distinguished by
12 the selection of the tobacco, ingredients, structural
13 materials, format, configuration, size, package, prod-
14 uct descriptor, amount of tobacco, or yield of “tar”
15 or nicotine.

16 (8) The term “Center” means the Tobacco
17 Harm Reduction Center.

18 (9) The term “cigar” has the meaning assigned
19 that term by the Alcohol and Tobacco Tax and
20 Trade Bureau in section 40.11 of title 27, Code of
21 Federal Regulations.

22 (10) The term “cigarette” means—

23 (A) any roll of tobacco wrapped in paper
24 or in any substance not containing tobacco; or

1 (B) any roll of tobacco wrapped in any
2 substance containing tobacco which, because of
3 the appearance of the roll of tobacco, the type
4 of tobacco used in the filler, or its package or
5 labeling, is likely to be offered to, or purchased
6 by, consumers as a cigarette described in para-
7 graph (1).

8 (11) The term “competent and reliable sci-
9 entific evidence” means evidence based on tests,
10 analyses, research, or studies, conducted and evalu-
11 ated in an objective manner by individuals qualified
12 to do so, using procedures generally accepted in the
13 relevant scientific disciplines to yield accurate and
14 reliable results.

15 (12) The term “distributor” means any person
16 who furthers the distribution of tobacco products,
17 whether domestic or imported, at any point from the
18 original place of manufacture to the person who sells
19 or distributes the tobacco product to individuals for
20 personal consumption. Common carriers, retailers,
21 and those engaged solely in advertising are not con-
22 sidered distributors for purposes of this Act.

23 (13) The terms “domestic” and “domestically”
24 mean within the United States, including activities
25 within the United States involving advertising, mar-

1 keting, distribution, or sale of tobacco products that
2 are intended for consumption within the United
3 States.

4 (14) The term “illicit tobacco product” means
5 any tobacco product intended for use by consumers
6 in the United States—

7 (A) as to which not all applicable duties or
8 taxes have been paid in full;

9 (B) that has been stolen, smuggled, or is
10 otherwise contraband;

11 (C) that is counterfeit; or

12 (D) that has or had a label, labeling, or
13 packaging stating, or that stated, that the prod-
14 uct is or was for export only, or that it is or
15 was at any time restricted by section 5704 of
16 title 26, United States Code.

17 (15) The term “illicit trade” means any trans-
18 fer, distribution, or sale in interstate commerce of
19 any illicit tobacco product.

20 (16) The term “immediate container” does not
21 include package liners.

22 (17) The term “Indian tribe” has the meaning
23 assigned that term in section 4(e) of the Indian Self
24 Determination and Education Assistance Act.

1 (18) The term “ingredient” means tobacco and
2 any substance added to tobacco to have an effect in
3 the final tobacco product or when the final tobacco
4 product is used by a consumer.

5 (19) The term “International Organization for
6 Standardization (ISO) testing regimen” means the
7 methods for measuring cigarette smoke yields, as set
8 forth in the most recent version of ISO 3308, enti-
9 tled “Routine analytical cigarette-smoking ma-
10 chine—Definition of standard conditions”; ISO
11 4387, entitled “Cigarettes—Determination of total
12 and nicotine-free dry particulate matter using a rou-
13 tine analytical smoking machine”; ISO 10315, enti-
14 tled “Cigarettes—Determination of nicotine in
15 smoke condensates—Gas-chromatographic method”;
16 ISO 10362–1, entitled “Cigarettes—Determination
17 of water in smoke condensates—Part 1: Gas-
18 chromatographic method”; and ISO 8454, entitled
19 “Cigarettes—Determination of carbon monoxide in
20 the vapour phase of cigarette smoke—NDIR meth-
21 od”. A cigarette that does not burn down in accord-
22 ance with the testing regimen standards may be
23 measured under the same puff regimen using the
24 number of puffs that such a cigarette delivers before
25 it extinguishes, plus an additional three puffs, or

1 with such other modifications as the Administrator
2 may approve.

3 (20) The term “interstate commerce” means all
4 trade, traffic, or other commerce—

5 (A) within the District of Columbia, or any
6 territory or possession of the United States;

7 (B) between any point in a State and any
8 point outside thereof;

9 (C) between points within the same State
10 through any place outside such State; or

11 (D) over which the United States has ju-
12 risdiction.

13 (21) The term “label” means a display of writ-
14 ten, printed, or graphic matter upon or applied se-
15 curely to the immediate container of a tobacco prod-
16 uct.

17 (22) The term “labeling” means all labels and
18 other written, printed, or graphic matter (1) upon or
19 applied securely to any tobacco product or any of its
20 containers or wrappers, or (2) accompanying a to-
21 bacco product.

22 (23) The term “little cigar” has the meaning
23 assigned that term by the Alcohol and Tobacco Tax
24 and Trade Bureau in section 40.11 of title 27, Code
25 of Federal Regulations.

1 (24) The term “loose tobacco” means any form
2 of tobacco, alone or in combination with any other
3 ingredient or material, that, because of its appear-
4 ance, form, type, packaging, or labeling, is suitable
5 for use and likely to be offered to, or purchased by,
6 consumers as tobacco for making or assembling
7 cigarettes, incorporation into pipes, or otherwise
8 used by consumers to make any tobacco product.

9 (25) The term “manufacture” means to design,
10 manufacture, fabricate, assemble, process, package,
11 or repackage, label, or relabel, import, or hold or
12 store in a commercial quantity, but does not in-
13 clude—

14 (A) the growing, curing, de-stemming, or
15 aging of tobacco; or

16 (B) the holding, storing or transporting of
17 a tobacco product by a common carrier for hire,
18 a public warehouse, a testing laboratory, a dis-
19 tributor, or a retailer.

20 (26) The term “nicotine-containing product”
21 means a product, other than a tobacco product, that
22 contains added nicotine, whether or not in the form
23 of a salt or solvate, that has been—

24 (A) synthetically produced, or

1 (B) obtained from tobacco or other source
2 of nicotine.

3 (27) The term “package” means a pack, box,
4 carton, pouch, or container of any kind in which a
5 tobacco product or tobacco products are offered for
6 sale, sold, or otherwise distributed to consumers.
7 The term “package” does not include an outer con-
8 tainer used solely for shipping one or more packages
9 of a tobacco product or tobacco products.

10 (28) The term “person” means any individual,
11 partnership, corporation, committee, association, or-
12 ganization or group of persons, or other legal or
13 business entity.

14 (29) The term “proof of age” means a driver’s
15 license or other form of identification that is issued
16 by a governmental authority and includes a photo-
17 graph and a date of birth of the individual.

18 (30) The term “raw tobacco” means tobacco in
19 a form that is received by a tobacco product manu-
20 facturer as an agricultural commodity, whether in a
21 form that is natural, stem, or leaf, cured or aged,
22 or as parts or pieces, but not in a reconstituted
23 form, extracted pulp form, or extract form.

24 (31) The term “reduced-exposure claim” means
25 a statement in advertising or labeling intended for

1 one or more consumers of tobacco products, that a
2 tobacco product provides a reduced exposure of
3 users of that tobacco product to one or more toxicants,
4 as compared to an appropriate reference tobacco product
5 or category of tobacco products. A statement or representation
6 that a tobacco product or the tobacco in a tobacco product
7 contains “no additives” or is “natural” or that uses a
8 substantially similar term is not a reduced-exposure claim
9 if the advertising or labeling that contains such statement
10 or representation also contains the disclosure required
11 by section 108(h) of this Act.
12

13 (32) The term “reduced-risk claim” means a
14 statement in advertising or labeling intended for one
15 or more consumers of smoking articles, that a smoking
16 article provides to users of that product a reduced risk
17 of morbidity or mortality resulting from one or more
18 chronic diseases or serious adverse health conditions
19 associated with tobacco use, as compared to an appropriate
20 reference smoking article or category of smoking articles,
21 even if it is not stated, represented, or implied that all
22 health risks associated with using that smoking article
23 have been reduced or eliminated. A statement or representation
24 that a smoking article or the tobacco in a smoking
25

1 article contains “no additives,” or is “natural,” or
2 that uses a substantially similar term is not a re-
3 duced-risk claim if the advertising or labeling that
4 contains such statement or representation also con-
5 tains the disclosure required by section 108(h).

6 (33) The term “retailer” means any person
7 that—

8 (A) sells tobacco products to individuals
9 for personal consumption; or

10 (B) operates a facility where the sale of to-
11 bacco products to individuals for personal con-
12 sumption is permitted.

13 (34) The term “small business” means a to-
14 bacco product manufacturer that—

15 (A) has 150 or fewer employees; and

16 (B) during the 3-year period prior to the
17 current calendar year, had an average annual
18 gross revenue from tobacco products that did
19 not exceed \$40,000,000.

20 (35) The term “smokeless tobacco product”
21 means any form of finely cut, ground, powdered, re-
22 constituted, processed or shaped tobacco, leaf to-
23 bacco, or stem tobacco, whether or not combined
24 with any other ingredient, whether or not in extract
25 or extracted form, and whether or not incorporated

1 within any carrier or construct, that is intended to
2 be placed in the oral or nasal cavity, including dry
3 snuff, moist snuff, and chewing tobacco.

4 (36) The term “smoking article” means any to-
5 bacco-containing article that is intended, when used
6 by a consumer, to be burned or otherwise to employ
7 heat to produce a vapor, aerosol or smoke that—

8 (A) incorporates components of tobacco or
9 derived from tobacco; and

10 (B) is intended to be inhaled by the user.

11 (37) The term “State” means any State of the
12 United States and, except as otherwise specifically
13 provided, includes any Indian tribe or tribal organi-
14 zation, the District of Columbia, the Commonwealth
15 of Puerto Rico, Guam, the Virgin Islands, American
16 Samoa, Wake Island, Midway Island, Kingman Reef,
17 Johnston Atoll, the Northern Marianas, and any
18 other trust territory or possession of the United
19 States.

20 (38) The term “tar” means nicotine-free dry
21 particulate matter as defined in ISO 4387, entitled
22 “Cigarettes—Determination of total and nicotine-
23 free dry particulate matter using a routine analytical
24 smoking machine”.

1 (39) The term “tobacco” means a tobacco plant
2 or any part of a harvested tobacco plant intended for
3 use in the production of a tobacco product, including
4 leaf, lamina, stem, or stalk, whether in green, cured,
5 or aged form, whether in raw, treated, or processed
6 form, and whether or not combined with other mate-
7 rials, including any by-product, extract, extracted
8 pulp material, or any other material (other than pu-
9 rified nicotine) derived from a tobacco plant or any
10 component thereof, and including strip, filler, stem,
11 powder, and granulated, blended, or reconstituted
12 forms of tobacco.

13 (40) The term “tobacco product” means—

14 (A) the singular of “tobacco products” as
15 defined in section 5702(c) of the Internal Rev-
16 enue Code of 1986;

17 (B) any other product that contains to-
18 bacco as a principal ingredient and that, be-
19 cause of its appearance, type, or the tobacco
20 used in the product, or its packaging and label-
21 ing, is likely to be offered to, or purchased by,
22 consumers as a tobacco product as described in
23 subparagraph (A); and

1 (C) any form of tobacco or any construct
2 incorporating tobacco, intended for human con-
3 sumption, whether by—

4 (i) placement in the oral or nasal cav-
5 ity;

6 (ii) inhalation of vapor, aerosol, or
7 smoke; or

8 (iii) any other means.

9 (41) The term “tobacco product category”
10 means a type of tobacco product characterized by its
11 composition, components, and intended use, and in-
12 cludes tobacco products classified as cigarettes, loose
13 tobacco for roll-your-own tobacco products, little ci-
14 gars, cigars, pipe tobacco, moist snuff, dry snuff,
15 chewing tobacco, and other forms of tobacco prod-
16 ucts (which are treated in this Act collectively as a
17 single category).

18 (42) The term “tobacco product communica-
19 tion” means any means, medium, or manner for pro-
20 viding information relating to any tobacco product,
21 including face-to-face interaction, mailings by postal
22 service or courier to an individual who is an ad-
23 dressee, and electronic mail to an individual who is
24 an addressee.

1 (43) The term “tobacco product manufacturer”
2 means an entity that directly—

3 (A) manufactures anywhere a tobacco
4 product that is intended to be distributed com-
5 mercially in the United States, including a to-
6 bacco product intended to be distributed com-
7 mercially in the United States through an im-
8 porter;

9 (B) is the first purchaser for resale in the
10 United States of tobacco products manufac-
11 tured outside the United States for distribution
12 commercially in the United States; or

13 (C) is a successor or assign of any of the
14 foregoing.

15 (44) The term “toxicant” means a chemical or
16 physical agent that produces an adverse biological
17 effect.

18 (45) The term “tribal organization” has the
19 meaning assigned that term in section 4(1) of the
20 Indian Self Determination and Education Assistance
21 Act.

22 (46) The term “United States” means the sev-
23 eral States, as defined in this Act.

24 (47) The term “youth” means any individual
25 who is not an adult.

1 **SEC. 101. CENTER AUTHORITY OVER TOBACCO PRODUCTS.**

2 (a) IN GENERAL.—Tobacco products, including
3 modified risk tobacco products for which an order has
4 been issued in accordance with section 117, shall be regu-
5 lated by the Administrator under this Act.

6 (b) APPLICABILITY.—This Act shall apply to all ciga-
7 rettes, cigarette tobacco, roll-your-own tobacco, and
8 smokeless tobacco and to any other tobacco products that
9 the Administrator by regulation deems to be subject to
10 this Act.

11 (c) CENTER.—The Secretary of Health and Human
12 Services shall establish within the Department of Health
13 and Human Services the Tobacco Harm Reduction Cen-
14 ter. The head of the Center shall be an Administrator,
15 who shall assume the statutory authority conferred by this
16 Act, perform the functions that relate to the subject mat-
17 ter of this Act, and have the authority to promulgate regu-
18 lations for the efficient enforcement of this Act. In pro-
19 mulgating any regulations under such authority, in whole
20 or in part or any regulation that is likely to have an an-
21 nual effect on the economy of \$50,000,000 or more or
22 have a material adverse effect on adult users of tobacco
23 products, tobacco product manufacturers, distributors, or
24 retailers, the Administrator shall—

1 (1) determine the technological and economic
2 ability of parties that would be required to comply
3 with the regulation to comply with it;

4 (2) consider experience gained under any rel-
5 evantly similar regulations at the Federal or State
6 level;

7 (3) determine the reasonableness of the rela-
8 tionship between the costs of complying with such
9 regulation and the public health benefits to be
10 achieved by such regulation;

11 (4) determine the reasonable likelihood of meas-
12 urable and substantial reductions in morbidity and
13 mortality among individual tobacco users;

14 (5) determine the impact to United States to-
15 bacco producers and farm operations;

16 (6) determine the impact on the availability and
17 use of tobacco products by minors; and

18 (7) determine the impact on illicit trade of to-
19 bacco products.

20 (d) LIMITATION OF AUTHORITY.—

21 (1) IN GENERAL.—The provisions of this Act
22 shall not apply to tobacco leaf that is not in the pos-
23 session of a manufacturer of tobacco products, or to
24 the producers of tobacco leaf, including tobacco
25 growers, tobacco warehouses, and tobacco grower co-

1 operatives, nor shall any employee of the Center
2 have any authority to enter onto a farm owned by
3 a producer of tobacco leaf without the written con-
4 sent of such producer.

5 (2) EXCEPTION.—Notwithstanding paragraph
6 (1), if a producer of tobacco leaf is also a tobacco
7 product manufacturer or controlled by a tobacco
8 product manufacturer, the producer shall be subject
9 to this Act in the producer’s capacity as a manufac-
10 turer. The exception in this subparagraph shall not
11 apply to a producer of tobacco leaf who grows to-
12 bacco under a contract with a tobacco product man-
13 ufacturer and who is not otherwise engaged in the
14 manufacturing process.

15 (3) RULE OF CONSTRUCTION.—Nothing in this
16 Act shall be construed to grant the Administrator
17 authority to promulgate regulations on any matter
18 that involves the production of tobacco leaf or a pro-
19 ducer thereof.

20 (e) RULEMAKING PROCEDURES.—Each rulemaking
21 under this Act shall be in accordance with chapter 5 of
22 title 5, United States Code.

23 (f) CONSULTATION PRIOR TO RULEMAKING.—Prior
24 to promulgating rules under this Act, the Administrator

1 shall endeavor to consult with other Federal agencies as
2 appropriate.

3 **SEC. 102. EXCLUSION OF OTHER REGULATORY PROGRAMS.**

4 (a) EXCLUSION OF TOBACCO PRODUCTS AND NICO-
5 TINE-CONTAINING PRODUCTS FROM THE FEDERAL
6 FOOD, DRUG, AND COSMETIC ACT.—No tobacco product
7 and no nicotine-containing product shall be regulated as
8 a food, drug, or device in accordance with section 201 (f),
9 (g) or (h) or Chapter IV or V of the Federal Food, Drug,
10 and Cosmetic Act, except that any tobacco product com-
11 mercially distributed domestically and any nicotine-con-
12 taining product commercially distributed domestically
13 shall be subject to Chapter V of the Federal Food, Drug,
14 and Cosmetic Act if the manufacturer or a distributor of
15 such product markets it with an explicit claim that the
16 product is intended for use in the cure, mitigation, treat-
17 ment, or prevention of disease in man or other animals,
18 within the meaning of section 201(g)(1)(C) or section
19 201(h)(2) of that Act.

20 (b) LIMITATION ON EFFECT OF THIS ACT.—Nothing
21 in this Act shall be construed to—

22 (1) establish a precedent with regard to any
23 other industry, situation, circumstance, or legal ac-
24 tion; or

1 (2) affect any action pending in any Federal,
2 State, or Tribal court, or any agreement, consent de-
3 cree, or contract of any kind.

4 (c) EXCLUSIONS FROM AUTHORITY OF ADMINIS-
5 TRATOR.—The authority granted to the Administrator
6 under this Act shall not apply to—

7 (1) raw tobacco that is not in the possession or
8 control of a tobacco product manufacturer;

9 (2) raw tobacco that is grown for a tobacco
10 product manufacturer by a grower, and that is in
11 the possession of that grower or of a person that is
12 not a tobacco product manufacturer and is within
13 the scope of subparagraphs (A) through(F) of para-
14 graph (3); or

15 (3) the activities, materials, facilities, or prac-
16 tices of persons that are not tobacco product manu-
17 facturers and that are—

18 (A) producers of raw tobacco, including to-
19 bacco growers;

20 (B) tobacco warehouses, and other persons
21 that receive raw tobacco from growers;

22 (C) tobacco grower cooperatives;

23 (D) persons that cure raw tobacco;

24 (E) persons that process raw tobacco; and

1 (F) persons that store raw tobacco for
2 aging.

3 If a producer of raw tobacco is also a tobacco prod-
4 uct manufacturer, an affiliate of a tobacco product
5 manufacturer, or a person producing raw tobacco for
6 a tobacco product manufacturer, then that producer
7 shall be subject to this Act only to the extent of that
8 producer's capacity as a tobacco product manufac-
9 turer.

10 **SEC. 103. EXISTING FEDERAL STATUTES MAINTAINED.**

11 Except as amended or repealed by this Act, all Fed-
12 eral statutes in effect as of the effective date of this Act
13 that regulate tobacco, tobacco products, or tobacco prod-
14 uct manufacturers shall remain in full force and effect.
15 Such statutes include, without limitation—

16 (1) the Federal Cigarette Labeling and Adver-
17 tising Act, sections 1331–1340 of title 15, United
18 States Code, except that section 1335 of title 15,
19 United States Code, is repealed;

20 (2) the Comprehensive Smokeless Tobacco
21 Health Education Act of 1986, sections 4401–4408
22 of title 15, United States Code, except that section
23 4402(f) of title 15, United States Code, is repealed;

24 (3) section 300x–26 of title 42, United States
25 Code; and

1 (4) those statutes authorizing regulation of to-
2 bacco, tobacco products, or tobacco product manu-
3 facturers by the Federal Trade Commission, the De-
4 partment of Agriculture, the Environmental Protec-
5 tion Agency, the Internal Revenue Service, and the
6 Alcohol and Tobacco Tax and Trade Bureau of the
7 Department of the Treasury.

8 **SEC. 104. PROCEEDINGS IN THE NAME OF THE UNITED**
9 **STATES; SUBPOENAS; PREEMPTION OF STATE**
10 **AND LOCAL LAW; NO PRIVATE RIGHT OF AC-**
11 **TION.**

12 In furtherance of this Act:

13 (1) All proceedings for the enforcement, or to
14 restrain violations, of this Act shall be by and in the
15 name of the United States. Subpoenas for witnesses
16 who are required to attend a court of the United
17 States, in any district, may run into any other dis-
18 trict in any proceeding under this section. No State,
19 or political subdivision thereof, may proceed or inter-
20 vene in any Federal or State court under this Act
21 or under any regulation promulgated under it, or al-
22 lege any violation thereof except a violation by the
23 Administrator. Nothing in this Act shall be con-
24 strued to create a right of action by any private per-

1 son for any violation of any provision of this Act or
2 of any regulation promulgated under it.

3 (2) With respect to any subject matter ad-
4 dressed by this Act or by any regulation promul-
5 gated under it, no requirement or prohibition shall
6 be imposed under State or local law upon any to-
7 bacco product manufacturer or distributor.

8 (3) Paragraph (2) shall not apply to any re-
9 quirement or prohibition imposed under State or
10 local law before the date of introduction of the bill
11 that was enacted as this Act.

12 **SEC. 105. ILLICIT TRADE.**

13 The Administrator shall not promulgate any regula-
14 tion or take any other action that has the effect of—

15 (1) increasing illicit trade involving tobacco or
16 any tobacco product, or

17 (2) making affected tobacco products unaccept-
18 able to a substantial number of then current users
19 of such products, thereby creating a substantial risk
20 that such users will resort to illicit tobacco products,
21 or tobacco products that are otherwise noncompliant
22 or unlawful.

23 **SEC. 106. ADULTERATED TOBACCO PRODUCTS.**

24 A tobacco product shall be deemed to be adulter-
25 ated—

1 (1) if it bears or contains any poisonous or del-
2 eterious substance other than—

3 (A) tobacco;

4 (B) a substance naturally present in to-
5 bacco;

6 (C) a pesticide or fungicide chemical res-
7 idue in or on tobacco if such pesticide or fun-
8 gicide chemical is registered by the Environ-
9 mental Protection Agency for use on tobacco in
10 the United States; or

11 (D) in the case of imported tobacco, a res-
12 idue of a pesticide or fungicide chemical that—

13 (i) is approved for use in the country
14 of origin of the tobacco; and

15 (ii) has not been banned, and the reg-
16 istration of which has not been canceled,
17 by the Environmental Protection Agency
18 for use on tobacco in the United States)
19 that may render it injurious to health; but,
20 in case the substance is not an added sub-
21 stance, such tobacco product shall not be
22 considered adulterated under this sub-
23 section if the quantity of such substance in
24 such tobacco product does not ordinarily
25 render it injurious to health;

1 (2) if there is significant scientific agreement
2 that, as a result of the tobacco it contains, the to-
3 bacco product presents a risk to human health that
4 is materially higher than the risk presented by—

5 (A) such product on the effective date of
6 this Act; or

7 (B) if such product was not distributed
8 commercially domestically on that date, by com-
9 parable tobacco products of the same style and
10 within the same category that were commer-
11 cially distributed domestically on that date;

12 (3) if it has been prepared, packed, or held
13 under unsanitary conditions whereby it may have be-
14 come contaminated with filth;

15 (4) if its package is composed, in whole or in
16 part, of any poisonous or deleterious substance that
17 may render the contents injurious to health; or

18 (5) if its “tar” yield is in violation of section
19 111.

20 **SEC. 107. MISBRANDED TOBACCO PRODUCTS.**

21 A tobacco product shall be deemed to be mis-
22 branded—

23 (1) if its labeling is false or misleading in any
24 particular;

1 (2) if in package form unless it bears a label
2 containing—

3 (A) an identification of the type of product
4 it is, by the common or usual name of such
5 type of product;

6 (B) an accurate statement of the quantity
7 of the contents in the package in terms of
8 weight, measure, or numerical count, except
9 that reasonable variations shall be permitted,
10 and exemptions as to small packages shall be
11 established by regulations promulgated by the
12 Administrator;

13 (C) the name and place of business of the
14 tobacco product manufacturer, packer, or dis-
15 tributor; and

16 (D) the information required by section
17 201(c) and (e) or section 202(c) and (e), as ap-
18 plicable;

19 (3) if any word, statement, or other information
20 required by or under authority of this Act to appear
21 on the label, labeling, or advertising is not promi-
22 nently placed thereon with such conspicuousness (as
23 compared with other words, statements, or designs
24 on the label, labeling, or advertising, as applicable)
25 and in such terms as to render it reasonably likely

1 to be read and understood by the ordinary individual
2 under customary conditions of purchase and use;

3 (4) if any word, statement, or other information
4 is required by or under this Act to appear on the
5 label, unless such word, statement, or other informa-
6 tion also appears on the outside container or wrap-
7 per, if any, of the retail package of such tobacco
8 product, or is easily legible through the outside con-
9 tainer or wrapper;

10 (5) if it was manufactured, prepared, or proc-
11 essed in an establishment not duly registered under
12 section 109, if it was not included in a list required
13 by section 109, or if a notice or other information
14 respecting it was not provided as required by section
15 109;

16 (6) if its packaging, labeling, or advertising is
17 in violation of this Act or of an applicable regulation
18 promulgated in accordance with this Act;

19 (7) if it contains tobacco or another ingredient
20 as to which a required disclosure under this Act was
21 not made;

22 (8) if it is labeled or advertised, or the tobacco
23 contained in it is advertised, as—

24 (A) containing “no additives,” or any sub-
25 stantially similar term, unless the labeling or

1 advertising, as applicable, also contains, clearly
2 and prominently, the following disclosure: “No
3 additives in our tobacco does NOT mean
4 safer.”; or

5 (B) being “natural,” or any substantially
6 similar term, unless the labeling or advertising,
7 as applicable, also contains, clearly and promi-
8 nently, the following disclosure: “Natural does
9 NOT mean safer.”;

10 (9) if in its labeling or advertising a term de-
11 scriptive of the tobacco in the tobacco product is
12 used otherwise than in accordance with a sanction or
13 approval granted by a Federal agency;

14 (10) if with respect to such tobacco product a
15 disclosure required by section 603 was not made;

16 (11) if with respect to such tobacco product a
17 certification required by section 803 was not sub-
18 mitted or is materially false or misleading; or

19 (12) if its manufacturer or distributor made
20 with respect to it a claim prohibited by section 115.

21 **SEC. 108. SUBMISSION OF HEALTH INFORMATION TO THE**
22 **ADMINISTRATOR.**

23 (a) REQUIREMENT.—Each tobacco product manufac-
24 turer or importer, or agents thereof, shall submit to the
25 Administrator the following information:

1 (1) Not later than 18 months after the date of
2 enactment of the Act, a listing of all ingredients, in-
3 cluding tobacco, substances, compounds, and addi-
4 tives that are, as of such date, added by the manu-
5 facturer to the tobacco, paper, filter, or other part
6 of each tobacco product by brand and by quantity in
7 each brand and brand style.

8 (2) A description of the content, delivery, and
9 form of nicotine in each tobacco product measured
10 in milligrams of nicotine in accordance with regula-
11 tions promulgated by the Administrator in accord-
12 ance with section 4(e) of the Federal Cigarette La-
13 beling and Advertising Act.

14 (3) Beginning 4 years after the date of enact-
15 ment of this Act, a listing of all constituents, includ-
16 ing smoke constituents as applicable, identified by
17 the Administrator as harmful to health in each to-
18 bacco product, and as applicable in the smoke of
19 each tobacco product, by brand and by quantity in
20 each brand and subbrand.

21 (b) DATA SUBMISSION.—At the request of the Ad-
22 ministrator, each tobacco product manufacturer or im-
23 porter of tobacco products, or agents thereof, shall submit
24 the following:

1 (1) Any or all documents (including underlying
2 scientific information) relating to research activities,
3 and research findings, conducted, supported, or pos-
4 sessed by the manufacturer (or agents thereof) on
5 the health, toxicological, or physiologic effects of to-
6 bacco products and their constituents (including
7 smoke constituents), ingredients, components, and
8 additives.

9 (2) Any or all documents (including underlying
10 scientific information) relating to research activities,
11 and research findings, conducted, supported, or pos-
12 sessed by the manufacturer (or agents thereof) that
13 relate to the issue of whether a significant reduction
14 in risk to health from tobacco products can occur
15 upon the employment of technology available to the
16 manufacturer.

17 An importer of a tobacco product not manufactured in the
18 United States shall supply the information required of a
19 tobacco product manufacturer under this subsection.

20 (c) DATA LIST.—

21 (1) IN GENERAL.—Not later than 4 years after
22 the date of enactment of the Act, and annually
23 thereafter, the Administrator shall publish in a for-
24 mat that is understandable and not misleading to a
25 lay person, and place on public display (in a manner

1 determined by the Administrator) the list established
2 under subsection (d).

3 (2) CONSUMER RESEARCH.—The Administrator
4 shall conduct periodic consumer research to ensure
5 that the list published under paragraph (1) is not
6 misleading to lay persons. Not later than 5 years
7 after the date of enactment of the Act, the Adminis-
8 trator shall submit to the appropriate committees of
9 Congress a report on the results of such research,
10 together with recommendations on whether such
11 publication should be continued or modified.

12 (d) DATA COLLECTION.—Not later than 36 months
13 after the date of enactment of this Act, the Administrator
14 shall establish, and periodically revise as appropriate, a
15 list of harmful constituents, including smoke constituents,
16 to health in each tobacco product by brand and by quan-
17 tity in each brand and subbrand.

18 **SEC. 109. REGISTRATION AND LISTING.**

19 (a) DEFINITIONS.—As used in this section:

20 (1) The term “manufacture, preparation, or
21 processing” shall include repackaging or otherwise
22 changing the container, wrapper, or label of any to-
23 bacco product package other than the carton in fur-
24 therance of the distribution of the tobacco product
25 from the original place of manufacture to the person

1 that makes final delivery or sale to the ultimate con-
2 sumer or user, but shall not include the addition of
3 a tax marking or other marking required by law to
4 an already packaged tobacco product.

5 (2) The term “name” shall include in the case
6 of a partnership the name of the general partner
7 and, in the case of a privately held corporation, the
8 name of the chief executive officer of the corporation
9 and the State of incorporation.

10 (b) ANNUAL REGISTRATION.—Commencing one year
11 after enactment, on or before December 31 of each year,
12 every person that owns or operates any establishment in
13 any State engaged in the manufacture, preparation, or
14 processing of a tobacco product or products for commer-
15 cial distribution domestically shall register with the Ad-
16 ministrator its name, places of business, and all such es-
17 tablishments.

18 (c) NEW PRODUCERS.—Every person upon first en-
19 gaging, for commercial distribution domestically, in the
20 manufacture, preparation, or processing of a tobacco prod-
21 uct or products in any establishment that it owns or oper-
22 ates in any State shall immediately register with the Ad-
23 ministrator its name, places of business, and such estab-
24 lishment.

1 (d) REGISTRATION OF FOREIGN ESTABLISH-
2 MENTS.—

3 (1) Commencing one year after enactment of
4 this Act, on or before December 31 of each year, the
5 person that, within any foreign country, owns or op-
6 erates any establishment engaged in the manufac-
7 ture, preparation, or processing of a tobacco product
8 that is imported or offered for import into the
9 United States shall, through electronic means or
10 other means permitted by the Administrator, reg-
11 ister with the Administrator the name and place of
12 business of each such establishment, the name of the
13 United States agent for the establishment, and the
14 name of each importer of such tobacco product in
15 the United States that is known to such person.

16 (2) Such person also shall provide the informa-
17 tion required by subsection (j), including sales made
18 by mail, or through the Internet, or other electronic
19 means.

20 (3) The Administrator is authorized to enter
21 into cooperative arrangements with officials of for-
22 eign countries to ensure that adequate and effective
23 means are available for purposes of determining,
24 from time to time, whether tobacco products manu-
25 factured, prepared, or processed by an establishment

1 described in paragraph (1), if imported or offered
2 for import into the United States, shall be refused
3 admission on any of the grounds set forth in section
4 708.

5 (e) ADDITIONAL ESTABLISHMENTS.—Every person
6 duly registered in accordance with the foregoing sub-
7 sections of this section shall immediately register with the
8 Administrator any additional establishment that it owns
9 or operates and in which it begins the manufacture, prepa-
10 ration, or processing of a tobacco product or products for
11 commercial distribution domestically or for import into the
12 United States.

13 (f) EXCLUSIONS FROM APPLICATION OF THIS SEC-
14 TION.—The foregoing subsections of this section shall not
15 apply to—

16 (1) persons that manufacture, prepare, or proc-
17 ess tobacco products solely for use in research,
18 teaching, chemical or biological analysis, or export;
19 or

20 (2) such other classes of persons as the Admin-
21 istrator may by regulation exempt from the applica-
22 tion of this section upon a finding that registration
23 by such classes of persons in accordance with this
24 section is not necessary for the protection of the
25 public health.

1 (g) INSPECTION OF PREMISES.—Every establishment
2 registered with the Administrator pursuant to this section
3 shall be subject to inspection pursuant to section 706; and
4 every such establishment engaged in the manufacture,
5 preparation, or processing of a tobacco product or prod-
6 ucts shall be so inspected by one or more officers or em-
7 ployees duly designated by the Administrator at least once
8 in the two-year period beginning with the date of registra-
9 tion of such establishment pursuant to this section and
10 at least once in every successive two-year period there-
11 after, except that inspection of establishments outside the
12 United States may be conducted by other personnel pursu-
13 ant to a cooperative arrangement under subsection (d)(3).

14 (h) FILING OF LISTS OF TOBACCO PRODUCTS MANU-
15 FACTURED, PREPARED, OR PROCESSED BY REGISTRANTS;
16 STATEMENTS; ACCOMPANYING DISCLOSURES.—

17 (1) Every person that registers with the Admin-
18 istrator under subsection (b), (c), (d), or (e) shall,
19 at the time of registration under any such sub-
20 section, file with the Administrator a list of all
21 brand styles (with each brand style in each list listed
22 by the common or usual name of the tobacco prod-
23 uct category to which it belongs and by any propri-
24 etary name) that are being manufactured, prepared,
25 or processed by such person for commercial distribu-

1 tion domestically or for import into the United
2 States, and that such person has not included in any
3 list of tobacco products filed by such person with the
4 Administrator under this paragraph or paragraph
5 (2) before such time of registration. Such list shall
6 be prepared in such form and manner as the Admin-
7 istrator may prescribe, and shall be accompanied by
8 the label for each such brand style and a representa-
9 tive sampling of any other labeling and advertising
10 for each;

11 (2) Each person that registers with the Admin-
12 istrator under this section shall report to the Admin-
13 istrator each August for the preceding six-month pe-
14 riod from January through June, and each February
15 for the preceding six-month period from July
16 through December, following information:

17 (A) A list of each brand style introduced
18 by the registrant for commercial distribution
19 domestically or for import into the United
20 States that has not been included in any list
21 previously filed by such registrant with the Ad-
22 ministrator under this subparagraph or para-
23 graph (1). A list under this subparagraph shall
24 list a brand style by the common or usual name
25 of the tobacco product category to which it be-

1 longs and by any proprietary name, and shall
2 be accompanied by the other information re-
3 quired by paragraph (1).

4 (B) If since the date the registrant last
5 made a report under this paragraph (or if such
6 registrant has not previously made a report
7 under this paragraph, since the effective date of
8 this Act) such registrant has discontinued the
9 manufacture, preparation, or processing for
10 commercial distribution domestically or for im-
11 port into the United States of a brand style in-
12 cluded in a list filed by such registrant under
13 subparagraph (A) or paragraph (1), notice of
14 such discontinuance, the date of such dis-
15 continuance, and the identity (by the common
16 or usual name of the tobacco product category
17 to which it belongs and by any proprietary
18 name) of such tobacco product.

19 (C) If, since the date the registrant re-
20 ported pursuant to subparagraph (B) a notice
21 of discontinuance of a tobacco product, the reg-
22 istrant has resumed the manufacture, prepara-
23 tion, or processing for commercial distribution
24 domestically or for import into the United
25 States of that brand style, notice of such re-

1 sumption, the date of such resumption, the
 2 identity of such brand style (by the common or
 3 usual name of the tobacco product category to
 4 which it belongs and by any proprietary name),
 5 and the other information required by para-
 6 graph (1), unless the registrant has previously
 7 reported such resumption to the Administrator
 8 pursuant to this subparagraph.

9 (D) Any material change in any informa-
 10 tion previously submitted pursuant to this para-
 11 graph (2) or paragraph (1).

12 (i) **ELECTRONIC REGISTRATION.**—Registrations
 13 under subsections (b), (c), (d), and (e) (including the sub-
 14 mission of updated information) shall be submitted to the
 15 Administrator by electronic means, unless the Adminis-
 16 trator grants a request for waiver of such requirement be-
 17 cause use of electronic means is not reasonable for the
 18 person requesting such waiver.

19 **SEC. 110. GENERAL PROVISIONS RESPECTING CONTROL OF**
 20 **TOBACCO PRODUCTS.**

21 (a) **IN GENERAL.**—Any requirement established by or
 22 under section 106, 107, or 113 applicable to a tobacco
 23 product shall apply to such tobacco product until the ap-
 24 plicability of the requirement to the tobacco product has
 25 been changed by action taken under section 111, section

1 114, section 115, or subsection (d) of this section, and
2 any requirement established by or under section 106, 107,
3 or 113 which is inconsistent with a requirement imposed
4 on such tobacco product under section 111, section 114,
5 section 115, or subsection (d) of this section shall not
6 apply to such tobacco product.

7 (b) INFORMATION ON PUBLIC ACCESS AND COM-
8 MENT.—Each notice of proposed rulemaking or other noti-
9 fication under section 111, 112, 113, 114, or 115 or under
10 this section, any other notice which is published in the
11 Federal Register with respect to any other action taken
12 under any such section and which states the reasons for
13 such action, and each publication of findings required to
14 be made in connection with rulemaking under any such
15 section shall set forth—

16 (1) the manner in which interested persons may
17 examine data and other information on which the
18 notice or findings is based; and

19 (2) the period within which interested persons
20 may present their comments on the notice or find-
21 ings (including the need therefore) orally or in writ-
22 ing, which period shall be at least 60 days but may
23 not exceed 90 days unless the time is extended by
24 the Administrator by a notice published in the Fed-
25 eral Register stating good cause therefore.

1 (c) LIMITED CONFIDENTIALITY OF INFORMATION.—

2 Any information reported to or otherwise obtained by the
3 Administrator or the Administrator's representative under
4 section 107, 108, 111, 112, 113, 114, 115, or 504, or
5 under subsection (e) or (f) of this section, which is exempt
6 from disclosure under subsection (a) of section 552 of title
7 5, United States Code, by reason of subsection (b)(4) of
8 that section shall be considered confidential and shall not
9 be disclosed, except that the information may be disclosed
10 to other officers or employees concerned with carrying out
11 this Act, or when relevant in any proceeding under this
12 Act.

13 (d) RESTRICTIONS.—

14 (1) IN GENERAL.—The Administrator may
15 issue regulations, consistent with this Act, regarding
16 tobacco products if the Administrator determines
17 that such regulation would be appropriate for the
18 protection of the public health. The finding as to
19 whether such regulation would be appropriate for
20 the protection of the public health shall be deter-
21 mined with respect to the risks and benefits to the
22 users of the tobacco product, and taking into ac-
23 count that the standard is reasonably likely to result
24 in measurable and substantial reductions in mor-
25 bidly and mortality among individual tobacco users.

1 (2) LABEL STATEMENTS.—The label of a to-
2 bacco product shall bear such appropriate state-
3 ments of the restrictions required by a regulation
4 under subsection (a) as the Administrator may in
5 such regulation prescribe.

6 (e) GOOD MANUFACTURING PRACTICE REQUIRE-
7 MENTS.—

8 (1) METHODS, FACILITIES, AND CONTROLS TO
9 CONFORM.—

10 (A) IN GENERAL.—In applying manufac-
11 turing restrictions to tobacco, the Administrator
12 shall, in accordance with subparagraph (B),
13 prescribe regulations (which may differ based
14 on the type of tobacco product involved) requir-
15 ing that the methods used in, and the facilities
16 and controls used for, the manufacture,
17 preproduction design validation (including a
18 process to assess the performance of a tobacco
19 product), packing, and storage of a tobacco
20 product conform to current good manufacturing
21 practice, or hazard analysis and critical control
22 point methodology, as prescribed in such regu-
23 lations to assure that the public health is pro-
24 tected and that the tobacco product is in com-
25 pliance with this Act. Such regulations may

1 provide for the testing of raw tobacco for pes-
2 ticide chemical residues after a tolerance for
3 such chemical residues has been established.

4 (B) REQUIREMENTS.—The Administrator
5 shall—

6 (i) before promulgating any regulation
7 under subparagraph (A), afford the To-
8 bacco Products Scientific Advisory Com-
9 mittee an opportunity to submit rec-
10 ommendations with respect to the regula-
11 tion proposed to be promulgated;

12 (ii) before promulgating any regula-
13 tion under subparagraph (A), afford oppor-
14 tunity for an oral hearing;

15 (iii) provide the Tobacco Products
16 Scientific Advisory Committee a reasonable
17 time to make its recommendation with re-
18 spect to proposed regulations under sub-
19 paragraph (A); and

20 (iv) in establishing the effective date
21 of a regulation promulgated under this
22 subsection, take into account the dif-
23 ferences in the manner in which the dif-
24 ferent types of tobacco products have his-
25 torically been produced, the financial re-

1 sources of the different tobacco product
2 manufacturers, and the state of their exist-
3 ing manufacturing facilities, and shall pro-
4 vide for a reasonable period of time for
5 such manufacturers to conform to good
6 manufacturing practices but no earlier
7 than four years from date of enactment.

8 (C) ADDITIONAL SPECIAL RULE.—A to-
9 bacco product manufactured in or imported into
10 the United States shall not contain foreign-
11 grown flue-cured or burley tobacco that—

12 (i) was knowingly grown or processed
13 using a pesticide chemical that is not ap-
14 proved under applicable Federal law for
15 use in domestic tobacco farming and proc-
16 essing; or

17 (ii) in the case of a pesticide chemical
18 that is so approved, was grown or proc-
19 essed using the pesticide chemical in a
20 manner inconsistent with the approved la-
21 beling for use of the pesticide chemical in
22 domestic tobacco farming and processing.

23 (D) EXCLUSION.—Subparagraph (C)(ii)
24 shall not apply to tobacco products manufac-
25 tured with foreign-grown flue-cured or burley

1 tobacco so long as that foreign grown tobacco
2 was either—

3 (i) in the inventory of a manufacturer
4 prior to the effective date, or

5 (ii) planted by the farmer prior to the
6 effective date of this Act and utilized by
7 the manufacturer no later than 3 years
8 after the effective date.

9 (E) SETTING OF MAXIMUM RESIDUE LIM-
10 ITS.—The Administrator shall adopt the fol-
11 lowing pesticide residue standards:

12 Pesticide residue standards

13 The maximum concentration of residues of the fol-
14 lowing pesticides allowed in flue-cured or burley tobacco,
15 expressed as parts by weight of the residue per one million
16 parts by weight of the tobacco (PPM) are:

17 CHLORDANE.....3.0

18 DIBROMOCHLOROPROPANE (DBCP).....1.0

19 DICAMBA (Temporary).... 5.0

20 ENDRIN....0.1

21 ETHYLENE DIBROMIDE (EDB)....0.1

22 FORMOTHION.....0.5

23 HEXACHLOROBENZENE (HCB)....0.1

24 METHOXYCHLOR.....0.1

25 TOXAPHENE.....0.3

1 2,4-D (Temporary).....5.0

2 2,4,5-T.....0.1

3 Sum of ALDRIN and DIELDRIN.....0.1

4 Sum of CYPERMETHRIN and PERMETHRIN
5 (Temporary).....3.0

6 Sum of DDT, TDE (DDD), and DDE0.4

7 Sum of HEPTACHLOR and HEPTACHLOR EP-
8 OXIDE.....0.1

9 (F) MAXIMUM RESIDUE LIMITS.—The Ad-
10 ministrator shall adopt regulations within one
11 year of the effective date of this Act to establish
12 maximum residue limits for pesticides identified
13 under subparagraph (E) but not included in the
14 table of such subparagraph to account for the
15 fact that weather and agronomic conditions will
16 cause pesticides identified in subparagraph (E)
17 to be detected in foreign-grown tobacco even
18 where the farmer has not knowingly added such
19 pesticide.

20 (2) EXEMPTIONS; VARIANCES.—

21 (A) PETITION.—Any person subject to any
22 requirement prescribed under paragraph (1)
23 may petition the Administrator for a permanent
24 or temporary exemption or variance from such
25 requirement. Such a petition shall be submitted

1 to the Administrator in such form and manner
2 as the Administrator shall prescribe and shall—

3 (i) in the case of a petition for an ex-
4 emption from a requirement, set forth the
5 basis for the petitioner's determination
6 that compliance with the requirement is
7 not required to assure that the tobacco
8 product will be in compliance with this Act;

9 (ii) in the case of a petition for a vari-
10 ance from a requirement, set forth the
11 methods proposed to be used in, and the
12 facilities and controls proposed to be used
13 for, the manufacture, packing, and storage
14 of the tobacco product in lieu of the meth-
15 ods, facilities, and controls prescribed by
16 the requirement; and

17 (iii) contain such other information as
18 the Administrator shall prescribe.

19 (B) REFERRAL TO THE TOBACCO PROD-
20 UCTS SCIENTIFIC ADVISORY COMMITTEE.—The
21 Administrator may refer to the Tobacco Prod-
22 ucts Scientific Advisory Committee any petition
23 submitted under subparagraph (A). The To-
24 bacco Products Scientific Advisory Committee
25 shall report its recommendations to the Admin-

1 istrator with respect to a petition referred to it
2 within 60 days after the date of the petition’s
3 referral. Within 60 days after—

4 (i) the date the petition was submitted
5 to the Administrator under subparagraph
6 (A); or

7 (ii) the day after the petition was re-
8 ferred to the Tobacco Products Scientific
9 Advisory Committee,

10 whichever occurs later, the Administrator shall
11 by order either deny the petition or approve it.

12 (C) APPROVAL.—The Administrator may
13 approve—

14 (i) a petition for an exemption for a
15 tobacco product from a requirement if the
16 Administrator determines that compliance
17 with such requirement is not required to
18 assure that the tobacco product will be in
19 compliance with this Act; and

20 (ii) a petition for a variance for a to-
21 bacco product from a requirement if the
22 Administrator determines that the methods
23 to be used in, and the facilities and con-
24 trols to be used for, the manufacture,
25 packing, and storage of the tobacco prod-

1 uct in lieu of the methods, facilities, and
2 controls prescribed by the requirement are
3 sufficient to assure that the tobacco prod-
4 uct will be in compliance with this Act.

5 (D) CONDITIONS.—An order of the Admin-
6 istrator approving a petition for a variance shall
7 prescribe such conditions respecting the meth-
8 ods used in, and the facilities and controls used
9 for, the manufacture, packing, and storage of
10 the tobacco product to be granted the variance
11 under the petition as may be necessary to as-
12 sure that the tobacco product will be in compli-
13 ance with this Act.

14 (E) HEARING.—After the issuance of an
15 order under subparagraph (B) respecting a pe-
16 tition, the petitioner shall have an opportunity
17 for an informal hearing on such order.

18 (3) COMPLIANCE.—Compliance with require-
19 ments under this subsection shall not be required be-
20 fore the end of the 3-year period following the date
21 of enactment of this Act.

22 (f) RESEARCH AND DEVELOPMENT.—The Adminis-
23 trator may enter into contracts for research, testing, and
24 demonstrations respecting tobacco products and may ob-

tain tobacco products for research, testing, and demonstration purposes.

SEC. 111. SMOKING ARTICLE STANDARDS.

(a) IN GENERAL.—

(1) RESTRICTIONS ON DESCRIPTORS USED IN MARKETING OF CIGARETTES.—

(A) IN GENERAL.—Except as provided in subparagraph (B), no person shall use, with respect to any cigarette brand style commercially distributed domestically, on the portion of the package of such cigarette brand style that customarily is visible to consumers before purchase, or in advertising of such cigarette brand style any of the following as a descriptor of any cigarette brand style—

(i) the name of any candy or fruit;

(ii) the word “candy,” “citrus,” “cream,” “fruit,” “sugar,” “sweet,” “tangy,” or “tart,”; or

(iii) any extension or variation of any of the words “candy,” “citrus,” “cream,” “fruit,” “sugar,” “sweet,” “tangy,” or “tart,” including but not limited to “creamy,” or “fruity.”

1 (B) LIMITATION.—Subparagraph (A) shall
2 not apply to the use of the following words or
3 to any extension or variation of any of them:
4 “coffee,” “mint,” and “menthol”.

5 (C) SCENTED MATERIALS.—No person
6 shall use, in the advertising or labeling of any
7 cigarette commercially distributed domestically,
8 any scented materials, except in an adult-only
9 facility.

10 (D) DEFINITIONS.—In this section:

11 (i) The term “candy” means a confec-
12 tion made from sugar or sugar substitute,
13 including any confection identified generi-
14 cally or by brand, and shall include the
15 words “cacao,” “chocolate,” “cinnamon,”
16 “cocoa,” “honey,” “licorice,” “maple,”
17 “mocha,” and “vanilla.”

18 (ii) The term “fruit” means any fruit
19 identified by generic name, type, or vari-
20 ety, including but not limited to “apple,”
21 “banana,” “cherry,” and “orange.” The
22 term “fruit” does not include words that
23 identify seeds, nuts or peppers, or types or
24 varieties thereof or words that are exten-
25 sions or variations of such words.

1 (2) SMOKING ARTICLE STANDARDS.—

2 (A) IN GENERAL.—The Administrator may
3 adopt smoking article standards in addition to
4 those in paragraph (1) if the Administrator
5 finds that a smoking article standard is appro-
6 priate for the protection of the public health.

7 (B) DETERMINATIONS.—

8 (i) CONSIDERATIONS.—In making a
9 finding described in subparagraph (A), the
10 Administrator shall consider scientific evi-
11 dence concerning—

12 (I) the risks and benefits to the
13 users of smoking articles of the pro-
14 posed standard; and

15 (II) that the standard is reason-
16 ably likely to result in measurable and
17 substantial reductions in morbidity
18 and mortality among individual to-
19 bacco users.

20 (ii) ADDITIONAL CONSIDERATIONS.—

21 In the event that the Administrator makes
22 a determination, set forth in a proposed
23 smoking article standard in a proposed
24 rule, that it is appropriate for the protec-
25 tion of public health to require the reduc-

1 tion or elimination of an additive, con-
2 stituent (including a smoke constituent), or
3 other component of a smoking article be-
4 cause the Administrator has found that the
5 additive, constituent, or other component is
6 harmful, any party objecting to the pro-
7 posed standard on the ground that the
8 proposed standard will not reduce or elimi-
9 nate the risk of illness or injury may pro-
10 vide for the Administrator’s consideration
11 scientific evidence that demonstrates that
12 the proposed standard will not reduce or
13 eliminate the risk of illness or injury.

14 (3) CONTENT OF SMOKING ARTICLE STAND-
15 ARDS.—A smoking article standard established
16 under this section for a smoking article—

17 (A) may include provisions that are appro-
18 priate for the protection of the public health,
19 including provisions, where appropriate—

20 (i) for “tar” and nicotine yields of the
21 product;

22 (ii) for the reduction of other constitu-
23 ents, including smoke constituents, or
24 harmful components of the product; or

1 (iii) relating to any other requirement
2 under subparagraph (B); and

3 (B) may, where appropriate for the protec-
4 tion of the public health, include—

5 (i) provisions respecting the construc-
6 tion, components, ingredients, additives,
7 constituents, including smoke constituents,
8 and properties of the smoking article;

9 (ii) provisions for the testing (on a
10 sample basis or, if necessary, on an indi-
11 vidual basis) of the smoking article;

12 (iii) provisions for the measurement of
13 the smoking article characteristics of the
14 smoking article; and

15 (iv) provisions requiring that the re-
16 sults of each or of certain of the tests of
17 the smoking article required to be made
18 under clause (ii) show that the smoking ar-
19 ticle is in conformity with the portions of
20 the standard for which the test or tests
21 were required.

22 (4) PERIODIC REEVALUATION OF SMOKING AR-
23 TICLE STANDARDS.—The Administrator may provide
24 for periodic evaluation of smoking article standards
25 established under this section to determine whether

1 such standards should be changed to reflect new
2 medical, scientific, or other technological data.

3 (5) CIGARETTE “TAR” LIMITS.—

4 (A) NO INCREASE IN “TAR” YIELDS.—No
5 cigarette manufacturer shall distribute for sale
6 domestically a brand style of cigarettes that
7 generates a “tar” yield greater than the “tar”
8 yield of that brand style of cigarettes on the
9 date of introduction of this Act, as determined
10 by the ISO smoking regimen and its associated
11 tolerances. The “tar” tolerances for cigarettes
12 with ISO “tar” yields in the range of 1 to 20
13 milligrams per cigarette, based on variations
14 arising from sampling procedure, test method,
15 and sampled product, itself, are the greater of
16 plus or minus—

17 (i) 15 percent; or

18 (ii) 1 milligram per cigarette.

19 (B) LIMIT ON NEW CIGARETTES.—After
20 the effective date of this Act, no cigarette man-
21 ufacturer shall manufacture for commercial dis-
22 tribution domestically a brand style of ciga-
23 rettes that both—

1 (i) was not in commercial distribution
2 domestically on the effective date of this
3 Act, and

4 (ii) generates a “tar” yield of greater
5 than 20 milligrams per cigarette as deter-
6 mined by the ISO smoking regimen and its
7 associated tolerances.

8 (C) LIMIT ON ALL CIGARETTES.—After
9 December 31, 2010, no cigarette manufacturer
10 shall manufacture for commercial distribution
11 domestically a brand style of cigarettes that
12 generates a “tar” yield greater than 20 milli-
13 grams per cigarette as determined by the ISO
14 smoking regimen and its associated tolerances.

15 (D) REVIEW BY ADMINISTRATOR.—After
16 the effective date of this Act, the Administrator
17 shall evaluate the available scientific evidence
18 addressing the potential relationship between
19 historical “tar” yield values and risk of harm to
20 smokers. If upon a review of that evidence, and
21 after consultation with technical experts of the
22 Tobacco Harm Reduction Center and the Cen-
23 ters for Disease Control and Prevention and no-
24 tice and an opportunity for public comment, the
25 Administrator determines, that a reduction in

1 “tar” yield may reasonably be expected to pro-
2 vide a meaningful reduction of the risk or risks
3 of harm to smokers, the Administrator shall
4 issue an order that—

5 (i) provides that no cigarette manu-
6 facturer shall manufacture for commercial
7 distribution domestically a cigarette that
8 generates a “tar” yield that exceeds 14
9 milligrams as determined by the ISO
10 smoking regimen and its associated toler-
11 ances; and

12 (ii) provides a reasonable time for
13 manufacturers to come into compliance
14 with such prohibition.

15 (6) INVOLVEMENT OF OTHER AGENCIES; IN-
16 FORMED PERSONS.—In carrying out duties under
17 this section, the Administrator shall endeavor to—

18 (A) use personnel, facilities, and other
19 technical support available in other Federal
20 agencies;

21 (B) consult with other Federal agencies
22 concerned with standard setting and other na-
23 tionally or internationally recognized standard-
24 setting entities; and

1 (C) invite appropriate participation,
2 through joint or other conferences, workshops,
3 or other means, by informed persons represent-
4 ative of scientific, professional, industry, agri-
5 cultural, or consumer organizations who in the
6 Administrator's judgment can make a signifi-
7 cant contribution.

8 (b) CONSIDERATIONS BY ADMINISTRATOR.—

9 (1) TECHNICAL ACHIEVABILITY.—The Adminis-
10 trator shall consider information submitted in con-
11 nection with a proposed standard regarding the tech-
12 nical achievability of compliance with such standard.

13 (2) OTHER CONSIDERATIONS.—The Adminis-
14 trator shall consider all other information submitted
15 in connection with a proposed standard, such as the
16 creation of a significant demand for contraband or
17 other tobacco products that do not meet the require-
18 ments of this Act and the significance of such de-
19 mand.

20 (c) PROPOSED STANDARDS.—

21 (1) IN GENERAL.—The Administrator shall
22 publish in the Federal Register a notice of proposed
23 rulemaking for the establishment, amendment, or
24 revocation of any smoking article standard.

1 (2) REQUIREMENTS OF NOTICE.—A notice of
2 proposed rulemaking for the establishment or
3 amendment of a smoking article standard shall—

4 (A) set forth a finding with supporting jus-
5 tification that the smoking article standard is
6 appropriate for the protection of the public
7 health;

8 (B) invite interested persons to submit a
9 draft or proposed smoking article standard for
10 consideration by the Administrator;

11 (C) invite interested persons to submit
12 comments on structuring the standard so that
13 it does not advantage foreign-grown tobacco
14 over domestically grown tobacco; and

15 (D) invite the Secretary of Agriculture to
16 provide any information or analysis which the
17 Secretary of Agriculture believes is relevant to
18 the proposed smoking article standard.

19 (3) FINDING.—A notice of proposed rulemaking
20 for the revocation of a smoking article standard
21 shall set forth a finding with supporting justification
22 that the smoking article standard is no longer ap-
23 appropriate for the protection of the public health.

24 (4) COMMENT.—The Administrator shall pro-
25 vide for a comment period of not less than 90 days.

1 (d) PROMULGATION.—

2 (1) IN GENERAL.—After the expiration of the
3 period for comment on a notice of proposed rule-
4 making published under subsection (c) respecting a
5 standard and after consideration of comments sub-
6 mitted under subsections (b) and (c) and any report
7 from the Tobacco Products Scientific Advisory Com-
8 mittee, if the Administrator determines that the
9 standard would be appropriate for the protection of
10 the public health, the Administrator shall—

11 (A) promulgate a regulation establishing a
12 smoking article standard and publish in the
13 Federal Register findings on the matters re-
14 ferred to in subsection (c); or

15 (B) publish a notice terminating the pro-
16 ceeding for the development of the standard to-
17 gether with the reasons for such termination.

18 (2) EFFECTIVE DATE.—A regulation estab-
19 lishing a smoking article standard shall set forth the
20 date or dates upon which the standard shall take ef-
21 fect, but no such regulation may take effect before
22 1 year after the date of its publication unless the
23 Administrator determines that an earlier effective
24 date is necessary for the protection of the public
25 health. Such date or dates shall be established so as

1 to minimize, consistent with the public health, eco-
2 nomic loss to, and disruption or dislocation of, do-
3 mestic and international trade. In establishing such
4 effective date or dates, the Administrator shall con-
5 sider information submitted in connection with a
6 proposed product standard by interested parties, in-
7 cluding manufacturers and tobacco growers, regard-
8 ing the technical achievability of compliance with the
9 standard, and including information concerning the
10 existence of patents that make it impossible to com-
11 ply in the timeframe envisioned in the proposed
12 standard.

13 (3) LIMITATION ON POWER GRANTED.—Be-
14 cause of the importance of a decision of the Admin-
15 istrator to issue a regulation—

16 (A) banning cigarettes, smokeless smoking
17 articles, little cigars, cigars other than little ci-
18 gars, pipe tobacco, or roll-your-own smoking ar-
19 ticles;

20 (B) requiring the reduction of “tar” or nie-
21 otine yields of a smoking article to zero;

22 (C) prohibiting the sale of any smoking ar-
23 ticle in face-to-face transactions by a specific
24 category of retail outlets;

1 (D) establishing a minimum age of sale of
2 smoking articles to any person older than 18
3 years of age; or

4 (E) requiring that the sale or distribution
5 of a smoking article be limited to the written or
6 oral authorization of a practitioner licensed by
7 law to prescribe medical products,
8 the Administrator is prohibited from taking such ac-
9 tions under this Act.

10 (4) MATCHBOOKS.—For purposes of any regu-
11 lations issued by the Administrator under this Act,
12 matchbooks of conventional size containing not more
13 than 20 paper matches, and which are customarily
14 given away for free with the purchase of smoking ar-
15 ticles, shall be considered as adult-written publica-
16 tions which shall be permitted to contain advertising.

17 (5) AMENDMENT; REVOCATION.—

18 (A) AUTHORITY.—The Administrator,
19 upon the Administrator's own initiative or upon
20 petition of an interested person, may by a regu-
21 lation, promulgated in accordance with the re-
22 quirements of subsection (c) and paragraph (2),
23 amend or revoke a smoking article standard.

24 (B) EFFECTIVE DATE.—The Adminis-
25 trator may declare a proposed amendment of a

1 smoking article standard to be effective on and
2 after its publication in the Federal Register and
3 until the effective date of any final action taken
4 on such amendment if the Administrator deter-
5 mines that making it so effective is in the pub-
6 lic interest.

7 (6) REFERRAL TO ADVISORY COMMITTEE.—

8 (A) IN GENERAL.—The Administrator
9 shall refer a proposed regulation for the estab-
10 lishment, amendment, or revocation of a smok-
11 ing article standard to the Tobacco Products
12 Scientific Advisory Committee for a report and
13 recommendation with respect to any matter in-
14 volved in the proposed regulation which requires
15 the exercise of scientific judgment.

16 (B) INITIATION OF REFERRAL.—The Ad-
17 ministrator shall make a referral under this
18 paragraph—

19 (i) on the Administrator's own initia-
20 tive; or

21 (ii) upon the request of an interested
22 person that—

23 (I) demonstrates good cause for
24 the referral; and

1 (II) is made before the expiration
2 of the period for submission of com-
3 ments on the proposed regulation.

4 (C) PROVISION OF DATA.—If a proposed
5 regulation is referred under this paragraph to
6 the Tobacco Products Scientific Advisory Com-
7 mittee, the Administrator shall provide the Ad-
8 visory Committee with the data and information
9 on which such proposed regulation is based.

10 (D) REPORT AND RECOMMENDATION.—
11 The Tobacco Products Scientific Advisory Com-
12 mittee shall, within 90 days after the referral of
13 a proposed regulation under this paragraph and
14 after independent study of the data and infor-
15 mation furnished to it by the Administrator and
16 other data and information before it, submit to
17 the Administrator a report and recommendation
18 respecting such regulation, together with all un-
19 derlying data and information and a statement
20 of the reason or basis for the recommendation.

21 (E) PUBLIC AVAILABILITY.—The Adminis-
22 trator shall make a copy of each report and rec-
23 ommendation under subparagraph (D) publicly
24 available.

1 **SEC. 112. NOTIFICATION AND OTHER REMEDIES.**

2 (a) NOTIFICATION.—If the Administrator determines
3 that—

4 (1) a tobacco product which is introduced or de-
5 livered for introduction into interstate commerce for
6 commercial distribution presents an unreasonable
7 risk of substantial harm materially above the risk
8 for death and disease of tobacco products currently
9 in interstate commerce, to the public health; and

10 (2) notification under this subsection is nec-
11 essary to eliminate the unreasonable risk of such
12 harm and no more practicable means is available
13 under the provisions of this Act (other than this sec-
14 tion) to eliminate such risk,

15 the Administrator may issue such order as may be nec-
16 essary to assure that adequate notification is provided in
17 an appropriate form, by the persons and means best suited
18 under the circumstances involved, to all persons who
19 should properly receive such notification in order to elimi-
20 nate such risk. The Administrator may order notification
21 by any appropriate means, including public service an-
22 nouncements. Before issuing an order under this sub-
23 section, the Administrator shall consult with the persons
24 who are to give notice under the order.

25 (b) NO EXEMPTION FROM OTHER LIABILITY.—Com-
26 pliance with an order issued under this section shall not

1 relieve any person from liability under Federal or State
2 law. In awarding damages for economic loss in an action
3 brought for the enforcement of any such liability, the value
4 to the plaintiff in such action of any remedy provided
5 under such order shall be taken into account.

6 (c) RECALL AUTHORITY.—

7 (1) IN GENERAL.—If the Administrator finds
8 that there is a reasonable probability that a tobacco
9 product contains a manufacturing or other defect
10 not ordinarily contained in tobacco products on the
11 market that would cause serious, acute adverse
12 health consequences or death, the Administrator
13 shall issue an order requiring the appropriate person
14 (including the manufacturers, importers, distribu-
15 tors, or retailers of the tobacco product) to imme-
16 diately cease distribution of such tobacco product.
17 The order shall provide the person subject to the
18 order with an opportunity for an informal hearing,
19 to be held not later than 10 days after the date of
20 the issuance of the order, on the actions required by
21 the order and on whether the order should be
22 amended to require a recall of such tobacco product.
23 If, after providing an opportunity for such a hear-
24 ing, the Administrator determines that inadequate

1 grounds exist to support the actions required by the
2 order, the Administrator shall vacate the order.

3 (2) AMENDMENT OF ORDER TO REQUIRE RE-
4 CALL.—

5 (A) IN GENERAL.—If, after providing an
6 opportunity for an informal hearing under
7 paragraph (1), the Administrator determines
8 that the order should be amended to include a
9 recall of the tobacco product with respect to
10 which the order was issued, the Administrator
11 shall, except as provided in subparagraph (B),
12 amend the order to require a recall. The Ad-
13 ministrator shall specify a timetable in which
14 the tobacco product recall will occur and shall
15 require periodic reports to the Administrator
16 describing the progress of the recall.

17 (B) NOTICE.—An amended order under
18 subparagraph (A)—

19 (i) shall not include recall of a tobacco
20 product from individuals; and

21 (ii) shall provide for notice to persons
22 subject to the risks associated with the use
23 of such tobacco product.

24 In providing the notice required by clause (ii),
25 the Administrator may use the assistance of re-

1 tailers and other persons who distributed such
2 tobacco product. If a significant number of such
3 persons cannot be identified, the Administrator
4 shall notify such persons under section 705(b).

5 (3) REMEDY NOT EXCLUSIVE.—The remedy
6 provided by this subsection shall be in addition to
7 remedies provided by subsection (a).

8 **SEC. 113. RECORDS AND REPORTS ON TOBACCO PROD-**
9 **UCTS.**

10 Every person who is a tobacco product manufacturer
11 or importer of a tobacco product shall establish and main-
12 tain such records, make such reports, and provide such
13 information, as the Administrator may by regulation rea-
14 sonably require to assure that such tobacco product is not
15 adulterated or misbranded.

16 **SEC. 114. APPLICATION FOR REVIEW OF CERTAIN SMOKING**
17 **ARTICLES.**

18 (a) IN GENERAL.—

19 (1) NEW SMOKING ARTICLE DEFINED.—For
20 purposes of this section the term “new smoking arti-
21 cle” means—

22 (A) any smoking article that was not com-
23 mercially marketed in the United States as of
24 the date of enactment of this Act; and

1 (B) any smoking article that incorporates
2 a significant modification (including changes in
3 design, component, part, or constituent, includ-
4 ing a smoke constituent, or in the content, de-
5 livery or form of nicotine, or other additive or
6 ingredient) of a smoking article where the
7 modified product was commercially marketed in
8 the United States after the date of enactment
9 of this Act.

10 (2) PREMARKET REVIEW REQUIRED.—

11 (A) NEW PRODUCTS.—An order under
12 subsection (c)(1)(A) for a new smoking article
13 is required unless the product—

14 (i) is substantially equivalent to a
15 smoking article commercially marketed in
16 the United States as of date of enactment
17 of this Act; and

18 (ii) is in compliance with the require-
19 ments of this Act.

20 (B) CONSUMER TESTING.—This section
21 shall not apply to smoking articles that are pro-
22 vided to adult tobacco consumers for purposes
23 of consumer testing. For purposes of this sec-
24 tion, the term “consumer testing” means an as-
25 sessment of smoking articles that is conducted

1 by or under the control and direction of a man-
2 ufacturer for the purpose of evaluating con-
3 sumer acceptance of such smoking articles, uti-
4 lizing only the quantity of cigarettes that is rea-
5 sonably necessary for such assessment

6 (3) SUBSTANTIALLY EQUIVALENT DEFINED.—

7 (A) IN GENERAL.—In this section, the
8 term “substantially equivalent” or “substantial
9 equivalence” means, with respect to the smok-
10 ing article being compared to the predicate
11 smoking article, that the Administrator by
12 order has found that the smoking article—

13 (i) has the same general characteris-
14 tics as the predicate smoking article; or

15 (ii) has different characteristics and
16 the information submitted contains infor-
17 mation, including clinical data if deemed
18 necessary by the Administrator, that dem-
19 onstrates that it is not appropriate to reg-
20 ulate the product under this section be-
21 cause the product does not raise different
22 questions of public health for the consumer
23 of the product.

24 (B) CHARACTERISTICS.—In subparagraph
25 (A), the term “characteristics” means the mate-

1 rials, ingredients, design, composition, heating
2 source, or other features of a smoking article.

3 (C) LIMITATION.—A smoking article may
4 not be found to be substantially equivalent to a
5 predicate smoking article that has been re-
6 moved from the market at the initiative of the
7 Administrator or that has been determined by
8 a judicial order to be misbranded or adulter-
9 ated.

10 (4) HEALTH INFORMATION.—As part of a sub-
11 mission respecting a smoking article, the person re-
12 quired to file a premarket notification shall provide
13 an adequate summary of any health information re-
14 lated to the smoking article or state that such infor-
15 mation will be made available upon request by any
16 person.

17 (b) APPLICATION.—

18 (1) CONTENTS.—An application under this sec-
19 tion shall contain—

20 (A) full reports of all information, pub-
21 lished or known to, or which should reasonably
22 be known to, the applicant, concerning inves-
23 tigations which have been made to show the
24 health risks of such smoking article and wheth-

1 er such smoking article presents less risk than
2 other smoking articles;

3 (B) a full statement of the components, in-
4 gredients, additives, and properties, and of the
5 principle or principles of operation, of such
6 smoking article;

7 (C) a full description of the methods used
8 in, and the facilities and controls used for, the
9 manufacture, processing, and, when relevant,
10 packing and installation of, such smoking arti-
11 cle;

12 (D) an identifying reference to any smok-
13 ing article standard under section 111 which
14 would be applicable to any aspect of such smok-
15 ing article, and either adequate information to
16 show that such aspect of such smoking article
17 fully meets such smoking article standard or
18 adequate information to justify any deviation
19 from such standard;

20 (E) such samples of such smoking article
21 and of components thereof as the Administrator
22 may reasonably require;

23 (F) specimens of the labeling proposed to
24 be used for such smoking article; and

1 (G) such other information relevant to the
2 subject matter of the application as the Admin-
3 istrator may require.

4 (2) REFERRAL TO TOBACCO PRODUCTS SCI-
5 ENTIFIC ADVISORY COMMITTEE.—Upon receipt of an
6 application meeting the requirements set forth in
7 paragraph (1), the Administrator—

8 (A) may, on the Administrator’s own ini-
9 tiative; or

10 (B) may, upon the request of an applicant,
11 refer such application to the Tobacco Products Sci-
12 entific Advisory Committee for reference and for
13 submission (within such period as the Administrator
14 may establish) of a report and recommendation re-
15 specting the application, together with all underlying
16 data and the reasons or basis for the recommenda-
17 tion.

18 (c) ACTION ON APPLICATION.—

19 (1) DEADLINE.—As promptly as possible, but
20 in no event later than 90 days after the receipt of
21 an application under subsection (b), the Adminis-
22 trator, after considering the report and rec-
23 ommendation submitted under subsection (b)(2),
24 shall—

1 (A) issue an order that the new product
2 may be introduced or delivered for introduction
3 into interstate commerce if the Administrator
4 finds that none of the grounds specified in
5 paragraph (2) of this subsection applies; or

6 (B) issue an order that the new product
7 may not be introduced or delivered for introduc-
8 tion into interstate commerce if the Adminis-
9 trator finds (and sets forth the basis for such
10 finding as part of or accompanying such denial)
11 that 1 or more grounds for denial specified in
12 paragraph (2) of this subsection apply.

13 (2) DENIAL OF APPLICATION.—The Adminis-
14 trator shall deny an application submitted under
15 subsection (b) if, upon the basis of the information
16 submitted to the Administrator as part of the appli-
17 cation and any other information before the Admin-
18 istrator with respect to such smoking article, the Ad-
19 ministrator finds that—

20 (A) there is a lack of a showing that per-
21 mitting such smoking article to be marketed
22 would be appropriate for the protection of the
23 public health;

24 (B) the methods used in, or the facilities
25 or controls used for, the manufacture, proc-

1 essing, or packing of such smoking article do
2 not conform to the requirements of section
3 110(e);

4 (C) based on a fair evaluation of all mate-
5 rial facts, the proposed labeling is false or mis-
6 leading in any particular; or

7 (D) such smoking article is not shown to
8 conform to a smoking article standard in effect
9 under section 111, and there is a lack of ade-
10 quate information to justify the deviation from
11 such standard.

12 (3) DENIAL INFORMATION.—Any denial of an
13 application shall, insofar as the Administrator deter-
14 mines to be practicable, be accompanied by a state-
15 ment informing the applicant of the measures re-
16 quired to remove such application from deniable
17 form (which measures may include further research
18 by the applicant in accordance with 1 or more proto-
19 cols prescribed by the Administrator).

20 (4) BASIS FOR FINDING.—For purposes of this
21 section, the finding as to whether the commercial in-
22 troduction of a smoking article for which an applica-
23 tion has been submitted is appropriate for the pro-
24 tection of the public health shall be determined with
25 respect to the risks and benefits to the users of the

1 smoking article, and taking into account whether
2 such commercial introduction is reasonably likely to
3 increase the morbidity and mortality among indi-
4 vidual tobacco users.

5 (d) WITHDRAWAL AND TEMPORARY SUSPENSION.—

6 (1) IN GENERAL.—The Administrator shall,
7 upon obtaining, where appropriate, advice on sci-
8 entific matters from the Tobacco Products Scientific
9 Advisory Committee, and after due notice and op-
10 portunity for informal hearing for a smoking article
11 for which an order was issued under subsection
12 (c)(1)(A), issue an order withdrawing the order if
13 the Administrator finds—

14 (A) that the continued marketing of such
15 smoking article no longer is appropriate for the
16 protection of the public health;

17 (B) that the application contained or was
18 accompanied by an untrue statement of a mate-
19 rial fact;

20 (C) that the applicant—

21 (i) has failed to establish a system for
22 maintaining records, or has repeatedly or
23 deliberately failed to maintain records or to
24 make reports, required by an applicable
25 regulation under section 113; or

1 (ii) has refused to permit access to, or
2 copying or verification of, such records as
3 required by section 110; or

4 (D) on the basis of new information before
5 the Administrator with respect to such smoking
6 article, evaluated together with the evidence be-
7 fore the Administrator when the application
8 was reviewed, that the methods used in, or the
9 facilities and controls used for, the manufac-
10 ture, processing, packing, or installation of such
11 smoking article do not conform with the re-
12 quirements of section 110(e) and were not
13 brought into conformity with such requirements
14 within a reasonable time after receipt of written
15 notice from the Administrator of noncon-
16 formity;

17 (E) on the basis of new information before
18 the Administrator, evaluated together with the
19 evidence before the Administrator when the ap-
20 plication was reviewed, that the labeling of such
21 smoking article, based on a fair evaluation of
22 all material facts, is false or misleading in any
23 particular and was not corrected within a rea-
24 sonable time after receipt of written notice from
25 the Administrator of such fact; or

1 (F) on the basis of new information before
2 the Administrator, evaluated together with the
3 evidence before the Administrator when such
4 order was issued, that such smoking article is
5 not shown to conform in all respects to a smok-
6 ing article standard which is in effect under
7 section 111, compliance with which was a con-
8 dition to the issuance of an order relating to
9 the application, and that there is a lack of ade-
10 quate information to justify the deviation from
11 such standard.

12 (2) APPEAL.—The holder of an application sub-
13 ject to an order issued under paragraph (1) with-
14 drawing an order issued pursuant to subsection
15 (c)(1)(A) may, by petition filed on or before the
16 30th day after the date upon which such holder re-
17 ceives notice of such withdrawal, obtain review there-
18 of in accordance with section 116.

19 (3) TEMPORARY SUSPENSION.—If, after pro-
20 viding an opportunity for an informal hearing, the
21 Administrator determines there is reasonable prob-
22 ability that the continuation of distribution of a
23 smoking article under an order would cause serious,
24 adverse health consequences or death, that is greater
25 than ordinarily caused by smoking articles on the

1 market, the Administrator shall by order temporarily
2 suspend the authority of the manufacturer to mar-
3 ket the product. If the Administrator issues such an
4 order, the Administrator shall proceed expeditiously
5 under paragraph (1) to withdraw such application.

6 (e) SERVICE OF ORDER.—An order issued by the Ad-
7 ministrator under this section shall be served—

8 (1) in person by any officer or employee of the
9 department designated by the Administrator; or

10 (2) by mailing the order by registered mail or
11 certified mail addressed to the applicant at the ap-
12 plicant's last known address in the records of the
13 Administrator.

14 (f) RECORDS.—

15 (1) ADDITIONAL INFORMATION.—In the case of
16 any smoking article for which an order issued pursu-
17 ant to subsection (c)(1)(A) for an application filed
18 under subsection (b) is in effect, the applicant shall
19 establish and maintain such records, and make such
20 reports to the Administrator, as the Administrator
21 may by regulation, or by order with respect to such
22 application, prescribe on the basis of a finding that
23 such records and reports are necessary in order to
24 enable the Administrator to determine, or facilitate
25 a determination of, whether there is or may be

1 grounds for withdrawing or temporarily suspending
2 such order.

3 (2) ACCESS TO RECORDS.—Each person re-
4 quired under this section to maintain records, and
5 each person in charge of custody thereof, shall, upon
6 request of an officer or employee designated by the
7 Administrator, permit such officer or employee at all
8 reasonable times to have access to and copy and
9 verify such records.

10 (g) INVESTIGATIONAL SMOKING ARTICLE EXEMP-
11 TION FOR INVESTIGATIONAL USE.—The Administrator
12 may exempt smoking articles intended for investigational
13 use from the provisions of this Act under such conditions
14 as the Administrator may by regulation prescribe.

15 **SEC. 115. MODIFIED RISK TOBACCO PRODUCTS.**

16 (a) IN GENERAL.—No person may introduce or de-
17 liver for introduction into interstate commerce any modi-
18 fied risk tobacco product unless an order issued pursuant
19 to subsection (g) is effective with respect to such product.

20 (b) DEFINITIONS.—In this section:

21 (1) MODIFIED RISK TOBACCO PRODUCT.—The
22 term “modified risk tobacco product” means any to-
23 bacco product that is sold or distributed for use to
24 reduce harm or the risk of tobacco-related disease

1 associated with commercially marketed tobacco prod-
2 ucts.

3 (2) SOLD OR DISTRIBUTED.—

4 (A) IN GENERAL.—With respect to a to-
5 bacco product, the term “sold or distributed for
6 use to reduce harm or the risk of tobacco-re-
7 lated disease associated with commercially mar-
8 keted tobacco products” means a tobacco prod-
9 uct—

10 (i) the label, labeling, or advertising of
11 which represents explicitly or implicitly
12 that—

13 (I) the tobacco product presents
14 a lower risk of tobacco-related disease
15 or is less harmful than one or more
16 other commercially marketed tobacco
17 products;

18 (II) the tobacco product or its
19 smoke contains a reduced level of a
20 substance or presents a reduced expo-
21 sure to a substance; or

22 (III) the tobacco product or its
23 smoke does not contain or is free of a
24 substance;

1 (ii) the label, labeling, or advertising
2 of which uses the descriptors “light”,
3 “mild”, “low”, “medium”, “ultra light”,
4 “low tar” or “ultra low tar”; or

5 (iii) the tobacco product manufacturer
6 of which has taken any action directed to
7 consumers through the media or otherwise,
8 other than by means of the tobacco prod-
9 uct’s label, labeling, or advertising, after
10 the date of enactment of the Act, respect-
11 ing the product that would be reasonably
12 expected to result in consumers believing
13 that the tobacco product or its smoke may
14 present a lower risk of disease or is less
15 harmful than one or more commercially
16 marketed tobacco products, or presents a
17 reduced exposure to, or does not contain or
18 is free of, a substance or substances.

19 (B) LIMITATION.—No tobacco product
20 shall be considered to be “sold or distributed
21 for use to reduce harm or the risk of tobacco-
22 related disease associated with commercially
23 marketed tobacco products”, except as de-
24 scribed in subparagraph (A).

1 (C) SMOKELESS TOBACCO PRODUCT.—No
2 smokeless tobacco product shall be considered
3 to be “sold or distributed for use to reduce
4 harm or the risk of tobacco-related disease as-
5 sociated with commercially marketed tobacco
6 products”.

7 (3) EFFECTIVE DATE.—The provisions of para-
8 graph (2)(A)(ii) shall take effect 12 months after
9 the date of enactment of the Act.

10 (c) TOBACCO DEPENDENCE PRODUCTS.—A product
11 that is intended to be used for the treatment of tobacco
12 dependence, including smoking cessation, is not a modified
13 risk tobacco product under this section if it has been ap-
14 proved as a drug or device by the Center and is subject
15 to the requirements of chapter V.

16 (d) FILING.—Any person may file with the Adminis-
17 trator an application for a modified risk tobacco product.
18 Such application shall include—

19 (1) a description of the proposed product and
20 any proposed advertising and labeling;

21 (2) the conditions for using the product;

22 (3) the formulation of the product;

23 (4) sample product labels and labeling;

24 (5) all documents (including underlying sci-
25 entific information) relating to research findings

1 conducted, supported, or possessed by the tobacco
2 product manufacturer relating to the effect of the
3 product on tobacco-related diseases and health-re-
4 lated conditions, including information both favor-
5 able and unfavorable to the ability of the product to
6 reduce risk or exposure and relating to human
7 health;

8 (6) data and information on how consumers ac-
9 tually use the tobacco product; and

10 (7) such other information as the Administrator
11 may require.

12 (e) PUBLIC AVAILABILITY.—The Administrator shall
13 make the application described in subsection (d) publicly
14 available (except matters in the application which are
15 trade secrets or otherwise confidential, commercial infor-
16 mation) and shall request comments by interested persons
17 on the information contained in the application and on the
18 label, labeling, and advertising accompanying such appli-
19 cation.

20 (f) ADVISORY COMMITTEE.—

21 (1) IN GENERAL.—The Administrator shall
22 refer to the Tobacco Products Scientific Advisory
23 Committee any application submitted under this sec-
24 tion.

1 (2) RECOMMENDATIONS.—Not later than 60
2 days after the date an application is referred to the
3 Tobacco Products Scientific Advisory Committee
4 under paragraph (1), the Advisory Committee shall
5 report its recommendations on the application to the
6 Administrator.

7 (g) MARKETING.—

8 (1) MODIFIED RISK PRODUCTS.—Except as
9 provided in paragraph (2), the Administrator shall,
10 with respect to an application submitted under this
11 section, issue an order that a modified risk product
12 may be commercially marketed only if the Adminis-
13 trator determines that the applicant has dem-
14 onstrated that such product, as it is actually used by
15 consumers, will—

16 (A) significantly reduce harm and the risk
17 of tobacco-related disease to individual tobacco
18 users; and

19 (B) is reasonably likely to result in meas-
20 urable and substantial reductions in morbidity
21 and mortality among individual tobacco users.

22 (2) SPECIAL RULE FOR CERTAIN PRODUCTS.—

23 (A) IN GENERAL.—The Administrator may
24 issue an order that a tobacco product may be
25 introduced or delivered for introduction into

1 interstate commerce, pursuant to an application
2 under this section, with respect to a tobacco
3 product that may not be commercially marketed
4 under paragraph (1) if the Secretary makes the
5 findings required under this paragraph and de-
6 termines that the applicant has demonstrated
7 that—

8 (i) such order would be appropriate to
9 promote the public health;

10 (ii) any aspect of the label, labeling,
11 and advertising for such product that
12 would cause the tobacco product to be a
13 modified risk tobacco product under sub-
14 section (b) is limited to an explicit or im-
15 plicit representation that such tobacco
16 product or its smoke does not contain or is
17 free of a substance or contains a reduced
18 level of a substance, or presents a reduced
19 exposure to a substance in tobacco smoke;

20 (iii) scientific evidence is not available
21 and, using the best available scientific
22 methods, cannot be made available without
23 conducting long-term epidemiological stud-
24 ies for an application to meet the stand-
25 ards set forth in paragraph (1); and

1 (iv) the scientific evidence that is
2 available without conducting long-term epi-
3 demiological studies demonstrates that a
4 measurable and substantial reduction in
5 morbidity or mortality among individual
6 tobacco users is reasonably likely in subse-
7 quent studies.

8 (B) ADDITIONAL FINDINGS REQUIRED.—

9 To issue an order under subparagraph (A) the
10 Administrator must also find that the applicant
11 has demonstrated that—

12 (i) the magnitude of the overall reduc-
13 tions in exposure to the substance or sub-
14 stances which are the subject of the appli-
15 cation is substantial, such substance or
16 substances are harmful, and the product as
17 actually used exposes consumers to the
18 specified reduced level of the substance or
19 substances;

20 (ii) the product as actually used by
21 consumers will not expose them to higher
22 levels of other harmful substances com-
23 pared to the similar types of tobacco prod-
24 ucts then on the market unless such in-
25 creases are minimal and the reasonably

1 likely overall impact of use of the product
2 remains a substantial and measurable re-
3 duction in overall morbidity and mortality
4 among individual tobacco users;

5 (iii) testing of actual consumer per-
6 ception shows that, as the applicant pro-
7 poses to label and market the product, con-
8 sumers will not be misled into believing
9 that the product—

10 (I) is or has been demonstrated
11 to be significantly less harmful; or

12 (II) presents or has been dem-
13 onstrated to present significant less of
14 a risk of disease than other commer-
15 cially marketed tobacco products; and

16 (iv) issuance of an order with respect
17 to the application is expected to benefit the
18 health of users of tobacco products.

19 (3) BASIS.—The determinations under para-
20 graphs (1) and (2) shall be based on—

21 (A) the scientific evidence submitted by the
22 applicant; and

23 (B) scientific evidence and other informa-
24 tion that is made available to the Adminis-
25 trator.

1 (h) ADDITIONAL CONDITIONS FOR MARKETING.—

2 (1) MODIFIED RISK PRODUCTS.—The Adminis-
3 trator shall require for the marketing of a product
4 under this section that any advertising or labeling
5 concerning modified risk products enable the public
6 to comprehend the information concerning modified
7 risk and to understand the relative significance of
8 such information in the context of total health and
9 in relation to all of the diseases and health-related
10 conditions associated with the use of tobacco prod-
11 ucts.

12 (2) COMPARATIVE CLAIMS.—

13 (A) IN GENERAL.—The Administrator may
14 require for the marketing of a product under
15 this subsection that a claim comparing a to-
16 bacco product to other commercially marketed
17 tobacco products shall compare the tobacco
18 product to a commercially marketed tobacco
19 product that is representative of that type of to-
20 bacco product on the market (for example the
21 average value of the top 3 brands of an estab-
22 lished regular tobacco product).

23 (B) QUANTITATIVE COMPARISONS.—The
24 Administrator may also require, for purposes of
25 subparagraph (A), that the percent (or fraction)

1 of change and identity of the reference tobacco
2 product and a quantitative comparison of the
3 amount of the substance claimed to be reduced
4 shall be stated in immediate proximity to the
5 most prominent claim.

6 (i) POSTMARKET SURVEILLANCE AND STUDIES.—

7 (1) IN GENERAL.—The Administrator shall re-
8 quire, with respect to a product for which an appli-
9 cant obtained an order under subsection (g)(1), that
10 the applicant conduct postmarket surveillance and
11 studies for such a tobacco product to determine the
12 impact of the order issuance on consumer percep-
13 tion, behavior, and health, to enable the Adminis-
14 trator to review the accuracy of the determinations
15 upon which the order was based, and to provide in-
16 formation that the Administrator determines is oth-
17 erwise necessary regarding the use or health risks
18 involving the tobacco product. The results of
19 postmarket surveillance and studies shall be sub-
20 mitted to the Administrator on an annual basis.

21 (2) SURVEILLANCE PROTOCOL.—Each appli-
22 cant required to conduct a surveillance of a tobacco
23 product under paragraph (1) shall, within 30 days
24 after receiving notice that the applicant is required
25 to conduct such surveillance, submit, for the ap-

1 proval of the Administrator, a protocol for the re-
2 quired surveillance. The Administrator, within 30
3 days of the receipt of such protocol, shall determine
4 if the principal investigator proposed to be used in
5 the surveillance has sufficient qualifications and ex-
6 perience to conduct such surveillance and if such
7 protocol will result in collection of the data or other
8 information designated by the Administrator as nec-
9 essary to protect the public health.

10 (j) WITHDRAWAL OF AUTHORIZATION.—The Admin-
11 istrator, after an opportunity for an informal hearing,
12 shall withdraw an order under subsection (g) if the Ad-
13 ministrator determines that—

14 (1) the applicant, based on new information,
15 can no longer make the demonstrations required
16 under subsection (g), or the Administrator can no
17 longer make the determinations required under sub-
18 section (g);

19 (2) the application failed to include material in-
20 formation or included any untrue statement of mate-
21 rial fact;

22 (3) any explicit or implicit representation that
23 the product reduces risk or exposure is no longer
24 valid, including if—

1 (A) a tobacco product standard is estab-
2 lished pursuant to section 111;

3 (B) an action is taken that affects the
4 risks presented by other commercially marketed
5 tobacco products that were compared to the
6 product that is the subject of the application; or

7 (C) any postmarket surveillance or studies
8 reveal that the order is no longer consistent
9 with the protection of the public health;

10 (4) the applicant failed to conduct or submit
11 the postmarket surveillance and studies required
12 under subsection (g)(2)(C)(ii) or subsection (i); or

13 (5) the applicant failed to meet a condition im-
14 posed under subsection (h).

15 (k) CHAPTER IV OR V.—A product for which the Ad-
16 ministrator has issued an order pursuant to subsection (g)
17 shall not be subject to chapter IV or V of the Federal
18 Food, Drug, and Cosmetic Act.

19 (l) IMPLEMENTING REGULATIONS OR GUIDANCE.—

20 (1) SCIENTIFIC EVIDENCE.—Not later than 2
21 years after the date of enactment of the Act, the Ad-
22 ministrator shall issue regulations or guidance (or
23 any combination thereof) on the scientific evidence
24 required for assessment and ongoing review of modi-

1 fied risk tobacco products. Such regulations or guid-
2 ance shall—

3 (A) to the extent that adequate scientific
4 evidence exists, establish minimum standards
5 for scientific studies needed prior to issuing an
6 order under subsection (g) to show a reasonable
7 likelihood that a substantial reduction in mor-
8 bidity or mortality among individual tobacco
9 users occurs for products described in sub-
10 section (g)(1) or is reasonably likely for prod-
11 ucts described in subsection (g)(2);

12 (B) include validated biomarkers, inter-
13 mediate clinical endpoints, and other feasible
14 outcome measures, as appropriate;

15 (C) establish minimum standards for
16 postmarket studies, that shall include regular
17 and long-term assessments of health outcomes
18 and mortality, intermediate clinical endpoints,
19 consumer perception of harm reduction, and the
20 impact on quitting behavior and new use of to-
21 bacco products, as appropriate;

22 (D) establish minimum standards for re-
23 quired postmarket surveillance, including ongo-
24 ing assessments of consumer perception; and

1 (E) establish a reasonable timetable for the
2 Administrator to review an application under
3 this section.

4 (2) CONSULTATION.—The regulations or guid-
5 ance issued under paragraph (1) may be developed
6 in consultation with the Institute of Medicine, and
7 with the input of other appropriate scientific and
8 medical experts, on the design and conduct of such
9 studies and surveillance.

10 (3) REVISION.—The regulations or guidance
11 under paragraph (1) shall be revised on a regular
12 basis as new scientific information becomes avail-
13 able.

14 (4) NEW TOBACCO PRODUCTS.—Not later than
15 2 years after the date of enactment of the Act, the
16 Administrator shall issue a regulation or guidance
17 that permits the filing of a single application for any
18 tobacco product that is a new tobacco product under
19 section 114 and which the applicant seeks to com-
20 mercially market under this section.

21 **SEC. 116. JUDICIAL REVIEW.**

22 (a) RIGHT TO REVIEW.—

23 (1) IN GENERAL.—Not later than 60 days
24 after—

1 (A) the promulgation of a regulation under
2 section 111 establishing, amending, or revoking
3 a tobacco product standard; or

4 (B) a denial of an application under sec-
5 tion 114(c),

6 any person adversely affected by such regulation or
7 denial may file a petition for judicial review of such
8 regulation or denial with the United States Court of
9 Appeals for the District of Columbia or for the cir-
10 cuit in which such person resides or has their prin-
11 cipal place of business.

12 (2) REQUIREMENTS.—

13 (A) COPY OF PETITION.—A copy of the pe-
14 tition filed under paragraph (1) shall be trans-
15 mitted by the clerk of the court involved to the
16 Administrator.

17 (B) RECORD OF PROCEEDINGS.—On re-
18 ceipt of a petition under subparagraph (A), the
19 Administrator shall file in the court in which
20 such petition was filed—

21 (i) the record of the proceedings on
22 which the regulation or order was based;
23 and

24 (ii) a statement of the reasons for the
25 issuance of such a regulation or order.

1 (C) DEFINITION OF RECORD.—In this sec-
2 tion, the term “record” means—

3 (i) all notices and other matter pub-
4 lished in the Federal Register with respect
5 to the regulation or order reviewed;

6 (ii) all information submitted to the
7 Administrator with respect to such regula-
8 tion or order;

9 (iii) proceedings of any panel or advi-
10 sory committee with respect to such regu-
11 lation or order;

12 (iv) any hearing held with respect to
13 such regulation or order; and

14 (v) any other information identified by
15 the Administrator, in the administrative
16 proceeding held with respect to such regu-
17 lation or order, as being relevant to such
18 regulation or order.

19 (b) STANDARD OF REVIEW.—Upon the filing of the
20 petition under subsection (a) for judicial review of a regu-
21 lation or order, the court shall have jurisdiction to review
22 the regulation or order in accordance with chapter 7 of
23 title 5, United States Code, and to grant appropriate re-
24 lief, including interim relief, as provided for in such chap-
25 ter. A regulation or denial described in subsection (a) shall

1 be reviewed in accordance with section 706(2)(A) of title
2 5, United States Code.

3 (c) FINALITY OF JUDGMENT.—The judgment of the
4 court affirming or setting aside, in whole or in part, any
5 regulation or order shall be final, subject to review by the
6 Supreme Court of the United States upon certiorari or
7 certification, as provided in section 1254 of title 28,
8 United States Code.

9 (d) OTHER REMEDIES.—The remedies provided for
10 in this section shall be in addition to, and not in lieu of,
11 any other remedies provided by law.

12 (e) REGULATIONS AND ORDERS MUST RECITE BASIS
13 IN RECORD.—To facilitate judicial review, a regulation or
14 order issued under section 110, 111, 112, 113, 114, or
15 119 shall contain a statement of the reasons for the
16 issuance of such regulation or order in the record of the
17 proceedings held in connection with its issuance.

18 **SEC. 117. JURISDICTION OF AND COORDINATION WITH THE**

19 **FEDERAL TRADE COMMISSION.**

20 Except where expressly provided in this Act, nothing
21 in this Act shall be construed as limiting or diminishing
22 the authority of the Federal Trade Commission to enforce
23 the laws under its jurisdiction with respect to the adver-
24 tising, sale, or distribution of tobacco products.

1 **SEC. 118. REGULATION REQUIREMENT.**

2 (a) TESTING, REPORTING, AND DISCLOSURE.—Not
3 later than 36 months after the date of enactment of the
4 Act, the Administrator shall promulgate regulations under
5 this Act that meet the requirements of subsection (b).

6 (b) CONTENTS OF RULES.—The regulations promul-
7 gated under subsection (a)—

8 (1) shall require annual testing and reporting of
9 tobacco product constituents, ingredients, and addi-
10 tives, including smoke constituents, by brand style
11 that the Administrator determines should be tested
12 to protect the public health, provided that, for pur-
13 poses of the testing requirements of this paragraph,
14 tobacco products manufactured and sold by a single
15 tobacco product manufacturer that are identical in
16 all respects except the labels, packaging design, logo,
17 trade dress, trademark, brand name, or any com-
18 bination thereof, shall be considered as a single
19 brand style; and

20 (2) may require that tobacco product manufac-
21 turers, packagers, or importers make disclosures re-
22 lating to the results of the testing of tar and nico-
23 tine through labels or advertising.

24 (c) AUTHORITY.—The Administrator shall have the
25 authority under this Act to conduct or to require the test-

1 ing, reporting, or disclosure of tobacco product constitu-
2 ents, including smoke constituents.

3 (d) JOINT LABORATORY TESTING SERVICES.—The
4 Administrator shall allow any 2 or more tobacco product
5 manufacturers to join together to purchase laboratory
6 testing services required by this section on a group basis
7 in order to ensure that such manufacturers receive access
8 to, and fair pricing of, such testing services.

9 (e) EXTENSIONS FOR LIMITED LABORATORY CAPAC-
10 ITY.—

11 (1) IN GENERAL.—The regulations promulgated
12 under subsection (a) shall provide that a tobacco
13 product manufacturer shall not be considered to be
14 in violation of this section before the applicable
15 deadline, if—

16 (A) the tobacco products of such manufac-
17 turer are in compliance with all other require-
18 ments of this Act; and

19 (B) the conditions described in paragraph
20 (2) are met.

21 (2) CONDITIONS.—Notwithstanding the require-
22 ments of this section, the Administrator may delay
23 the date by which a tobacco product manufacturer
24 must be in compliance with the testing and reporting
25 required by this section until such time as the test-

1 ing is reported if, not later than 90 days before the
2 deadline for reporting in accordance with this sec-
3 tion, a tobacco product manufacturer provides evi-
4 dence to the Administrator demonstrating that—

5 (A) the manufacturer has submitted the
6 required products for testing to a laboratory
7 and has done so sufficiently in advance of the
8 deadline to create a reasonable expectation of
9 completion by the deadline;

10 (B) the products currently are awaiting
11 testing by the laboratory; and

12 (C) neither that laboratory nor any other
13 laboratory is able to complete testing by the
14 deadline at customary, nonexpedited testing
15 fees.

16 (3) EXTENSION.—The Administrator, taking
17 into account the laboratory testing capacity that is
18 available to tobacco product manufacturers, shall re-
19 view and verify the evidence submitted by a tobacco
20 product manufacturer in accordance with paragraph
21 (2). If the Administrator finds that the conditions
22 described in such paragraph are met, the Adminis-
23 trator shall notify the tobacco product manufacturer
24 that the manufacturer shall not be considered to be
25 in violation of the testing and reporting require-

1 ments of this section until the testing is reported or
2 until 1 year after the reporting deadline has passed,
3 whichever occurs sooner. If, however, the Adminis-
4 trator has not made a finding before the reporting
5 deadline, the manufacturer shall not be considered
6 to be in violation of such requirements until the Ad-
7 ministrators finds that the conditions described in
8 paragraph (2) have not been met, or until 1 year
9 after the reporting deadline, whichever occurs soon-
10 er.

11 (4) ADDITIONAL EXTENSION.—In addition to
12 the time that may be provided under paragraph (3),
13 the Administrator may provide further extensions of
14 time, in increments of no more than 1 year, for re-
15 quired testing and reporting to occur if the Adminis-
16 trator determines, based on evidence properly and
17 timely submitted by a tobacco product manufacturer
18 in accordance with paragraph (2), that a lack of
19 available laboratory capacity prevents the manufac-
20 turer from completing the required testing during
21 the period described in paragraph (3).

22 (f) RULE OF CONSTRUCTION.—Nothing in subsection
23 (d) or (e) shall be construed to authorize the extension
24 of any deadline, or to otherwise affect any timeframe,
25 under any provision of this Act other than this section.

1 **SEC. 119. PRESERVATION OF STATE AND LOCAL AUTHOR-**
2 **ITY.**

3 (a) IN GENERAL.—

4 (1) PRESERVATION.—Except as provided in
5 paragraph (2)(A), nothing in this Act, or rules pro-
6 mulgated under this Act, shall be construed to limit
7 the authority of a Federal agency (including the
8 Armed Forces), a State or political subdivision of a
9 State, or the government of an Indian tribe to enact,
10 adopt, promulgate, and enforce any law, rule, regu-
11 lation, or other measure with respect to tobacco
12 products that is in addition to requirements estab-
13 lished under this Act, including a law, rule, regula-
14 tion, or other measure relating to or prohibiting the
15 sale, distribution, possession, or use of tobacco prod-
16 ucts by individuals of any age, information reporting
17 to the State. No provision of this Act shall limit or
18 otherwise affect any State, Tribal, or local taxation
19 of tobacco products.

20 (2) PREEMPTION OF CERTAIN STATE AND
21 LOCAL REQUIREMENTS.—

22 (A) IN GENERAL.—No State or political
23 subdivision of a State may establish or continue
24 in effect with respect to a tobacco product any
25 requirement which is different from, or in addi-
26 tion to, any requirement under the provisions of

1 this Act relating to tobacco product standards,
2 premarket review, adulteration, misbranding,
3 labeling, registration, good manufacturing
4 standards, or modified risk tobacco products.

5 (B) EXCEPTION.—Subparagraph (A) does
6 not apply to requirements relating to the sale,
7 distribution, possession, information reporting
8 to the State, use of, tobacco product by individ-
9 uals of any age. Information disclosed to a
10 State under subparagraph (A) that is exempt
11 from disclosure under section 552(b)(4) of title
12 5, United States Code, shall be treated as a
13 trade secret and confidential information by the
14 State.

15 (b) RULE OF CONSTRUCTION REGARDING PRODUCT
16 LIABILITY.—No provision of this Act relating to a tobacco
17 product shall be construed to modify or otherwise affect
18 any action or the liability of any person under the product
19 liability law of any State.

20 **SEC. 120. TOBACCO PRODUCTS SCIENTIFIC ADVISORY COM-**
21 **MITTEE.**

22 (a) ESTABLISHMENT.—Not later than 6 months after
23 the date of enactment of this Act, the Administrator shall
24 establish a 16-member advisory committee, to be known

1 as the Tobacco Products Scientific Advisory Committee
2 (in this section referred to as the “Advisory Committee”).

3 (b) MEMBERSHIP.—

4 (1) IN GENERAL.—

5 (A) MEMBERS.—The Administrator shall
6 appoint as members of the Tobacco Harm Re-
7 duction Advisory Committee individuals who are
8 technically qualified by training and experience
9 in medicine, medical ethics, science, or tech-
10 nology involving the manufacture, evaluation, or
11 use of tobacco products, who are of appro-
12 priately diversified professional backgrounds.

13 The committee shall be composed of—

14 (i) 6 individuals who are physicians,
15 dentists, scientists, or health care profes-
16 sionals practicing in the area of oncology,
17 pulmonology, cardiology, toxicology, phar-
18 macology, addiction, or any other relevant
19 specialty;

20 (ii) 2 individuals who are an officer or
21 employee of a State or local government or
22 of the Federal Government;

23 (iii) 2 representatives of the general
24 public;

1 (iv) 2 representatives of the interests
2 of the tobacco manufacturing industry;

3 (v) 1 representative of the interests of
4 the small business tobacco manufacturing
5 industry, which position may be filled on a
6 rotating, sequential basis by representa-
7 tives of different small business tobacco
8 manufacturers based on areas of expertise
9 relevant to the topics being considered by
10 the Advisory Committee;

11 (vi) 1 individual as a representative of
12 the interests of the tobacco growers; and

13 (vii) 1 individual who is an expert in
14 illicit trade of tobacco products.

15 (B) CONFLICTS OF INTEREST.—No mem-
16 bers of the committee, other than members ap-
17 pointed pursuant to clauses (iv), (v), and (vi) of
18 subparagraph (A) shall, during the member's
19 tenure on the committee or for the 18-month
20 period prior to becoming such a member, re-
21 ceive any salary, grants, or other payments or
22 support from any business that manufactures,
23 distributes, markets, or sells cigarettes or other
24 tobacco products or government agency with
25 any form of jurisdiction over tobacco products.

1 (2) LIMITATION.—The Administrator may not
2 appoint to the Advisory Committee any individual
3 who is in the regular full-time employ of the To-
4 bacco Harm Reduction Center or any agency respon-
5 sible for the enforcement of this Act. The Adminis-
6 trator may appoint Federal officials as ex officio
7 members.

8 (3) CHAIRPERSON.—The Administrator shall
9 designate 1 of the members appointed under clauses
10 (i), (ii), and (iii) of paragraph (1)(A) to serve as
11 chairperson.

12 (c) DUTIES.—The Tobacco Products Scientific Advi-
13 sory Committee shall provide advice, information, and rec-
14 ommendations to the Administrator—

15 (1) as provided in this Act;

16 (2) on the implementation of prevention, ces-
17 sation, and harm reduction policies;

18 (3) on implementation of policies and programs
19 to fully inform consumers of the respective risks of
20 tobacco products; and

21 (4) on its review of other safety, dependence, or
22 health issues relating to tobacco products as re-
23 quested by the Administrator.

24 (d) COMPENSATION; SUPPORT; FACA.—

1 (1) COMPENSATION AND TRAVEL.—Members of
2 the Advisory Committee who are not officers or em-
3 ployees of the United States, while attending con-
4 ferences or meetings of the committee or otherwise
5 engaged in its business, shall be entitled to receive
6 compensation at rates to be fixed by the Adminis-
7 trator, which may not exceed the daily equivalent of
8 the rate in effect under the Senior Executive Sched-
9 ule under section 5382 of title 5, United States
10 Code, for each day (including travel time) they are
11 so engaged; and while so serving away from their
12 homes or regular places of business each member
13 may be allowed travel expenses, including per diem
14 in lieu of subsistence, as authorized by section 5703
15 of title 5, United States Code, for persons in the
16 Government service employed intermittently.

17 (2) ADMINISTRATIVE SUPPORT.—The Adminis-
18 trator shall furnish the Advisory Committee clerical
19 and other assistance.

20 (3) NONAPPLICATION OF FACA.—Section 14 of
21 the Federal Advisory Committee Act does not apply
22 to the Advisory Committee.

23 (e) PROCEEDINGS OF ADVISORY PANELS AND COM-
24 MITTEES.—The Advisory Committee shall make and
25 maintain a transcript of any proceeding of the panel or

1 committee. Each such panel and committee shall delete
2 from any transcript made under this subsection informa-
3 tion which is exempt from disclosure under section 552(b)
4 of title 5, United States Code.

5 **SEC. 121. DRUG PRODUCTS USED TO TREAT TOBACCO DE-**
6 **PENDENCE.**

7 (a) REPORT ON INNOVATIVE PRODUCTS.—

8 (1) IN GENERAL.—Not later than 3 years after
9 the date of enactment of this Act, the Administrator,
10 after consultation with recognized scientific, medical,
11 and public health experts (including both Federal
12 agencies and nongovernmental entities, the Institute
13 of Medicine of the National Academy of Sciences,
14 and the Society for Research on Nicotine and To-
15 bacco), shall submit to the Congress a report that
16 examines how best to promote, and encourage the
17 development and use by current tobacco users of in-
18 novative tobacco and nicotine products and treat-
19 ments (including nicotine-based and non-nicotine-
20 based products and treatments) to better achieve, in
21 a manner that best protects and promotes the public
22 health—

23 (A) total abstinence from tobacco use;

24 (B) reductions in consumption of tobacco;

25 and

1 (C) reductions in the harm associated with
2 continued tobacco use by moving current users
3 to noncombustible tobacco products.

4 (2) RECOMMENDATIONS.—The report under
5 paragraph (1) shall include the recommendations of
6 the Administrator on how the Tobacco Harm and
7 Reduction Center should coordinate and facilitate
8 the exchange of information on such innovative
9 products and treatments among relevant offices and
10 centers within the Center and within the National
11 Institutes of Health, the Centers for Disease Control
12 and Prevention, and other relevant Federal and
13 State agencies.

14 **SEC. 122. ADVERTISING AND MARKETING OF TOBACCO**
15 **PRODUCTS.**

16 (a) Within 18 months of enactment of the Act, the
17 Administrator shall report to Congress on the benefits to
18 public health of imposing restrictions or prohibitions on
19 the advertising and marketing, consistent with or in addi-
20 tion to such restrictions or prohibitions contained in the
21 Master Settlement Agreement, on tobacco products.

22 (b) The Administrator shall specify in the report con-
23 stitutional free speech implications for each recommended
24 restriction or prohibition.

1 (c) The Administrator shall also specify the class of
2 tobacco products to which the prohibition or restriction
3 would be applicable and the impact of such actions on
4 harm reduction policies, practices, and accurate informa-
5 tion available to tobacco users.

6 (d) The Administrator shall establish and consult
7 with an advisory committee consisting of experts in con-
8 stitutional law, harm reduction policies, marketing prac-
9 tices, and consumer behavior in preparing this report.

10 **TITLE II—TOBACCO PRODUCTS**
11 **WARNINGS; CONSTITUENT**
12 **AND SMOKE CONSTITUENT**
13 **DISCLOSURE**

14 **SEC. 201. CIGARETTE LABEL AND ADVERTISING WARNINGS.**

15 (a) AMENDMENT.—Section 4 of the Federal Ciga-
16 rette Labeling and Advertising Act (15 U.S.C. 1333) is
17 amended to read as follows:

18 **“SEC. 4. LABELING.**

19 **“(a) LABEL REQUIREMENTS.—**

20 **“(1) IN GENERAL.—**It shall be unlawful for any
21 person to manufacture, package, sell, offer to sell,
22 distribute, or import for sale or distribution within
23 the United States any cigarettes the package of
24 which fails to bear, in accordance with the require-
25 ments of this section, one of the following labels:

1 “WARNING: Cigarettes are addictive.

2 “WARNING: Tobacco smoke can harm
3 your children.

4 “WARNING: Cigarettes cause fatal lung
5 disease.

6 “WARNING: Cigarettes cause cancer.

7 “WARNING: Cigarettes cause strokes and
8 heart disease.

9 “WARNING: Smoking during pregnancy
10 can harm your baby.

11 “WARNING: Smoking can kill you.

12 “WARNING: Tobacco smoke causes fatal
13 lung disease in nonsmokers.

14 “WARNING: Quitting smoking now great-
15 ly reduces serious risks to your health.

16 “(2) PLACEMENT; TYPOGRAPHY; ETC.—Each
17 label statement required by paragraph (1) shall be
18 located in the lower portion of the front panel of the
19 package, directly on the package underneath the cel-
20 lophane or other clear wrapping. Each label state-
21 ment shall comprise at least the bottom 25 percent
22 of the front panel of the package. The word
23 ‘WARNING’ shall appear in capital letters and all
24 text shall be in conspicuous and legible 17-point
25 type, unless the text of the label statement would oc-

1 copy more than 70 percent of such area, in which
2 case the text may be in a smaller conspicuous and
3 legible type size, provided that at least 60 percent of
4 such area is occupied by required text. The text shall
5 be black on a white background, or white on a black
6 background, in a manner that contrasts, by typog-
7 raphy, layout, or color, with all other printed mate-
8 rial on the package, in an alternating fashion under
9 the plan submitted under subsection (c).

10 “(3) DOES NOT APPLY TO FOREIGN DISTRIBUTION.—The provisions of this subsection do not
11 apply to a tobacco product manufacturer or dis-
12 tributor of cigarettes which does not manufacture,
13 package, or import cigarettes for sale or distribution
14 within the United States.

16 “(4) APPLICABILITY TO RETAILERS.—A retailer
17 of cigarettes shall not be in violation of this sub-
18 section for packaging that—

19 “(A) contains a warning label;

20 “(B) is supplied to the retailer by a
21 license- or permit-holding smoking article man-
22 ufacturer, importer, or distributor; and

23 “(C) is not altered by the retailer in a way
24 that is material to the requirements of this sub-
25 section.

1 “(b) ADVERTISING REQUIREMENTS.—

2 “(1) IN GENERAL.—It shall be unlawful for any
3 tobacco product manufacturer, importer, distributor,
4 or retailer of cigarettes to advertise or cause to be
5 advertised within the United States any cigarette
6 unless its advertising bears, in accordance with the
7 requirements of this section, one of the labels speci-
8 fied in subsection (a).

9 “(2) TYPOGRAPHY, ETC.—Each label statement
10 required by subsection (a) in cigarette advertising
11 shall comply with the standards set forth in this
12 paragraph. For press and poster advertisements,
13 each such statement and (where applicable) any re-
14 quired statement relating to tar, nicotine, or other
15 constituent (including a smoke constituent) yield
16 shall comprise at least 20 percent of the area of the
17 advertisement and shall appear in a conspicuous and
18 prominent format and location at the bottom of each
19 advertisement within the trim area. The word
20 ‘WARNING’ shall appear in capital letters, and each
21 label statement shall appear in conspicuous and leg-
22 ible type. The text of the label statement shall be
23 black if the background is white and white if the
24 background is black, under the plan submitted under
25 subsection (c). The label statements shall be en-

1 closed by a rectangular border that is the same color
2 as the letters of the statements and that is the width
3 of the first downstroke of the capital ‘W’ of the word
4 ‘WARNING’ in the label statements. The text of
5 such label statements shall be in a typeface pro rata
6 to the following requirements: 45-point type for a
7 whole-page broadsheet newspaper advertisement; 39-
8 point type for a half-page broadsheet newspaper ad-
9 vertisement; 39-point type for a whole-page tabloid
10 newspaper advertisement; 27-point type for a half-
11 page tabloid newspaper advertisement; 31.5-point
12 type for a double page spread magazine or whole-
13 page magazine advertisement; 22.5-point type for a
14 28 centimeter by 3 column advertisement; and 15-
15 point type for a 20 centimeter by 2 column adver-
16 tisement. The label statements shall be in English,
17 except that—

18 “(A) in the case of an advertisement that
19 appears in a newspaper, magazine, periodical,
20 or other publication that is not in English, the
21 statements shall appear in the predominant lan-
22 guage of the publication; and

23 “(B) in the case of any other advertise-
24 ment that is not in English, the statements

1 shall appear in the same language as that prin-
2 cipally used in the advertisement.

3 “(3) MATCHBOOKS.—Notwithstanding para-
4 graph (2), for matchbooks (defined as containing not
5 more than 20 matches) customarily given away with
6 the purchase of smokeless tobacco products, each
7 label statement required by subsection (a) may be
8 printed on the inside cover of the matchbook.

9 “(c) MARKETING REQUIREMENTS.—

10 “(1) RANDOM DISPLAY.—The label statements
11 specified in subsection (a)(1) shall be randomly dis-
12 played in each 12-month period, in as equal a num-
13 ber of times as is possible on each brand of the
14 product and be randomly distributed in all areas of
15 the United States in which the product is marketed
16 in accordance with a plan submitted by the smoke-
17 less tobacco product manufacturer, importer, dis-
18 tributor, or retailer and approved by the Secretary.

19 “(2) ROTATION.—The label statements speci-
20 fied in subsection (a)(1) shall be rotated quarterly in
21 alternating sequence in advertisements for each
22 brand of cigarettes in accordance with a plan sub-
23 mitted by the smokeless tobacco product manufac-
24 turer, importer, distributor, or retailer to, and ap-
25 proved by, the Secretary.

1 “(3) REVIEW.—The Secretary shall review each
2 plan submitted under paragraph (2) and approve it
3 if the plan—

4 “(A) will provide for the equal distribution
5 and display on packaging and the rotation re-
6 quired in advertising under this subsection; and

7 “(B) assures that all of the labels required
8 under this section will be displayed by the
9 smokeless tobacco product manufacturer, im-
10 porter, distributor, or retailer at the same time.

11 “(4) APPLICABILITY TO RETAILERS.—This sub-
12 section and subsection (b) apply to a retailer only if
13 that retailer is responsible for or directs the label
14 statements required under this section except that
15 this paragraph shall not relieve a retailer of liability
16 if the retailer displays, in a location open to the pub-
17 lic, an advertisement that does not contain a warn-
18 ing label or has been altered by the retailer in a way
19 that is material to the requirements of this sub-
20 section and subsection (b).”.

21 (b) EFFECTIVE DATE.—The amendment made by
22 subsection (a) shall take effect 24 months after the date
23 of enactment of this Act. Such effective date shall be with
24 respect to the date of manufacture, provided that, in any
25 case, beginning 30 days after such effective date, a manu-

1 factorer shall not introduce into the domestic commerce
2 of the United States any product, irrespective of the date
3 of manufacture, that is not in conformance with section
4 4 of the Federal Cigarette Labeling and Advertising Act
5 (15 U.S.C. 1333), as amended by subsection (a).

6 **SEC. 202. SMOKELESS TOBACCO LABELS AND ADVERTISING**
7 **WARNINGS.**

8 (a) AMENDMENT.—Section 3 of the Comprehensive
9 Smokeless Tobacco Health Education Act of 1986 (15
10 U.S.C. 4402) is amended to read as follows:

11 **“SEC. 3. SMOKELESS TOBACCO WARNING.**

12 “(a) GENERAL RULE.—

13 “(1) It shall be unlawful for any person to man-
14 ufacture, package, sell, offer to sell, distribute, or
15 import for sale or distribution within the United
16 States any smokeless tobacco product unless the
17 product package bears, in accordance with the re-
18 quirements of this Act, one of the following labels:

19 “WARNING: This product can cause
20 mouth cancer.

21 “WARNING: This product can cause gum
22 disease and tooth loss.

23 “WARNING: This product has signifi-
24 cantly lower risks for diseases associated with
25 cigarettes.

1 “WARNING: Smokeless tobacco is addict-
2 ive.

3 “(2) The label statements required by para-
4 graph (1) shall be introduced by each smokeless to-
5 bacco product manufacturer, packager, importer,
6 distributor, or retailer of smokeless tobacco products
7 concurrently into the distribution chain of such
8 products.

9 “(3) The provisions of this subsection do not
10 apply to a smokeless tobacco product manufacturer
11 or distributor of any smokeless tobacco product that
12 does not manufacture, package, or import smokeless
13 tobacco products for sale or distribution within the
14 United States.

15 “(4) A retailer of smokeless tobacco products
16 shall not be in violation of this subsection for pack-
17 aging that—

18 “(A) contains a warning label;

19 “(B) is supplied to the retailer by a
20 license- or permit-holding smokeless tobacco
21 product manufacturer, importer, or distributor;
22 and

23 “(C) is not altered by the retailer in a way
24 that is material to the requirements of this sub-
25 section.

1 “(b) REQUIRED LABELS.—

2 “(1) It shall be unlawful for any smokeless to-
3 bacco product manufacturer, packager, importer,
4 distributor, or retailer of smokeless tobacco products
5 to advertise or cause to be advertised within the
6 United States any smokeless tobacco product unless
7 its advertising bears, in accordance with the require-
8 ments of this section, one of the labels specified in
9 subsection (a).

10 “(2)(A) Each label statement required by sub-
11 section (a) in smokeless tobacco advertising shall
12 comply with the standards set forth in this para-
13 graph.

14 “(B) For press and poster advertisements, each
15 such statement and (where applicable) any required
16 statement relating to nicotine, or other constituent
17 yield shall comprise at least 20 percent of the area
18 of the advertisement.

19 “(C) The word ‘WARNING’ shall appear in
20 capital letters, and each label statement shall appear
21 in conspicuous and legible type.

22 “(D) The text of the label statement shall be
23 black on a white background, or white on a black
24 background, in an alternating fashion under the
25 plan submitted under paragraph (3).

1 “(E) The label statements shall be enclosed by
2 a rectangular border that is the same color as the
3 letters of the statements and that is the width of the
4 first downstroke of the capital ‘W’ of the word
5 ‘WARNING’ in the label statements.

6 “(F) The text of such label statements shall be
7 in a typeface pro rata to the following requirements:
8 45-point type for a whole-page broadsheet newspaper
9 advertisement; 39-point type for a half-page
10 broadsheet newspaper advertisement; 39-point type
11 for a whole-page tabloid newspaper advertisement;
12 27-point type for a half-page tabloid newspaper ad-
13 vertisement; 31.5-point type for a double page
14 spread magazine or whole-page magazine advertise-
15 ment; 22.5-point type for a 28 centimeter by 3 col-
16 umn advertisement; and 15-point type for a 20 cen-
17 timeter by 2 column advertisement.

18 “(G) The label statements shall be in English,
19 except that—

20 “(i) in the case of an advertisement that
21 appears in a newspaper, magazine, periodical,
22 or other publication that is not in English, the
23 statements shall appear in the predominant lan-
24 guage of the publication; and

1 “(ii) in the case of any other advertisement
2 that is not in English, the statements shall ap-
3 pear in the same language as that principally
4 used in the advertisement.

5 “(3)(A) The label statements specified in sub-
6 section (a)(1) shall be randomly displayed in each
7 12-month period, in as equal a number of times as
8 is possible on each brand of the product and be ran-
9 domly distributed in all areas of the United States
10 in which the product is marketed in accordance with
11 a plan submitted by the smokeless tobacco product
12 manufacturer, importer, distributor, or retailer and
13 approved by the Secretary.

14 “(B) The label statements specified in sub-
15 section (a)(1) shall be rotated quarterly in alter-
16 nating sequence in advertisements for each brand of
17 smokeless tobacco product in accordance with a plan
18 submitted by the smokeless tobacco product manu-
19 facturer, importer, distributor, or retailer to, and ap-
20 proved by, the Secretary.

21 “(C) The Secretary shall review each plan sub-
22 mitted under subparagraphs (A) and (B) and ap-
23 prove it if the plan—

1 “(i) will provide for the equal distribution
2 and display on packaging and the rotation re-
3 quired in advertising under this subsection; and

4 “(ii) assures that all of the labels required
5 under this section will be displayed by the
6 smokeless tobacco product manufacturer, im-
7 porter, distributor, or retailer at the same time.

8 “(D) This paragraph applies to a retailer only
9 if that retailer is responsible for or directs the label
10 statements under this section, unless the retailer dis-
11 plays, in a location open to the public, an advertise-
12 ment that does not contain a warning label or has
13 been altered by the retailer in a way that is material
14 to the requirements of this subsection.

15 “(c) TELEVISION AND RADIO ADVERTISING.—It is
16 unlawful to advertise smokeless tobacco on any medium
17 of electronic communications subject to the jurisdiction of
18 the Federal Communications Commission.”.

19 (b) EFFECTIVE DATE.—The amendment made by
20 subsection (a) shall take effect 24 months after the date
21 of enactment of this Act. Such effective date shall be with
22 respect to the date of manufacture, provided that, in any
23 case, beginning 30 days after such effective date, a manu-
24 facturer shall not introduce into the domestic commerce
25 of the United States any product, irrespective of the date

1 of manufacture, that is not in conformance with section
2 3 of the Comprehensive Smokeless Tobacco Health Edu-
3 cation Act of 1986 (15 U.S.C. 4402), as amended by sub-
4 section (a).

5 **TITLE III—PUBLIC DISCLOSURES**
6 **BY TOBACCO PRODUCTS**
7 **MANUFACTURERS**

8 **SEC. 301. DISCLOSURES ON PACKAGES OF TOBACCO PROD-**
9 **UCTS.**

10 (a) **BACK FACE FOR REQUIRED DISCLOSURES.**—For
11 purposes of this section—

12 (1) the principal face of a package of a tobacco
13 product is the face that has the largest surface area
14 or, for faces with identical surface areas, any of the
15 faces that have the largest surface area; a package
16 shall not be characterized as having more than 2
17 principal faces;

18 (2) the front face shall be the principal face of
19 the package;

20 (3) if the front and back faces are of different
21 sizes in terms of area, then the larger face shall be
22 the front face;

23 (4) the back face shall be the principal face of
24 a package that is opposite the front face of the pack-
25 age;

1 (5) the bottom 50 percent of the back face of
2 the package shall be allocated for required package
3 disclosures in accordance with this section; and

4 (6) if a package of a tobacco product is cylin-
5 drical, a contiguous area constituting 30 percent of
6 the total surface area of the cylinder shall be deemed
7 the back face.

8 (b) REQUIRED INFORMATION ON BACK FACE.—Not
9 later than 24 months after the effective date of this Act,
10 the bottom 50 percent of the back face of a package of
11 a tobacco product shall be available solely for disclosures
12 required by or under this Act, the Federal Cigarette La-
13 beling and Advertising Act, sections 1331–1340 of title
14 15, United States Code, and any other Federal statute.
15 Such disclosures shall include—

16 (1) the printed name and address of the manu-
17 facturer, packer, or distributor, and any other iden-
18 tification associated with the manufacturer, packer,
19 or distributor or with the tobacco product that the
20 Administrator may require;

21 (2) a list of ingredients as required by sub-
22 section (e); and

23 (3) the appropriate tax registration number.

24 (c) PACKAGE DISCLOSURE OF INGREDIENTS.—Not
25 later than 24 months after the effective date of this Act,

1 the package of a tobacco product shall bear a list of the
2 common or usual names of the ingredients present in the
3 tobacco product in an amount greater than 0.1 percent
4 of the total dry weight of the tobacco (including all ingre-
5 dients), that shall comply with the following:

6 (1) Such listing of ingredients shall appear
7 under, or be conspicuously accompanied by, the
8 heading “Tobacco and principal tobacco ingredi-
9 ents”.

10 (2) Tobacco may be listed as “tobacco,” and
11 shall be the first listed ingredient.

12 (3) After tobacco, the ingredients shall be listed
13 in descending order of predominance, by weight.

14 (4) Spices and natural and artificial flavors
15 may be listed, respectively, as “spices” and “natural
16 and artificial flavors” without naming each.

17 (5) Preservatives may be listed as “preserva-
18 tives” without naming each.

19 (6) The disclosure of any ingredient in accord-
20 ance with this section may, at the option of the to-
21 bacco product manufacturer, designate the
22 functionality or purpose of that ingredient.

23 (7) The package say state “Not for sale to mi-
24 nors”.

1 (8) In the case of a package of cigarettes, the
2 package shall state that smokeless tobacco has sig-
3 nificantly lower risks for disease and death than
4 cigarettes.

5 **SEC. 302. DISCLOSURES ON PACKAGES OF SMOKELESS TO-**
6 **BACCO.**

7 (a) **BACK FACE FOR REQUIRED DISCLOSURES.**—For
8 purposes of this section—

9 (1) the principal face of a package of smokeless
10 tobacco is the face that has the largest surface area
11 or, for faces with identical surface areas, any of the
12 faces that have the largest surface area; a package
13 shall not be characterized as having more than two
14 principal faces;

15 (2) the front or top face shall be the principal
16 face of the package;

17 (3) if the front or top and back or bottom faces
18 are of different sizes in terms of area, then the larg-
19 er face shall be the front or top face;

20 (4) the back or bottom face of the package shall
21 be the principal face of a package that is opposite
22 the front or top face of the package;

23 (5) beginning 24 months after the effective date
24 of this Act, 50 percent of the back or bottom face

1 of the package shall be allocated for required pack-
2 age disclosures in accordance with this section; and

3 (6) if the package is cylindrical, a contiguous
4 area constituting 30 percent of the total surface
5 area of the cylinder shall be deemed the back face.

6 (b) REQUIRED INFORMATION ON BACK OR BOTTOM
7 FACE.—50 percent of the back or bottom face of a pack-
8 age of smokeless tobacco shall be available solely for dis-
9 closures required by or under this Act, the Comprehensive
10 Smokeless Tobacco Health Education Act of 1986, sec-
11 tions 4401–4408 of title 15, United States Code, and any
12 other Federal statute. Such disclosures shall include a list
13 of ingredients as required by subsection (e).

14 (c) PACKAGE DISCLOSURE OF INGREDIENTS.—Com-
15 mencing 24 months after the effective date of this Act,
16 a package of smokeless tobacco shall bear a list of the
17 common or usual names of the ingredients present in the
18 smokeless tobacco in an amount greater than 0.1 percent
19 of the total dry weight of the tobacco (including all ingre-
20 dients).

21 (1) Such listing of ingredients shall appear
22 under, or be conspicuously accompanied by, the
23 heading “Tobacco and principal tobacco ingredi-
24 ents”.

1 (2) Tobacco may be listed as “tobacco,” and
2 shall be the first listed ingredient.

3 (3) After tobacco, the ingredients shall be listed
4 in descending order of predominance, by weight.

5 (4) Spices and natural and artificial flavors
6 may be listed, respectively, as “spices” and “natural
7 and artificial flavors” without naming each.

8 (5) Preservatives may be listed as “preserva-
9 tives” without naming each.

10 (6) The disclosure of any ingredient in accord-
11 ance with this section may, at the option of the to-
12 bacco product manufacturer, designate the
13 functionality or purpose of that ingredient.

14 (7) Not for sale to minors.

15 **SEC. 303. PUBLIC DISCLOSURE OF INGREDIENTS.**

16 (a) REGULATIONS.—Not later than 24 months after
17 the effective date of this Act, the Administrator shall, by
18 regulation, establish standards under which each tobacco
19 product manufacturer shall disclose publicly, and update
20 at least annually—

21 (1) a list of the ingredients it uses in each
22 brand style it manufactures for commercial distribu-
23 tion domestically, as provided in subsection (b); and

24 (2) a composite list of all the ingredients it uses
25 in any of the brand styles it manufactures for com-

1 merchial distribution domestically, as provided in sub-
2 section (c).

3 (b) INGREDIENTS TO BE DISCLOSED AS TO EACH
4 BRAND STYLE.—

5 (1) IN GENERAL.—With respect to the public
6 disclosure required by subsection (a)(1), as to each
7 brand style, the tobacco product manufacture shall
8 disclose the common or usual name of each ingre-
9 dient present in the brand style in an amount great-
10 er than 0.1 percent of the total dry weight of the to-
11 bacco (including all ingredients).

12 (2) REQUIREMENTS.—Disclosure under para-
13 graph (1) shall comply with the following:

14 (A) Tobacco may be listed as “tobacco,”
15 and shall be the first listed ingredient.

16 (B) After tobacco, the ingredients shall be
17 listed in descending order of predominance, by
18 weight.

19 (C) Spices and natural and artificial fla-
20 vors may be listed, respectively, as “spices” and
21 “natural and artificial flavors” without naming
22 each.

23 (D) Preservatives may be listed as “pre-
24 servatives” without naming each.

1 (E) The disclosure of any ingredient in ac-
2 cordance with this section may, at the option of
3 the tobacco product manufacturer, designate
4 the functionality or purpose of that ingredient.

5 (c) AGGREGATE DISCLOSURE OF INGREDIENTS.—

6 (1) IN GENERAL.—The public disclosure re-
7 quired of a tobacco product manufacturer by sub-
8 section (a)(2) shall consist of a single list of all in-
9 gredients used in any brand style a tobacco product
10 manufacturer manufactures for commercial distribu-
11 tion domestically, without regard to the quantity
12 used, and including, separately, each spice, each nat-
13 ural or artificial flavoring, and each preservative.

14 (2) LISTING.—The ingredients shall be listed by
15 their respective common or usual names in descend-
16 ing order of predominance by the total weight used
17 annually by the tobacco product manufacturer in
18 manufacturing tobacco products for commercial dis-
19 tribution domestically.

20 (d) NO REQUIRED DISCLOSURE OF QUANTITIES.—

21 The Administrator shall not require any public disclosure
22 of quantitative information about any ingredient in a to-
23 bacco product.

24 (e) DISCLOSURE ON WEBSITE.—The public dislo-
25 sures required by subsection (a) of this section may be

1 by posting on an Internet-accessible website, or other loca-
2 tion electronically accessible to the public, which is identi-
3 fied on all packages of a tobacco product manufacturer's
4 tobacco products.

5 (f) TIMING OF INITIAL REQUIRED DISCLOSURES.—
6 No disclosure pursuant to this section shall be required
7 to commence until the regulations under subsection (a)
8 have been in effect for not less than 1 year.

9 **TITLE IV—PREVENTION OF IL-**
10 **LICIT TRADE IN TOBACCO**
11 **PRODUCTS**

12 **SEC. 401. STUDY AND REPORT ON ILLICIT TRADE.**

13 (a) The Administrator shall, after consultation with
14 other relevant agencies including Customs and Tobacco
15 Tax Bureau, conduct a study of trade in tobacco products
16 that involves passage of tobacco products either between
17 the States or from or to any other country across any bor-
18 der of the United States to—

19 (1) collect data on such trade in tobacco prod-
20 ucts, including illicit trade involving tobacco prod-
21 ucts, and make recommendations on the monitoring
22 and enforcement of such trade;

23 (2) collect data on any advertising intended to
24 be broadcast, transmitted, or distributed from or to
25 the United States from or to another country and

1 make recommendations on how to prevent or elimi-
2 nate, and what technologies could help facilitate the
3 elimination of, such advertising; and

4 (3) collect data on such trade in tobacco prod-
5 ucts by person that is not—

6 (A) a participating manufacturer (as that
7 term is defined in section II(jj) of the Master
8 Settlement Agreement of November 23, 1998,
9 between certain of the States and certain to-
10 bacco product manufacturers); or

11 (B) an affiliate or subsidiary of a partici-
12 pating manufacturer.

13 (b) Not later than 18 months after the effective date
14 of this Act, the Administrator shall submit to the Sec-
15 retary, and committees of relevant jurisdiction in Con-
16 gress, a report the recommendations of the study con-
17 ducted under subsection (a).

18 **SEC. 402. AMENDMENT TO SECTION 1926 OF THE PUBLIC**

19 **HEALTH SERVICE ACT.**

20 Section 1926 of the Public Health Service Act (42
21 U.S.C. § 300x-26) is amended by adding at the end there-
22 of the following:

23 “(e)(1) Subject to paragraphs (2) and (3), for the
24 first fiscal year after enactment and each subsequent fiscal
25 year, the Secretary shall reduce, as provided in subsection

1 (h), the amount of any grant under section 300x-21 of
2 this title for any State that does not have in effect a stat-
3 ute with substantially the following provisions:

4 **“SEC. 1. DISTRIBUTION TO MINORS.**

5 “(a) No person shall distribute a tobacco product
6 to an individual under 18 years of age or a different min-
7 imum age established under State law. A person who vio-
8 lates this subsection is liable for a civil money penalty of
9 not less than \$25 nor more than \$125 for each violation
10 of this subsection;

11 “(b) The employer of an employee who has violated
12 subsection (a) twice while in the employ of such employer
13 is liable for a civil money penalty of \$125 for each subse-
14 quent violation by such employee.

15 “(c) It shall be a defense to a charge brought under
16 subsection (a) that—

17 “(1) the defendant—

18 “(A) relied upon proof of age that ap-
19 peared on its face to be valid in accordance with
20 the Federal Tobacco Act of 2007;

21 “(B) had complied with the requirements
22 of section 5 and, if applicable, section 7; or

23 “(C) relied upon a commercially available
24 electronic age verification service to confirm
25 that the person was an age-verified adult; or

1 “(2) the individual to whom the tobacco prod-
2 uct was distributed was at the time of the distribu-
3 tion used in violation of subsection 8(b).

4 **“SEC. 2. PURCHASE, RECEIPT, OR POSSESSION BY MINORS**
5 **PROHIBITED.**

6 “(a) An individual under 18 years of age or a dif-
7 ferent minimum age established under State law shall not
8 purchase or attempt to purchase, receive or attempt to re-
9 ceive, possess or attempt to possess, a tobacco product.
10 An individual who violates this subsection is liable for a
11 civil money penalty of not less than \$25 nor more than
12 \$125 for each such violation, and shall be required to per-
13 form not less than four hours nor more than ten hours
14 of community service. Upon the second or each subsequent
15 violation of this subsection, such individual shall be re-
16 quired to perform not less than eight hours nor more than
17 twenty hours of community service.

18 “(b) A law enforcement agency, upon determining
19 that an individual under 18 years of age or a different
20 minimum age established under State law allegedly pur-
21 chased, received, possessed, or attempted to purchase, re-
22 ceive, or possess, a tobacco product in violation of sub-
23 section (a) shall notify the individual’s parent or parents,
24 custodian, or guardian as to the nature of the alleged vio-
25 lation if the name and address of a parent or parents,

1 guardian, or custodian is reasonably ascertainable by the
2 law enforcement agency. The notice required by this sub-
3 section shall be made not later than 48 hours after the
4 individual who allegedly violated subsection (a) is cited by
5 such agency for the violation. The notice may be made
6 by any means reasonably calculated to give prompt actual
7 notice, including notice in person, by telephone, or by first-
8 class mail.

9 “(c) Subsection (a) does not prohibit an individual
10 under 18 years of age or a different minimum age estab-
11 lished under State law from possessing a tobacco product
12 during regular working hours and in the course of such
13 individual’s employment if the tobacco product is not pos-
14 sessed for such individual’s consumption.

15 **“SEC. 3. OUT-OF-PACKAGE DISTRIBUTION.**

16 ““It shall be unlawful for any person to distribute
17 cigarettes or a smokeless tobacco product other than in
18 an unopened package that complies in full with section
19 108 of the Federal Tobacco Act of 2007. A person who
20 distributes a cigarette or a smokeless tobacco product in
21 violation of this section is liable for a civil money penalty
22 of not less than \$25 nor more than \$125 for each such
23 violation.

1 **“SEC. 4. SIGNAGE.**

2 “It shall be unlawful for any person who sells to-
3 bacco products over-the-counter to fail to post conspicu-
4 ously on the premises where such person sells tobacco
5 products over-the-counter a sign communicating that—

6 ““(1) the sale of tobacco products to individuals
7 under 18 years of age or a different minimum age
8 established under State law is prohibited by law;

9 ““(2) the purchase of tobacco products by indi-
10 viduals under 18 years of age or a different min-
11 imum age established under State law is prohibited
12 by law; and

13 ““(3) proof of age may be demanded before to-
14 bacco products are sold.

15 A person who fails to post a sign that complies fully with
16 this section is liable for a civil money penalty of not less
17 than \$25 nor more than \$125.

18 **“SEC. 5. NOTIFICATION OF EMPLOYEES.**

19 ““(a) Within 180 days of the effective date of the
20 Youth Prevention and Tobacco Harm Reduction Act,
21 every person engaged in the business of selling tobacco
22 products at retail shall implement a program to notify
23 each employee employed by that person who sells tobacco
24 products at retail that—

25 ““(1) the sale or other distribution of tobacco
26 products to any individual under 18 years of age or

1 a different minimum age established under State
2 law, and the purchase, receipt, or possession of to-
3 bacco products in a place open to the public by any
4 individual under 18 years of age or a different min-
5 imum age established under State law, is prohibited;
6 and

7 ““(2) out-of-package distribution of cigarettes
8 and smokeless tobacco products is prohibited.

9 Any employer failing to provide the required notice to any
10 employee shall be liable for a civil money penalty of not
11 less than \$25 nor more than \$125 for each such violation.

12 ““(b) It shall be a defense to a charge that an em-
13 ployer violated subsection (a) of this section that the em-
14 ployee acknowledged receipt, either in writing or by elec-
15 tronic means, prior to the alleged violation, of a statement
16 in substantially the following form:

17 ““I understand that State law prohibits the distribu-
18 tion of tobacco products to individuals under 18 years of
19 age or a different minimum age established under State
20 law and out-of-package distribution of cigarettes and
21 smokeless tobacco products, and permits a defense based
22 on evidence that a prospective purchaser’s proof of age
23 was reasonably relied upon and appeared on its face to
24 be valid. I understand that if I sell, give, or voluntarily
25 provide a tobacco product to an individual under 18 years

1 of age or a different minimum age established under State
2 law, I may be found responsible for a civil money penalty
3 of not less than \$25 nor more than \$125 for each viola-
4 tion. I promise to comply with this law.’”

5 ““(c) If an employer is charged with a violation of
6 subsection (a) and the employer uses as a defense to such
7 charge the defense provided by subsection (b), the em-
8 ployer shall be deemed to be liable for such violation if
9 such employer pays the penalty imposed on the employee
10 involved in such violation or in any way reimburses the
11 employee for such penalty.

12 **“SEC. 6. SELF-SERVICE DISPLAYS.**

13 ““(a) It shall be unlawful for any person who sells
14 tobacco products over-the-counter at retail to maintain
15 packages of such products in any location accessible to
16 customers that is not under the control of a cashier or
17 other employee during regular business hours. This sub-
18 section does not apply to any adult-only facility.

19 ““(b) Any person who violates subsection (a) is liable
20 for a civil money penalty of not less than \$25 nor more
21 than \$125 for each such violation, except that no person
22 shall be responsible for more than one violation per day
23 at any one retail store.

1 **“SEC. 7. DISTRIBUTION BY MAIL OR COURIER.**

2 ““(a) It shall be unlawful to distribute or sell tobacco
3 products directly to consumers by mail or courier, unless
4 the person receiving purchase requests for tobacco prod-
5 ucts takes reasonable action to prevent delivery to individ-
6 uals who are not adults by—

7 ““(1) requiring that addressees of the tobacco
8 products be age-verified adults;

9 ““(2) making good faith efforts to verify that
10 such addressees have attained the minimum age for
11 purchase of tobacco products established by the re-
12 spective States wherein the addresses of the address-
13 ees are located; and

14 ““(3) addressing the tobacco products delivered
15 by mail or courier to a physical addresses and not
16 to post office boxes.

17 ““(b) Any person who violates subsection (a) is liable
18 for a civil money penalty of not less than \$25 nor more
19 than \$125 for each such violation.

20 **“SEC. 8. RANDOM UNANNOUNCED INSPECTIONS; REPORT-**
21 **ING; AND COMPLIANCE.**

22 ““(a) The State Police, or a local law enforcement
23 authority duly designated by the State Police, shall en-
24 force this Act in a manner that can reasonably be expected
25 to reduce the extent to which tobacco products are distrib-
26 uted to individuals under 18 years of age or a different

1 minimum age established under State law and shall con-
2 duct random, unannounced inspections in accordance with
3 the procedures set forth in this Act and in regulations
4 issued under section 1926 of the Federal Public Health
5 Service Act (42 U.S.C. § 300x-26).

6 “(b) The State may engage an individual under 18
7 years of age or a different minimum age established under
8 State law to test compliance with this Act, except that
9 such an individual may be used to test compliance with
10 this Act only if the testing is conducted under the fol-
11 lowing conditions:

12 “(1) Prior to use of any individual under 18
13 years of age or a different minimum age established
14 under State law in a random, unannounced inspec-
15 tion, written consent shall be obtained from a par-
16 ent, custodian, or guardian of such individual;

17 “(2) An individual under 18 years of age or a
18 different minimum age established under State law
19 shall act solely under the supervision and direction
20 of the State Police or a local law enforcement au-
21 thority duly designated by the State Police during a
22 random, unannounced inspection;

23 “(3) An individual under 18 years of age or a
24 different minimum age established under State law
25 used in random, unannounced inspections shall not

1 be used in any such inspection at a store in which
2 such individual is a regular customer; and

3 ““(4) If an individual under 18 years of age or
4 a different minimum age established under State law
5 participating in random, unannounced inspections is
6 questioned during such an inspection about such in-
7 dividual’s age, such individual shall state his or her
8 actual age and shall present a true and correct proof
9 of age if requested at any time during the inspection
10 to present it.

11 ““(c) Any person who uses any individual under 18
12 years of age or a different minimum age established under
13 State law, other than as permitted by subsection (b), to
14 test compliance with this Act, is liable for a civil money
15 penalty of not less than \$25 nor more than \$125 for each
16 such violation.

17 ““(d) Civil money penalties collected for violations of
18 this Act and fees collected under section 9 shall be used
19 only to defray the costs of administration and enforcement
20 of this Act.

21 **““SEC. 9. LICENSURE.**

22 ““(a) Each person engaged in the over-the-counter
23 distribution at retail of tobacco products shall hold a li-
24 cense issued under this section. A separate license shall
25 be required for each place of business where tobacco prod-

1 icts are distributed at retail. A license issued under this
2 section is not assignable and is valid only for the person
3 in whose name it is issued and for the place of business
4 designated in the license.

5 “(b) The annual license fee is \$25 for each place
6 of business where tobacco products are distributed at re-
7 tail.

8 “(c) Every application for a license, including re-
9 newal of a license, under this section shall be made upon
10 a form provided by the appropriate State agency or de-
11 partment, and shall set forth the name under which the
12 applicant transacts or intends to transact business, the lo-
13 cation of the place of business for which the license is to
14 be issued, the street address to which all notices relevant
15 to the license are to be sent (in this Act referred to as
16 “notice address”), and any other identifying information
17 that the appropriate State agency or department may re-
18 quire.

19 “(d) The appropriate State agency or department
20 shall issue or renew a license or deny an application for
21 a license or the renewal of a license within 30 days of
22 receiving a properly completed application and the license
23 fee. The appropriate State agency or department shall
24 provide notice to an applicant of action on an application

1 denying the issuance of a license or refusing to renew a
2 license.

3 “(e) Every license issued by the appropriate State
4 agency or department pursuant to this section shall be
5 valid for 1 year from the date of issuance and shall be
6 renewed upon application except as otherwise provided in
7 this Act.

8 “(f) Upon notification of a change of address for a
9 place of business for which a license has been issued, a
10 license shall be reissued for the new address without the
11 filing of a new application.

12 “(g) The appropriate State agency or department
13 shall notify every person in the State who is engaged in
14 the distribution at retail of tobacco products of the license
15 requirements of this section and of the date by which such
16 person should have obtained a license.

17 “(h)(1) Except as provided in paragraph (2), any
18 person who engages in the distribution at retail of tobacco
19 products without a license required by this section is liable
20 for a civil money penalty in an amount equal to (i) two
21 times the applicable license fee, and (ii) \$50 for each day
22 that such distribution continues without a license.

23 “(2) Any person who engages in the distribu-
24 tion at retail of tobacco products after a license
25 issued under this section has been suspended or re-

1 voked is liable for a civil money penalty of \$100 per
2 day for each day on which such distribution con-
3 tinues after the date such person received notice of
4 such suspension or revocation.

5 “(i) No person shall engage in the distribution at
6 retail of tobacco products on or after 180 days after the
7 date of enactment this Act unless such person is author-
8 ized to do so by a license issued pursuant to this section
9 or is an employee or agent of a person that has been
10 issued such a license.

11 **“SEC. 10. SUSPENSION, REVOCATION, DENIAL, AND NON-**
12 **RENEWAL OF LICENSES.**

13 “(a) Upon a finding that a licensee has been deter-
14 mined by a court of competent jurisdiction to have violated
15 this Act during the license term, the State shall notify the
16 licensee in writing, served personally or by registered mail
17 at the notice address, that any subsequent violation of this
18 Act at the same place of business may result in an admin-
19 istrative action to suspend the license for a period deter-
20 mined by the specify the appropriate State agency or de-
21 partment.

22 “(b) Upon finding that a further violation by this
23 Act has occurred involving the same place of business for
24 which the license was issued and the licensee has been
25 served notice once under subsection (a), the appropriate

1 State agency or department may initiate an administrative
2 action to suspend the license for a period to be determined
3 by the appropriate State agency or department but not
4 to exceed six months. If an administrative action to sus-
5 pend a license is initiated, the appropriate State agency
6 or department shall immediately notify the licensee in
7 writing at the notice address of the initiation of the action
8 and the reasons therefor and permit the licensee an oppor-
9 tunity, at least 30 days after written notice is served per-
10 sonally or by registered mail upon the licensee, to show
11 why suspension of the license would be unwarranted or
12 unjust.

13 “(c) The appropriate State agency or department
14 may initiate an administrative action to revoke a license
15 that previously has been suspended under subsection (b)
16 if, after the suspension and during the one-year period for
17 which the license was issued, the licensee committed a fur-
18 ther violation of this Act, at the same place of business
19 for which the license was issued. If an administrative ac-
20 tion to revoke a license is initiated, the appropriate State
21 agency or department shall immediately notify the licensee
22 in writing at the notice address of the initiation of the
23 action and the reasons therefor and permit the licensee
24 an opportunity, at least 30 days after written notice is
25 served personally or by registered mail upon the licensee,

1 to show why revocation of the license would be unwar-
2 ranted or unjust.

3 ““(d) A person whose license has been suspended or
4 revoked with respect to a place of business pursuant to
5 this section shall pay a fee of \$50 for the renewal or
6 reissuance of the license at that same place of business,
7 in addition to any applicable annual license fees.

8 ““(e) Revocation of a license under subsection (c)
9 with respect to a place of business shall not be grounds
10 to deny an application by any person for a new license
11 with respect to such place of business for more than 12
12 months subsequent to the date of such revocation. Revoca-
13 tion or suspension of a license with respect to a particular
14 place of business shall not be grounds to deny an applica-
15 tion for a new license, to refuse to renew a license, or to
16 revoke or suspend an existing license at any other place
17 of business.

18 ““(f) A licensee may seek judicial review of an action
19 of the appropriate State agency or department sus-
20 pending, revoking, denying, or refusing to renew a license
21 under this section by filing a complaint in a court of com-
22 petent jurisdiction. Any such complaint shall be filed with-
23 in 30 days after the date on which notice of the action
24 is received by the licensee. The court shall review the evi-
25 dence de novo.

1 “(g) The State shall not report any action sus-
2 pending, revoking, denying, or refusing to renew a license
3 under this section to the Federal Secretary of Health and
4 Human Services, unless the opportunity for judicial review
5 of the action pursuant to subsection (f), if any, has been
6 exhausted or the time for seeking such judicial review has
7 expired.

8 **“SEC. 11. NO PRIVATE RIGHT OF ACTION.**

9 “‘Nothing in this Act shall be construed to create
10 a right of action by any private person for any violation
11 of any provision of this Act.

12 **“SEC. 12. JURISDICTION AND VENUE.**

13 “‘Any action alleging a violation of this Act may be
14 brought only in a court of general jurisdiction in the city
15 or county where the violation is alleged to have occurred.

16 **“SEC. 13. REPORT.**

17 “‘The appropriate State agency or department shall
18 prepare for submission annually to the Federal Secretary
19 of Health and Human Services the report required by sec-
20 tion 1926 of the Federal Public Health Service Act (42
21 U.S.C. 300x-26).’”.

22 “(2) In the case of a State whose legislature
23 does not convene a regular session in fiscal year
24 2007, and in the case of a State whose legislature
25 does not convene a regular session in fiscal year

1 2008, the requirement described in subsection (e)(1)
2 as a condition of a receipt of a grant under section
3 300x-21 of this title shall apply only for fiscal year
4 2009 and subsequent fiscal years.

5 “(3) Subsection (e)(1) shall not affect any
6 State or local law that (A) was in effect on the date
7 of introduction of the Federal Tobacco Act of 2007,
8 and (B) covers the same subject matter as the law
9 described in subsection (e)(1). Any State law that
10 meets the conditions of this paragraph shall also be
11 deemed to meet the requirement described in sub-
12 section (e)(1) as a condition of a receipt of a grant
13 under section 300x-21 of this title, if such State law
14 is at least as stringent as the law described in sub-
15 section (e)(1).

16 “(f)(1) For the first applicable fiscal year and for
17 each subsequent fiscal year, a funding agreement for a
18 grant under section 300x-21 of this title is a funding
19 agreement under which the State involved will enforce the
20 law described in subsection (e)(1) of this section in a man-
21 ner that can reasonably be expected to reduce the extent
22 to which tobacco products are available to individuals
23 under the age of 18 or a different minimum age estab-
24 lished under State law for the purchase of tobacco prod-
25 ucts.

1 “(2) For the first applicable fiscal year and for each
2 subsequent fiscal year, a funding agreement for a grant
3 under section 300x-21 of this title is a funding agreement
4 under which the State involved will—

5 “(A) conduct random, unannounced inspections
6 to ensure compliance with the law described in sub-
7 section (e)(1); and

8 “(B) annually submit to the Secretary a report
9 describing—

10 “(i) the activities carried out by the State
11 to enforce such law during the fiscal year pre-
12 ceding the fiscal year for which the State is
13 seeking the grant;

14 “(ii) the extent of success the State has
15 achieved in reducing the availability of tobacco
16 products to individuals under 18 years of age or
17 a different minimum age established under
18 State law, including the results of the inspec-
19 tions conducted under subparagraph (A); and

20 “(iii) the strategies to be utilized by the
21 State for enforcing such law during the fiscal
22 year for which the grant is sought.

23 “(g) The law specified in subsection (e)(1) may be
24 administered and enforced by a State using—

1 “(1) any amounts made available to the State
2 through a grant under section 300x–21 of this title;

3 “(2) any amounts made available to the State
4 under section 300w of this title;

5 “(3) any fees collected for licenses issued pursu-
6 ant to the law described in subsection (e)(1);

7 “(4) any fines or penalties assessed for viola-
8 tions of the law specified in subsection (e)(1); or

9 “(5) any other funding source that the legisla-
10 ture of the State may prescribe by statute.

11 “(h) Before making a grant under section 300x–21
12 of this title to a State for the first applicable fiscal year
13 or any subsequent fiscal year, the Secretary shall make
14 a determination of whether the State has maintained com-
15 pliance with subsections (e) and (f) of this section. If, after
16 notice to the State and an opportunity for a hearing, the
17 Secretary determines that the State is not in compliance
18 with such subsections, the Secretary shall reduce the
19 amount of the allotment under section 300x–21 of this
20 title for the State for the fiscal year involved by an amount
21 equal to—

22 “(1) In the case of the first applicable fiscal
23 year, 10 percent of the amount determined under
24 section 300x–33 for the State for the fiscal year;

1 “(2) In the case of the first fiscal year following
2 such applicable fiscal year, 20 percent of the amount
3 determined under section 300x–33 for the State for
4 the fiscal year;

5 “(3) In the case of the second such fiscal year,
6 30 percent of the amount determined under section
7 300x–33 for the State for the fiscal year; and

8 “(4) In the case of the third such fiscal year or
9 any subsequent fiscal year, 40 percent of the amount
10 determined under section 300x–33 for the State for
11 the fiscal year.

12 The Secretary shall not have authority or discretion to
13 grant to any State a waiver of the terms and requirements
14 of this subsection or subsection (e) or (f).

15 “(i) For the purposes of subsections (e) through (h)
16 of this section the term ‘first applicable fiscal year’
17 means—

18 “(1) fiscal year 2009, in the case of any State
19 described in subsection (e)(2) of this section; and

20 “(2) fiscal year 2008, in the case of any other
21 State.

22 “(j) For purposes of subsections (e) through (h) of
23 this section, references to section 300x–21 shall include
24 any successor grant programs.’”

1 “(k) As required by paragraph (1), and subject to
2 paragraph (4), an Indian tribe shall satisfy the require-
3 ments of subsection (e)(1) of this section by enacting a
4 law or ordinance with substantially the same provisions
5 as the law described in subsection (e)(1).

6 “(1) An Indian tribe shall comply with sub-
7 section (e)(1) of this section within 180 days after
8 the Administrator finds, in accordance with this
9 paragraph, that—

10 “(A) the Indian tribe has a governing body
11 carrying out substantial governmental powers
12 and duties;

13 “(B) the functions to be exercised by the
14 Indian tribe under this Act pertain to activities
15 on trust land within the jurisdiction of the
16 tribe; and

17 “(C) the Indian tribe is reasonably ex-
18 pected to be capable of carrying out the func-
19 tions required under this section.

20 Within 2 years of the date of enactment of the Fed-
21 eral Tobacco Act of 2007, as to each Indian tribe in
22 the United States, the Administrator shall make the
23 findings contemplated by this paragraph or deter-
24 mine that such findings cannot be made, in accord-
25 ance with the procedures specified in paragraph (4).

1 “(2) As to Indian tribes subject to subsection
2 (e)(1) of this section, the Administrator shall pro-
3 mulgate regulations that—

4 “(A) provide whether and to what extent,
5 if any, the law described in subsection (e)(1)
6 may be modified as adopted by Indian tribes;
7 and

8 “(B) ensure, to the extent possible, that
9 each Indian tribe’s retailer licensing program
10 under subsection (e)(1) is no less stringent than
11 the program of the State or States in which the
12 Indian tribe is located.

13 “(3) If with respect to any Indian tribe the Ad-
14 ministrator determines that compliance with the re-
15 quirements of subsection (e)(1) is inappropriate or
16 administratively infeasible, the Administrator shall
17 specify other means for the Indian tribe to achieve
18 the purposes of the law described in subsection
19 (e)(1) with respect to persons who engage in the dis-
20 tribution at retail of tobacco products on tribal
21 lands.

22 “(4) The findings and regulations promulgated
23 under paragraphs (1) and (2) shall be promulgated
24 in conformance with section 553 of title 5, United

1 States Code, and shall comply with the following
2 provisions:

3 “(A) In making findings as provided in
4 paragraph (1), and in drafting and promul-
5 gating regulations as provided in paragraph (2)
6 (including drafting and promulgating any re-
7 vised regulations), the Administrator shall con-
8 fer with, and allow for active participation by,
9 representatives and members of Indian tribes,
10 and tribal organizations.

11 “(B) In carrying out rulemaking processes
12 under this subsection, the Administrator shall
13 follow the guidance of subchapter III of chapter
14 5 of title 5, United States Code, commonly
15 known as the ‘Negotiated Rulemaking Act of
16 1990.’

17 “(C) The tribal participants in the negotia-
18 tion process referred to in subparagraph (B)
19 shall be nominated by and shall represent the
20 groups described in this subsection and shall in-
21 clude tribal representatives from all geographic
22 regions.

23 “(D) The negotiations conducted under
24 this paragraph (4) shall be conducted in a time-
25 ly manner.

1 “(E) If the Administrator determines that
2 an extension of the deadlines under subsection
3 (k)(1) of this section is appropriate, the Sec-
4 retary may submit proposed legislation to Con-
5 gress for the extension of such deadlines.

6 “(5) This subsection shall not affect any law or
7 ordinance that (A) was in effect on tribal lands on
8 the date of introduction of the Youth Prevention and
9 Tobacco Harm Reduction Act, and (B) covers the
10 same subject matter as the law described in sub-
11 section (e)(1). Any law or ordinance that meets the
12 conditions of this paragraph shall also be deemed to
13 meet the requirement described in subsection (k)(1),
14 if such law or ordinance is at least as stringent as
15 the law described in subsection (e)(1).

16 “(6) For purposes of this subsection—

17 “(A) ‘Administrator’ means the Adminis-
18 trator of the Tobacco Harm Reduction Center.

19 “(B) ‘Indian tribe’ has the meaning as-
20 signed that term in section 4(e) of the Indian
21 Self Determination and Education Assistance
22 Act, section 450b(e) of title 25, United States
23 Code.

24 “(C) ‘Tribal lands’ means all lands within
25 the exterior boundaries of any Indian reserva-

1 tion, all lands the title to which is held by the
2 United States in trust for an Indian tribe, or
3 lands the title to which is held by an Indian
4 tribe subject to a restriction by the United
5 States against alienation, and all dependent In-
6 dian communities.

7 “(D) ‘tribal organization’ has the meaning
8 assigned that term in section 4(1) of the Indian
9 Self Determination and Education Assistance
10 Act, section 450b(1) of title 25, United States
11 Code.”.

12 **SEC. 403. ESTABLISHMENT OF RANKINGS.**

13 (a) STANDARDS AND PROCEDURES FOR
14 RANKINGS.—Within 24 months after the effective date of
15 this Act, the Administrator shall, by regulation, after con-
16 sultation with an Advisory Committee established for such
17 purpose, establish the standards and procedures for pro-
18 mulgating rankings, comprehensible to consumers of to-
19 bacco products, of the following categories of tobacco
20 products and also nicotine-containing products on the
21 basis of the relative risks of serious or chronic tobacco-
22 related diseases and adverse health conditions those cat-
23 egories of tobacco products and also nicotine-containing
24 products respectively present—

25 (1) cigarettes;

- 1 (2) loose tobacco for roll-your-own tobacco
- 2 products;
- 3 (3) little cigars;
- 4 (4) cigars;
- 5 (5) pipe tobacco;
- 6 (6) moist snuff;
- 7 (7) dry snuff;
- 8 (8) chewing tobacco;
- 9 (9) other forms of tobacco products, including
- 10 pelletized tobacco and compressed tobacco, treated
- 11 collectively as a single category; and
- 12 (10) other nicotine-containing products, treated
- 13 collectively as a single category.

14 The Administrator shall not have authority or discretion
15 to establish a relative-risk ranking of any category or sub-
16 category of tobacco products or any category or sub-
17 category of nicotine-containing products other than the
18 ten categories specified in this subsection.

19 (b) CONSIDERATIONS IN PROMULGATING REGULA-
20 TIONS.—In promulgating regulations under this section,
21 the Administrator—

- 22 (1) shall take into account relevant epidemio-
23 logic studies and other relevant competent and reli-
24 able scientific evidence; and

1 (2) in assessing the risks of serious or chronic
2 tobacco-related diseases and adverse health condi-
3 tions presented by a particular category, shall con-
4 sider the range of tobacco products or nicotine-con-
5 taining products within the category, and shall give
6 appropriate weight to the market shares of the re-
7 spective products in the category.

8 (c) PROMULGATION OF RANKINGS OF CAT-
9 EGORIES.—Once the initial regulations required by sub-
10 section (a) are in effect, the Administrator shall promptly,
11 by order, after notice and an opportunity for comment,
12 promulgate to the general public rankings of the cat-
13 egories of tobacco products and nicotine-containing prod-
14 ucts in accordance with those regulations. The Adminis-
15 trator shall promulgate the initial rankings of those cat-
16 egories of tobacco products and nicotine-containing prod-
17 ucts to the general public not later than January 1, 2010.
18 Thereafter, on an annual basis, the Administrator shall,
19 by order, promulgate to the general public updated
20 rankings that are (1) in accordance with those regulations,
21 and (2) reflect the scientific evidence available at the time
22 of promulgation. The Administrator shall open and main-
23 tain an ongoing public docket for receipt of data and other
24 information submitted by any person with respect to such
25 annual promulgation of rankings.

1 **TITLE V—ENFORCEMENT**
2 **PROVISIONS**

3 **SEC. 501. PROHIBITED ACTS.**

4 The following acts and the causing thereof are hereby
5 prohibited—

6 (1) the introduction or delivery for introduction
7 into interstate commerce of any tobacco product that
8 is adulterated or misbranded;

9 (2) the adulteration or misbranding of any to-
10 bacco product in interstate commerce;

11 (3) the receipt in interstate commerce of any
12 tobacco product that is known to be adulterated or
13 misbranded, and the delivery or proffered delivery
14 thereof for pay or otherwise;

15 (4) the failure to establish or maintain any
16 record, or make any report or other submission, or
17 to provide any notice required by or under this Act;
18 or the refusal to permit access to, verification of, or
19 copying of any record as required by this Act;

20 (5) the refusal to permit entry or inspection as
21 authorized by this Act;

22 (6) the making to the Administrator of a state-
23 ment, report, certification or other submission re-
24 quired by this Act, with knowledge that such state-

1 ment, report, certification, or other submission is
2 false in a material aspect;

3 (7) the manufacturing, shipping, receiving, stor-
4 ing, selling, distributing, possession, or use of any
5 tobacco product with knowledge that it is an illicit
6 tobacco product;

7 (8) the forging, simulating without proper per-
8 mission, falsely representing, or without proper au-
9 thority using any brand name;

10 (9) the using by any person to his or her own
11 advantage, or revealing, other than to the Adminis-
12 trator or officers or employees of the Agency, or to
13 the courts when relevant in any judicial proceeding
14 under this Act, any information acquired under au-
15 thority of this Act concerning any item which as a
16 trade secret is entitled to protection; except that the
17 foregoing does not authorize the withholding of in-
18 formation from either House of Congress or from, to
19 the extent of matter within its jurisdiction, any com-
20 mittee or subcommittee of such committee or any
21 joint committee of Congress or any subcommittee of
22 such joint committee;

23 (10) the alteration, mutilation, destruction, ob-
24 literation, or removal of the whole or any part of the
25 labeling of, or the doing of any other act with re-

1 spect to, a tobacco product, if such act is done while
2 such tobacco product is held for sale (whether or not
3 the first sale) after shipment in interstate commerce,
4 and results in such tobacco product being adulter-
5 ated or misbranded;

6 (11) the importation of any tobacco product
7 that is adulterated, misbranded, or otherwise not in
8 compliance with this Act; and

9 (12) the commission of any act prohibited by
10 section 201 of this Act.

11 **SEC. 502. INJUNCTION PROCEEDINGS.**

12 (a) The district courts of the United States shall have
13 jurisdiction, for cause shown, to restrain violations of this
14 Act, except for violations of section 701(k).

15 (b) In case of an alleged violation of an injunction
16 or restraining order issued under this section, which also
17 constitutes a violation of this Act, trial shall be by the
18 court, or upon demand of the defendant, by a jury.

19 **SEC. 503. PENALTIES.**

20 (a) **CRIMINAL PENALTIES.**—Any person who willfully
21 violates a provision of section 501 of this Act shall be im-
22 prisoned for not more than one year or fined not more
23 than \$25,000, or both.

24 (b) **CIVIL PENALTIES FOR VIOLATION OF SECTION**
25 **803.**—

1 (1) Any person who knowingly distributes or
2 sells, other than through retail sale or retail offer for
3 sale, any cigarette brand style in violation of section
4 803(a)—

5 (A) for a first offense shall be liable for a
6 civil penalty not to exceed \$10,000 for each dis-
7 tribution or sale, or

8 (B) for a second offense shall be liable for
9 a civil penalty not to exceed \$25,000 for each
10 distribution or sale,

11 except that the penalty imposed against any person
12 with respect to violations during any 30-day period
13 shall not exceed \$100,000.

14 (2) Any retailer who knowingly distributes, sells
15 or offers for sale any cigarette brand style in viola-
16 tion of section 803(a) shall—

17 (A) for a first offense for each sale or offer
18 for sale of cigarettes, if the total number of
19 packages of cigarettes sold or offered for sale—

20 (i) does not exceed 50 packages of
21 cigarettes, be liable for a civil penalty not
22 to exceed \$500 for each sale or offer for
23 sale, and

1 (ii) exceeds 50 packages of cigarettes,
2 be liable for a civil penalty not to exceed
3 \$1,000 for each sale or offer for sale;

4 (B) for each subsequent offense for each
5 sale or offer for sale of cigarettes, if the total
6 number of cigarettes sold or offered for sale—

7 (i) does not exceed 50 packages of
8 cigarettes, be liable for a civil penalty not
9 to exceed \$2,000 for each sale or offer for
10 sale, and

11 (ii) exceeds 50 packages of cigarettes,
12 be liable for a civil penalty not to exceed
13 \$5,000 for each sale or offer for sale;

14 except that the penalty imposed against any
15 person during any 30-day period shall not ex-
16 ceed \$25,000.

17 **SEC. 504. SEIZURE.**

18 (a) ARTICLES SUBJECT TO SEIZURE.—

19 (1) Any tobacco product that is adulterated or
20 misbranded when introduced into or while in inter-
21 state commerce or while held for sale (whether or
22 not the first sale) after shipment in interstate com-
23 merce, or which may not, under the provisions of
24 this Act, be introduced into interstate commerce,
25 shall be liable to be proceeded against while in inter-

1 state commerce, or at any time thereafter, on libel
2 of information and condemned in any district court
3 of the United States within the jurisdiction of which
4 the tobacco product is found. No libel for condemna-
5 tion shall be instituted under this Act for any al-
6 leged misbranding if there is pending in any court
7 a libel for condemnation proceeding under this Act
8 based upon the same alleged misbranding, and not
9 more than one such proceeding shall be instituted if
10 no such proceeding is so pending, except that such
11 limitations shall not apply—

12 (A) when such misbranding has been the
13 basis of a prior judgment in favor of the United
14 States, in a criminal, injunction, or libel for
15 condemnation proceeding under this Act, or

16 (B) when the Administrator has probable
17 cause to believe from facts found, without hear-
18 ing, by the Administrator or any officer or em-
19 ployee of the Agency that the misbranded to-
20 bacco product is dangerous to health beyond
21 the inherent danger to health posed by tobacco,
22 or that the labeling of the misbranded tobacco
23 product is fraudulent, or would be in a material
24 respect misleading to the injury or damage of
25 the purchaser or consumer. In any case where

1 the number of libel for condemnation pro-
2 ceedings is limited as above provided, the pro-
3 ceeding pending or instituted shall, on applica-
4 tion of the claimant, seasonably made, be re-
5 moved for trial to any district agreed upon by
6 stipulation between the parties, or, in case of
7 failure to so stipulate within a reasonable time,
8 the claimant may apply to the court of the dis-
9 trict in which the seizure has been made, and
10 such court (after giving the United States at-
11 torney for such district reasonable notice and
12 opportunity to be heard) shall by order, unless
13 good cause to the contrary is shown, specify a
14 district of reasonable proximity to the claim-
15 ant's principal place of business, to which the
16 case shall be removed for trial.

17 (2) The following shall be liable to be proceeded
18 against at any time on libel of information and con-
19 demned in any district court of the United States
20 within the jurisdiction of which they are found—

21 (A) any tobacco product that is an illicit
22 tobacco product;

23 (B) any container of an illicit tobacco
24 product;

1 (C) any equipment or thing used in mak-
2 ing an illicit tobacco product; and

3 (D) any adulterated or misbranded tobacco
4 product.

5 (3)(A) Except as provided in subparagraph (B),
6 no libel for condemnation may be instituted under
7 paragraph (1) or (2) against any tobacco product
8 which—

9 (i) is misbranded under this Act be-
10 cause of its advertising, and

11 (ii) is being held for sale to the ulti-
12 mate consumer in an establishment other
13 than an establishment owned or operated
14 by a manufacturer, packer, or distributor
15 of the tobacco product.

16 (B) A libel for condemnation may be insti-
17 tuted under paragraph (1) or (2) against a to-
18 bacco product described in subparagraph (A) if
19 the tobacco product's advertising which resulted
20 in the tobacco product being misbranded was
21 disseminated in the establishment in which the
22 tobacco product is being held for sale to the ul-
23 timate consumer—

1 (i) such advertising was disseminated
2 by, or under the direction of, the owner or
3 operator of such establishment, or

4 (ii) all or part of the cost of such ad-
5 vertising was paid by such owner or oper-
6 ator.

7 (b) PROCEDURES.—The tobacco product, equipment,
8 or other thing proceeded against shall be liable to seizure
9 by process pursuant to the libel, and the procedure in
10 cases under this section shall conform, as nearly as may
11 be, to the procedure in admiralty; except that on demand
12 of either party any issue of fact joined in any such case
13 shall be tried by jury. When libel for condemnation pro-
14 ceedings under this section, involving the same claimant
15 and the same issues of adulteration or misbranding, are
16 pending in two or more jurisdictions, such pending pro-
17 ceedings, upon application of the claimant seasonably
18 made to the court of one such jurisdiction, shall be consoli-
19 dated for trial by order of such court, and tried in (1)
20 any district selected by the claimant where one of such
21 proceedings is pending; or (2) a district agreed upon by
22 stipulation between the parties. If no order for consolida-
23 tion is so made within a reasonable time, the claimant may
24 apply to the court of one such jurisdiction and such court
25 (after giving the United States attorney for such district

1 reasonable notice and opportunity to be heard) shall by
2 order, unless good cause to the contrary is shown, specify
3 a district of reasonable proximity to the claimant's prin-
4 cipal place of business, in which all such pending pro-
5 ceedings shall be consolidated for trial and tried. Such
6 order of consolidation shall not apply so as to require the
7 removal of any case the date for trial of which has been
8 fixed. The court granting such order shall give prompt no-
9 tification thereof to the other courts having jurisdiction
10 of the cases covered thereby.

11 (c) SAMPLES AND ANALYSES.—The court at any time
12 after seizure up to a reasonable time before trial shall by
13 order allow any party to a condemnation proceeding, the
14 party's attorney or agent, to obtain a representative sam-
15 ple of the article seized and a true copy of the analysis,
16 if any, on which the proceeding is based and the identi-
17 fying marks or numbers, if any, of the packages from
18 which the samples analyzed were obtained.

19 (d) DISPOSITION OF CONDEMNED TOBACCO PROD-
20 UCTS.—(1) Any tobacco product condemned under this
21 section shall, after entry of the decree, be disposed of by
22 destruction or sale as the court may, in accordance with
23 the provisions of this section, direct; and the proceeds
24 thereof, if sold, less the legal costs and charges, shall be
25 paid into the Treasury of the United States; but such to-

1 bacco product shall not be sold under such decree contrary
2 to the provisions of this Act or the laws of the jurisdiction
3 in which sold. After entry of the decree and upon the pay-
4 ment of the costs of such proceedings and the execution
5 of a good and sufficient bond conditioned that such article
6 shall not be sold or disposed of contrary to the provisions
7 of this Act or the laws of any State in which sold, the
8 court may by order direct that such tobacco product be
9 delivered to the owner thereof to be destroyed or brought
10 into compliance with the provisions of this Act, under the
11 supervision of an officer or employee duly designated by
12 the Administrator; and the expenses of such supervision
13 shall be paid by the person obtaining release of the tobacco
14 product under bond. If the tobacco product was imported
15 into the United States and the person seeking its release
16 establishes (A) that the adulteration, misbranding, or vio-
17 lation did not occur after the tobacco product was im-
18 ported, and (B) that the person seeking the release of the
19 tobacco product had no cause for believing that it was
20 adulterated, misbranded, or in violation before it was re-
21 leased from customs custody, the court may permit the
22 tobacco product to be delivered to the owner for expor-
23 tation under section 709 in lieu of destruction upon a
24 showing by the owner that there is a reasonable certainty

1 that the tobacco product will not be re-imported into the
2 United States.

3 (2) The provisions of paragraph (1) of this subsection
4 shall, to the extent deemed appropriate by the court, apply
5 to any equipment or other thing which is not otherwise
6 within the scope of such paragraph and which is referred
7 to in paragraph (2) of subsection (a).

8 (3) Whenever in any proceeding under this section,
9 involving paragraph (2) of subsection (a), the condemna-
10 tion of any equipment or thing (other than a tobacco prod-
11 uct) is decreed, the court shall allow the claim of any
12 claimant, to the extent of such claimant's interest, for re-
13 mission or mitigation of such forfeiture if such claimant
14 proves to the satisfaction of the court (A) that such claim-
15 ant has not caused the equipment or thing to be within
16 one of the categories referred to in such paragraph (2)
17 and has no interest in any tobacco product referred to
18 therein, (B) that such claimant has an interest in such
19 equipment or other thing as owner or lienor or otherwise,
20 acquired by such claimant in good faith, and (C) that such
21 claimant at no time had any knowledge or reason to be-
22 lieve that such equipment or other thing was being or
23 would be used in, or to facilitate, the violation of laws of
24 the United States relating to any illicit tobacco product.

1 (e) COSTS AND FEES.—When a decree of condemna-
2 tion is entered against the tobacco product or other article,
3 court costs and fees, and storage and other proper ex-
4 penses shall be awarded against the person, if any, inter-
5 vening as claimant of the tobacco product or other article.

6 (f) REMOVAL FOR TRIAL.—In the case of removal for
7 trial of any case as provided by subsection (a) or (b)—

8 (1) The clerk of the court from which removal
9 is made shall promptly transmit to the court in
10 which the case is to be tried all records in the case
11 necessary in order that such court may exercise ju-
12 risdiction.

13 (2) The court to which such case was removed
14 shall have the powers and be subject to the duties,
15 for purposes of such case, which the court from
16 which removal was made would have had, or to
17 which such court would have been subject, if such
18 case had not been removed.

19 (g) ADMINISTRATIVE DETENTION OF TOBACCO
20 PRODUCTS.—

21 (1) DETENTION AUTHORITY.—

22 (A) IN GENERAL.—An officer or qualified
23 employee of the Agency may order the deten-
24 tion, in accordance with this subsection, of any
25 tobacco product that is found during an inspec-

1 tion, examination, or investigation under this
2 Act conducted by such officer or qualified em-
3 ployee, if the officer or qualified employee has
4 credible evidence or information indicating that
5 such article presents a threat of serious adverse
6 health consequences beyond those normally in-
7 herent in the use of tobacco products.

8 (B) ADMINISTRATOR'S APPROVAL.—A to-
9 bacco product or component thereof may be or-
10 dered detained under subparagraph (A) if, but
11 only if, the Administrator or an official des-
12 ignated by the Administrator approves the
13 order. An official may not be so designated un-
14 less the official is an officer with supervisory re-
15 sponsibility for the inspection, examination, or
16 investigation that led to the order.

17 (2) PERIOD OF DETENTION.—A tobacco prod-
18 uct may be detained under paragraph (1) for a rea-
19 sonable period, not to exceed 20 days, unless a
20 greater period, not to exceed 30 days, is necessary,
21 to institute an action under subsection (a) or section
22 702.

23 (3) SECURITY OF DETAINED TOBACCO PROD-
24 UCT.—An order under paragraph (1) may require
25 that the tobacco product to be detained be labeled

1 or marked as detained, and shall require that the to-
2 bacco product be maintained in or removed to a se-
3 cure facility, as appropriate. A tobacco product sub-
4 ject to such an order shall not be transferred by any
5 person from the place at which the tobacco product
6 is ordered detained, or from the place to which the
7 tobacco product is so removed, as the case may be,
8 until released by the Administrator or until the expi-
9 ration of the detention period applicable under such
10 order, whichever occurs first. This subsection may
11 not be construed as authorizing the delivery of the
12 tobacco product pursuant to the execution of a bond
13 while the tobacco product is subject to the order,
14 and section 709 does not authorize the delivery of
15 the tobacco product pursuant to the execution of a
16 bond while the article is subject to the order.

17 (4) APPEAL OF DETENTION ORDER.—

18 (A) IN GENERAL.—With respect to a to-
19 bacco product ordered detained under para-
20 graph (1), any person who would be entitled to
21 be a claimant of such tobacco product if the to-
22 bacco product were seized under subsection (a)
23 may appeal the order to the Administrator.
24 Within five days after such an appeal is filed,
25 the Administrator, after providing opportunity

1 for an informal hearing, shall confirm or termi-
2 nate the order involved, and such confirmation
3 by the Administrator shall be considered a final
4 agency action for purposes of section 702 of
5 title 5, United States Code. If during such five-
6 day period the Administrator fails to provide
7 such an opportunity, or to confirm or terminate
8 such order, the order is deemed to be termi-
9 nated.

10 (B) EFFECT OF INSTITUTING COURT AC-
11 TION.—The process under subparagraph (A)
12 for the appeal of an order under paragraph (1)
13 terminates if the Administrator institutes an
14 action under subsection (a) or section 702 re-
15 garding the tobacco product involved.

16 **SEC. 505. REPORT OF MINOR VIOLATIONS.**

17 Nothing in this Act shall be construed as requiring
18 the Administrator to report for prosecution, or for institu-
19 tion of libel or injunction proceedings, minor violations of
20 this Act whenever the Administrator believes that the pub-
21 lic interest will be adequately served by a suitable written
22 notice or warning.

23 **SEC. 506. INSPECTION.**

24 (a) AUTHORITY TO INSPECT.—The Administrator
25 shall have the power to inspect the premises of a tobacco

1 product manufacturer for purposes of determining compli-
2 ance with this Act, or the regulations promulgated under
3 it. Officers of the Agency designated by the Administrator,
4 upon presenting appropriate credentials and a written no-
5 tice to the person in charge of the premises, are authorized
6 to enter, at reasonable times, without a search warrant,
7 any factory, warehouse, or other establishment in which
8 tobacco products are manufactured, processed, packaged,
9 or held for domestic distribution. Any such inspection shall
10 be conducted within reasonable limits and in a reasonable
11 manner, and shall be limited to examining only those
12 things, including but not limited to records, relevant to
13 determining whether violations of this Act, or regulations
14 under it, have occurred. No inspection authorized by this
15 section shall extend to financial data, sales data other than
16 shipment data, pricing data, personnel data (other than
17 data as to qualifications of technical and professional per-
18 sonnel performing functions subject to this Act), or re-
19 search data. A separate notice shall be given for each such
20 inspection, but a notice shall not be required for each
21 entry made during the period covered by the inspection.
22 Each such inspection shall be commenced and completed
23 with reasonable promptness.

24 (b) REPORT OF OBSERVATIONS.—Before leaving the
25 premises, the officer of the Agency who has supervised or

1 conducted the inspection shall give to the person in charge
2 of the premises a report in writing setting forth any condi-
3 tions or practices that appear to manifest a violation of
4 this Act, or the regulations under it.

5 (c) SAMPLES.—If the officer has obtained any sample
6 in the course of inspection, prior to leaving the premises
7 that officer shall give to the person in charge of the prem-
8 ises a receipt describing the samples obtained. As to each
9 sample obtained, the officer shall furnish promptly to the
10 person in charge of the premises a copy of the sample and
11 of any analysis made upon the sample.

12 **SEC. 507. EFFECT OF COMPLIANCE.**

13 Compliance with the provisions of this Act and the
14 regulations promulgated under it shall constitute a com-
15 plete defense to any civil action, including but not limited
16 to any products liability action, that seeks to recover dam-
17 ages, whether compensatory or punitive, based upon an
18 alleged defect in the labeling or advertising of any tobacco
19 product distributed for sale domestically.

20 **SEC. 508. IMPORTS.**

21 (a) IMPORTS; LIST OF REGISTERED FOREIGN ES-
22 TABLISHMENTS; SAMPLES FROM UNREGISTERED FOR-
23 EIGN ESTABLISHMENTS; EXAMINATION AND REFUSAL OF
24 ADMISSION.—The Secretary of Homeland Security shall
25 deliver to the Administrator, upon request by the Adminis-

1 trator, samples of tobacco products that are being im-
2 ported or offered for import into the United States, giving
3 notice thereof to the owner or consignee, who may appear
4 before the Administrator and have the right to introduce
5 testimony. The Administrator shall furnish to the Sec-
6 retary of Homeland Security a list of establishments reg-
7 istered pursuant to subsection (d) of section 109 of this
8 Act, and shall request that, if any tobacco products manu-
9 factured, prepared, or processed in an establishment not
10 so registered are imported or offered for import into the
11 United States, samples of such tobacco products be deliv-
12 ered to the Administrator, with notice of such delivery to
13 the owner or consignee, who may appear before the Ad-
14 ministrator and have the right to introduce testimony. If
15 it appears from the examination of such samples or other-
16 wise that (1) such tobacco product is forbidden or re-
17 stricted in sale in the country in which it was produced
18 or from which it was exported, or (2) such tobacco product
19 is adulterated, misbranded, or otherwise in violation of
20 this Act, then such tobacco product shall be refused ad-
21 mission, except as provided in subsection (b) of this sec-
22 tion. The Secretary of Homeland Security shall cause the
23 destruction of any such tobacco product refused admission
24 unless such tobacco product is exported, under regulations
25 prescribed by the Secretary of Homeland Security, within

1 ninety days of the date of notice of such refusal or within
2 such additional time as may be permitted pursuant to such
3 regulations.

4 (b) DISPOSITION OF REFUSED TOBACCO PROD-
5 UCTS.—Pending decision as to the admission of a tobacco
6 product being imported or offered for import, the Sec-
7 retary of Homeland Security may authorize delivery of
8 such tobacco product to the owner or consignee upon the
9 execution by such consignee of a good and sufficient bond
10 providing for the payment of such liquidated damages in
11 the event of default as may be required pursuant to regu-
12 lations of the Secretary of Homeland Security. If it ap-
13 pears to the Administrator that a tobacco product in-
14 cluded within the provisions of clause (3) of subsection
15 (a) of this section can, by relabeling or other action, be
16 brought into compliance with this Act or rendered other
17 than a tobacco product, final determination as to admis-
18 sion of such tobacco product may be deferred and, upon
19 filing of timely written application by the owner or con-
20 signee and the execution by such consignee of a bond as
21 provided in the preceding provisions of this subsection, the
22 Administrator may, in accordance with regulations, au-
23 thorize the applicant to perform such relabeling or other
24 action specified in such authorization (including destruc-
25 tion or export of rejected tobacco products or portions

1 thereof, as may be specified in the Administrator's author-
2 ization). All such relabeling or other action pursuant to
3 such authorization shall in accordance with regulations be
4 under the supervision of an officer or employee of the
5 Agency designated by the Administrator, or an officer or
6 employee of the Department of Homeland Security des-
7 igned by the Secretary of Homeland Security.

8 (c) CHARGES CONCERNING REFUSED TOBACCO
9 PRODUCTS.—All expenses (including travel, per diem or
10 subsistence, and salaries of officers or employees of the
11 United States) in connection with the destruction provided
12 for in subsection (a) of this section and the supervision
13 of the relabeling or other action authorized under the pro-
14 visions of subsection (b) of this section, the amount of
15 such expenses to be determined in accordance with regula-
16 tions, and all expenses in connection with the storage,
17 cartage, or labor with respect to any tobacco product re-
18 fused admission under subsection (a) of this section, shall
19 be paid by the owner or consignee and, in default of such
20 payment, shall constitute a lien against any future impor-
21 tations made by such owner or consignee.

22 **SEC. 509. TOBACCO PRODUCTS FOR EXPORT.**

23 (a) EXEMPTION FOR TOBACCO PRODUCTS EX-
24 PORTED.—Except as provided in subsection (b), a tobacco

1 product intended for export shall be exempt from this Act
2 if—

3 (1) it is not in conflict with the laws of the
4 country to which it is intended fore export, as shown
5 by either (A) a document issued by the government
6 of that country or (B) a document provided by a
7 person knowledgeable with respect to the relevant
8 laws of that country and qualified by training and
9 experience to opine on whether the tobacco product
10 is or is not in conflict with such laws;

11 (2) it is labeled on the outside of the shipping
12 package that it is intended for export; and

13 (3) the particular units of tobacco product in-
14 tended for export have not been sold or offered for
15 sale in domestic commerce.

16 (b) PRODUCTS FOR U.S. ARMED FORCES OVER-
17 SEAS.—A tobacco product intended for export shall not
18 be exempt from this Act if it is intended for sale or dis-
19 tribution to members or units of the Armed Forces of the
20 United States located outside of the United States.

21 (c) This Act shall not apply to a person that manu-
22 factures and/or distributes tobacco products solely for ex-
23 port under subsection (a), except to the extent such to-
24 bacco products are subject to subsection (b).

1 **TITLE VI—MISCELLANEOUS**
2 **PROVISIONS**

3 **SEC. 601. USE OF PAYMENTS UNDER THE MASTER SETTLE-**
4 **MENT AGREEMENT AND INDIVIDUAL STATE**
5 **SETTLEMENT AGREEMENTS.**

6 (a) REDUCTION OF GRANT AMOUNTS.—(1) For fiscal
7 year 2010 and each subsequent fiscal year, the Secretary
8 shall reduce, as provided in subsection (b), the amount
9 of any grant under section 1921 of the Public Health
10 Service Act (42 U.S.C. § 300x-21) for any State that
11 spends on tobacco control programs from the funds re-
12 ceived by such State pursuant to the Master Settlement
13 Agreement, the Florida Settlement Agreement, the Min-
14 nesota Settlement Agreement, the Mississippi Memo-
15 randum of Understanding, or the Texas Settlement Agree-
16 ment, as applicable, less than 20 percent of the amounts
17 received by that State from settlement payments.

18 (2) In the case of a State whose legislature does not
19 convene a regular session in fiscal year 2009 or 2010, and
20 in the case of a State whose legislature does not convene
21 a regular session in fiscal year 2010, the requirement de-
22 scribed in subsection (a)(1) as a condition of receipt of
23 a grant under section 1921 of the Public Health Service
24 Act shall apply only for fiscal year 2009 and subsequent
25 fiscal years.

1 (b) DETERMINATION OF STATE SPENDING.—Before
2 making a grant under section 1921 of the Public Health
3 Service Act, section 300x–21 of title 42, United States
4 Code, to a State for the first applicable fiscal year or any
5 subsequent fiscal year, the Secretary shall make a deter-
6 mination of whether, during the immediately preceding fis-
7 cal year, the State has spent on tobacco control programs,
8 from the funds received by such State pursuant to the
9 Master Settlement Agreement, the Florida Settlement
10 Agreement, the Minnesota Settlement Agreement, the
11 Mississippi Memorandum of Understanding, or the Texas
12 Settlement Agreement, as applicable, at least the amount
13 referenced in (a)(1). If, after notice to the State and an
14 opportunity for a hearing, the Secretary determines that
15 the State has spent less than such amount, the Secretary
16 shall reduce the amount of the allotment under section
17 300x–21 of title 42, United States Code, for the State for
18 the fiscal year involved by an amount equal to—

19 (1) in the case of the first applicable fiscal year,
20 10 percent of the amount determined under section
21 300x–33 of title 42, United States Code, for the
22 State for the fiscal year;

23 (2) in the case of the first fiscal year following
24 such applicable fiscal year, 20 percent of the amount

1 determined under section 300x-33 of title 42,
2 United States Code, for the State for the fiscal year;

3 (3) in the case of the second such fiscal year,
4 30 percent of the amount determined under section
5 300x-33 of title 42, United States Code, for the
6 State for the fiscal year; and

7 (4) in the case of the third such fiscal year or
8 any subsequent fiscal year, 40 percent of the amount
9 determined under section 300x-33 of title 42,
10 United States Code, for the State for the fiscal year.

11 The Secretary shall not have authority or discretion to
12 grant to any State a waiver of the terms and requirements
13 of this subsection or subsection (a).

14 (c) DEFINITIONS.—For the purposes of this sec-
15 tion—

16 (1) The term “first applicable fiscal year”
17 means—

18 (A) fiscal year 2011, in the case of any
19 State described in subsection (a)(2) of this sec-
20 tion; and

21 (B) fiscal year 2010, in the case of any
22 other State.

23 (2) The term “Florida Settlement Agreement”
24 means the Settlement Agreement, together with the
25 exhibits thereto, entered into on August 25, 1997,

1 between the State of Florida and signatory tobacco
2 product manufacturers, as specified therein.

3 (3) The term “Master Settlement Agreement”
4 means the Master Settlement Agreement, together
5 with the exhibits thereto, entered into on November
6 23, 1998, between the signatory States and signa-
7 tory tobacco product manufacturers, as specified
8 therein.

9 (4) The term “Minnesota Settlement Agree-
10 ment” means the Settlement Agreement, together
11 with the exhibits thereto, entered into on May 8,
12 1998, between the State of Minnesota and signatory
13 tobacco product manufacturers, as specified therein.

14 (5) The term “Mississippi Memorandum of Un-
15 derstanding” means the Memorandum of Under-
16 standing, together with the exhibits thereto and Set-
17 tlement Agreement contemplated therein, entered
18 into on July 2, 1997, between the State of Mis-
19 sissippi and signatory tobacco product manufactur-
20 ers, as specified therein.

21 (6) The term “Secretary” means the Secretary
22 of Health and Human Services.

23 (7) The term “Texas Settlement Agreement”
24 means the Settlement Agreement, together with the
25 exhibits thereto, entered into on January 16, 1998,

1 between the State of Texas and signatory tobacco
2 product manufacturers, as specified therein.

3 **SEC. 602. PREEMPTION OF STATE LAWS IMPLEMENTING**
4 **FIRE SAFETY STANDARD FOR CIGARETTES.**

5 (a) IN GENERAL.—With respect to fire safety stand-
6 ards for cigarettes, no State or political subdivision shall—

7 (1) require testing of cigarettes that would be
8 in addition to, or different from, the testing pre-
9 scribed in subsection (b); or

10 (2) require a performance standard that is in
11 addition to, or different from, the performance
12 standard set forth in subsection (b).

13 (b) TEST METHOD AND PERFORMANCE STAND-
14 ARD.—

15 (1) To the extent a State or political subdivi-
16 sion enacts or has enacted legislation or a regulation
17 setting a fire safety standard for cigarettes, the test
18 method employed shall be—

19 (A) the American Society of Testing and
20 Materials (“ASTM”) standard E2187–4, enti-
21 tled “Standard Test Method for Measuring the
22 Ignition Strength of Cigarettes”;

23 (B) for each cigarette on 10 layers of filter
24 paper;

1 (C) so that a replicate test of 40 cigarettes
2 for each brand style of cigarettes comprises a
3 complete test trial for that brand style; and

4 (D) in a laboratory that has been accred-
5 ited in accordance with ISO/IEC 17205 of the
6 International Organization for Standardization
7 (“ISO”) and that has an implemented quality
8 control and quality assurance program that in-
9 cludes a procedure capable of determining the
10 repeatability of the testing results to a repeat-
11 ability value that is no greater than 0.19.

12 (2) To the extent a State or political subdivi-
13 sion enacts or has enacted legislation or a regulation
14 setting a fire safety standard for cigarettes, the per-
15 formance standard employed shall be that no more
16 than 25 percent of the cigarettes of that brand style
17 tested in a complete test in accordance with para-
18 graph (1) exhibit full-length burns

19 (c) EXCEPTION TO SUBSECTION (b).—In the event
20 that a manufacturer of a cigarette that a State or political
21 subdivision or its respective delegated agency determines
22 cannot be tested in accordance with the test method pre-
23 scribed in subsection (b)(1)(A), the manufacturer shall
24 propose a test method and performance standard for the
25 cigarette to the State or political subdivision. Upon ap-

1 proval of the proposed test method and a determination
 2 by the State or political division that the performance
 3 standard proposed by the manufacturer is equivalent to
 4 the performance standard prescribed in subsection (b)(2),
 5 the manufacturer may employ such test method and per-
 6 formance standard to certify such cigarette pursuant to
 7 this subsection notwithstanding subsection (b).

8 **SEC. 603. INSPECTION BY THE ALCOHOL AND TOBACCO**
 9 **TAX TRADE BUREAU OF RECORDS OF CER-**
 10 **TAIN CIGARETTE AND SMOKELESS TOBACCO**
 11 **SELLERS.**

12 (a) IN GENERAL.—Any officer of the Bureau of the
 13 Alcohol and Tobacco Tax Trade Bureau may, during nor-
 14 mal business hours, enter the premises of any person de-
 15 scribed in subsection (b) for the purposes of inspecting—

16 (1) any records or information required to be
 17 maintained by such person under the provisions of
 18 law referred to in subsection (d); or

19 (2) any cigarettes or smokeless tobacco kept or
 20 stored by such person at such premises.

21 (b) COVERED PERSONS.—Subsection (a) applies to
 22 any person who engages in a delivery sale, and who ships,
 23 sells, distributes, or receives any quantity in excess of
 24 10,000 cigarettes, or any quantity in excess of 500 single-

1 unit consumer-sized cans or packages of smokeless to-
2 bacco, within a single month.

3 (c) RELIEF.—

4 (1) IN GENERAL.—The district courts of the
5 United States shall have the authority in a civil ac-
6 tion under this subsection to compel inspections au-
7 thorized by subsection (a).

8 (2) VIOLATIONS.—Whoever violates subsection
9 (a) or an order issued pursuant to paragraph (1)
10 shall be subject to a civil penalty in an amount not
11 to exceed \$10,000 for each violation.

12 (d) COVERED PROVISIONS OF LAW.—The provisions
13 of law referred to in this subsection are—

14 (1) the Act of October 19, 1949 (15 U.S.C.
15 375; commonly referred to as the “Jenkins Act”);

16 (2) chapter 114 of title 18, United States Code;
17 and

18 (3) this Act.

19 (e) DELIVERY SALE DEFINED.—In this section, the
20 term “delivery sale” has the meaning given that term in
21 2343(e) of title 18, United States Code, as amended by
22 this Act.

23 **SEC. 604. SEVERABILITY.**

24 If any provision of this Act, the amendments made
25 by this Act, or the application of any provision of this Act

1 to any person or circumstance is held to be invalid, the
2 remainder of this Act, the amendments made by this Act,
3 and the application of the provisions of this Act to any
4 other person or circumstance shall not be affected, and
5 shall continue to be enforced to the fullest extent possible.

6 **TITLE VII—TOBACCO GROWER**
7 **PROTECTION**

8 **SEC. 701. TOBACCO GROWER PROTECTION.**

9 No provision in this Act shall allow the Administrator
10 or any other person to require changes to traditional farm-
11 ing practices, including standard cultivation practices, cur-
12 ing processes, seed composition, tobacco type, fertilization,
13 soil, record keeping, or any other requirement affecting
14 farming practices.

○