111th Congress

1st Session

H. RES. ____

Providing for consideration of the bill (H.R. 1256) to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products.

IN THE HOUSE OF REPRESENTATIVES

March 31, 2009

Mr. Polis, from the Committee on Rules, reported the following resolution; which was referred to the House Calendar and ordered to be printed.

RESOLUTION

Providing for consideration of the bill (H.R. 1256) to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products.

Resolved, That upon the adoption of this resolution it shall be in order to consider in the House the bill (H.R. 1256) to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products. All points of order against consideration of the bill are waived except those arising under clause 9 or 10 of rule XXI. The amendment printed in part A of the report of the Committee on Rules accompanying this resolution shall be considered as adopted. The bill, as amended, shall be considered as read. All points of order against provisions in the bill, as amended, are waived. The previous question shall be considered as ordered on the bill, as amended, to final passage without intervening motion except: (1) one hour of debate on the bill, as amended, equally divided and controlled by the chair and ranking minority member of the Committee on Energy and Commerce; (2) the amendment in the nature of a substitute printed in part B of the report on the Committee on Rules, if offered by Representative Buyer of Indiana, or his designee, which shall be in order without intervention of any point of order except those arising under clause 9 or 10 of rule XXI, shall be considered as read, and shall be separately debatable for thirty minutes equally divided and controlled by the proponent and an opponent; and (3) one motion to recommit with or without instructions.

Sec. 2. (a) In the engrossment of H.R. 1256, the Clerk shall --

(1) add the text of H.R. 1804, as passed by the House, as new matter at the end of H.R. 1256;

(2) conform the title of H.R. 1256 to reflect the addition to the engrossment of H.R. 1804;

(3) assign appropriate designations to provisions within the engrossment; and

(4) conform provisions for short titles within the engrossment.

(b) Upon the addition of the text of H.R. 1804 to the engrossment of H.R. 1256, H.R. 1804 shall be laid on the table.

111th Congress } {Report
1st Session } HOUSE OF REPRESENTATIVES {111-

Providing for consideration of the bill (H.R. 1256) to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products.

March 31, 2009. --Referred to the House Calendar and ordered to be printed

---

Mr. Polis, from the Committee on Rules,
submitted the following

REPORT

[To accompany H. Res. _____]

The Committee on Rules, having had under consideration House Resolution ____, by a non-record vote, report the same to the House with the recommendation that the resolution be adopted.

SUMMARY OF PROVISIONS OF THE RESOLUTION

The resolution provides for consideration of H.R. 1256, the "Family Smoking Prevention and Tobacco Control Act," under a structured rule. The resolution provides one hour of general debate equally divided and controlled by the chair and ranking minority member of the Committee on Energy and Commerce.

The resolution waives all points of order against consideration of the bill except those arising under clause 9 or 10 of rule XXI. It provides that the amendment printed in part A of this report shall be considered as adopted and the bill, as amended, shall be considered as read. The resolution waives all points of order against provisions in the bill, as amended. This waiver does not affect the point of order available under clause 9 of rule XXI (regarding earmark disclosure).

The resolution makes in order the amendment printed in part B of this report if offered by Rep. Steve Buyer of Indiana or his designee. The amendment printed in part B of this report shall be considered as read and shall be debatable for 30 minutes equally divided and controlled by the proponent and an opponent. The resolution waives all points of order against the amendment printed in part B of this report except those arising under clause 9 or 10 of rule XXI. The resolution provides one motion to recommit with or without instructions.

The resolution provides that, in the engrossment of H.R. 1256, the Clerk shall add at the end of H.R. 1256 as new matter the text of H.R. 1804, as passed by the House. H.R. 1804 shall be laid on the table.

EXPLANATION OF WAIVERS

Although the rule waives all points of order against consideration of the bill (except those arising under clause 9 or 10 of rule XXI), the Committee is not aware of any points of order against consideration of the bill. The waiver of all points of order against consideration of the bill is prophylactic.

Although the resolution waives all points of order against the bill, the Committee is not aware of any points of order. The waiver of all points of order against the bill is prophylactic.

COMMITTEE VOTES

The results of each record vote on an amendment or motion to report, together with the names of those voting for and against, are printed below:

Rules Committee Record Vote No. 56

Date: March 31, 2009
Measure: H.R. 1256
Motion By: Mr. Dreier
Summary of Motion: To make in order and provide appropriate waivers for an amendment by Rep. Rogers, Mike (MI) #4, which would ensure that no FDA general funds would be used to fund the regulation of tobacco.
Results: Defeated 2-7

Vote by Member:

MCGOVERN	NAY
HASTINGS	NAY
MATSUI	
CARDOZA	
ARCURI	NAY
PERLMUTTER	NAY
PINGREE	NAY
POLIS	NAY
DREIER	YEA
DIAZ-BALART	
SESSIONS	
FOXX	YEA
SLAUGHTER	NAY

Rules Committee Record Vote No. 57

Date: March 31, 2009
Measure: H.R. 1256
Motion By: Dr. Foxx
Summary of Motion: To make in order and provide appropriate waivers for an amendment by Rep. Burgess, Michael (TX) #1, which would give the FDA the power to reduce nicotine levels to zero.
Results: Defeated 2-7

Vote by Member:

MCGOVERN	NAY
HASTINGS	NAY
MATSUI	
CARDOZA	
ARCURI	NAY
PERLMUTTER	NAY
PINGREE	NAY
POLIS	NAY
DREIER	YEA
DIAZ-BALART	
SESSIONS	
FOXX	YEA
SLAUGHTER	NAY

SUMMARY OF AMENDMENT IN PART A TO BE CONSIDERED AS ADOPTED

The amendment adds language making clear that the report required by section 907(e) will examine the impact of the use of menthol in cigarettes among children. It makes technical corrections to fully integrate new tobacco provisions contained in the bill into the Federal Food, Drug, and Cosmetic Act. It adds language clarifying application of the bill's provisions to exported tobacco products. It adds language making clear that the Secretary should consult as appropriate with the Departments of Treasury and Justice in carrying out section 301 of the bill. Finally, it strikes Title IV of the bill (relating to TSP and other federal programs).

SUMMARY OF AMENDMENT IN PART B TO BE MADE IN ORDER

The amendment in the nature of a substitute would create a Tobacco Harm Reduction Center under the Department of HHS to regulate all tobacco products and establishes a regulatory scheme to provide for tobacco prevention, education, and cessation programs.

PART A: TEXT OF AMENDMENT TO BE CONSIDERED AS ADOPTED

AMENDMENT TO H.R. 1256

OFFERED BY MR. WAXMAN OF CALIFORNIA

Page and line numbers refer to the introduced version of H.R. 1256

Page 75, line 1, insert "children," before "African Americans".

Page 157, lines 8 to 24, move the margin of paragraph (8) 2 ems to the left.

Page 159, lines 19 through 24, strike paragraphs (1) and (2) and insert the following:

(1) in subsection (a)(1)—

(A) by striking "devices, or cosmetics" each place it appears and inserting "devices, tobacco products, or cosmetics";

(B) by striking "or restricted devices" each place it appears and inserting "restricted devices, or tobacco products";

(C) by striking "and devices and subject to" and all that follows through "other drugs or devices" and inserting "devices, and tobacco products and subject to reporting and inspection under regulations lawfully issued pursuant to section 505(i) or (k), section 519, section

1 520(g), or chapter IX and data relating to
2 other drugs, devices, or tobacco products";

Page 160, lines 1 and 3, redesignate paragraphs (3) and (4) as paragraphs (2) and (3), respectively.

Page 160, lines 20 and 21, strike paragraph (2) and insert the following:

3 (2) in subsection (e)(1)—
4 (A) by inserting "tobacco product" after
5 "drug, device,"; and
6 (B) by inserting ", and a tobacco product
7 intended for export shall not be deemed to be
8 in violation of section 906(e), 907, 911, or
9 920(a)," before "if it—";

Page 194, line 6, strike the close quotation mark and the period at the end and insert the following:

10 "(e) CONSULTATION.—In carrying out this section,
11 the Secretary shall consult with the Attorney General of
12 the United States and the Secretary of the Treasury, as
13 appropriate.".

Strike title IV of the bill (and make such conforming changes to the table of contents in section 1(b) of the bill as may be appropriate).

PART B: TEXT OF AMENDMENT TO BE MADE IN ORDER

3

AMENDMENT IN THE NATURE OF A SUBSTITUTE TO H.R. 1256 OFFERED BY MR. BUYER OF INDIANA

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

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

(b) TABLE OF CONTENTS.—The table of contents of 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—PUBIC 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:

1 (1) Cigarette smoking is a leading cause of pre-
2 ventable deaths in the United States. Cigarette
3 smoking significantly increases the risk of developing
4 lung cancer, heart disease, chronic bronchitis, em-
5 physema and other serious diseases with adverse
6 health conditions.
7 (2) The risk for serious diseases is significantly
8 affected by the type of tobacco product and the fre-
9 quency, duration and manner of use.
10 (3) No tobacco product has been shown to be
11 safe and without risks. The health risks associated
12 with cigarettes are significantly greater than those
13 associated with the use of smoke-free tobacco and
14 nicotine products.
15 (4) Nicotine in tobacco products is addictive but
16 is not considered a significant threat to health.
17 (5) It is the smoke inhaled from burning to-
18 bacco which poses the most significant risk of seri-
19 ous diseases.
20 (6) Quitting cigarette smoking significantly re-
21 duces the risk for serious diseases.
22 (7) Adult tobacco consumers have a right to be
23 fully and accurately informed about the risks of seri-
24 ous diseases, the significant differences in the com-
25 parative risks of different tobacco and nicotine-based

1 products, and the benefits of quitting. This informa-
2 tion should be based on sound science.
3 (8) Governments, public health officials, tobacco
4 manufacturers and others share a responsibility to
5 provide adult tobacco consumers with accurate infor-
6 mation about the various health risks and compara-
7 tive risks associated with the use of different tobacco
8 and nicotine products.
9 (9) Tobacco products should be regulated in a
10 manner that is designed to achieve significant and
11 measurable reductions in the morbidity and mor-
12 tality associated with tobacco use. Regulations
13 should enhance the information available to adult
14 consumers to permit them to make informed choices,
15 and encourage the development of tobacco and nico-
16 tine products with lower risks than cigarettes cur-
17 rently sold in the United States.
18 (10) The form of regulation should be based on
19 the risks and comparative risks of tobacco and nico-
20 tine products and their respective product categories.
21 (11) The regulation of marketing of tobacco
22 products should be consistent with constitutional
23 protections and enhance an adult consumer's ability
24 to make an informed choice by providing accurate

1 information on the risks and comparative risks of to-
2 bacco products.
3 (12) Reducing the diseases and deaths associ-
4 ated with the use of cigarettes serves public health
5 goals and is in the best interest of consumers and
6 society. Harm reduction should be the critical ele-
7 ment of any comprehensive public policy surrounding
8 the health consequences of tobacco use.
9 (13) Significant reductions in the harm associ-
10 ated with the use of cigarettes can be achieved by
11 providing accurate information regarding the com-
12 parative risks of tobacco products to adult tobacco
13 consumers, thereby encouraging smokers to migrate
14 to the use of smoke-free tobacco and nicotine prod-
15 ucts, and by developing new smoke-free tobacco and
16 nicotine products and other actions.
17 (14) Governments, public health officials, man-
18 ufacturers, tobacco producers and consumers should
19 support the development, production, and commer-
20 cial introduction of tobacco leaf, and tobacco and
21 nicotine-based products that are scientifically shown
22 to reduce the risks associated with the use of exist-
23 ing tobacco products, particularly cigarettes.

1 (15) Adult tobacco consumers should have ac-
2 cess to a range of commercially viable tobacco and
3 nicotine-based products.
4 (16) There is substantial scientific evidence
5 that selected smokeless tobacco products can satisfy
6 the nicotine addiction of inveterate smokers while
7 eliminating most, if not all, risk of pulmonary and
8 cardiovascular complications of smoking and while
9 reducing the risk of cancer by more than 95 percent.
10 (17) Transitioning smokers to selected smoke-
11 less tobacco products will eliminate environmental
12 tobacco smoke and fire-related hazards.
13 (18) Current "abstain, quit, or die" tobacco
14 control policies in the United States may have
15 reached their maximum possible public health ben-
16 efit because of the large number of cigarette smok-
17 ers either unwilling or unable to discontinue their
18 addiction to nicotine.
19 (19) There is evidence that harm reduction
20 works and can be accomplished in a way that will
21 not increase initiation or impede smoking cessation.
22 (20) Health-related agencies and organizations,
23 both within the United States and abroad have al-
24 ready gone on record endorsing Harm Reduction as

1 an approach to further reducing tobacco related ill-
2 ness and death.
3 (21) Current Federal policy requires tobacco
4 product labeling that leaves the incorrect impression
5 that all tobacco product present equal risk.

6 **SEC. 3. PURPOSE.**

7 The purposes of this Act are—
8 (1) to provide authority to the Tobacco Harm
9 Reduction Center by recognizing it as the primary
10 Federal regulatory authority with respect to tobacco
11 products as provided for in this Act;
12 (2) to ensure that the Center has the authority
13 to address issues of particular concern to public
14 health officials, especially the use of tobacco by
15 young people and dependence on tobacco;
16 (3) to authorize the Center to set national
17 standards controlling the manufacture of tobacco
18 products and the identity, public disclosure, and
19 amount of ingredients used in such products;
20 (4) to provide new and flexible enforcement au-
21 thority to ensure that there is effective oversight of
22 the tobacco industry's efforts to develop, introduce,
23 and promote less harmful tobacco products;

1 (5) to vest the Center with the authority to reg-
2 ulate the levels of tar, nicotine, and other harmful
3 components of tobacco products;
4 (6) to ensure that consumers are better in-
5 formed regarding the relative risks for death and
6 disease between categories of tobacco products;
7 (7) to continue to allow the sale of tobacco
8 products to adults in conjunction with measures to
9 ensure that they are not sold or accessible to under-
10 age purchasers;
11 (8) to impose appropriate regulatory controls on
12 the tobacco industry;
13 (9) to promote prevention, cessation, and harm
14 reduction policies and regulations to reduce disease
15 risk and the social costs associated with tobacco-re-
16 lated diseases;
17 (10) to provide authority to the Department of
18 Health and Human Services to regulate tobacco
19 products;
20 (11) to establish national policies that effec-
21 tively reduce disease and death associated with ciga-
22 rette smoking and other tobacco use;
23 (12) to establish national policies that encour-
24 age prevention, cessation, and harm reduction meas-
25 ures regarding the use of tobacco products;

1 (13) to encourage current cigarette smokers
2 who will not quit to use noncombustible tobacco or
3 nicotine products that have significantly less risk
4 than cigarettes;
5 (14) to establish national policies that accu-
6 rately and consistently inform adult tobacco con-
7 sumers of significant differences in risk between re-
8 spective tobacco products;
9 (15) to establish national policies that encour-
10 age and assist the development and awareness of
11 noncombustible tobacco and nicotine products;
12 (16) to coordinate national and State preven-
13 tion, cessation, and harm reduction programs;
14 (17) to impose measures to ensure tobacco
15 products are not sold or accessible to underage pur-
16 chasers; and
17 (18) to strengthen Federal and State legislation
18 to prevent illicit trade in tobacco products.
19 **SEC. 4. SCOPE AND EFFECT.**
20 (a) INTENDED EFFECT.—Nothing in this Act (or an
21 amendment made by 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;

1 (2) affect any action pending in Federal, State,
2 or Tribal court, or any agreement, consent decree, or
3 contract of any kind; or
4 (3) be applicable to tobacco products or compo-
5 nent parts manufactured in the United States for
6 export.
7 (b) AGRICULTURAL ACTIVITIES.—The provisions of
8 this Act (or an amendment made by this Act) which au-
9 thorize the Administrator to take certain actions with re-
10 gard to tobacco and tobacco products shall not be con-
11 strued to affect any authority of the Secretary of Agri-
12 culture under existing law regarding the growing, cultiva-
13 tion, or curing of raw tobacco.
14 (c) REVENUE ACTIVITIES.—The provisions of this
15 Act (or an amendment made by this Act) which authorize
16 the Administrator to take certain actions with regard to
17 tobacco products shall not be construed to affect any au-
18 thority of the Secretary of the Treasury under chapter 52
19 of the Internal Revenue Code of 1986.
20 **SEC. 5. SEVERABILITY.**
21 If any provision of this Act, the amendments made
22 by this Act, or the application of any provision of this Act
23 to any person or circumstance is held to be invalid, the
24 remainder of this Act, the amendments made by this Act,
25 and the application of the provisions of this Act to any

1 other person or circumstance shall not be affected and
2 shall continue to be enforced to the fullest extent possible.

3 **SEC. 6. EFFECTIVE DATE.**

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

6 TITLE I—AUTHORITY OF THE TO-
7 BACCO HARM REDUCTION
8 CENTER

9 **SEC. 100. DEFINITIONS.**

10 In this Act:

11 (1) The term "Administrator" means the chief
12 executive of the Tobacco Harm Reduction Center.

13 (2) The term "adult" means any individual who
14 has attained the minimum age under applicable
15 State law to be an individual to whom tobacco prod-
16 ucts may lawfully be sold.

17 (3) The term "adult-only facility" means a fa-
18 cility or restricted area, whether open-air or en-
19 closed, where the operator ensures, or has a reason-
20 able basis to believe, that no youth is present. A fa-
21 cility or restricted area need not be permanently re-
22 stricted to adults in order to constitute an adult-only
23 facility, if the operator ensures, or has a reasonable
24 basis to believe, that no youth is present during any
25 period of operation as an adult-only facility.

1 (4) The term "affiliate" means a person that
2 directly or indirectly owns or controls, is owned or
3 controlled by, or is under common ownership or con-
4 trol with, another person. The terms "owns," "is
5 owned", and "ownership" refer to ownership of an
6 equity interest, or the equivalent thereof, of 50 per-
7 cent or more.
8 (5) The term "annual report" means a tobacco
9 product manufacturer's annual report to the Center,
10 which provides ingredient information and nicotine
11 yield ratings for each brand style that tobacco prod-
12 uct manufacturer manufactures for commercial dis-
13 tribution domestically.
14 (6) The term "brand name" means a brand
15 name of a tobacco product distributed or sold do-
16 mestically, alone, or in conjunction with any other
17 word, trademark, logo, symbol, motto, selling mes-
18 sage, recognizable pattern of colors, or any other in-
19 dicium of product identification identical or similar
20 to, or identifiable with, those used for any domestic
21 brand of tobacco product. The term shall not include
22 the corporate name of any tobacco product manufac-
23 turer that does not, after the effective date of this
24 Act, sell a brand style of tobacco product in the
25 United States that includes such corporate name.

1 (7) The term "brand style" means a tobacco
2 product having a brand name, and distinguished by
3 the selection of the tobacco, ingredients, structural
4 materials, format, configuration, size, package, prod-
5 uct descriptor, amount of tobacco, or yield of "tar"
6 or nicotine.
7 (8) The term "Center" means the Tobacco
8 Harm Reduction Center.
9 (9) The term "cigar" has the meaning assigned
10 that term by the Alcohol and Tobacco Tax and
11 Trade Bureau in section 40.11 of title 27, Code of
12 Federal Regulations.
13 (10) The term "cigarette" means—
14 (A) any roll of tobacco wrapped in paper
15 or in any substance not containing tobacco; or
16 (B) any roll of tobacco wrapped in any
17 substance containing tobacco which, because of
18 the appearance of the roll of tobacco, the type
19 of tobacco used in the filler, or its package or
20 labeling, is likely to be offered to, or purchased
21 by, consumers as a cigarette described in para-
22 graph (1).
23 (11) The term "competent and reliable sci-
24 entific evidence" means evidence based on tests,
25 analyses, research, or studies, conducted and evalu-

1 ated in an objective manner by individuals qualified
2 to do so, using procedures generally accepted in the
3 relevant scientific disciplines to yield accurate and
4 reliable results.

5 (12) The term "distributor" means any person
6 who furthers the distribution of tobacco products,
7 whether domestic or imported, at any point from the
8 original place of manufacture to the person who sells
9 or distributes the tobacco product to individuals for
10 personal consumption. Common carriers, retailers,
11 and those engaged solely in advertising are not con-
12 sidered distributors for purposes of this Act.

13 (13) The terms "domestic" and "domestically"
14 mean within the United States, including activities
15 within the United States involving advertising, mar-
16 keting, distribution, or sale of tobacco products that
17 are intended for consumption within the United
18 States.

19 (14) The term "illicit tobacco product" means
20 any tobacco product intended for use by consumers
21 in the United States—

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

24 (B) that has been stolen, smuggled, or is
25 otherwise contraband;

1 (C) that is counterfeit; or

2 (D) that has or had a label, labeling, or
3 packaging stating, or that stated, that the prod-
4 uct is or was for export only, or that it is or
5 was at any time restricted by section 5704 of
6 title 26, United States Code.

7 (15) The term "illicit trade" means any trans-
8 fer, distribution, or sale in interstate commerce of
9 any illicit tobacco product.

10 (16) The term "immediate container" does not
11 include package liners.

12 (17) The term "Indian tribe" has the meaning
13 assigned that term in section 4(e) of the Indian Self
14 Determination and Education Assistance Act.

15 (18) The term "ingredient" means tobacco and
16 any substance added to tobacco to have an effect in
17 the final tobacco product or when the final tobacco
18 product is used by a consumer.

19 (19) The term "International Organization for
20 Standardization (ISO) testing regimen" means the
21 methods for measuring cigarette smoke yields, as set
22 forth in the most recent version of ISO 3308, enti-
23 tled "Routine analytical cigarette-smoking ma-
24 chine—Definition of standard conditions"; ISO
25 4387, entitled "Cigarettes—Determination of total

1 and nicotine-free dry particulate matter using a rou-
2 tine analytical smoking machine"; ISO 10315, enti-
3 tled "Cigarettes—Determination of nicotine in
4 smoke condensates—Gas-chromatographic method";
5 ISO 10362–1, entitled "Cigarettes—Determination
6 of water in smoke condensates—Part 1: Gas-
7 chromatographic method"; and ISO 8454, entitled
8 "Cigarettes—Determination of carbon monoxide in
9 the vapour phase of cigarette smoke—NDIR meth-
10 od". A cigarette that does not burn down in accord-
11 ance with the testing regimen standards may be
12 measured under the same puff regimen using the
13 number of puffs that such a cigarette delivers before
14 it extinguishes, plus an additional three puffs, or
15 with such other modifications as the Administrator
16 may approve.
17 (20) The term "interstate commerce" means all
18 trade, traffic, or other commerce—
19 (A) within the District of Columbia, or any
20 territory or possession of the United States;
21 (B) between any point in a State and any
22 point outside thereof;
23 (C) between points within the same State
24 through any place outside such State; or

1 (D) over which the United States has ju-
2 risdiction.
3 (21) The term "label" means a display of writ-
4 ten, printed, or graphic matter upon or applied se-
5 curely to the immediate container of a tobacco prod-
6 uct.
7 (22) The term "labeling" means all labels and
8 other written, printed, or graphic matter (1) upon or
9 applied securely to any tobacco product or any of its
10 containers or wrappers, or (2) accompanying a to-
11 bacco product.
12 (23) The term "little cigar" has the meaning
13 assigned that term by the Alcohol and Tobacco Tax
14 and Trade Bureau in section 40.11 of title 27, Code
15 of Federal Regulations.
16 (24) The term "loose tobacco" means any form
17 of tobacco, alone or in combination with any other
18 ingredient or material, that, because of its appear-
19 ance, form, type, packaging, or labeling, is suitable
20 for use and likely to be offered to, or purchased by,
21 consumers as tobacco for making or assembling
22 cigarettes, incorporation into pipes, or otherwise
23 used by consumers to make any tobacco product.
24 (25) The term "manufacture" means to design,
25 manufacture, fabricate, assemble, process, package,

1 or repackage, label, or relabel, import, or hold or
2 store in a commercial quantity, but does not in-
3 clude—
4 (A) the growing, curing, de-stemming, or
5 aging of tobacco; or
6 (B) the holding, storing or transporting of
7 a tobacco product by a common carrier for hire,
8 a public warehouse, a testing laboratory, a dis-
9 tributor, or a retailer.
10 (26) The term "nicotine-containing product"
11 means a product, other than a tobacco product, that
12 contains added nicotine, whether or not in the form
13 of a salt or solvate, that has been—
14 (A) synthetically produced, or
15 (B) obtained from tobacco or other source
16 of nicotine.
17 (27) The term "package" means a pack, box,
18 carton, pouch, or container of any kind in which a
19 tobacco product or tobacco products are offered for
20 sale, sold, or otherwise distributed to consumers.
21 The term "package" does not include an outer con-
22 tainer used solely for shipping one or more packages
23 of a tobacco product or tobacco products.
24 (28) The term "person" means any individual,
25 partnership, corporation, committee, association, or-

1 ganization or group of persons, or other legal or
2 business entity.
3 (29) The term "proof of age" means a driver's
4 license or other form of identification that is issued
5 by a governmental authority and includes a photo-
6 graph and a date of birth of the individual.
7 (30) The term "raw tobacco" means tobacco in
8 a form that is received by a tobacco product manu-
9 facturer as an agricultural commodity, whether in a
10 form that is natural, stem, or leaf, cured or aged,
11 or as parts or pieces, but not in a reconstituted
12 form, extracted pulp form, or extract form.
13 (31) The term "reduced-exposure claim" means
14 a statement in advertising or labeling intended for
15 one or more consumers of tobacco products, that a
16 tobacco product provides a reduced exposure of
17 users of that tobacco product to one or more toxi-
18 cants, as compared to an appropriate reference to-
19 bacco product or category of tobacco products. A
20 statement or representation that a tobacco product
21 or the tobacco in a tobacco product contains "no ad-
22 ditives" or is "natural" or that uses a substantially
23 similar term is not a reduced-exposure claim if the
24 advertising or labeling that contains such statement

1 or representation also contains the disclosure re-
2 quired by section 108(h) of this Act.
3 (32) The term "reduced-risk claim" means a
4 statement in advertising or labeling intended for one
5 or more consumers of smoking articles, that a smok-
6 ing article provides to users of that product a re-
7 duced risk of morbidity or mortality resulting from
8 one or more chronic diseases or serious adverse
9 health conditions associated with tobacco use, as
10 compared to an appropriate reference smoking arti-
11 cle or category of smoking articles, even if it is not
12 stated, represented, or implied that all health risks
13 associated with using that smoking article have been
14 reduced or eliminated. A statement or representation
15 that a smoking article or the tobacco in a smoking
16 article contains "no additives," or is "natural," or
17 that uses a substantially similar term is not a re-
18 duced-risk claim if the advertising or labeling that
19 contains such statement or representation also con-
20 tains the disclosure required by section 108(h).
21 (33) The term "retailer" means any person
22 that—
23 (A) sells tobacco products to individuals
24 for personal consumption; or

1 (B) operates a facility where the sale of to-
2 bacco products to individuals for personal con-
3 sumption is permitted.
4 (34) The term "small business" means a to-
5 bacco product manufacturer that—
6 (A) has 150 or fewer employees; and
7 (B) during the 3-year period prior to the
8 current calendar year, had an average annual
9 gross revenue from tobacco products that did
10 not exceed $40,000,000.
11 (35) The term "smokeless tobacco product"
12 means any form of finely cut, ground, powdered, re-
13 constituted, processed or shaped tobacco, leaf to-
14 bacco, or stem tobacco, whether or not combined
15 with any other ingredient, whether or not in extract
16 or extracted form, and whether or not incorporated
17 within any carrier or construct, that is intended to
18 be placed in the oral or nasal cavity, including dry
19 snuff, moist snuff, and chewing tobacco.
20 (36) The term "smoking article" means any to-
21 bacco-containing article that is intended, when used
22 by a consumer, to be burned or otherwise to employ
23 heat to produce a vapor, aerosol or smoke that—
24 (A) incorporates components of tobacco or
25 derived from tobacco; and

1 (B) is intended to be inhaled by the user.
2 (37) The term "State" means any State of the
3 United States and, except as otherwise specifically
4 provided, includes any Indian tribe or tribal organi-
5 zation, the District of Columbia, the Commonwealth
6 of Puerto Rico, Guam, the Virgin Islands, American
7 Samoa, Wake Island, Midway Island, Kingman Reef,
8 Johnston Atoll, the Northern Marianas, and any
9 other trust territory or possession of the United
10 States.
11 (38) The term "tar" means nicotine-free dry
12 particulate matter as defined in ISO 4387, entitled
13 "Cigarettes—Determination of total and nicotine-
14 free dry particulate matter using a routine analytical
15 smoking machine".
16 (39) The term "tobacco" means a tobacco plant
17 or any part of a harvested tobacco plant intended for
18 use in the production of a tobacco product, including
19 leaf, lamina, stem, or stalk, whether in green, cured,
20 or aged form, whether in raw, treated, or processed
21 form, and whether or not combined with other mate-
22 rials, including any by-product, extract, extracted
23 pulp material, or any other material (other than pu-
24 rified nicotine) derived from a tobacco plant or any
25 component thereof, and including strip, filler, stem,

1 powder, and granulated, blended, or reconstituted
2 forms of tobacco.
3 (40) The term "tobacco product" means—
4 (A) the singular of "tobacco products" as
5 defined in section 5702(c) of the Internal Rev-
6 enue Code of 1986;
7 (B) any other product that contains to-
8 bacco as a principal ingredient and that, be-
9 cause of its appearance, type, or the tobacco
10 used in the product, or its packaging and label-
11 ing, is likely to be offered to, or purchased by,
12 consumers as a tobacco product as described in
13 subparagraph (A); and
14 (C) any form of tobacco or any construct
15 incorporating tobacco, intended for human con-
16 sumption, whether by—
17 (i) placement in the oral or nasal cav-
18 ity;
19 (ii) inhalation of vapor, aerosol, or
20 smoke; or
21 (iii) any other means.
22 (41) The term "tobacco product category"
23 means a type of tobacco product characterized by its
24 composition, components, and intended use, and in-
25 cludes tobacco products classified as cigarettes, loose

1 tobacco for roll-your-own tobacco products, little ci-
2 gars, cigars, pipe tobacco, moist snuff, dry snuff,
3 chewing tobacco, and other forms of tobacco prod-
4 ucts (which are treated in this Act collectively as a
5 single category).

6 (42) The term "tobacco product communica-
7 tion" means any means, medium, or manner for pro-
8 viding information relating to any tobacco product,
9 including face-to-face interaction, mailings by postal
10 service or courier to an individual who is an ad-
11 dressee, and electronic mail to an individual who is
12 an addressee.

13 (43) The term "tobacco product manufacturer"
14 means an entity that directly—

15 (A) manufactures anywhere a tobacco
16 product that is intended to be distributed com-
17 mercially in the United States, including a to-
18 bacco product intended to be distributed com-
19 mercially in the United States through an im-
20 porter;

21 (B) is the first purchaser for resale in the
22 United States of tobacco products manufac-
23 tured outside the United States for distribution
24 commercially in the United States; or

1 (C) is a successor or assign of any of the
2 foregoing.
3 (44) The term "toxicant" means a chemical or
4 physical agent that produces an adverse biological
5 effect.
6 (45) The term "tribal organization" has the
7 meaning assigned that term in section 4(1) of the
8 Indian Self Determination and Education Assistance
9 Act.
10 (46) The term "United States" means the sev-
11 eral States, as defined in this Act.
12 (47) The term "youth" means any individual
13 who in not an adult.
14 **SEC. 101. CENTER AUTHORITY OVER TOBACCO PRODUCTS.**
15 (a) IN GENERAL.—Tobacco products, including
16 modified risk tobacco products for which an order has
17 been issued in accordance with section 117, shall be regu-
18 lated by the Administrator under this Act.
19 (b) APPLICABILITY.—This Act shall apply to all ciga-
20 rettes, cigarette tobacco, roll-your-own tobacco, and
21 smokeless tobacco and to any other tobacco products that
22 the Administrator by regulation deems to be subject to
23 this Act.
24 (c) CENTER.—The Secretary of Health and Human
25 Services shall establish within the Department of Health

1 and Human Services the Tobacco Harm Reduction Cen-
2 ter. The head of the Center shall be an Administrator,
3 who shall assume the statutory authority conferred by this
4 Act, perform the functions that relate to the subject mat-
5 ter of this Act, and have the authority to promulgate regu-
6 lations for the efficient enforcement of this Act. In pro-
7 mulgating any regulations under such authority, in whole
8 or in part or any regulation that is likely to have an an-
9 nual effect on the economy of $50,000,000 or more or
10 have a material adverse effect on adult users of tobacco
11 products, tobacco product manufacturers, distributors, or
12 retailers, the Administrator shall—
13 (1) determine the technological and economic
14 ability of parties that would be required to comply
15 with the regulation to comply with it;
16 (2) consider experience gained under any rel-
17 evantly similar regulations at the Federal or State
18 level;
19 (3) determine the reasonableness of the rela-
20 tionship between the costs of complying with such
21 regulation and the public health benefits to be
22 achieved by such regulation;
23 (4) determine the reasonable likelihood of meas-
24 urable and substantial reductions in morbidity and
25 mortality among individual tobacco users;

1 (5) determine the impact to United States to-
2 bacco producers and farm operations;
3 (6) determine the impact on the availability and
4 use of tobacco products by minors; and
5 (7) determine the impact on illicit trade of to-
6 bacco products.
7 (d) LIMITATION OF AUTHORITY.—
8 (1) IN GENERAL.—The provisions of this Act
9 shall not apply to tobacco leaf that is not in the pos-
10 session of a manufacturer of tobacco products, or to
11 the producers of tobacco leaf, including tobacco
12 growers, tobacco warehouses, and tobacco grower co-
13 operatives, nor shall any employee of the Center
14 have any authority to enter onto a farm owned by
15 a producer of tobacco leaf without the written con-
16 sent of such producer.
17 (2) EXCEPTION.—Notwithstanding paragraph
18 (1), if a producer of tobacco leaf is also a tobacco
19 product manufacturer or controlled by a tobacco
20 product manufacturer, the producer shall be subject
21 to this Act in the producer's capacity as a manufac-
22 turer. The exception in this subparagraph shall not
23 apply to a producer of tobacco leaf who grows to-
24 bacco under a contract with a tobacco product man-

1 ufacturer and who is not otherwise engaged in the
2 manufacturing process.
3 (3) RULE OF CONSTRUCTION.—Nothing in this
4 Act shall be construed to grant the Administrator
5 authority to promulgate regulations on any matter
6 that involves the production of tobacco leaf or a pro-
7 ducer thereof.
8 (e) RULEMAKING PROCEDURES.—Each rulemaking
9 under this Act shall be in accordance with chapter 5 of
10 title 5, United States Code.
11 (f) CONSULTATION PRIOR TO RULEMAKING.—Prior
12 to promulgating rules under this Act, the Administrator
13 shall endeavor to consult with other Federal agencies as
14 appropriate.
15 **SEC. 102. EXCLUSION OF OTHER REGULATORY PROGRAMS.**
16 (a) EXCLUSION OF TOBACCO PRODUCTS AND NICO-
17 TINE-CONTAINING PRODUCTS FROM THE FEDERAL
18 FOOD, DRUG, AND COSMETIC ACT.—No tobacco product
19 and no nicotine-containing product shall be regulated as
20 a food, drug, or device in accordance with section 201 (f),
21 (g) or (h) or Chapter IV or V of the Federal Food, Drug,
22 and Cosmetic Act, except that any tobacco product com-
23 mercially distributed domestically and any nicotine-con-
24 taining product commercially distributed domestically
25 shall be subject to Chapter V of the Federal Food, Drug,

1 and Cosmetic Act if the manufacturer or a distributor of
2 such product markets it with an explicit claim that the
3 product is intended for use in the cure, mitigation, treat-
4 ment, or prevention of disease in man or other animals,
5 within the meaning of section 201(g)(1)(C) or section
6 201(h)(2) of that Act.

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

9 (1) establish a precedent with regard to any
10 other industry, situation, circumstance, or legal ac-
11 tion; or

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

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

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

20 (2) raw tobacco that is grown for a tobacco
21 product manufacturer by a grower, and that is in
22 the possession of that grower or of a person that is
23 not a tobacco product manufacturer and is within
24 the scope of subparagraphs (A) through(F) of para-
25 graph (3); or

1 (3) the activities, materials, facilities, or prac-
2 tices of persons that are not tobacco product manu-
3 facturers and that are—
4 (A) producers of raw tobacco, including to-
5 bacco growers;
6 (B) tobacco warehouses, and other persons
7 that receive raw tobacco from growers;
8 (C) tobacco grower cooperatives;
9 (D) persons that cure raw tobacco;
10 (E) persons that process raw tobacco; and
11 (F) persons that store raw tobacco for
12 aging.
13 If a producer of raw tobacco is also a tobacco prod-
14 uct manufacturer, an affiliate of a tobacco product
15 manufacturer, or a person producing raw tobacco for
16 a tobacco product manufacturer, then that producer
17 shall be subject to this Act only to the extent of that
18 producer's capacity as a tobacco product manufac-
19 turer.
20 **SEC. 103. EXISTING FEDERAL STATUTES MAINTAINED.**
21 Except as amended or repealed by this Act, all Fed-
22 eral statutes in effect as of the effective date of this Act
23 that regulate tobacco, tobacco products, or tobacco prod-
24 uct manufacturers shall remain in full force and effect.
25 Such statutes include, without limitation—

1 (1) the Federal Cigarette Labeling and Adver-
2 tising Act, sections 1331–1340 of title 15, United
3 States Code, except that section 1335 of title 15,
4 United States Code, is repealed;
5 (2) the Comprehensive Smokeless Tobacco
6 Health Education Act of 1986, sections 4401–4408
7 of title 15, United States Code, except that section
8 4402(f) of title 15, United States Code, is repealed;
9 (3) section 300x–26 of title 42, United States
10 Code; and
11 (4) those statutes authorizing regulation of to-
12 bacco, tobacco products, or tobacco product manu-
13 facturers by the Federal Trade Commission, the De-
14 partment of Agriculture, the Environmental Protec-
15 tion Agency, the Internal Revenue Service, and the
16 Alcohol and Tobacco Tax and Trade Bureau of the
17 Department of the Treasury.
18 **SEC. 104. PROCEEDINGS IN THE NAME OF THE UNITED**
19 **STATES; SUBPOENAS; PREEMPTION OF STATE**
20 **AND LOCAL LAW; NO PRIVATE RIGHT OF AC-**
21 **TION.**
22 In furtherance of this Act:
23 (1) All proceedings for the enforcement, or to
24 restrain violations, of this Act shall be by and in the
25 name of the United States. Subpoenas for witnesses

1 who are required to attend a court of the United
2 States, in any district, may run into any other dis-
3 trict in any proceeding under this section. No State,
4 or political subdivision thereof, may proceed or inter-
5 vene in any Federal or State court under this Act
6 or under any regulation promulgated under it, or al-
7 lege any violation thereof except a violation by the
8 Administrator. Nothing in this Act shall be con-
9 strued to create a right of action by any private per-
10 son for any violation of any provision of this Act or
11 of any regulation promulgated under it.
12 (2) With respect to any subject matter ad-
13 dressed by this Act or by any regulation promul-
14 gated under it, no requirement or prohibition shall
15 be imposed under State or local law upon any to-
16 bacco product manufacturer or distributor.
17 (3) Paragraph (2) shall not apply to any re-
18 quirement or prohibition imposed under State or
19 local law before the date of introduction of the bill
20 that was enacted as this Act.
21 **SEC. 105. ILLICIT TRADE.**
22 The Administrator shall not promulgate any regula-
23 tion or take any other action that has the effect of—
24 (1) increasing illicit trade involving tobacco or
25 any tobacco product, or

1 (2) making affected tobacco products unacceptable to a substantial number of then current users of such products, thereby creating a substantial risk that such users will resort to illicit tobacco products, or tobacco products that are otherwise noncompliant or unlawful.

SEC. 106. ADULTERATED TOBACCO PRODUCTS.

A tobacco product shall be deemed to be adulterated—

(1) if it bears or contains any poisonous or deleterious substance other than—

(A) tobacco;

(B) a substance naturally present in tobacco;

(C) a pesticide or fungicide chemical residue in or on tobacco if such pesticide or fungicide chemical is registered by the Environmental Protection Agency for use on tobacco in the United States; or

(D) in the case of imported tobacco, a residue of a pesticide or fungicide chemical that—

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

(ii) has not been banned, and the registration of which has not been canceled,

1 by the Environmental Protection Agency
2 for use on tobacco in the United States)
3 that may render it injurious to health; but,
4 in case the substance is not an added sub-
5 stance, such tobacco product shall not be
6 considered adulterated under this sub-
7 section if the quantity of such substance in
8 such tobacco product does not ordinarily
9 render it injurious to health;
10 (2) if there is significant scientific agreement
11 that, as a result of the tobacco it contains, the to-
12 bacco product presents a risk to human health that
13 is materially higher than the risk presented by—
14 (A) such product on the effective date of
15 this Act; or
16 (B) if such product was not distributed
17 commercially domestically on that date, by com-
18 parable tobacco products of the same style and
19 within the same category that were commer-
20 cially distributed domestically on that date;
21 (3) if it has been prepared, packed, or held
22 under unsanitary conditions whereby it may have be-
23 come contaminated with filth;

1 (4) if its package is composed, in whole or in
2 part, of any poisonous or deleterious substance that
3 may render the contents injurious to health; or
4 (5) if its "tar" yield is in violation of section
5 111.

6 **SEC. 107. MISBRANDED TOBACCO PRODUCTS.**

7 A tobacco product shall be deemed to be mis-
8 branded—
9 (1) if its labeling is false or misleading in any
10 particular;
11 (2) if in package form unless it bears a label
12 containing—
13 (A) an identification of the type of product
14 it is, by the common or usual name of such
15 type of product;
16 (B) an accurate statement of the quantity
17 of the contents in the package in terms of
18 weight, measure, or numerical count, except
19 that reasonable variations shall be permitted,
20 and exemptions as to small packages shall be
21 established by regulations promulgated by the
22 Administrator;
23 (C) the name and place of business of the
24 tobacco product manufacturer, packer, or dis-
25 tributor; and

1 (D) the information required by section
2 201(c) and (e) or section 202(c) and (e), as ap-
3 plicable;
4 (3) if any word, statement, or other information
5 required by or under authority of this Act to appear
6 on the label, labeling, or advertising is not promi-
7 nently placed thereon with such conspicuousness (as
8 compared with other words, statements, or designs
9 on the label, labeling, or advertising, as applicable)
10 and in such terms as to render it reasonably likely
11 to be read and understood by the ordinary individual
12 under customary conditions of purchase and use;
13 (4) if any word, statement, or other information
14 is required by or under this Act to appear on the
15 label, unless such word, statement, or other informa-
16 tion also appears on the outside container or wrap-
17 per, if any, of the retail package of such tobacco
18 product, or is easily legible through the outside con-
19 tainer or wrapper;
20 (5) if it was manufactured, prepared, or proc-
21 essed in an establishment not duly registered under
22 section 109, if it was not included in a list required
23 by section 109, or if a notice or other information
24 respecting it was not provided as required by section
25 109;

1 (6) if its packaging, labeling, or advertising is
2 in violation of this Act or of an applicable regulation
3 promulgated in accordance with this Act;
4 (7) if it contains tobacco or another ingredient
5 as to which a required disclosure under this Act was
6 not made;
7 (8) if it is labeled or advertised, or the tobacco
8 contained in it is advertised, as—
9 (A) containing "no additives," or any sub-
10 stantially similar term, unless the labeling or
11 advertising, as applicable, also contains, clearly
12 and prominently, the following disclosure: "No
13 additives in our tobacco does NOT mean
14 safer."; or
15 (B) being "natural," or any substantially
16 similar term, unless the labeling or advertising,
17 as applicable, also contains, clearly and promi-
18 nently, the following disclosure: "Natural does
19 NOT mean safer.";
20 (9) if in its labeling or advertising a term de-
21 scriptive of the tobacco in the tobacco product is
22 used otherwise than in accordance with a sanction or
23 approval granted by a Federal agency;
24 (10) if with respect to such tobacco product a
25 disclosure required by section 603 was not made;

1 (11) if with respect to such tobacco product a
2 certification required by section 803 was not sub-
3 mitted or is materially false or misleading; or
4 (12) if its manufacturer or distributor made
5 with respect to it a claim prohibited by section 115.

6 **SEC. 108. SUBMISSION OF HEALTH INFORMATION TO THE**
7 **ADMINISTRATOR.**

8 (a) REQUIREMENT.—Each tobacco product manufac-
9 turer or importer, or agents thereof, shall submit to the
10 Administrator the following information:
11 (1) Not later than 18 months after the date of
12 enactment of the Act, a listing of all ingredients, in-
13 cluding tobacco, substances, compounds, and addi-
14 tives that are, as of such date, added by the manu-
15 facturer to the tobacco, paper, filter, or other part
16 of each tobacco product by brand and by quantity in
17 each brand and brand style.
18 (2) A description of the content, delivery, and
19 form of nicotine in each tobacco product measured
20 in milligrams of nicotine in accordance with regula-
21 tions promulgated by the Administrator in accord-
22 ance with section 4(e) of the Federal Cigarette La-
23 beling and Advertising Act.
24 (3) Beginning 4 years after the date of enact-
25 ment of this Act, a listing of all constituents, includ-

1 ing smoke constituents as applicable, identified by
2 the Administrator as harmful to health in each to-
3 bacco product, and as applicable in the smoke of
4 each tobacco product, by brand and by quantity in
5 each brand and subbrand.

6 (b) DATA SUBMISSION.—At the request of the Ad-
7 ministrator, each tobacco product manufacturer or im-
8 porter of tobacco products, or agents thereof, shall submit
9 the following:

10 (1) Any or all documents (including underlying
11 scientific information) relating to research activities,
12 and research findings, conducted, supported, or pos-
13 sessed by the manufacturer (or agents thereof) on
14 the health, toxicological, or physiologic effects of to-
15 bacco products and their constituents (including
16 smoke constituents), ingredients, components, and
17 additives.

18 (2) Any or all documents (including underlying
19 scientific information) relating to research activities,
20 and research findings, conducted, supported, or pos-
21 sessed by the manufacturer (or agents thereof) that
22 relate to the issue of whether a significant reduction
23 in risk to health from tobacco products can occur
24 upon the employment of technology available to the
25 manufacturer.

1 An importer of a tobacco product not manufactured in the
2 United States shall supply the information required of a
3 tobacco product manufacturer under this subsection.

4 (c) DATA LIST.—

5 (1) IN GENERAL.—Not later than 4 years after
6 the date of enactment of the Act, and annually
7 thereafter, the Administrator shall publish in a for-
8 mat that is understandable and not misleading to a
9 lay person, and place on public display (in a manner
10 determined by the Administrator) the list established
11 under subsection (d).

12 (2) CONSUMER RESEARCH.—The Administrator
13 shall conduct periodic consumer research to ensure
14 that the list published under paragraph (1) is not
15 misleading to lay persons. Not later than 5 years
16 after the date of enactment of the Act, the Adminis-
17 trator shall submit to the appropriate committees of
18 Congress a report on the results of such research,
19 together with recommendations on whether such
20 publication should be continued or modified.

21 (d) DATA COLLECTION.—Not later than 36 months
22 after the date of enactment of this Act, the Administrator
23 shall establish, and periodically revise as appropriate, a
24 list of harmful constituents, including smoke constituents,

1 to health in each tobacco product by brand and by quan-
2 tity in each brand and subbrand.

3 **SEC. 109. REGISTRATION AND LISTING.**

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

5 (1) The term "manufacture, preparation, or
6 processing" shall include repackaging or otherwise
7 changing the container, wrapper, or label of any to-
8 bacco product package other than the carton in fur-
9 therance of the distribution of the tobacco product
10 from the original place of manufacture to the person
11 that makes final delivery or sale to the ultimate con-
12 sumer or user, but shall not include the addition of
13 a tax marking or other marking required by law to
14 an already packaged tobacco product.

15 (2) The term "name" shall include in the case
16 of a partnership the name of the general partner
17 and, in the case of a privately held corporation, the
18 name of the chief executive officer of the corporation
19 and the State of incorporation.

20 (b) ANNUAL REGISTRATION.—Commencing one year
21 after enactment, on or before December 31 of each year,
22 every person that owns or operates any establishment in
23 any State engaged in the manufacture, preparation, or
24 processing of a tobacco product or products for commer-
25 cial distribution domestically shall register with the Ad-

1 ministrator its name, places of business, and all such es-
2 tablishments.

3 (c) NEW PRODUCERS.—Every person upon first en-
4 gaging, for commercial distribution domestically, in the
5 manufacture, preparation, or processing of a tobacco prod-
6 uct or products in any establishment that it owns or oper-
7 ates in any State shall immediately register with the Ad-
8 ministrator its name, places of business, and such estab-
9 lishment.

10 (d) REGISTRATION OF FOREIGN ESTABLISH-
11 MENTS.—

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

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

5 (3) The Administrator is authorized to enter
6 into cooperative arrangements with officials of for-
7 eign countries to ensure that adequate and effective
8 means are available for purposes of determining,
9 from time to time, whether tobacco products manu-
10 factured, prepared, or processed by an establishment
11 described in paragraph (1), if imported or offered
12 for import into the United States, shall be refused
13 admission on any of the grounds set forth in section
14 708.

15 (e) ADDITIONAL ESTABLISHMENTS.—Every person
16 duly registered in accordance with the foregoing sub-
17 sections of this section shall immediately register with the
18 Administrator any additional establishment that it owns
19 or operates and in which it begins the manufacture, prepa-
20 ration, or processing of a tobacco product or products for
21 commercial distribution domestically or for import into the
22 United States.

23 (f) EXCLUSIONS FROM APPLICATION OF THIS SEC-
24 TION.—The foregoing subsections of this section shall not
25 apply to—

1 (1) persons that manufacture, prepare, or proc-
2 ess tobacco products solely for use in research,
3 teaching, chemical or biological analysis, or export;
4 or
5 (2) such other classes of persons as the Admin-
6 istrator may by regulation exempt from the applica-
7 tion of this section upon a finding that registration
8 by such classes of persons in accordance with this
9 section is not necessary for the protection of the
10 public health.
11 (g) INSPECTION OF PREMISES.—Every establishment
12 registered with the Administrator pursuant to this section
13 shall be subject to inspection pursuant to section 706; and
14 every such establishment engaged in the manufacture,
15 preparation, or processing of a tobacco product or prod-
16 ucts shall be so inspected by one or more officers or em-
17 ployees duly designated by the Administrator at least once
18 in the two-year period beginning with the date of registra-
19 tion of such establishment pursuant to this section and
20 at least once in every successive two-year period there-
21 after, except that inspection of establishments outside the
22 United States may be conducted by other personnel pursu-
23 ant to a cooperative arrangement under subsection (d)(3).

1 (h) FILING OF LISTS OF TOBACCO PRODUCTS MANU-
2 FACTURED, PREPARED, OR PROCESSED BY REGISTRANTS;
3 STATEMENTS; ACCOMPANYING DISCLOSURES.—
4 (1) Every person that registers with the Admin-
5 istrator under subsection (b), (c), (d), or (e) shall,
6 at the time of registration under any such sub-
7 section, file with the Administrator a list of all
8 brand styles (with each brand style in each list listed
9 by the common or usual name of the tobacco prod-
10 uct category to which it belongs and by any propri-
11 etary name) that are being manufactured, prepared,
12 or processed by such person for commercial distribu-
13 tion domestically or for import into the United
14 States, and that such person has not included in any
15 list of tobacco products filed by such person with the
16 Administrator under this paragraph or paragraph
17 (2) before such time of registration. Such list shall
18 be prepared in such form and manner as the Admin-
19 istrator may prescribe, and shall be accompanied by
20 the label for each such brand style and a representa-
21 tive sampling of any other labeling and advertising
22 for each;
23 (2) Each person that registers with the Admin-
24 istrator under this section shall report to the Admin-
25 istrator each August for the preceding six-month pe-

1 riod from January through June, and each February
2 for the preceding six-month period form July
3 through December, following information:
4 (A) A list of each brand style introduced
5 by the registrant for commercial distribution
6 domestically or for import into the United
7 States that has not been included in any list
8 previously filed by such registrant with the Ad-
9 ministrator under this subparagraph or para-
10 graph (1). A list under this subparagraph shall
11 list a brand style by the common or usual name
12 of the tobacco product category to which it be-
13 longs and by any proprietary name, and shall
14 be accompanied by the other information re-
15 quired by paragraph (1).
16 (B) If since the date the registrant last
17 made a report under this paragraph (or if such
18 registrant has not previously made a report
19 under this paragraph, since the effective date of
20 this Act) such registrant has discontinued the
21 manufacture, preparation, or processing for
22 commercial distribution domestically or for im-
23 port into the United States of a brand style in-
24 cluded in a list filed by such registrant under
25 subparagraph (A) or paragraph (1), notice of

1 such discontinuance, the date of such dis-
2 continuance, and the identity (by the common
3 or usual name of the tobacco product category
4 to which it belongs and by any proprietary
5 name) of such tobacco product.

6 (C) If, since the date the registrant re-
7 ported pursuant to subparagraph (B) a notice
8 of discontinuance of a tobacco product, the reg-
9 istrant has resumed the manufacture, prepara-
10 tion, or processing for commercial distribution
11 domestically or for import into the United
12 States of that brand style, notice of such re-
13 sumption, the date of such resumption, the
14 identity of such brand style (by the common or
15 usual name of the tobacco product category to
16 which it belongs and by any proprietary name),
17 and the other information required by para-
18 graph (1), unless the registrant has previously
19 reported such resumption to the Administrator
20 pursuant to this subparagraph.

21 (D) Any material change in any informa-
22 tion previously submitted pursuant to this para-
23 graph (2) or paragraph (1).

24 (i) ELECTRONIC REGISTRATION.—Registrations
25 under subsections (b), (c), (d), and (e) (including the sub-

1 mission of updated information) shall be submitted to the
2 Administrator by electronic means, unless the Adminis-
3 trator grants a request for waiver of such requirement be-
4 cause use of electronic means is not reasonable for the
5 person requesting such waiver.

6 **SEC. 110. GENERAL PROVISIONS RESPECTING CONTROL OF**
7 **TOBACCO PRODUCTS.**

8 (a) IN GENERAL.—Any requirement established by or
9 under section 106, 107, or 113 applicable to a tobacco
10 product shall apply to such tobacco product until the ap-
11 plicability of the requirement to the tobacco product has
12 been changed by action taken under section 111, section
13 114, section 115, or subsection (d) of this section, and
14 any requirement established by or under section 106, 107,
15 or 113 which is inconsistent with a requirement imposed
16 on such tobacco product under section 111, section 114,
17 section 115, or subsection (d) of this section shall not
18 apply to such tobacco product.

19 (b) INFORMATION ON PUBLIC ACCESS AND COM-
20 MENT.—Each notice of proposed rulemaking or other noti-
21 fication under section 111, 112, 113, 114, or 115 or under
22 this section, any other notice which is published in the
23 Federal Register with respect to any other action taken
24 under any such section and which states the reasons for
25 such action, and each publication of findings required to

1 be made in connection with rulemaking under any such
2 section shall set forth—
3 (1) the manner in which interested persons may
4 examine data and other information on which the
5 notice or findings is based; and
6 (2) the period within which interested persons
7 may present their comments on the notice or find-
8 ings (including the need therefore) orally or in writ-
9 ing, which period shall be at least 60 days but may
10 not exceed 90 days unless the time is extended by
11 the Administrator by a notice published in the Fed-
12 eral Register stating good cause therefore.
13 (c) LIMITED CONFIDENTIALITY OF INFORMATION.—
14 Any information reported to or otherwise obtained by the
15 Administrator or the Administrator's representative under
16 section 107, 108, 111, 112, 113, 114, 115, or 504, or
17 under subsection (e) or (f) of this section, which is exempt
18 from disclosure under subsection (a) of section 552 of title
19 5, United States Code, by reason of subsection (b)(4) of
20 that section shall be considered confidential and shall not
21 be disclosed, except that the information may be disclosed
22 to other officers or employees concerned with carrying out
23 this Act, or when relevant in any proceeding under this
24 Act.
25 (d) RESTRICTIONS.—

1 (1) IN GENERAL.—The Administrator may
2 issue regulations, consistent with this Act, regarding
3 tobacco products if the Administrator determines
4 that such regulation would be appropriate for the
5 protection of the public health. The finding as to
6 whether such regulation would be appropriate for
7 the protection of the public health shall be deter-
8 mined with respect to the risks and benefits to the
9 users of the tobacco product, and taking into ac-
10 count that the standard is reasonably likely to result
11 in measurable and substantial reductions in mor-
12 bidly and mortality among individual tobacco users.
13 (2) LABEL STATEMENTS.—The label of a to-
14 bacco product shall bear such appropriate state-
15 ments of the restrictions required by a regulation
16 under subsection (a) as the Administrator may in
17 such regulation prescribe.
18 (e) GOOD MANUFACTURING PRACTICE REQUIRE-
19 MENTS.—
20 (1) METHODS, FACILITIES, AND CONTROLS TO
21 CONFORM.—
22 (A) IN GENERAL.—In applying manufac-
23 turing restrictions to tobacco, the Administrator
24 shall, in accordance with subparagraph (B),
25 prescribe regulations (which may differ based

1 on the type of tobacco product involved) requir-
2 ing that the methods used in, and the facilities
3 and controls used for, the manufacture,
4 preproduction design validation (including a
5 process to assess the performance of a tobacco
6 product), packing, and storage of a tobacco
7 product conform to current good manufacturing
8 practice, or hazard analysis and critical control
9 point methodology, as prescribed in such regu-
10 lations to assure that the public health is pro-
11 tected and that the tobacco product is in com-
12 pliance with this Act. Such regulations may
13 provide for the testing of raw tobacco for pes-
14 ticide chemical residues after a tolerance for
15 such chemical residues has been established.
16 (B) REQUIREMENTS.—The Administrator
17 shall—
18 (i) before promulgating any regulation
19 under subparagraph (A), afford the To-
20 bacco Products Scientific Advisory Com-
21 mittee an opportunity to submit rec-
22 ommendations with respect to the regula-
23 tion proposed to be promulgated;

1 (ii) before promulgating any regula-
2 tion under subparagraph (A), afford oppor-
3 tunity for an oral hearing;
4 (iii) provide the Tobacco Products
5 Scientific Advisory Committee a reasonable
6 time to make its recommendation with re-
7 spect to proposed regulations under sub-
8 paragraph (A); and
9 (iv) in establishing the effective date
10 of a regulation promulgated under this
11 subsection, take into account the dif-
12 ferences in the manner in which the dif-
13 ferent types of tobacco products have his-
14 torically been produced, the financial re-
15 sources of the different tobacco product
16 manufacturers, and the state of their exist-
17 ing manufacturing facilities, and shall pro-
18 vide for a reasonable period of time for
19 such manufacturers to conform to good
20 manufacturing practices but no earlier
21 than four years from date of enactment.
22 (C) ADDITIONAL SPECIAL RULE.—A to-
23 bacco product manufactured in or imported into
24 the United States shall not contain foreign-
25 grown flue-cured or burley tobacco that—

1 (i) was knowingly grown or processed
2 using a pesticide chemical that is not ap-
3 proved under applicable Federal law for
4 use in domestic tobacco farming and proc-
5 essing; or
6 (ii) in the case of a pesticide chemical
7 that is so approved, was grown or proc-
8 essed using the pesticide chemical in a
9 manner inconsistent with the approved la-
10 beling for use of the pesticide chemical in
11 domestic tobacco farming and processing.
12 (D) EXCLUSION.—Subparagraph (C)(ii)
13 shall not apply to tobacco products manufac-
14 tured with foreign-grown flue-cured or burley
15 tobacco so long as that foreign grown tobacco
16 was either—
17 (i) in the inventory of a manufacturer
18 prior to the effective date, or
19 (ii) planted by the farmer prior to the
20 effective date of this Act and utilized by
21 the manufacturer no later than 3 years
22 after the effective date.
23 (E) SETTING OF MAXIMUM RESIDUE LIM-
24 ITS.—The Administrator shall adopt the fol-
25 lowing pesticide residue standards:

1 Pesticide residue standards

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

6 CHLORDANE.....3.0

7 DIBROMOCHLOROPROPANE (DBCP).....1.0

8 DICAMBA (Temporary).... 5.0

9 ENDRIN....0.1

10 ETHYLENE DIBROMIDE (EDB)....0.1

11 FORMOTHION.....0.5

12 HEXACHLOROBENZENE (HCB)....0.1

13 METHOXYCHLOR.....0.1

14 TOXAPHENE.....0.3

15 2,4-D (Temporary).....5.0

16 2,4,5-T.....0.1

17 Sum of ALDRIN and DIELDRIN.....0.1

18 Sum of CYPERMETHRIN and PERMETHRIN
19 (Temporary).....3.0

20 Sum of DDT, TDE (DDD), and DDE 0.4

21 Sum of HEPTACHLOR and HEPTACHLOR EP-
22 OXIDE.....0.1

23 (F) MAXIMUM RESIDUE LIMITS.—The Ad-
24 ministrator shall adopt regulations within one
25 year of the effective date of this Act to establish

1 maximum residue limits for pesticides identified
2 under subparagraph (E) but not included in the
3 table of such subparagraph to account for the
4 fact that weather and agronomic conditions will
5 cause pesticides identified in subparagraph (E)
6 to be detected in foreign-grown tobacco even
7 where the farmer has not knowingly added such
8 pesticide.
9 (2) EXEMPTIONS; VARIANCES.—
10 (A) PETITION.—Any person subject to any
11 requirement prescribed under paragraph (1)
12 may petition the Administrator for a permanent
13 or temporary exemption or variance from such
14 requirement. Such a petition shall be submitted
15 to the Administrator in such form and manner
16 as the Administrator shall prescribe and shall—
17 (i) in the case of a petition for an ex-
18 emption from a requirement, set forth the
19 basis for the petitioner's determination
20 that compliance with the requirement is
21 not required to assure that the tobacco
22 product will be in compliance with this Act;
23 (ii) in the case of a petition for a vari-
24 ance from a requirement, set forth the
25 methods proposed to be used in, and the

1 facilities and controls proposed to be used
2 for, the manufacture, packing, and storage
3 of the tobacco product in lieu of the meth-
4 ods, facilities, and controls prescribed by
5 the requirement; and
6 (iii) contain such other information as
7 the Administrator shall prescribe.
8 (B) REFERRAL TO THE TOBACCO PROD-
9 UCTS SCIENTIFIC ADVISORY COMMITTEE.—The
10 Administrator may refer to the Tobacco Prod-
11 ucts Scientific Advisory Committee any petition
12 submitted under subparagraph (A). The To-
13 bacco Products Scientific Advisory Committee
14 shall report its recommendations to the Admin-
15 istrator with respect to a petition referred to it
16 within 60 days after the date of the petition's
17 referral. Within 60 days after—
18 (i) the date the petition was submitted
19 to the Administrator under subparagraph
20 (A); or
21 (ii) the day after the petition was re-
22 ferred to the Tobacco Products Scientific
23 Advisory Committee,
24 whichever occurs later, the Administrator shall
25 by order either deny the petition or approve it.

1 (C) APPROVAL.—The Administrator may
2 approve—
3 (i) a petition for an exemption for a
4 tobacco product from a requirement if the
5 Administrator determines that compliance
6 with such requirement is not required to
7 assure that the tobacco product will be in
8 compliance with this Act; and
9 (ii) a petition for a variance for a to-
10 bacco product from a requirement if the
11 Administrator determines that the methods
12 to be used in, and the facilities and con-
13 trols to be used for, the manufacture,
14 packing, and storage of the tobacco prod-
15 uct in lieu of the methods, facilities, and
16 controls prescribed by the requirement are
17 sufficient to assure that the tobacco prod-
18 uct will be in compliance with this Act.
19 (D) CONDITIONS.—An order of the Admin-
20 istrator approving a petition for a variance shall
21 prescribe such conditions respecting the meth-
22 ods used in, and the facilities and controls used
23 for, the manufacture, packing, and storage of
24 the tobacco product to be granted the variance
25 under the petition as may be necessary to as-

1 sure that the tobacco product will be in compli-
2 ance with this Act.
3 (E) HEARING.—After the issuance of an
4 order under subparagraph (B) respecting a pe-
5 tition, the petitioner shall have an opportunity
6 for an informal hearing on such order.
7 (3) COMPLIANCE.—Compliance with require-
8 ments under this subsection shall not be required be-
9 fore the end of the 3-year period following the date
10 of enactment of this Act.
11 (f) RESEARCH AND DEVELOPMENT.—The Adminis-
12 trator may enter into contracts for research, testing, and
13 demonstrations respecting tobacco products and may ob-
14 tain tobacco products for research, testing, and dem-
15 onstration purposes.
16 **SEC. 111. SMOKING ARTICLE STANDARDS.**
17 (a) IN GENERAL.—
18 (1) RESTRICTIONS ON DESCRIPTORS USED IN
19 MARKETING OF CIGARETTES.—
20 (A) IN GENERAL.—Except as provided in
21 subparagraph (B), no person shall use, with re-
22 spect to any cigarette brand style commercially
23 distributed domestically, on the portion of the
24 package of such cigarette brand style that cus-
25 tomarily is visible to consumers before pur-

1 chase, or in advertising of such cigarette brand
2 style any of the following as a descriptor of any
3 cigarette brand style—
4 (i) the name of any candy or fruit;
5 (ii) the word "candy," "citrus,"
6 "cream," "fruit," "sugar," "sweet,"
7 "tangy," or "tart,"; or
8 (iii) any extension or variation of any
9 of the words "candy," "citrus," "cream,"
10 "fruit," "sugar," "sweet," "tangy," or
11 "tart," including but not limited to
12 "creamy," or "fruity."
13 (B) LIMITATION.—Subparagraph (A) shall
14 not apply to the use of the following words or
15 to any extension or variation of any of them:
16 "coffee," "mint," and "menthol".
17 (C) SCENTED MATERIALS.—No person
18 shall use, in the advertising or labeling of any
19 cigarette commercially distributed domestically,
20 any scented materials, except in an adult-only
21 facility.
22 (D) DEFINITIONS.—In this section:
23 (i) The term "candy" means a confec-
24 tion made from sugar or sugar substitute,
25 including any confection identified generi-

1 cally or by brand, and shall include the
2 words "cacao," "chocolate," "cinnamon,"
3 "cocoa," "honey," "licorice," "maple,"
4 "mocha," and "vanilla."
5 (ii) The term "fruit" means any fruit
6 identified by generic name, type, or vari-
7 ety, including but not limited to "apple,"
8 "banana," "cherry," and "orange." The
9 term "fruit" does not include words that
10 identify seeds, nuts or peppers, or types or
11 varieties thereof or words that are exten-
12 sions or variations of such words.
13 (2) SMOKING ARTICLE STANDARDS.—
14 (A) IN GENERAL.—The Administrator may
15 adopt smoking article standards in addition to
16 those in paragraph (1) if the Administrator
17 finds that a smoking article standard is appro-
18 priate for the protection of the public health.
19 (B) DETERMINATIONS.—
20 (i) CONSIDERATIONS.—In making a
21 finding described in subparagraph (A), the
22 Administrator shall consider scientific evi-
23 dence concerning—

1 (I) the risks and benefits to the
2 users of smoking articles of the pro-
3 posed standard; and
4 (II) that the standard is reason-
5 ably likely to result in measurable and
6 substantial reductions in morbidity
7 and mortality among individual to-
8 bacco users.
9 (ii) ADDITIONAL CONSIDERATIONS.—
10 In the event that the Administrator makes
11 a determination, set forth in a proposed
12 smoking article standard in a proposed
13 rule, that it is appropriate for the protec-
14 tion of public health to require the reduc-
15 tion or elimination of an additive, con-
16 stituent (including a smoke constituent), or
17 other component of a smoking article be-
18 cause the Administrator has found that the
19 additive, constituent, or other component is
20 harmful, any party objecting to the pro-
21 posed standard on the ground that the
22 proposed standard will not reduce or elimi-
23 nate the risk of illness or injury may pro-
24 vide for the Administrator's consideration
25 scientific evidence that demonstrates that

1 the proposed standard will not reduce or
2 eliminate the risk of illness or injury.
3 (3) CONTENT OF SMOKING ARTICLE STAND-
4 ARDS.—A smoking article standard established
5 under this section for a smoking article—
6 (A) may include provisions that are appro-
7 priate for the protection of the public health,
8 including provisions, where appropriate—
9 (i) for "tar" and nicotine yields of the
10 product;
11 (ii) for the reduction of other constitu-
12 ents, including smoke constituents, or
13 harmful components of the product; or
14 (iii) relating to any other requirement
15 under subparagraph (B); and
16 (B) may, where appropriate for the protec-
17 tion of the public health, include—
18 (i) provisions respecting the construc-
19 tion, components, ingredients, additives,
20 constituents, including smoke constituents,
21 and properties of the smoking article;
22 (ii) provisions for the testing (on a
23 sample basis or, if necessary, on an indi-
24 vidual basis) of the smoking article;

1 (iii) provisions for the measurement of
2 the smoking article characteristics of the
3 smoking article; and
4 (iv) provisions requiring that the re-
5 sults of each or of certain of the tests of
6 the smoking article required to be made
7 under clause (ii) show that the smoking ar-
8 ticle is in conformity with the portions of
9 the standard for which the test or tests
10 were required.
11 (4) PERIODIC REEVALUATION OF SMOKING AR-
12 TICLE STANDARDS.—The Administrator may provide
13 for periodic evaluation of smoking article standards
14 established under this section to determine whether
15 such standards should be changed to reflect new
16 medical, scientific, or other technological data.
17 (5) CIGARETTE "TAR" LIMITS.—
18 (A) NO INCREASE IN "TAR" YIELDS.—No
19 cigarette manufacturer shall distribute for sale
20 domestically a brand style of cigarettes that
21 generates a "tar" yield greater than the "tar"
22 yield of that brand style of cigarettes on the
23 date of introduction of this Act, as determined
24 by the ISO smoking regimen and its associated
25 tolerances. The "tar" tolerances for cigarettes

1 with ISO "tar" yields in the range of 1 to 20
2 milligrams per cigarette, based on variations
3 arising from sampling procedure, test method,
4 and sampled product, itself, are the greater of
5 plus or minus—
6 (i) 15 percent; or
7 (ii) 1 milligram per cigarette.
8 (B) LIMIT ON NEW CIGARETTES.—After
9 the effective date of this Act, no cigarette man-
10 ufacturer shall manufacture for commercial dis-
11 tribution domestically a brand style of ciga-
12 rettes that both—
13 (i) was not in commercial distribution
14 domestically on the effective date of this
15 Act, and
16 (ii) generates a "tar" yield of greater
17 than 20 milligrams per cigarette as deter-
18 mined by the ISO smoking regimen and its
19 associated tolerances.
20 (C) LIMIT ON ALL CIGARETTES.—After
21 December 31, 2010, no cigarette manufacturer
22 shall manufacture for commercial distribution
23 domestically a brand style of cigarettes that
24 generates a "tar" yield greater than 20 milli-

1 grams per cigarette as determined by the ISO
2 smoking regimen and its associated tolerances.
3 (D) REVIEW BY ADMINISTRATOR.—After
4 the effective date of this Act, the Administrator
5 shall evaluate the available scientific evidence
6 addressing the potential relationship between
7 historical "tar" yield values and risk of harm to
8 smokers. If upon a review of that evidence, and
9 after consultation with technical experts of the
10 Tobacco Harm Reduction Center and the Cen-
11 ters for Disease Control and Prevention and no-
12 tice and an opportunity for public comment, the
13 Administrator determines, that a reduction in
14 "tar" yield may reasonably be expected to pro-
15 vide a meaningful reduction of the risk or risks
16 of harm to smokers, the Administrator shall
17 issue an order that—
18 (i) provides that no cigarette manu-
19 facturer shall manufacture for commercial
20 distribution domestically a cigarette that
21 generates a "tar" yield that exceeds 14
22 milligrams as determined by the ISO
23 smoking regimen and its associated toler-
24 ances; and

1 (ii) provides a reasonable time for
2 manufacturers to come into compliance
3 with such prohibition.
4 (6) INVOLVEMENT OF OTHER AGENCIES; IN-
5 FORMED PERSONS.—In carrying out duties under
6 this section, the Administrator shall endeavor to—
7 (A) use personnel, facilities, and other
8 technical support available in other Federal
9 agencies;
10 (B) consult with other Federal agencies
11 concerned with standard setting and other na-
12 tionally or internationally recognized standard-
13 setting entities; and
14 (C) invite appropriate participation,
15 through joint or other conferences, workshops,
16 or other means, by informed persons represent-
17 ative of scientific, professional, industry, agri-
18 cultural, or consumer organizations who in the
19 Administrator's judgment can make a signifi-
20 cant contribution.
21 (b) CONSIDERATIONS BY ADMINISTRATOR.—
22 (1) TECHNICAL ACHIEVABILITY.—The Admini-
23 strator shall consider information submitted in con-
24 nection with a proposed standard regarding the tech-
25 nical achievability of compliance with such standard.

1 (2) OTHER CONSIDERATIONS.—The Adminis-
2 trator shall consider all other information submitted
3 in connection with a proposed standard, such as the
4 creation of a significant demand for contraband or
5 other tobacco products that do not meet the require-
6 ments of this Act and the significance of such de-
7 mand.
8 (c) PROPOSED STANDARDS.—
9 (1) IN GENERAL.—The Administrator shall
10 publish in the Federal Register a notice of proposed
11 rulemaking for the establishment, amendment, or
12 revocation of any smoking article standard.
13 (2) REQUIREMENTS OF NOTICE.—A notice of
14 proposed rulemaking for the establishment or
15 amendment of a smoking article standard shall—
16 (A) set forth a finding with supporting jus-
17 tification that the smoking article standard is
18 appropriate for the protection of the public
19 health;
20 (B) invite interested persons to submit a
21 draft or proposed smoking article standard for
22 consideration by the Administrator;
23 (C) invite interested persons to submit
24 comments on structuring the standard so that

1 it does not advantage foreign-grown tobacco
2 over domestically grown tobacco; and
3 (D) invite the Secretary of Agriculture to
4 provide any information or analysis which the
5 Secretary of Agriculture believes is relevant to
6 the proposed smoking article standard.
7 (3) FINDING.—A notice of proposed rulemaking
8 for the revocation of a smoking article standard
9 shall set forth a finding with supporting justification
10 that the smoking article standard is no longer ap-
11 propriate for the protection of the public health.
12 (4) COMMENT.—The Administrator shall pro-
13 vide for a comment period of not less than 90 days.
14 (d) PROMULGATION.—
15 (1) IN GENERAL.—After the expiration of the
16 period for comment on a notice of proposed rule-
17 making published under subsection (c) respecting a
18 standard and after consideration of comments sub-
19 mitted under subsections (b) and (c) and any report
20 from the Tobacco Products Scientific Advisory Com-
21 mittee, if the Administrator determines that the
22 standard would be appropriate for the protection of
23 the public health, the Administrator shall—
24 (A) promulgate a regulation establishing a
25 smoking article standard and publish in the

1 Federal Register findings on the matters re-
2 ferred to in subsection (c); or
3 (B) publish a notice terminating the pro-
4 ceeding for the development of the standard to-
5 gether with the reasons for such termination.
6 (2) EFFECTIVE DATE.—A regulation estab-
7 lishing a smoking article standard shall set forth the
8 date or dates upon which the standard shall take ef-
9 fect, but no such regulation may take effect before
10 1 year after the date of its publication unless the
11 Administrator determines that an earlier effective
12 date is necessary for the protection of the public
13 health. Such date or dates shall be established so as
14 to minimize, consistent with the public health, eco-
15 nomic loss to, and disruption or dislocation of, do-
16 mestic and international trade. In establishing such
17 effective date or dates, the Administrator shall con-
18 sider information submitted in connection with a
19 proposed product standard by interested parties, in-
20 cluding manufacturers and tobacco growers, regard-
21 ing the technical achievability of compliance with the
22 standard, and including information concerning the
23 existence of patents that make it impossible to com-
24 ply in the timeframe envisioned in the proposed
25 standard.

1 (3) LIMITATION ON POWER GRANTED.—Be-
2 cause of the importance of a decision of the Admin-
3 istrator to issue a regulation—
4 (A) banning cigarettes, smokeless smoking
5 articles, little cigars, cigars other than little ci-
6 gars, pipe tobacco, or roll-your-own smoking ar-
7 ticles;
8 (B) requiring the reduction of "tar" or nic-
9 otine yields of a smoking article to zero;
10 (C) prohibiting the sale of any smoking ar-
11 ticle in face-to-face transactions by a specific
12 category of retail outlets;
13 (D) establishing a minimum age of sale of
14 smoking articles to any person older than 18
15 years of age; or
16 (E) requiring that the sale or distribution
17 of a smoking article be limited to the written or
18 oral authorization of a practitioner licensed by
19 law to prescribe medical products,
20 the Administrator is prohibited from taking such ac-
21 tions under this Act.
22 (4) MATCHBOOKS.—For purposes of any regu-
23 lations issued by the Administrator under this Act,
24 matchbooks of conventional size containing not more
25 than 20 paper matches, and which are customarily

1 given away for free with the purchase of smoking ar-
2 ticles, shall be considered as adult-written publica-
3 tions which shall be permitted to contain advertising.
4 (5) AMENDMENT; REVOCATION.—
5 (A) AUTHORITY.—The Administrator,
6 upon the Administrator's own initiative or upon
7 petition of an interested person, may by a regu-
8 lation, promulgated in accordance with the re-
9 quirements of subsection (c) and paragraph (2),
10 amend or revoke a smoking article standard.
11 (B) EFFECTIVE DATE.—The Adminis-
12 trator may declare a proposed amendment of a
13 smoking article standard to be effective on and
14 after its publication in the Federal Register and
15 until the effective date of any final action taken
16 on such amendment if the Administrator deter-
17 mines that making it so effective is in the pub-
18 lic interest.
19 (6) REFERRAL TO ADVISORY COMMITTEE.—
20 (A) IN GENERAL.—The Administrator
21 shall refer a proposed regulation for the estab-
22 lishment, amendment, or revocation of a smok-
23 ing article standard to the Tobacco Products
24 Scientific Advisory Committee for a report and
25 recommendation with respect to any matter in-

1 volved in the proposed regulation which requires
2 the exercise of scientific judgment.
3 (B) INITIATION OF REFERRAL.—The Ad-
4 ministrator shall make a referral under this
5 paragraph—
6 (i) on the Administrator's own initia-
7 tive; or
8 (ii) upon the request of an interested
9 person that—
10 (I) demonstrates good cause for
11 the referral; and
12 (II) is made before the expiration
13 of the period for submission of com-
14 ments on the proposed regulation.
15 (C) PROVISION OF DATA.—If a proposed
16 regulation is referred under this paragraph to
17 the Tobacco Products Scientific Advisory Com-
18 mittee, the Administrator shall provide the Ad-
19 visory Committee with the data and information
20 on which such proposed regulation is based.
21 (D) REPORT AND RECOMMENDATION.—
22 The Tobacco Products Scientific Advisory Com-
23 mittee shall, within 90 days after the referral of
24 a proposed regulation under this paragraph and
25 after independent study of the data and infor-

1 mation furnished to it by the Administrator and
2 other data and information before it, submit to
3 the Administrator a report and recommendation
4 respecting such regulation, together with all un-
5 derlying data and information and a statement
6 of the reason or basis for the recommendation.
7 (E) PUBLIC AVAILABILITY.—The Adminis-
8 trator shall make a copy of each report and rec-
9 ommendation under subparagraph (D) publicly
10 available.

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

12 (a) NOTIFICATION.—If the Administrator determines
13 that—
14 (1) a tobacco product which is introduced or de-
15 livered for introduction into interstate commerce for
16 commercial distribution presents an unreasonable
17 risk of substantial harm materially above the risk
18 for death and disease of tobacco products currently
19 in interstate commerce, to the public health; and
20 (2) notification under this subsection is nec-
21 essary to eliminate the unreasonable risk of such
22 harm and no more practicable means is available
23 under the provisions of this Act (other than this sec-
24 tion) to eliminate such risk,

1 the Administrator may issue such order as may be nec-
2 essary to assure that adequate notification is provided in
3 an appropriate form, by the persons and means best suited
4 under the circumstances involved, to all persons who
5 should properly receive such notification in order to elimi-
6 nate such risk. The Administrator may order notification
7 by any appropriate means, including public service an-
8 nouncements. Before issuing an order under this sub-
9 section, the Administrator shall consult with the persons
10 who are to give notice under the order.

11 (b) NO EXEMPTION FROM OTHER LIABILITY.—Com-
12 pliance with an order issued under this section shall not
13 relieve any person from liability under Federal or State
14 law. In awarding damages for economic loss in an action
15 brought for the enforcement of any such liability, the value
16 to the plaintiff in such action of any remedy provided
17 under such order shall be taken into account.

18 (c) RECALL AUTHORITY.—

19 (1) IN GENERAL.—If the Administrator finds
20 that there is a reasonable probability that a tobacco
21 product contains a manufacturing or other defect
22 not ordinarily contained in tobacco products on the
23 market that would cause serious, acute adverse
24 health consequences or death, the Administrator
25 shall issue an order requiring the appropriate person

1 (including the manufacturers, importers, distribu-
2 tors, or retailers of the tobacco product) to imme-
3 diately cease distribution of such tobacco product.
4 The order shall provide the person subject to the
5 order with an opportunity for an informal hearing,
6 to be held not later than 10 days after the date of
7 the issuance of the order, on the actions required by
8 the order and on whether the order should be
9 amended to require a recall of such tobacco product.
10 If, after providing an opportunity for such a hear-
11 ing, the Administrator determines that inadequate
12 grounds exist to support the actions required by the
13 order, the Administrator shall vacate the order.
14 (2) AMENDMENT OF ORDER TO REQUIRE RE-
15 CALL.—
16 (A) IN GENERAL.—If, after providing an
17 opportunity for an informal hearing under
18 paragraph (1), the Administrator determines
19 that the order should be amended to include a
20 recall of the tobacco product with respect to
21 which the order was issued, the Administrator
22 shall, except as provided in subparagraph (B),
23 amend the order to require a recall. The Ad-
24 ministrator shall specify a timetable in which
25 the tobacco product recall will occur and shall

1 require periodic reports to the Administrator
2 describing the progress of the recall.
3 (B) NOTICE.—An amended order under
4 subparagraph (A)—
5 (i) shall not include recall of a tobacco
6 product from individuals; and
7 (ii) shall provide for notice to persons
8 subject to the risks associated with the use
9 of such tobacco product.
10 In providing the notice required by clause (ii),
11 the Administrator may use the assistance of re-
12 tailers and other persons who distributed such
13 tobacco product. If a significant number of such
14 persons cannot be identified, the Administrator
15 shall notify such persons under section 705(b).
16 (3) REMEDY NOT EXCLUSIVE.—The remedy
17 provided by this subsection shall be in addition to
18 remedies provided by subsection (a).

19 **SEC. 113. RECORDS AND REPORTS ON TOBACCO PROD-**
20 **UCTS.**

21 Every person who is a tobacco product manufacturer
22 or importer of a tobacco product shall establish and main-
23 tain such records, make such reports, and provide such
24 information, as the Administrator may by regulation rea-

1 sonably require to assure that such tobacco product is not
2 adulterated or misbranded.

3 **SEC. 114. APPLICATION FOR REVIEW OF CERTAIN SMOKING**
4 **ARTICLES.**

5 (a) IN GENERAL.—

6 (1) NEW SMOKING ARTICLE DEFINED.—For
7 purposes of this section the term "new smoking arti-
8 cle" means—

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

12 (B) any smoking article that incorporates
13 a significant modification (including changes in
14 design, component, part, or constituent, includ-
15 ing a smoke constituent, or in the content, de-
16 livery or form of nicotine, or other additive or
17 ingredient) of a smoking article where the
18 modified product was commercially marketed in
19 the United States after the date of enactment
20 of this Act.

21 (2) PREMARKET REVIEW REQUIRED.—

22 (A) NEW PRODUCTS.—An order under
23 subsection (c)(1)(A) for a new smoking article
24 is required unless the product—

1 (i) is substantially equivalent to a
2 smoking article commercially marketed in
3 the United States as of date of enactment
4 of this Act; and
5 (ii) is in compliance with the require-
6 ments of this Act.
7 (B) CONSUMER TESTING.—This section
8 shall not apply to smoking articles that are pro-
9 vided to adult tobacco consumers for purposes
10 of consumer testing. For purposes of this sec-
11 tion, the term "consumer testing" means an as-
12 sessment of smoking articles that is conducted
13 by or under the control and direction of a man-
14 ufacturer for the purpose of evaluating con-
15 sumer acceptance of such smoking articles, uti-
16 lizing only the quantity of cigarettes that is rea-
17 sonably necessary for such assessment
18 (3) SUBSTANTIALLY EQUIVALENT DEFINED.—
19 (A) IN GENERAL.—In this section, the
20 term "substantially equivalent" or "substantial
21 equivalence" means, with respect to the smok-
22 ing article being compared to the predicate
23 smoking article, that the Administrator by
24 order has found that the smoking article—

1 (i) has the same general characteris-
2 tics as the predicate smoking article; or
3 (ii) has different characteristics and
4 the information submitted contains infor-
5 mation, including clinical data if deemed
6 necessary by the Administrator, that dem-
7 onstrates that it is not appropriate to reg-
8 ulate the product under this section be-
9 cause the product does not raise different
10 questions of public health for the consumer
11 of the product.
12 (B) CHARACTERISTICS.—In subparagraph
13 (A), the term "characteristics" means the mate-
14 rials, ingredients, design, composition, heating
15 source, or other features of a smoking article.
16 (C) LIMITATION.—A smoking article may
17 not be found to be substantially equivalent to a
18 predicate smoking article that has been re-
19 moved from the market at the initiative of the
20 Administrator or that has been determined by
21 a judicial order to be misbranded or adulter-
22 ated.
23 (4) HEALTH INFORMATION.—As part of a sub-
24 mission respecting a smoking article, the person re-
25 quired to file a premarket notification shall provide

1 an adequate summary of any health information re-
2 lated to the smoking article or state that such infor-
3 mation will be made available upon request by any
4 person.
5 (b) APPLICATION.—
6 (1) CONTENTS.—An application under this sec-
7 tion shall contain—
8 (A) full reports of all information, pub-
9 lished or known to, or which should reasonably
10 be known to, the applicant, concerning inves-
11 tigations which have been made to show the
12 health risks of such smoking article and wheth-
13 er such smoking article presents less risk than
14 other smoking articles;
15 (B) a full statement of the components, in-
16 gredients, additives, and properties, and of the
17 principle or principles of operation, of such
18 smoking article;
19 (C) a full description of the methods used
20 in, and the facilities and controls used for, the
21 manufacture, processing, and, when relevant,
22 packing and installation of, such smoking arti-
23 cle;
24 (D) an identifying reference to any smok-
25 ing article standard under section 111 which

1 would be applicable to any aspect of such smok-
2 ing article, and either adequate information to
3 show that such aspect of such smoking article
4 fully meets such smoking article standard or
5 adequate information to justify any deviation
6 from such standard;
7 (E) such samples of such smoking article
8 and of components thereof as the Administrator
9 may reasonably require;
10 (F) specimens of the labeling proposed to
11 be used for such smoking article; and
12 (G) such other information relevant to the
13 subject matter of the application as the Admin-
14 istrator may require.
15 (2) REFERRAL TO TOBACCO PRODUCTS SCI-
16 ENTIFIC ADVISORY COMMITTEE.—Upon receipt of an
17 application meeting the requirements set forth in
18 paragraph (1), the Administrator—
19 (A) may, on the Administrator's own ini-
20 tiative; or
21 (B) may, upon the request of an applicant,
22 refer such application to the Tobacco Products Sci-
23 entific Advisory Committee for reference and for
24 submission (within such period as the Administrator
25 may establish) of a report and recommendation re-

1 specting the application, together with all underlying
2 data and the reasons or basis for the recommenda-
3 tion.
4 (c) ACTION ON APPLICATION.—
5 (1) DEADLINE.—As promptly as possible, but
6 in no event later than 90 days after the receipt of
7 an application under subsection (b), the Adminis-
8 trator, after considering the report and rec-
9 ommendation submitted under subsection (b)(2),
10 shall—
11 (A) issue an order that the new product
12 may be introduced or delivered for introduction
13 into interstate commerce if the Administrator
14 finds that none of the grounds specified in
15 paragraph (2) of this subsection applies; or
16 (B) issue an order that the new product
17 may not be introduced or delivered for introduc-
18 tion into interstate commerce if the Adminis-
19 trator finds (and sets forth the basis for such
20 finding as part of or accompanying such denial)
21 that 1 or more grounds for denial specified in
22 paragraph (2) of this subsection apply.
23 (2) DENIAL OF APPLICATION.—The Adminis-
24 trator shall deny an application submitted under
25 subsection (b) if, upon the basis of the information

1 submitted to the Administrator as part of the appli-
2 cation and any other information before the Admin-
3 istrator with respect to such smoking article, the Ad-
4 ministrator finds that—
5 (A) there is a lack of a showing that per-
6 mitting such smoking article to be marketed
7 would be appropriate for the protection of the
8 public health;
9 (B) the methods used in, or the facilities
10 or controls used for, the manufacture, proc-
11 essing, or packing of such smoking article do
12 not conform to the requirements of section
13 110(e);
14 (C) based on a fair evaluation of all mate-
15 rial facts, the proposed labeling is false or mis-
16 leading in any particular; or
17 (D) such smoking article is not shown to
18 conform to a smoking article standard in effect
19 under section 111, and there is a lack of ade-
20 quate information to justify the deviation from
21 such standard.
22 (3) DENIAL INFORMATION.—Any denial of an
23 application shall, insofar as the Administrator deter-
24 mines to be practicable, be accompanied by a state-
25 ment informing the applicant of the measures re-

1 quired to remove such application from deniable
2 form (which measures may include further research
3 by the applicant in accordance with 1 or more proto-
4 cols prescribed by the Administrator).
5 (4) BASIS FOR FINDING.—For purposes of this
6 section, the finding as to whether the commercial in-
7 troduction of a smoking article for which an applica-
8 tion has been submitted is appropriate for the pro-
9 tection of the public health shall be determined with
10 respect to the risks and benefits to the users of the
11 smoking article, and taking into account whether
12 such commercial introduction is reasonably likely to
13 increase the morbidly and mortality among indi-
14 vidual tobacco users.
15 (d) WITHDRAWAL AND TEMPORARY SUSPENSION.—
16 (1) IN GENERAL.—The Administrator shall,
17 upon obtaining, where appropriate, advice on sci-
18 entific matters from the Tobacco Products Scientific
19 Advisory Committee, and after due notice and op-
20 portunity for informal hearing for a smoking article
21 for which an order was issued under subsection
22 (c)(1)(A), issue an order withdrawing the order if
23 the Administrator finds—

1 (A) that the continued marketing of such
2 smoking article no longer is appropriate for the
3 protection of the public health;
4 (B) that the application contained or was
5 accompanied by an untrue statement of a mate-
6 rial fact;
7 (C) that the applicant—
8 (i) has failed to establish a system for
9 maintaining records, or has repeatedly or
10 deliberately failed to maintain records or to
11 make reports, required by an applicable
12 regulation under section 113; or
13 (ii) has refused to permit access to, or
14 copying or verification of, such records as
15 required by section 110; or
16 (D) on the basis of new information before
17 the Administrator with respect to such smoking
18 article, evaluated together with the evidence be-
19 fore the Administrator when the application
20 was reviewed, that the methods used in, or the
21 facilities and controls used for, the manufac-
22 ture, processing, packing, or installation of such
23 smoking article do not conform with the re-
24 quirements of section 110(e) and were not
25 brought into conformity with such requirements

1 within a reasonable time after receipt of written
2 notice from the Administrator of noncon-
3 formity;
4 (E) on the basis of new information before
5 the Administrator, evaluated together with the
6 evidence before the Administrator when the ap-
7 plication was reviewed, that the labeling of such
8 smoking article, based on a fair evaluation of
9 all material facts, is false or misleading in any
10 particular and was not corrected within a rea-
11 sonable time after receipt of written notice from
12 the Administrator of such fact; or
13 (F) on the basis of new information before
14 the Administrator, evaluated together with the
15 evidence before the Administrator when such
16 order was issued, that such smoking article is
17 not shown to conform in all respects to a smok-
18 ing article standard which is in effect under
19 section 111, compliance with which was a con-
20 dition to the issuance of an order relating to
21 the application, and that there is a lack of ade-
22 quate information to justify the deviation from
23 such standard.
24 (2) APPEAL.—The holder of an application sub-
25 ject to an order issued under paragraph (1) with-

1 drawing an order issued pursuant to subsection
2 (c)(1)(A) may, by petition filed on or before the
3 30th day after the date upon which such holder re-
4 ceives notice of such withdrawal, obtain review there-
5 of in accordance with section 116.

6 (3) TEMPORARY SUSPENSION.—If, after pro-
7 viding an opportunity for an informal hearing, the
8 Administrator determines there is reasonable prob-
9 ability that the continuation of distribution of a
10 smoking article under an order would cause serious,
11 adverse health consequences or death, that is greater
12 than ordinarily caused by smoking articles on the
13 market, the Administrator shall by order temporarily
14 suspend the authority of the manufacturer to mar-
15 ket the product. If the Administrator issues such an
16 order, the Administrator shall proceed expeditiously
17 under paragraph (1) to withdraw such application.

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

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

22 (2) by mailing the order by registered mail or
23 certified mail addressed to the applicant at the ap-
24 plicant's last known address in the records of the
25 Administrator.

1 (f) RECORDS.—

2 (1) ADDITIONAL INFORMATION.—In the case of
3 any smoking article for which an order issued pursu-
4 ant to subsection (c)(1)(A) for an application filed
5 under subsection (b) is in effect, the applicant shall
6 establish and maintain such records, and make such
7 reports to the Administrator, as the Administrator
8 may by regulation, or by order with respect to such
9 application, prescribe on the basis of a finding that
10 such records and reports are necessary in order to
11 enable the Administrator to determine, or facilitate
12 a determination of, whether there is or may be
13 grounds for withdrawing or temporarily suspending
14 such order.

15 (2) ACCESS TO RECORDS.—Each person re-
16 quired under this section to maintain records, and
17 each person in charge of custody thereof, shall, upon
18 request of an officer or employee designated by the
19 Administrator, permit such officer or employee at all
20 reasonable times to have access to and copy and
21 verify such records.

22 (g) INVESTIGATIONAL SMOKING ARTICLE EXEMP-
23 TION FOR INVESTIGATIONAL USE.—The Administrator
24 may exempt smoking articles intended for investigational

1 use from the provisions of this Act under such conditions
2 as the Administrator may by regulation prescribe.

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

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

8 (b) DEFINITIONS.—In this section:

9 (1) MODIFIED RISK TOBACCO PRODUCT.—The
10 term "modified risk tobacco product" means any to-
11 bacco product that is sold or distributed for use to
12 reduce harm or the risk of tobacco-related disease
13 associated with commercially marketed tobacco prod-
14 ucts.

15 (2) SOLD OR DISTRIBUTED.—

16 (A) IN GENERAL.—With respect to a to-
17 bacco product, the term "sold or distributed for
18 use to reduce harm or the risk of tobacco-re-
19 lated disease associated with commercially mar-
20 keted tobacco products" means a tobacco prod-
21 uct—

22 (i) the label, labeling, or advertising of
23 which represents explicitly or implicitly
24 that—

1 (I) the tobacco product presents
2 a lower risk of tobacco-related disease
3 or is less harmful than one or more
4 other commercially marketed tobacco
5 products;
6 (II) the tobacco product or its
7 smoke contains a reduced level of a
8 substance or presents a reduced expo-
9 sure to a substance; or
10 (III) the tobacco product or its
11 smoke does not contain or is free of a
12 substance;
13 (ii) the label, labeling, or advertising
14 of which uses the descriptors "light",
15 "mild", "low", "medium", "ultra light",
16 "low tar" or "ultra low tar"; or
17 (iii) the tobacco product manufacturer
18 of which has taken any action directed to
19 consumers through the media or otherwise,
20 other than by means of the tobacco prod-
21 uct's label, labeling, or advertising, after
22 the date of enactment of the Act, respect-
23 ing the product that would be reasonably
24 expected to result in consumers believing
25 that the tobacco product or its smoke may

1 present a lower risk of disease or is less
2 harmful than one or more commercially
3 marketed tobacco products, or presents a
4 reduced exposure to, or does not contain or
5 is free of, a substance or substances.
6 (B) LIMITATION.—No tobacco product
7 shall be considered to be "sold or distributed
8 for use to reduce harm or the risk of tobacco-
9 related disease associated with commercially
10 marketed tobacco products", except as de-
11 scribed in subparagraph (A).
12 (C) SMOKELESS TOBACCO PRODUCT.—No
13 smokeless tobacco product shall be considered
14 to be "sold or distributed for use to reduce
15 harm or the risk of tobacco-related disease as-
16 sociated with commercially marketed tobacco
17 products".
18 (3) EFFECTIVE DATE.—The provisions of para-
19 graph (2)(A)(ii) shall take effect 12 months after
20 the date of enactment of the Act.
21 (c) TOBACCO DEPENDENCE PRODUCTS.—A product
22 that is intended to be used for the treatment of tobacco
23 dependence, including smoking cessation, is not a modified
24 risk tobacco product under this section if it has been ap-

1 proved as a drug or device by the Center and is subject
2 to the requirements of chapter V.
3 (d) FILING.—Any person may file with the Adminis-
4 trator an application for a modified risk tobacco product.
5 Such application shall include—
6 (1) a description of the proposed product and
7 any proposed advertising and labeling;
8 (2) the conditions for using the product;
9 (3) the formulation of the product;
10 (4) sample product labels and labeling;
11 (5) all documents (including underlying sci-
12 entific information) relating to research findings
13 conducted, supported, or possessed by the tobacco
14 product manufacturer relating to the effect of the
15 product on tobacco-related diseases and health-re-
16 lated conditions, including information both favor-
17 able and unfavorable to the ability of the product to
18 reduce risk or exposure and relating to human
19 health;
20 (6) data and information on how consumers ac-
21 tually use the tobacco product; and
22 (7) such other information as the Administrator
23 may require.
24 (e) PUBLIC AVAILABILITY.—The Administrator shall
25 make the application described in subsection (d) publicly

1 available (except matters in the application which are
2 trade secrets or otherwise confidential, commercial infor-
3 mation) and shall request comments by interested persons
4 on the information contained in the application and on the
5 label, labeling, and advertising accompanying such appli-
6 cation.

7 (f) ADVISORY COMMITTEE.—

8 (1) IN GENERAL.—The Administrator shall
9 refer to the Tobacco Products Scientific Advisory
10 Committee any application submitted under this sec-
11 tion.

12 (2) RECOMMENDATIONS.—Not later than 60
13 days after the date an application is referred to the
14 Tobacco Products Scientific Advisory Committee
15 under paragraph (1), the Advisory Committee shall
16 report its recommendations on the application to the
17 Administrator.

18 (g) MARKETING.—

19 (1) MODIFIED RISK PRODUCTS.—Except as
20 provided in paragraph (2), the Administrator shall,
21 with respect to an application submitted under this
22 section, issue an order that a modified risk product
23 may be commercially marketed only if the Adminis-
24 trator determines that the applicant has dem-

1 onstrated that such product, as it is actually used by
2 consumers, will—
3 (A) significantly reduce harm and the risk
4 of tobacco-related disease to individual tobacco
5 users; and
6 (B) is reasonably likely to result in meas-
7 urable and substantial reductions in morbidity
8 and mortality among individual tobacco users.
9 (2) SPECIAL RULE FOR CERTAIN PRODUCTS.—
10 (A) IN GENERAL.—The Administrator may
11 issue an order that a tobacco product may be
12 introduced or delivered for introduction into
13 interstate commerce, pursuant to an application
14 under this section, with respect to a tobacco
15 product that may not be commercially marketed
16 under paragraph (1) if the Secretary makes the
17 findings required under this paragraph and de-
18 termines that the applicant has demonstrated
19 that—
20 (i) such order would be appropriate to
21 promote the public health;
22 (ii) any aspect of the label, labeling,
23 and advertising for such product that
24 would cause the tobacco product to be a
25 modified risk tobacco product under sub-

1 section (b) is limited to an explicit or im-
2 plicit representation that such tobacco
3 product or its smoke does not contain or is
4 free of a substance or contains a reduced
5 level of a substance, or presents a reduced
6 exposure to a substance in tobacco smoke;
7 (iii) scientific evidence is not available
8 and, using the best available scientific
9 methods, cannot be made available without
10 conducting long-term epidemiological stud-
11 ies for an application to meet the stand-
12 ards set forth in paragraph (1); and
13 (iv) the scientific evidence that is
14 available without conducting long-term epi-
15 demiological studies demonstrates that a
16 measurable and substantial reduction in
17 morbidity or mortality among individual
18 tobacco users is reasonably likely in subse-
19 quent studies.
20 (B) ADDITIONAL FINDINGS REQUIRED.—
21 To issue an order under subparagraph (A) the
22 Administrator must also find that the applicant
23 has demonstrated that—
24 (i) the magnitude of the overall reduc-
25 tions in exposure to the substance or sub-

1 stances which are the subject of the appli-
2 cation is substantial, such substance or
3 substances are harmful, and the product as
4 actually used exposes consumers to the
5 specified reduced level of the substance or
6 substances;
7 (ii) the product as actually used by
8 consumers will not expose them to higher
9 levels of other harmful substances com-
10 pared to the similar types of tobacco prod-
11 ucts then on the market unless such in-
12 creases are minimal and the reasonably
13 likely overall impact of use of the product
14 remains a substantial and measurable re-
15 duction in overall morbidity and mortality
16 among individual tobacco users;
17 (iii) testing of actual consumer per-
18 ception shows that, as the applicant pro-
19 poses to label and market the product, con-
20 sumers will not be misled into believing
21 that the product—
22 (I) is or has been demonstrated
23 to be significantly less harmful; or
24 (II) presents or has been dem-
25 onstrated to present significant less of

1 a risk of disease than other commer-
2 cially marketed tobacco products; and
3 (iv) issuance of an order with respect
4 to the application is expected to benefit the
5 health of users of tobacco products.
6 (3) BASIS.—The determinations under para-
7 graphs (1) and (2) shall be based on—
8 (A) the scientific evidence submitted by the
9 applicant; and
10 (B) scientific evidence and other informa-
11 tion that is made available to the Adminis-
12 trator.
13 (h) ADDITIONAL CONDITIONS FOR MARKETING.—
14 (1) MODIFIED RISK PRODUCTS.—The Adminis-
15 trator shall require for the marketing of a product
16 under this section that any advertising or labeling
17 concerning modified risk products enable the public
18 to comprehend the information concerning modified
19 risk and to understand the relative significance of
20 such information in the context of total health and
21 in relation to all of the diseases and health-related
22 conditions associated with the use of tobacco prod-
23 ucts.
24 (2) COMPARATIVE CLAIMS.—

1 (A) IN GENERAL.—The Administrator may
2 require for the marketing of a product under
3 this subsection that a claim comparing a to-
4 bacco product to other commercially marketed
5 tobacco products shall compare the tobacco
6 product to a commercially marketed tobacco
7 product that is representative of that type of to-
8 bacco product on the market (for example the
9 average value of the top 3 brands of an estab-
10 lished regular tobacco product).
11 (B) QUANTITATIVE COMPARISONS.—The
12 Administrator may also require, for purposes of
13 subparagraph (A), that the percent (or fraction)
14 of change and identity of the reference tobacco
15 product and a quantitative comparison of the
16 amount of the substance claimed to be reduced
17 shall be stated in immediate proximity to the
18 most prominent claim.
19 (i) POSTMARKET SURVEILLANCE AND STUDIES.—
20 (1) IN GENERAL.—The Administrator shall re-
21 quire, with respect to a product for which an appli-
22 cant obtained an order under subsection (g)(1), that
23 the applicant conduct postmarket surveillance and
24 studies for such a tobacco product to determine the
25 impact of the order issuance on consumer percep-

1 tion, behavior, and health, to enable the Adminis-
2 trator to review the accuracy of the determinations
3 upon which the order was based, and to provide in-
4 formation that the Administrator determines is oth-
5 erwise necessary regarding the use or health risks
6 involving the tobacco product. The results of
7 postmarket surveillance and studies shall be sub-
8 mitted to the Administrator on an annual basis.
9 (2) SURVEILLANCE PROTOCOL.—Each appli-
10 cant required to conduct a surveillance of a tobacco
11 product under paragraph (1) shall, within 30 days
12 after receiving notice that the applicant is required
13 to conduct such surveillance, submit, for the ap-
14 proval of the Administrator, a protocol for the re-
15 quired surveillance. The Administrator, within 30
16 days of the receipt of such protocol, shall determine
17 if the principal investigator proposed to be used in
18 the surveillance has sufficient qualifications and ex-
19 perience to conduct such surveillance and if such
20 protocol will result in collection of the data or other
21 information designated by the Administrator as nec-
22 essary to protect the public health.
23 (j) WITHDRAWAL OF AUTHORIZATION.—The Admin-
24 istrator, after an opportunity for an informal hearing,

1 shall withdraw an order under subsection (g) if the Ad-
2 ministrator determines that—
3 (1) the applicant, based on new information,
4 can no longer make the demonstrations required
5 under subsection (g), or the Administrator can no
6 longer make the determinations required under sub-
7 section (g);
8 (2) the application failed to include material in-
9 formation or included any untrue statement of mate-
10 rial fact;
11 (3) any explicit or implicit representation that
12 the product reduces risk or exposure is no longer
13 valid, including if—
14 (A) a tobacco product standard is estab-
15 lished pursuant to section 111;
16 (B) an action is taken that affects the
17 risks presented by other commercially marketed
18 tobacco products that were compared to the
19 product that is the subject of the application; or
20 (C) any postmarket surveillance or studies
21 reveal that the order is no longer consistent
22 with the protection of the public health;
23 (4) the applicant failed to conduct or submit
24 the postmarket surveillance and studies required
25 under subsection (g)(2)(C)(ii) or subsection (i); or

1 (5) the applicant failed to meet a condition im-
2 posed under subsection (h).
3 (k) CHAPTER IV OR V.—A product for which the Ad-
4 ministrator has issued an order pursuant to subsection (g)
5 shall not be subject to chapter IV or V of the Federal
6 Food, Drug, and Cosmetic Act.
7 (l) IMPLEMENTING REGULATIONS OR GUIDANCE.—
8 (1) SCIENTIFIC EVIDENCE.—Not later than 2
9 years after the date of enactment of the Act, the Ad-
10 ministrator shall issue regulations or guidance (or
11 any combination thereof) on the scientific evidence
12 required for assessment and ongoing review of modi-
13 fied risk tobacco products. Such regulations or guid-
14 ance shall—
15 (A) to the extent that adequate scientific
16 evidence exists, establish minimum standards
17 for scientific studies needed prior to issuing an
18 order under subsection (g) to show a reasonable
19 likelihood that a substantial reduction in mor-
20 bidity or mortality among individual tobacco
21 users occurs for products described in sub-
22 section (g)(1) or is reasonably likely for prod-
23 ucts described in subsection (g)(2);

1 (B) include validated biomarkers, inter-
2 mediate clinical endpoints, and other feasible
3 outcome measures, as appropriate;
4 (C) establish minimum standards for
5 postmarket studies, that shall include regular
6 and long-term assessments of health outcomes
7 and mortality, intermediate clinical endpoints,
8 consumer perception of harm reduction, and the
9 impact on quitting behavior and new use of to-
10 bacco products, as appropriate;
11 (D) establish minimum standards for re-
12 quired postmarket surveillance, including ongo-
13 ing assessments of consumer perception; and
14 (E) establish a reasonable timetable for the
15 Administrator to review an application under
16 this section.
17 (2) CONSULTATION.—The regulations or guid-
18 ance issued under paragraph (1) may be developed
19 in consultation with the Institute of Medicine, and
20 with the input of other appropriate scientific and
21 medical experts, on the design and conduct of such
22 studies and surveillance.
23 (3) REVISION.—The regulations or guidance
24 under paragraph (1) shall be revised on a regular

1 basis as new scientific information becomes avail-
2 able.
3 (4) NEW TOBACCO PRODUCTS.—Not later than
4 2 years after the date of enactment of the Act, the
5 Administrator shall issue a regulation or guidance
6 that permits the filing of a single application for any
7 tobacco product that is a new tobacco product under
8 section 114 and which the applicant seeks to com-
9 mercially market under this section.
10 **SEC. 116. JUDICIAL REVIEW.**
11 (a) RIGHT TO REVIEW.—
12 (1) IN GENERAL.—Not later than 60 days
13 after—
14 (A) the promulgation of a regulation under
15 section 111 establishing, amending, or revoking
16 a tobacco product standard; or
17 (B) a denial of an application under sec-
18 tion 114(c),
19 any person adversely affected by such regulation or
20 denial may file a petition for judicial review of such
21 regulation or denial with the United States Court of
22 Appeals for the District of Columbia or for the cir-
23 cuit in which such person resides or has their prin-
24 cipal place of business.
25 (2) REQUIREMENTS.—

1 (A) COPY OF PETITION.—A copy of the pe-
2 tition filed under paragraph (1) shall be trans-
3 mitted by the clerk of the court involved to the
4 Administrator.
5 (B) RECORD OF PROCEEDINGS.—On re-
6 ceipt of a petition under subparagraph (A), the
7 Administrator shall file in the court in which
8 such petition was filed—
9 (i) the record of the proceedings on
10 which the regulation or order was based;
11 and
12 (ii) a statement of the reasons for the
13 issuance of such a regulation or order.
14 (C) DEFINITION OF RECORD.—In this sec-
15 tion, the term "record" means—
16 (i) all notices and other matter pub-
17 lished in the Federal Register with respect
18 to the regulation or order reviewed;
19 (ii) all information submitted to the
20 Administrator with respect to such regula-
21 tion or order;
22 (iii) proceedings of any panel or advi-
23 sory committee with respect to such regu-
24 lation or order;

1 (iv) any hearing held with respect to
2 such regulation or order; and
3 (v) any other information identified by
4 the Administrator, in the administrative
5 proceeding held with respect to such regu-
6 lation or order, as being relevant to such
7 regulation or order.
8 (b) STANDARD OF REVIEW.—Upon the filing of the
9 petition under subsection (a) for judicial review of a regu-
10 lation or order, the court shall have jurisdiction to review
11 the regulation or order in accordance with chapter 7 of
12 title 5, United States Code, and to grant appropriate re-
13 lief, including interim relief, as provided for in such chap-
14 ter. A regulation or denial described in subsection (a) shall
15 be reviewed in accordance with section 706(2)(A) of title
16 5, United States Code.
17 (c) FINALITY OF JUDGMENT.—The judgment of the
18 court affirming or setting aside, in whole or in part, any
19 regulation or order shall be final, subject to review by the
20 Supreme Court of the United States upon certiorari or
21 certification, as provided in section 1254 of title 28,
22 United States Code.
23 (d) OTHER REMEDIES.—The remedies provided for
24 in this section shall be in addition to, and not in lieu of,
25 any other remedies provided by law.

1 (e) REGULATIONS AND ORDERS MUST RECITE BASIS
2 IN RECORD.—To facilitate judicial review, a regulation or
3 order issued under section 110, 111, 112, 113, 114, or
4 119 shall contain a statement of the reasons for the
5 issuance of such regulation or order in the record of the
6 proceedings held in connection with its issuance.

7 **SEC. 117. JURISDICTION OF AND COORDINATION WITH THE**
8 **FEDERAL TRADE COMMISSION.**

9 Except where expressly provided in this Act, nothing
10 in this Act shall be construed as limiting or diminishing
11 the authority of the Federal Trade Commission to enforce
12 the laws under its jurisdiction with respect to the adver-
13 tising, sale, or distribution of tobacco products.

14 **SEC. 118. REGULATION REQUIREMENT.**

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

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

21 (1) shall require annual testing and reporting of
22 tobacco product constituents, ingredients, and addi-
23 tives, including smoke constituents, by brand style
24 that the Administrator determines should be tested
25 to protect the public health, provided that, for pur-

1 poses of the testing requirements of this paragraph,
2 tobacco products manufactured and sold by a single
3 tobacco product manufacturer that are identical in
4 all respects except the labels, packaging design, logo,
5 trade dress, trademark, brand name, or any com-
6 bination thereof, shall be considered as a single
7 brand style; and
8 (2) may require that tobacco product manufac-
9 turers, packagers, or importers make disclosures re-
10 lating to the results of the testing of tar and nico-
11 tine through labels or advertising.
12 (c) AUTHORITY.—The Administrator shall have the
13 authority under this Act to conduct or to require the test-
14 ing, reporting, or disclosure of tobacco product constitu-
15 ents, including smoke constituents.
16 (d) JOINT LABORATORY TESTING SERVICES.—The
17 Administrator shall allow any 2 or more tobacco product
18 manufacturers to join together to purchase laboratory
19 testing services required by this section on a group basis
20 in order to ensure that such manufacturers receive access
21 to, and fair pricing of, such testing services.
22 (e) EXTENSIONS FOR LIMITED LABORATORY CAPAC-
23 ITY.—
24 (1) IN GENERAL.—The regulations promulgated
25 under subsection (a) shall provide that a tobacco

1 product manufacturer shall not be considered to be
2 in violation of this section before the applicable
3 deadline, if—
4 (A) the tobacco products of such manufac-
5 turer are in compliance with all other require-
6 ments of this Act; and
7 (B) the conditions described in paragraph
8 (2) are met.
9 (2) CONDITIONS.—Notwithstanding the require-
10 ments of this section, the Administrator may delay
11 the date by which a tobacco product manufacturer
12 must be in compliance with the testing and reporting
13 required by this section until such time as the test-
14 ing is reported if, not later than 90 days before the
15 deadline for reporting in accordance with this sec-
16 tion, a tobacco product manufacturer provides evi-
17 dence to the Administrator demonstrating that—
18 (A) the manufacturer has submitted the
19 required products for testing to a laboratory
20 and has done so sufficiently in advance of the
21 deadline to create a reasonable expectation of
22 completion by the deadline;
23 (B) the products currently are awaiting
24 testing by the laboratory; and

1 (C) neither that laboratory nor any other
2 laboratory is able to complete testing by the
3 deadline at customary, nonexpedited testing
4 fees.
5 (3) EXTENSION.—The Administrator, taking
6 into account the laboratory testing capacity that is
7 available to tobacco product manufacturers, shall re-
8 view and verify the evidence submitted by a tobacco
9 product manufacturer in accordance with paragraph
10 (2). If the Administrator finds that the conditions
11 described in such paragraph are met, the Adminis-
12 trator shall notify the tobacco product manufacturer
13 that the manufacturer shall not be considered to be
14 in violation of the testing and reporting require-
15 ments of this section until the testing is reported or
16 until 1 year after the reporting deadline has passed,
17 whichever occurs sooner. If, however, the Adminis-
18 trator has not made a finding before the reporting
19 deadline, the manufacturer shall not be considered
20 to be in violation of such requirements until the Ad-
21 ministrator finds that the conditions described in
22 paragraph (2) have not been met, or until 1 year
23 after the reporting deadline, whichever occurs soon-
24 er.

1 (4) ADDITIONAL EXTENSION.—In addition to
2 the time that may be provided under paragraph (3),
3 the Administrator may provide further extensions of
4 time, in increments of no more than 1 year, for re-
5 quired testing and reporting to occur if the Adminis-
6 trator determines, based on evidence properly and
7 timely submitted by a tobacco product manufacturer
8 in accordance with paragraph (2), that a lack of
9 available laboratory capacity prevents the manufac-
10 turer from completing the required testing during
11 the period described in paragraph (3).
12 (f) RULE OF CONSTRUCTION.—Nothing in subsection
13 (d) or (e) shall be construed to authorize the extension
14 of any deadline, or to otherwise affect any timeframe,
15 under any provision of this Act other than this section.
16 **SEC. 119. PRESERVATION OF STATE AND LOCAL AUTHOR-**
17 **ITY.**
18 (a) IN GENERAL.—
19 (1) PRESERVATION.—Except as provided in
20 paragraph (2)(A), nothing in this Act, or rules pro-
21 mulgated under this Act, shall be construed to limit
22 the authority of a Federal agency (including the
23 Armed Forces), a State or political subdivision of a
24 State, or the government of an Indian tribe to enact,
25 adopt, promulgate, and enforce any law, rule, regu-

1 lation, or other measure with respect to tobacco
2 products that is in addition to requirements estab-
3 lished under this Act, including a law, rule, regula-
4 tion, or other measure relating to or prohibiting the
5 sale, distribution, possession, or use of tobacco prod-
6 ucts by individuals of any age, information reporting
7 to the State. No provision of this Act shall limit or
8 otherwise affect any State, Tribal, or local taxation
9 of tobacco products.

10 (2) PREEMPTION OF CERTAIN STATE AND
11 LOCAL REQUIREMENTS.—

12 (A) IN GENERAL.—No State or political
13 subdivision of a State may establish or continue
14 in effect with respect to a tobacco product any
15 requirement which is different from, or in addi-
16 tion to, any requirement under the provisions of
17 this Act relating to tobacco product standards,
18 premarket review, adulteration, misbranding,
19 labeling, registration, good manufacturing
20 standards, or modified risk tobacco products.

21 (B) EXCEPTION.—Subparagraph (A) does
22 not apply to requirements relating to the sale,
23 distribution, possession, information reporting
24 to the State, use of, tobacco product by individ-
25 uals of any age. Information disclosed to a

1 State under subparagraph (A) that is exempt
2 from disclosure under section 552(b)(4) of title
3 5, United States Code, shall be treated as a
4 trade secret and confidential information by the
5 State.

6 (b) RULE OF CONSTRUCTION REGARDING PRODUCT
7 LIABILITY.—No provision of this Act relating to a tobacco
8 product shall be construed to modify or otherwise affect
9 any action or the liability of any person under the product
10 liability law of any State.

11 **SEC. 120. TOBACCO PRODUCTS SCIENTIFIC ADVISORY COM-**
12 **MITTEE.**

13 (a) ESTABLISHMENT.—Not later than 6 months after
14 the date of enactment of this Act, the Administrator shall
15 establish a 16-member advisory committee, to be known
16 as the Tobacco Products Scientific Advisory Committee
17 (in this section referred to as the "Advisory Committee").

18 (b) MEMBERSHIP.—

19 (1) IN GENERAL.—

20 (A) MEMBERS.—The Administrator shall
21 appoint as members of the Tobacco Harm Re-
22 duction Advisory Committee individuals who are
23 technically qualified by training and experience
24 in medicine, medical ethics, science, or tech-
25 nology involving the manufacture, evaluation, or

1 use of tobacco products, who are of appro-
2 priately diversified professional backgrounds.
3 The committee shall be composed of—
4 (i) 6 individuals who are physicians,
5 dentists, scientists, or health care profes-
6 sionals practicing in the area of oncology,
7 pulmonology, cardiology, toxicology, phar-
8 macology, addiction, or any other relevant
9 specialty;
10 (ii) 2 individuals who are an officer or
11 employee of a State or local government or
12 of the Federal Government;
13 (iii) 2 representatives of the general
14 public;
15 (iv) 2 representatives of the interests
16 of the tobacco manufacturing industry;
17 (v) 1 representative of the interests of
18 the small business tobacco manufacturing
19 industry, which position may be filled on a
20 rotating, sequential basis by representa-
21 tives of different small business tobacco
22 manufacturers based on areas of expertise
23 relevant to the topics being considered by
24 the Advisory Committee;

1 (vi) 1 individual as a representative of
2 the interests of the tobacco growers; and
3 (vii) 1 individual who is an expert in
4 illicit trade of tobacco products.
5 (B) CONFLICTS OF INTEREST.—No mem-
6 bers of the committee, other than members ap-
7 pointed pursuant to clauses (iv), (v), and (vi) of
8 subparagraph (A) shall, during the member's
9 tenure on the committee or for the 18-month
10 period prior to becoming such a member, re-
11 ceive any salary, grants, or other payments or
12 support from any business that manufactures,
13 distributes, markets, or sells cigarettes or other
14 tobacco products or government agency with
15 any form of jurisdiction over tobacco products.
16 (2) LIMITATION.—The Administrator may not
17 appoint to the Advisory Committee any individual
18 who is in the regular full-time employ of the To-
19 bacco Harm Reduction Center or any agency respon-
20 sible for the enforcement of this Act. The Admini-
21 strator may appoint Federal officials as ex officio
22 members.
23 (3) CHAIRPERSON.—The Administrator shall
24 designate 1 of the members appointed under clauses

1 (i), (ii), and (iii) of paragraph (1)(A) to serve as
2 chairperson.
3 (c) DUTIES.—The Tobacco Products Scientific Advi-
4 sory Committee shall provide advice, information, and rec-
5 ommendations to the Administrator—
6 (1) as provided in this Act;
7 (2) on the implementation of prevention, ces-
8 sation, and harm reduction policies;
9 (3) on implementation of policies and programs
10 to fully inform consumers of the respective risks of
11 tobacco products; and
12 (4) on its review of other safety, dependence, or
13 health issues relating to tobacco products as re-
14 quested by the Administrator.
15 (d) COMPENSATION; SUPPORT; FACA.—
16 (1) COMPENSATION AND TRAVEL.—Members of
17 the Advisory Committee who are not officers or em-
18 ployees of the United States, while attending con-
19 ferences or meetings of the committee or otherwise
20 engaged in its business, shall be entitled to receive
21 compensation at rates to be fixed by the Adminis-
22 trator, which may not exceed the daily equivalent of
23 the rate in effect under the Senior Executive Sched-
24 ule under section 5382 of title 5, United States
25 Code, for each day (including travel time) they are

1 so engaged; and while so serving away from their
2 homes or regular places of business each member
3 may be allowed travel expenses, including per diem
4 in lieu of subsistence, as authorized by section 5703
5 of title 5, United States Code, for persons in the
6 Government service employed intermittently.
7 (2) ADMINISTRATIVE SUPPORT.—The Adminis-
8 trator shall furnish the Advisory Committee clerical
9 and other assistance.
10 (3) NONAPPLICATION OF FACA.—Section 14 of
11 the Federal Advisory Committee Act does not apply
12 to the Advisory Committee.
13 (e) PROCEEDINGS OF ADVISORY PANELS AND COM-
14 MITTEES.—The Advisory Committee shall make and
15 maintain a transcript of any proceeding of the panel or
16 committee. Each such panel and committee shall delete
17 from any transcript made under this subsection informa-
18 tion which is exempt from disclosure under section 552(b)
19 of title 5, United States Code.
20 **SEC. 121. DRUG PRODUCTS USED TO TREAT TOBACCO DE-**
21 **PENDENCE.**
22 (a) REPORT ON INNOVATIVE PRODUCTS.—
23 (1) IN GENERAL.—Not later than 3 years after
24 the date of enactment of this Act, the Administrator,
25 after consultation with recognized scientific, medical,

1 and public health experts (including both Federal
2 agencies and nongovernmental entities, the Institute
3 of Medicine of the National Academy of Sciences,
4 and the Society for Research on Nicotine and To-
5 bacco), shall submit to the Congress a report that
6 examines how best to promote, and encourage the
7 development and use by current tobacco users of in-
8 novative tobacco and nicotine products and treat-
9 ments (including nicotine-based and non-nicotine-
10 based products and treatments) to better achieve, in
11 a manner that best protects and promotes the public
12 health—
13 (A) total abstinence from tobacco use;
14 (B) reductions in consumption of tobacco;
15 and
16 (C) reductions in the harm associated with
17 continued tobacco use by moving current users
18 to noncombustible tobacco products.
19 (2) RECOMMENDATIONS.—The report under
20 paragraph (1) shall include the recommendations of
21 the Administrator on how the Tobacco Harm and
22 Reduction Center should coordinate and facilitate
23 the exchange of information on such innovative
24 products and treatments among relevant offices and
25 centers within the Center and within the National

1 Institutes of Health, the Centers for Disease Control
2 and Prevention, and other relevant Federal and
3 State agencies.

4 **SEC. 122. ADVERTISING AND MARKETING OF TOBACCO**
5 **PRODUCTS.**

6 (a) Within 18 months of enactment of the Act, the
7 Administrator shall report to Congress on the benefits to
8 public health of imposing restrictions or prohibitions on
9 the advertising and marketing, consistent with or in addi-
10 tion to such restrictions or prohibitions contained in the
11 Master Settlement Agreement, on tobacco products.

12 (b) The Administrator shall specify in the report con-
13 stitutional free speech implications for each recommended
14 restriction or prohibition.

15 (c) The Administrator shall also specify the class of
16 tobacco products to which the prohibition or restriction
17 would be applicable and the impact of such actions on
18 harm reduction policies, practices, and accurate informa-
19 tion available to tobacco users.

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

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

SEC. 201. CIGARETTE LABEL AND ADVERTISING WARNINGS.

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

"SEC. 4. LABELING.

"(a) LABEL REQUIREMENTS.—

"(1) IN GENERAL.—It shall be unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any cigarettes the package of which fails to bear, in accordance with the requirements of this section, one of the following labels:

"WARNING: Cigarettes are addictive.

"WARNING: Tobacco smoke can harm your children.

"WARNING: Cigarettes cause fatal lung disease.

"WARNING: Cigarettes cause cancer.

"WARNING: Cigarettes cause strokes and heart disease.

1 "WARNING: Smoking during pregnancy
2 can harm your baby.
3 "WARNING: Smoking can kill you.
4 "WARNING: Tobacco smoke causes fatal
5 lung disease in nonsmokers.
6 "WARNING: Quitting smoking now great-
7 ly reduces serious risks to your health.
8 "(2) PLACEMENT; TYPOGRAPHY; ETC.—Each
9 label statement required by paragraph (1) shall be
10 located in the lower portion of the front panel of the
11 package, directly on the package underneath the cel-
12 lophane or other clear wrapping. Each label state-
13 ment shall comprise at least the bottom 25 percent
14 of the front panel of the package. The word
15 'WARNING' shall appear in capital letters and all
16 text shall be in conspicuous and legible 17-point
17 type, unless the text of the label statement would oc-
18 cupy more than 70 percent of such area, in which
19 case the text may be in a smaller conspicuous and
20 legible type size, provided that at least 60 percent of
21 such area is occupied by required text. The text shall
22 be black on a white background, or white on a black
23 background, in a manner that contrasts, by typog-
24 raphy, layout, or color, with all other printed mate-

1 rial on the package, in an alternating fashion under
2 the plan submitted under subsection (c).
3 "(3) DOES NOT APPLY TO FOREIGN DISTRIBU-
4 TION.—The provisions of this subsection do not
5 apply to a tobacco product manufacturer or dis-
6 tributor of cigarettes which does not manufacture,
7 package, or import cigarettes for sale or distribution
8 within the United States.
9 "(4) APPLICABILITY TO RETAILERS.—A retailer
10 of cigarettes shall not be in violation of this sub-
11 section for packaging that—
12 "(A) contains a warning label;
13 "(B) is supplied to the retailer by a
14 license- or permit-holding smoking article man-
15 ufacturer, importer, or distributor; and
16 "(C) is not altered by the retailer in a way
17 that is material to the requirements of this sub-
18 section.
19 "(b) ADVERTISING REQUIREMENTS.—
20 "(1) IN GENERAL.—It shall be unlawful for any
21 tobacco product manufacturer, importer, distributor,
22 or retailer of cigarettes to advertise or cause to be
23 advertised within the United States any cigarette
24 unless its advertising bears, in accordance with the

1 requirements of this section, one of the labels speci-
2 fied in subsection (a).
3 "(2) TYPOGRAPHY, ETC.—Each label statement
4 required by subsection (a) in cigarette advertising
5 shall comply with the standards set forth in this
6 paragraph. For press and poster advertisements,
7 each such statement and (where applicable) any re-
8 quired statement relating to tar, nicotine, or other
9 constituent (including a smoke constituent) yield
10 shall comprise at least 20 percent of the area of the
11 advertisement and shall appear in a conspicuous and
12 prominent format and location at the bottom of each
13 advertisement within the trim area. The word
14 'WARNING' shall appear in capital letters, and each
15 label statement shall appear in conspicuous and leg-
16 ible type. The text of the label statement shall be
17 black if the background is white and white if the
18 background is black, under the plan submitted under
19 subsection (c). The label statements shall be en-
20 closed by a rectangular border that is the same color
21 as the letters of the statements and that is the width
22 of the first downstroke of the capital 'W' of the word
23 'WARNING' in the label statements. The text of
24 such label statements shall be in a typeface pro rata
25 to the following requirements: 45-point type for a

1 whole-page broadsheet newspaper advertisement; 39-
2 point type for a half-page broadsheet newspaper ad-
3 vertisement; 39-point type for a whole-page tabloid
4 newspaper advertisement; 27-point type for a half-
5 page tabloid newspaper advertisement; 31.5-point
6 type for a double page spread magazine or whole-
7 page magazine advertisement; 22.5-point type for a
8 28 centimeter by 3 column advertisement; and 15-
9 point type for a 20 centimeter by 2 column adver-
10 tisement. The label statements shall be in English,
11 except that—
12 "(A) in the case of an advertisement that
13 appears in a newspaper, magazine, periodical,
14 or other publication that is not in English, the
15 statements shall appear in the predominant lan-
16 guage of the publication; and
17 "(B) in the case of any other advertise-
18 ment that is not in English, the statements
19 shall appear in the same language as that prin-
20 cipally used in the advertisement.
21 "(3) MATCHBOOKS.—Notwithstanding para-
22 graph (2), for matchbooks (defined as containing not
23 more than 20 matches) customarily given away with
24 the purchase of smokeless tobacco products, each

1 label statement required by subsection (a) may be
2 printed on the inside cover of the matchbook.
3 "(c) MARKETING REQUIREMENTS.—
4 "(1) RANDOM DISPLAY.—The label statements
5 specified in subsection (a)(1) shall be randomly dis-
6 played in each 12-month period, in as equal a num-
7 ber of times as is possible on each brand of the
8 product and be randomly distributed in all areas of
9 the United States in which the product is marketed
10 in accordance with a plan submitted by the smoke-
11 less tobacco product manufacturer, importer, dis-
12 tributor, or retailer and approved by the Secretary.
13 "(2) ROTATION.—The label statements speci-
14 fied in subsection (a)(1) shall be rotated quarterly in
15 alternating sequence in advertisements for each
16 brand of cigarettes in accordance with a plan sub-
17 mitted by the smokeless tobacco product manufac-
18 turer, importer, distributor, or retailer to, and ap-
19 proved by, the Secretary.
20 "(3) REVIEW.—The Secretary shall review each
21 plan submitted under paragraph (2) and approve it
22 if the plan—
23 "(A) will provide for the equal distribution
24 and display on packaging and the rotation re-
25 quired in advertising under this subsection; and

1 "(B) assures that all of the labels required
2 under this section will be displayed by the
3 smokeless tobacco product manufacturer, im-
4 porter, distributor, or retailer at the same time.
5 "(4) APPLICABILITY TO RETAILERS.—This sub-
6 section and subsection (b) apply to a retailer only if
7 that retailer is responsible for or directs the label
8 statements required under this section except that
9 this paragraph shall not relieve a retailer of liability
10 if the retailer displays, in a location open to the pub-
11 lic, an advertisement that does not contain a warn-
12 ing label or has been altered by the retailer in a way
13 that is material to the requirements of this sub-
14 section and subsection (b).".
15 (b) EFFECTIVE DATE.—The amendment made by
16 subsection (a) shall take effect 24 months after the date
17 of enactment of this Act. Such effective date shall be with
18 respect to the date of manufacture, provided that, in any
19 case, beginning 30 days after such effective date, a manu-
20 facturer shall not introduce into the domestic commerce
21 of the United States any product, irrespective of the date
22 of manufacture, that is not in conformance with section
23 4 of the Federal Cigarette Labeling and Advertising Act
24 (15 U.S.C. 1333), as amended by subsection (a).

1 **SEC. 202. SMOKELESS TOBACCO LABELS AND ADVERTISING**
2 **WARNINGS.**
3 (a) AMENDMENT.—Section 3 of the Comprehensive
4 Smokeless Tobacco Health Education Act of 1986 (15
5 U.S.C. 4402) is amended to read as follows:
6 **"SEC. 3. SMOKELESS TOBACCO WARNING.**
7 "(a) GENERAL RULE.—
8 "(1) It shall be unlawful for any person to man-
9 ufacture, package, sell, offer to sell, distribute, or
10 import for sale or distribution within the United
11 States any smokeless tobacco product unless the
12 product package bears, in accordance with the re-
13 quirements of this Act, one of the following labels:
14 "WARNING: This product can cause
15 mouth cancer.
16 "WARNING: This product can cause gum
17 disease and tooth loss.
18 "WARNING: This product has signifi-
19 cantly lower risks for diseases associated with
20 cigarettes.
21 "WARNING: Smokeless tobacco is addict-
22 ive.
23 "(2) The label statements required by para-
24 graph (1) shall be introduced by each smokeless to-
25 bacco product manufacturer, packager, importer,
26 distributor, or retailer of smokeless tobacco products

1 concurrently into the distribution chain of such
2 products.
3 "(3) The provisions of this subsection do not
4 apply to a smokeless tobacco product manufacturer
5 or distributor of any smokeless tobacco product that
6 does not manufacture, package, or import smokeless
7 tobacco products for sale or distribution within the
8 United States.
9 "(4) A retailer of smokeless tobacco products
10 shall not be in violation of this subsection for pack-
11 aging that—
12 "(A) contains a warning label;
13 "(B) is supplied to the retailer by a
14 license- or permit-holding smokeless tobacco
15 product manufacturer, importer, or distributor;
16 and
17 "(C) is not altered by the retailer in a way
18 that is material to the requirements of this sub-
19 section.
20 "(b) REQUIRED LABELS.—
21 "(1) It shall be unlawful for any smokeless to-
22 bacco product manufacturer, packager, importer,
23 distributor, or retailer of smokeless tobacco products
24 to advertise or cause to be advertised within the
25 United States any smokeless tobacco product unless

1 its advertising bears, in accordance with the require-
2 ments of this section, one of the labels specified in
3 subsection (a).

4 "(2)(A) Each label statement required by sub-
5 section (a) in smokeless tobacco advertising shall
6 comply with the standards set forth in this para-
7 graph.

8 "(B) For press and poster advertisements, each
9 such statement and (where applicable) any required
10 statement relating to nicotine, or other constituent
11 yield shall comprise at least 20 percent of the area
12 of the advertisement.

13 "(C) The word 'WARNING' shall appear in
14 capital letters, and each label statement shall appear
15 in conspicuous and legible type.

16 "(D) The text of the label statement shall be
17 black on a white background, or white on a black
18 background, in an alternating fashion under the
19 plan submitted under paragraph (3).

20 "(E) The label statements shall be enclosed by
21 a rectangular border that is the same color as the
22 letters of the statements and that is the width of the
23 first downstroke of the capital 'W' of the word
24 'WARNING' in the label statements.

1 "(F) The text of such label statements shall be
2 in a typeface pro rata to the following requirements:
3 45-point type for a whole-page broadsheet newspaper
4 advertisement; 39-point type for a half-page
5 broadsheet newspaper advertisement; 39-point type
6 for a whole-page tabloid newspaper advertisement;
7 27-point type for a half-page tabloid newspaper ad-
8 vertisement; 31.5-point type for a double page
9 spread magazine or whole-page magazine advertise-
10 ment; 22.5-point type for a 28 centimeter by 3 col-
11 umn advertisement; and 15-point type for a 20 cen-
12 timeter by 2 column advertisement.
13 "(G) The label statements shall be in English,
14 except that—
15 "(i) in the case of an advertisement that
16 appears in a newspaper, magazine, periodical,
17 or other publication that is not in English, the
18 statements shall appear in the predominant lan-
19 guage of the publication; and
20 "(ii) in the case of any other advertisement
21 that is not in English, the statements shall ap-
22 pear in the same language as that principally
23 used in the advertisement.
24 "(3)(A) The label statements specified in sub-
25 section (a)(1) shall be randomly displayed in each

1 12-month period, in as equal a number of times as
2 is possible on each brand of the product and be ran-
3 domly distributed in all areas of the United States
4 in which the product is marketed in accordance with
5 a plan submitted by the smokeless tobacco product
6 manufacturer, importer, distributor, or retailer and
7 approved by the Secretary.

8 "(B) The label statements specified in sub-
9 section (a)(1) shall be rotated quarterly in alter-
10 nating sequence in advertisements for each brand of
11 smokeless tobacco product in accordance with a plan
12 submitted by the smokeless tobacco product manu-
13 facturer, importer, distributor, or retailer to, and ap-
14 proved by, the Secretary.

15 "(C) The Secretary shall review each plan sub-
16 mitted under subparagraphs (A) and (B) and ap-
17 prove it if the plan—

18 "(i) will provide for the equal distribution
19 and display on packaging and the rotation re-
20 quired in advertising under this subsection; and

21 "(ii) assures that all of the labels required
22 under this section will be displayed by the
23 smokeless tobacco product manufacturer, im-
24 porter, distributor, or retailer at the same time.

1 "(D) This paragraph applies to a retailer only
2 if that retailer is responsible for or directs the label
3 statements under this section, unless the retailer dis-
4 plays, in a location open to the public, an advertise-
5 ment that does not contain a warning label or has
6 been altered by the retailer in a way that is material
7 to the requirements of this subsection.
8 "(c) TELEVISION AND RADIO ADVERTISING.—It is
9 unlawful to advertise smokeless tobacco on any medium
10 of electronic communications subject to the jurisdiction of
11 the Federal Communications Commission.".
12 (b) EFFECTIVE DATE.—The amendment made by
13 subsection (a) shall take effect 24 months after the date
14 of enactment of this Act. Such effective date shall be with
15 respect to the date of manufacture, provided that, in any
16 case, beginning 30 days after such effective date, a manu-
17 facturer shall not introduce into the domestic commerce
18 of the United States any product, irrespective of the date
19 of manufacture, that is not in conformance with section
20 3 of the Comprehensive Smokeless Tobacco Health Edu-
21 cation Act of 1986 (15 U.S.C. 4402), as amended by sub-
22 section (a).

TITLE III—PUBIC DISCLOSURES BY TOBACCO PRODUCTS MANUFACTURERS

SEC. 301. DISCLOSURES ON PACKAGES OF TOBACCO PRODUCTS.

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

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

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

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

(4) the back face shall be the principal face of a package that is opposite the front face of the package;

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

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

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

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

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

20 (3) the appropriate tax registration number.

21 (c) PACKAGE DISCLOSURE OF INGREDIENTS.—Not
22 later than 24 months after the effective date of this Act,
23 the package of a tobacco product shall bear a list of the
24 common or usual names of the ingredients present in the
25 tobacco product in an amount greater than 0.1 percent

1 of the total dry weight of the tobacco (including all ingre-
2 dients), that shall comply with the following:
3 (1) Such listing of ingredients shall appear
4 under, or be conspicuously accompanied by, the
5 heading "Tobacco and principal tobacco ingredi-
6 ents".
7 (2) Tobacco may be listed as "tobacco," and
8 shall be the first listed ingredient.
9 (3) After tobacco, the ingredients shall be listed
10 in descending order of predominance, by weight.
11 (4) Spices and natural and artificial flavors
12 may be listed, respectively, as "spices" and "natural
13 and artificial flavors" without naming each.
14 (5) Preservatives may be listed as "preserva-
15 tives" without naming each.
16 (6) The disclosure of any ingredient in accord-
17 ance with this section may, at the option of the to-
18 bacco product manufacturer, designate the
19 functionality or purpose of that ingredient.
20 (7) The package say state "Not for sale to mi-
21 nors".
22 (8) In the case of a package of cigarettes, the
23 package shall state that smokeless tobacco has sig-
24 nificantly lower risks for disease and death than
25 cigarettes.

1 **SEC. 302. DISCLOSURES ON PACKAGES OF SMOKELESS TO-**
2 **BACCO.**

3 (a) BACK FACE FOR REQUIRED DISCLOSURES.—For
4 purposes of this section—

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

11 (2) the front or top face shall be the principal
12 face of the package;

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

16 (4) the back or bottom face of the package shall
17 be the principal face of a package that is opposite
18 the front or top face of the package;

19 (5) beginning 24 months after the effective date
20 of this Act, 50 percent of the back or bottom face
21 of the package shall be allocated for required pack-
22 age disclosures in accordance with this section; and

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

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

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

16 (1) Such listing of ingredients shall appears
17 under, or be conspicuously accompanied by, the
18 heading "Tobacco and principal tobacco ingredi-
19 ents".

20 (2) Tobacco may be listed as "tobacco," and
21 shall be the first listed ingredient.

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

1 (4) Spices and natural and artificial flavors
2 may be listed, respectively, as "spices" and "natural
3 and artificial flavors" without naming each.
4 (5) Preservatives may be listed as "preserva-
5 tives" without naming each.
6 (6) The disclosure of any ingredient in accord-
7 ance with this section may, at the option of the to-
8 bacco product manufacturer, designate the
9 functionality or purpose of that ingredient.
10 (7) Not for sale to minors.

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

12 (a) REGULATIONS.—Not later than 24 months after
13 the effective date of this Act, the Administrator shall, by
14 regulation, establish standards under which each tobacco
15 product manufacturer shall disclose publicly, and update
16 at least annually—
17 (1) a list of the ingredients it uses in each
18 brand style it manufactures for commercial distribu-
19 tion domestically, as provided in subsection (b); and
20 (2) a composite list of all the ingredients it uses
21 in any of the brand styles it manufactures for com-
22 mercial distribution domestically, as provided in sub-
23 section (c).
24 (b) INGREDIENTS TO BE DISCLOSED AS TO EACH
25 BRAND STYLE.—

1 (1) IN GENERAL.—With respect to the public
2 disclosure required by subsection (a)(1), as to each
3 brand style, the tobacco product manufacture shall
4 disclose the common or usual name of each ingre-
5 dient present in the brand style in an amount great-
6 er than 0.1 percent of the total dry weight of the to-
7 bacco (including all ingredients).
8 (2) REQUIREMENTS.—Disclosure under para-
9 graph (1) shall comply with the following:
10 (A) Tobacco may be listed as "tobacco,"
11 and shall be the first listed ingredient.
12 (B) After tobacco, the ingredients shall be
13 listed in descending order of predominance, by
14 weight.
15 (C) Spices and natural and artificial fla-
16 vors may be listed, respectively, as "spices" and
17 "natural and artificial flavors" without naming
18 each.
19 (D) Preservatives may be listed as "pre-
20 servatives" without naming each.
21 (E) The disclosure of any ingredient in ac-
22 cordance with this section may, at the option of
23 the tobacco product manufacturer, designate
24 the functionality or purpose of that ingredient.
25 (c) AGGREGATE DISCLOSURE OF INGREDIENTS.—

1 (1) IN GENERAL.—The public disclosure re-
2 quired of a tobacco product manufacturer by sub-
3 section (a)(2) shall consist of a single list of all in-
4 gredients used in any brand style a tobacco product
5 manufacturer manufactures for commercial distribu-
6 tion domestically, without regard to the quantity
7 used, and including, separately, each spice, each nat-
8 ural or artificial flavoring, and each preservative.
9 (2) LISTING.—The ingredients shall be listed by
10 their respective common or usual names in descend-
11 ing order of predominance by the total weight used
12 annually by the tobacco product manufacturer in
13 manufacturing tobacco products for commercial dis-
14 tribution domestically.
15 (d) NO REQUIRED DISCLOSURE OF QUANTITIES.—
16 The Administrator shall not require any public disclosure
17 of quantitative information about any ingredient in a to-
18 bacco product.
19 (e) DISCLOSURE ON WEBSITE.—The public disclo-
20 sures required by subsection (a) of this section may be
21 by posting on an Internet-accessible website, or other loca-
22 tion electronically accessible to the public, which is identi-
23 fied on all packages of a tobacco product manufacturer's
24 tobacco products.

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

5 TITLE IV—PREVENTION OF IL-
6 LICIT TRADE IN TOBACCO
7 PRODUCTS

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

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

15 (1) collect data on such trade in tobacco prod-
16 ucts, including illicit trade involving tobacco prod-
17 ucts, and make recommendations on the monitoring
18 and enforcement of such trade;

19 (2) collect data on any advertising intended to
20 be broadcast, transmitted, or distributed from or to
21 the United States from or to another country and
22 make recommendations on how to prevent or elimi-
23 nate, and what technologies could help facilitate the
24 elimination of, such advertising; and

1 (3) collect data on such trade in tobacco prod-
2 ucts by person that is not—
3 (A) a participating manufacturer (as that
4 term is defined in section II(jj) of the Master
5 Settlement Agreement of November 23, 1998,
6 between certain of the States and certain to-
7 bacco product manufacturers); or
8 (B) an affiliate or subsidiary of a partici-
9 pating manufacturer.
10 (b) Not later than 18 months after the effective date
11 of this Act, the Administrator shall submit to the Sec-
12 retary, and committees of relevant jurisdiction in Con-
13 gress, a report the recommendations of the study con-
14 ducted under subsection (a).

15 **SEC. 402. AMENDMENT TO SECTION 1926 OF THE PUBLIC**
16 **HEALTH SERVICE ACT.**

17 Section 1926 of the Public Health Service Act (42
18 U.S.C. § 300x–26) is amended by adding at the end there-
19 of the following:
20 "(e)(1) Subject to paragraphs (2) and (3), for the
21 first fiscal year after enactment and each subsequent fiscal
22 year, the Secretary shall reduce, as provided in subsection
23 (h), the amount of any grant under section 300x–21 of
24 this title for any State that does not have in effect a stat-
25 ute with substantially the following provisions:

1 **"'SEC. 1. DISTRIBUTION TO MINORS.**

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

8 "'(b) The employer of an employee who has violated
9 subsection (a) twice while in the employ of such employer
10 is liable for a civil money penalty of $125 for each subse-
11 quent violation by such employee.

12 "'(c) It shall be a defense to a charge brought under
13 subsection (a) that—

14 "'(1) the defendant—

15 "'(A) relied upon proof of age that ap-
16 peared on its face to be valid in accordance with
17 the Federal Tobacco Act of 2007;

18 "'(B) had complied with the requirements
19 of section 5 and, if applicable, section 7; or

20 "'(C) relied upon a commercially available
21 electronic age verification service to confirm
22 that the person was an age-verified adult; or

23 "'(2) the individual to whom the tobacco prod-
24 uct was distributed was at the time of the distribu-
25 tion used in violation of subsection 8(b).

1 **"'SEC. 2. PURCHASE, RECEIPT, OR POSSESSION BY MINORS**
2 **PROHIBITED.**

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

15 "'(b) A law enforcement agency, upon determining
16 that an individual under 18 years of age or a different
17 minimum age established under State law allegedly pur-
18 chased, received, possessed, or attempted to purchase, re-
19 ceive, or possess, a tobacco product in violation of sub-
20 section (a) shall notify the individual's parent or parents,
21 custodian, or guardian as to the nature of the alleged vio-
22 lation if the name and address of a parent or parents,
23 guardian, or custodian is reasonably ascertainable by the
24 law enforcement agency. The notice required by this sub-
25 section shall be made not later than 48 hours after the
26 individual who allegedly violated subsection (a) is cited by

1 such agency for the violation. The notice may be made
2 by any means reasonably calculated to give prompt actual
3 notice, including notice in person, by telephone, or by first-
4 class mail.

5 "'(c) Subsection (a) does not prohibit an individual
6 under 18 years of age or a different minimum age estab-
7 lished under State law from possessing a tobacco product
8 during regular working hours and in the course of such
9 individual's employment if the tobacco product is not pos-
10 sessed for such individual's consumption.

11 **"'SEC. 3. OUT-OF-PACKAGE DISTRIBUTION.**

12 "'It shall be unlawful for any person to distribute
13 cigarettes or a smokeless tobacco product other than in
14 an unopened package that complies in full with section
15 108 of the Federal Tobacco Act of 2007. A person who
16 distributes a cigarette or a smokeless tobacco product in
17 violation of this section is liable for a civil money penalty
18 of not less than $25 nor more than $125 for each such
19 violation.

20 **"'SEC. 4. SIGNAGE.**

21 "'It shall be unlawful for any person who sells to-
22 bacco products over-the-counter to fail to post conspicu-
23 ously on the premises where such person sells tobacco
24 products over-the-counter a sign communicating that—

1 "'(1) the sale of tobacco products to individuals
2 under 18 years of age or a different minimum age
3 established under State law is prohibited by law;
4 "'(2) the purchase of tobacco products by indi-
5 viduals under 18 years of age or a different min-
6 imum age established under State law is prohibited
7 by law; and
8 "'(3) proof of age may be demanded before to-
9 bacco products are sold.
10 A person who fails to post a sign that complies fully with
11 this section is liable for a civil money penalty of not less
12 than $25 nor more than $125.
13 **"'SEC. 5. NOTIFICATION OF EMPLOYEES.**
14 "'(a) Within 180 days of the effective date of the
15 Youth Prevention and Tobacco Harm Reduction Act,
16 every person engaged in the business of selling tobacco
17 products at retail shall implement a program to notify
18 each employee employed by that person who sells tobacco
19 products at retail that—
20 "'(1) the sale or other distribution of tobacco
21 products to any individual under 18 years of age or
22 a different minimum age established under State
23 law, and the purchase, receipt, or possession of to-
24 bacco products in a place open to the public by any
25 individual under 18 years of age or a different min-

1 imum age established under State law, is prohibited;
2 and
3 "'(2) out-of-package distribution of cigarettes
4 and smokeless tobacco products is prohibited.
5 Any employer failing to provide the required notice to any
6 employee shall be liable for a civil money penalty of not
7 less than $25 nor more than $125 for each such violation.
8 "'(b) It shall be a defense to a charge that an em-
9 ployer violated subsection (a) of this section that the em-
10 ployee acknowledged receipt, either in writing or by elec-
11 tronic means, prior to the alleged violation, of a statement
12 in substantially the following form:
13 "I understand that State law prohibits the distribu-
14 tion of tobacco products to individuals under 18 years of
15 age or a different minimum age established under State
16 law and out-of-package distribution of cigarettes and
17 smokeless tobacco products, and permits a defense based
18 on evidence that a prospective purchaser's proof of age
19 was reasonably relied upon and appeared on its face to
20 be valid. I understand that if I sell, give, or voluntarily
21 provide a tobacco product to an individual under 18 years
22 of age or a different minimum age established under State
23 law, I may be found responsible for a civil money penalty
24 of not less than $25 nor more than $125 for each viola-
25 tion. I promise to comply with this law.'"

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

8 **"'SEC. 6. SELF-SERVICE DISPLAYS.**

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

15 "'(b) Any person who violates subsection (a) is liable
16 for a civil money penalty of not less than $25 nor more
17 than $125 for each such violation, except that no person
18 shall be responsible for more than one violation per day
19 at any one retail store.

20 **"'SEC. 7. DISTRIBUTION BY MAIL OR COURIER.**

21 "'(a) It shall be unlawful to distribute or sell tobacco
22 products directly to consumers by mail or courier, unless
23 the person receiving purchase requests for tobacco prod-
24 ucts takes reasonable action to prevent delivery to individ-
25 uals who are not adults by—

1 "'(1) requiring that addressees of the tobacco
2 products be age-verified adults;
3 "'(2) making good faith efforts to verify that
4 such addressees have attained the minimum age for
5 purchase of tobacco products established by the re-
6 spective States wherein the addresses of the address-
7 ees are located; and
8 "'(3) addressing the tobacco products delivered
9 by mail or courier to a physical addresses and not
10 to post office boxes.
11 "'(b) Any person who violates subsection (a) is liable
12 for a civil money penalty of not less than $25 nor more
13 than $125 for each such violation.
14 **"'SEC. 8. RANDOM UNANNOUNCED INSPECTIONS; REPORT-**
15 **ING; AND COMPLIANCE.**
16 "'(a) The State Police, or a local law enforcement
17 authority duly designated by the State Police, shall en-
18 force this Act in a manner that can reasonably be expected
19 to reduce the extent to which tobacco products are distrib-
20 uted to individuals under 18 years of age or a different
21 minimum age established under State law and shall con-
22 duct random, unannounced inspections in accordance with
23 the procedures set forth in this Act and in regulations
24 issued under section 1926 of the Federal Public Health
25 Service Act (42 U.S.C. § 300x–26).

1 "'(b) The State may engage an individual under 18
2 years of age or a different minimum age established under
3 State law to test compliance with this Act, except that
4 such an individual may be used to test compliance with
5 this Act only if the testing is conducted under the fol-
6 lowing conditions:

7 "'(1) Prior to use of any individual under 18
8 years of age or a different minimum age established
9 under State law in a random, unannounced inspec-
10 tion, written consent shall be obtained from a par-
11 ent, custodian, or guardian of such individual;

12 "'(2) An individual under 18 years of age or a
13 different minimum age established under State law
14 shall act solely under the supervision and direction
15 of the State Police or a local law enforcement au-
16 thority duly designated by the State Police during a
17 random, unannounced inspection;

18 "'(3) An individual under 18 years of age or a
19 different minimum age established under State law
20 used in random, unannounced inspections shall not
21 be used in any such inspection at a store in which
22 such individual is a regular customer; and

23 "'(4) If an individual under 18 years of age or
24 a different minimum age established under State law
25 participating in random, unannounced inspections is

1 questioned during such an inspection about such in-
2 dividual's age, such individual shall state his or her
3 actual age and shall present a true and correct proof
4 of age if requested at any time during the inspection
5 to present it.

6 "'(c) Any person who uses any individual under 18
7 years of age or a different minimum age established under
8 State law, other than as permitted by subsection (b), to
9 test compliance with this Act, is liable for a civil money
10 penalty of not less than $25 nor more than $125 for each
11 such violation.

12 "'(d) Civil money penalties collected for violations of
13 this Act and fees collected under section 9 shall be used
14 only to defray the costs of administration and enforcement
15 of this Act.

16 **"'SEC. 9. LICENSURE.**

17 "'(a) Each person engaged in the over-the-counter
18 distribution at retail of tobacco products shall hold a li-
19 cense issued under this section. A separate license shall
20 be required for each place of business where tobacco prod-
21 ucts are distributed at retail. A license issued under this
22 section is not assignable and is valid only for the person
23 in whose name it is issued and for the place of business
24 designated in the license.

1 "'(b) The annual license fee is $25 for each place
2 of business where tobacco products are distributed at re-
3 tail.

4 "'(c) Every application for a license, including re-
5 newal of a license, under this section shall be made upon
6 a form provided by the appropriate State agency or de-
7 partment, and shall set forth the name under which the
8 applicant transacts or intends to transact business, the lo-
9 cation of the place of business for which the license is to
10 be issued, the street address to which all notices relevant
11 to the license are to be sent (in this Act referred to as
12 "notice address"), and any other identifying information
13 that the appropriate State agency or department may re-
14 quire.

15 "'(d) The appropriate State agency or department
16 shall issue or renew a license or deny an application for
17 a license or the renewal of a license within 30 days of
18 receiving a properly completed application and the license
19 fee. The appropriate State agency or department shall
20 provide notice to an applicant of action on an application
21 denying the issuance of a license or refusing to renew a
22 license.

23 "'(e) Every license issued by the appropriate State
24 agency or department pursuant to this section shall be
25 valid for 1 year from the date of issuance and shall be

1 renewed upon application except as otherwise provided in
2 this Act.
3 "'(f) Upon notification of a change of address for a
4 place of business for which a license has been issued, a
5 license shall be reissued for the new address without the
6 filing of a new application.
7 "'(g) The appropriate State agency or department
8 shall notify every person in the State who is engaged in
9 the distribution at retail of tobacco products of the license
10 requirements of this section and of the date by which such
11 person should have obtained a license.
12 "'(h)(1) Except as provided in paragraph (2), any
13 person who engages in the distribution at retail of tobacco
14 products without a license required by this section is liable
15 for a civil money penalty in an amount equal to (i) two
16 times the applicable license fee, and (ii) $50 for each day
17 that such distribution continues without a license.
18 "'(2) Any person who engages in the distribu-
19 tion at retail of tobacco products after a license
20 issued under this section has been suspended or re-
21 voked is liable for a civil money penalty of $100 per
22 day for each day on which such distribution con-
23 tinues after the date such person received notice of
24 such suspension or revocation.

1 "'(i) No person shall engage in the distribution at
2 retail of tobacco products on or after 180 days after the
3 date of enactment this Act unless such person is author-
4 ized to do so by a license issued pursuant to this section
5 or is an employee or agent of a person that has been
6 issued such a license.

7 **"'SEC. 10. SUSPENSION, REVOCATION, DENIAL, AND NON-**
8 **RENEWAL OF LICENSES.**

9 "'(a) Upon a finding that a licensee has been deter-
10 mined by a court of competent jurisdiction to have violated
11 this Act during the license term, the State shall notify the
12 licensee in writing, served personally or by registered mail
13 at the notice address, that any subsequent violation of this
14 Act at the same place of business may result in an admin-
15 istrative action to suspend the license for a period deter-
16 mined by the specify the appropriate State agency or de-
17 partment.

18 "'(b) Upon finding that a further violation by this
19 Act has occurred involving the same place of business for
20 which the license was issued and the licensee has been
21 served notice once under subsection (a), the appropriate
22 State agency or department may initiate an administrative
23 action to suspend the license for a period to be determined
24 by the appropriate State agency or department but not
25 to exceed six months. If an administrative action to sus-

1 pend a license is initiated, the appropriate State agency
2 or department shall immediately notify the licensee in
3 writing at the notice address of the initiation of the action
4 and the reasons therefor and permit the licensee an oppor-
5 tunity, at least 30 days after written notice is served per-
6 sonally or by registered mail upon the licensee, to show
7 why suspension of the license would be unwarranted or
8 unjust.

9 "'(c) The appropriate State agency or department
10 may initiate an administrative action to revoke a license
11 that previously has been suspended under subsection (b)
12 if, after the suspension and during the one-year period for
13 which the license was issued, the licensee committed a fur-
14 ther violation of this Act, at the same place of business
15 for which the license was issued. If an administrative ac-
16 tion to revoke a license is initiated, the appropriate State
17 agency or department shall immediately notify the licensee
18 in writing at the notice address of the initiation of the
19 action and the reasons therefor and permit the licensee
20 an opportunity, at least 30 days after written notice is
21 served personally or by registered mail upon the licensee,
22 to show why revocation of the license would be unwar-
23 ranted or unjust.

24 "'(d) A person whose license has been suspended or
25 revoked with respect to a place of business pursuant to

1 this section shall pay a fee of $50 for the renewal or
2 reissuance of the license at that same place of business,
3 in addition to any applicable annual license fees.

4 "'(e) Revocation of a license under subsection (c)
5 with respect to a place of business shall not be grounds
6 to deny an application by any person for a new license
7 with respect to such place of business for more than 12
8 months subsequent to the date of such revocation. Revoca-
9 tion or suspension of a license with respect to a particular
10 place of business shall not be grounds to deny an applica-
11 tion for a new license, to refuse to renew a license, or to
12 revoke or suspend an existing license at any other place
13 of business.

14 "'(f) A licensee may seek judicial review of an action
15 of the appropriate State agency or department sus-
16 pending, revoking, denying, or refusing to renew a license
17 under this section by filing a complaint in a court of com-
18 petent jurisdiction. Any such complaint shall be filed with-
19 in 30 days after the date on which notice of the action
20 is received by the licensee. The court shall review the evi-
21 dence de novo.

22 "'(g) The State shall not report any action sus-
23 pending, revoking, denying, or refusing to renew a license
24 under this section to the Federal Secretary of Health and
25 Human Services, unless the opportunity for judicial review

1 of the action pursuant to subsection (f), if any, has been
2 exhausted or the time for seeking such judicial review has
3 expired.

4 **"'SEC. 11. NO PRIVATE RIGHT OF ACTION.**

5 "'Nothing in this Act shall be construed to create
6 a right of action by any private person for any violation
7 of any provision of this Act.

8 **"'SEC. 12. JURISDICTION AND VENUE.**

9 "'Any action alleging a violation of this Act may be
10 brought only in a court of general jurisdiction in the city
11 or county where the violation is alleged to have occurred.

12 **"'SEC. 13. REPORT.**

13 "'The appropriate State agency or department shall
14 prepare for submission annually to the Federal Secretary
15 of Health and Human Services the report required by sec-
16 tion 1926 of the Federal Public Health Service Act (42
17 U.S.C. 300x–26).'".

18 "(2) In the case of a State whose legislature
19 does not convene a regular session in fiscal year
20 2007, and in the case of a State whose legislature
21 does not convene a regular session in fiscal year
22 2008, the requirement described in subsection (e)(1)
23 as a condition of a receipt of a grant under section
24 300x–21 of this title shall apply only for fiscal year
25 2009 and subsequent fiscal years.

1 "(3) Subsection (e)(1) shall not affect any
2 State or local law that (A) was in effect on the date
3 of introduction of the Federal Tobacco Act of 2007,
4 and (B) covers the same subject matter as the law
5 described in subsection (e)(1). Any State law that
6 meets the conditions of this paragraph shall also be
7 deemed to meet the requirement described in sub-
8 section (e)(1) as a condition of a receipt of a grant
9 under section 300x–21 of this title, if such State law
10 is at least as stringent as the law described in sub-
11 section (e)(1).
12 "(f)(1) For the first applicable fiscal year and for
13 each subsequent fiscal year, a funding agreement for a
14 grant under section 300x–21 of this title is a funding
15 agreement under which the State involved will enforce the
16 law described in subsection (e)(1) of this section in a man-
17 ner that can reasonably be expected to reduce the extent
18 to which tobacco products are available to individuals
19 under the age of 18 or a different minimum age estab-
20 lished under State law for the purchase of tobacco prod-
21 ucts.
22 "(2) For the first applicable fiscal year and for each
23 subsequent fiscal year, a funding agreement for a grant
24 under section 300x–21 of this title is a funding agreement
25 under which the State involved will—

1 "(A) conduct random, unannounced inspections
2 to ensure compliance with the law described in sub-
3 section (e)(1); and
4 "(B) annually submit to the Secretary a report
5 describing—
6 "(i) the activities carried out by the State
7 to enforce such law during the fiscal year pre-
8 ceding the fiscal year for which the State is
9 seeking the grant;
10 "(ii) the extent of success the State has
11 achieved in reducing the availability of tobacco
12 products to individuals under 18 years of age or
13 a different minimum age established under
14 State law, including the results of the inspec-
15 tions conducted under subparagraph (A); and
16 "(iii) the strategies to be utilized by the
17 State for enforcing such law during the fiscal
18 year for which the grant is sought.
19 "(g) The law specified in subsection (e)(1) may be
20 administered and enforced by a State using—
21 "(1) any amounts made available to the State
22 through a grant under section 300x–21 of this title;
23 "(2) any amounts made available to the State
24 under section 300w of this title;

1 "(3) any fees collected for licenses issued pursu-
2 ant to the law described in subsection (e)(1);
3 "(4) any fines or penalties assessed for viola-
4 tions of the law specified in subsection (e)(1); or
5 "(5) any other funding source that the legisla-
6 ture of the State may prescribe by statute.
7 "(h) Before making a grant under section 300x–21
8 of this title to a State for the first applicable fiscal year
9 or any subsequent fiscal year, the Secretary shall make
10 a determination of whether the State has maintained com-
11 pliance with subsections (e) and (f) of this section. If, after
12 notice to the State and an opportunity for a hearing, the
13 Secretary determines that the State is not in compliance
14 with such subsections, the Secretary shall reduce the
15 amount of the allotment under section 300x–21 of this
16 title for the State for the fiscal year involved by an amount
17 equal to—
18 "(1) In the case of the first applicable fiscal
19 year, 10 percent of the amount determined under
20 section 300x–33 for the State for the fiscal year;
21 "(2) In the case of the first fiscal year following
22 such applicable fiscal year, 20 percent of the amount
23 determined under section 300x–33 for the State for
24 the fiscal year;

1 "(3) In the case of the second such fiscal year,
2 30 percent of the amount determined under section
3 300x–33 for the State for the fiscal year; and
4 "(4) In the case of the third such fiscal year or
5 any subsequent fiscal year, 40 percent of the amount
6 determined under section 300x–33 for the State for
7 the fiscal year.
8 The Secretary shall not have authority or discretion to
9 grant to any State a waiver of the terms and requirements
10 of this subsection or subsection (e) or (f).
11 "(i) For the purposes of subsections (e) through (h)
12 of this section the term 'first applicable fiscal year'
13 means—
14 "(1) fiscal year 2009, in the case of any State
15 described in subsection (e)(2) of this section; and
16 "(2) fiscal year 2008, in the case of any other
17 State.
18 "(j) For purposes of subsections (e) through (h) of
19 this section, references to section 300x–21 shall include
20 any successor grant programs."
21 "(k) As required by paragraph (1), and subject to
22 paragraph (4), an Indian tribe shall satisfy the require-
23 ments of subsection (e)(1) of this section by enacting a
24 law or ordinance with substantially the same provisions
25 as the law described in subsection (e)(1).

1 "(1) An Indian tribe shall comply with sub-
2 section (e)(1) of this section within 180 days after
3 the Administrator finds, in accordance with this
4 paragraph, that—
5 "(A) the Indian tribe has a governing body
6 carrying out substantial governmental powers
7 and duties;
8 "(B) the functions to be exercised by the
9 Indian tribe under this Act pertain to activities
10 on trust land within the jurisdiction of the
11 tribe; and
12 "(C) the Indian tribe is reasonably ex-
13 pected to be capable of carrying out the func-
14 tions required under this section.
15 Within 2 years of the date of enactment of the Fed-
16 eral Tobacco Act of 2007, as to each Indian tribe in
17 the United States, the Administrator shall make the
18 findings contemplated by this paragraph or deter-
19 mine that such findings cannot be made, in accord-
20 ance with the procedures specified in paragraph (4).
21 "(2) As to Indian tribes subject to subsection
22 (e)(1) of this section, the Administrator shall pro-
23 mulgate regulations that—
24 "(A) provide whether and to what extent,
25 if any, the law described in subsection (e)(1)

1 may be modified as adopted by Indian tribes;
2 and
3 "(B) ensure, to the extent possible, that
4 each Indian tribe's retailer licensing program
5 under subsection (e)(1) is no less stringent than
6 the program of the State or States in which the
7 Indian tribe is located.
8 "(3) If with respect to any Indian tribe the Ad-
9 ministrator determines that compliance with the re-
10 quirements of subsection (e)(1) is inappropriate or
11 administratively infeasible, the Administrator shall
12 specify other means for the Indian tribe to achieve
13 the purposes of the law described in subsection
14 (e)(1) with respect to persons who engage in the dis-
15 tribution at retail of tobacco products on tribal
16 lands.
17 "(4) The findings and regulations promulgated
18 under paragraphs (1) and (2) shall be promulgated
19 in conformance with section 553 of title 5, United
20 States Code, and shall comply with the following
21 provisions:
22 "(A) In making findings as provided in
23 paragraph (1), and in drafting and promul-
24 gating regulations as provided in paragraph (2)
25 (including drafting and promulgating any re-

1 vised regulations), the Administrator shall con-
2 fer with, and allow for active participation by,
3 representatives and members of Indian tribes,
4 and tribal organizations.
5 "(B) In carrying out rulemaking processes
6 under this subsection, the Administrator shall
7 follow the guidance of subchapter III of chapter
8 5 of title 5, United States Code, commonly
9 known as the 'Negotiated Rulemaking Act of
10 1990.'
11 "(C) The tribal participants in the negotia-
12 tion process referred to in subparagraph (B)
13 shall be nominated by and shall represent the
14 groups described in this subsection and shall in-
15 clude tribal representatives from all geographic
16 regions.
17 "(D) The negotiations conducted under
18 this paragraph (4) shall be conducted in a time-
19 ly manner.
20 "(E) If the Administrator determines that
21 an extension of the deadlines under subsection
22 (k)(1) of this section is appropriate, the Sec-
23 retary may submit proposed legislation to Con-
24 gress for the extension of such deadlines.

1 "(5) This subsection shall not affect any law or
2 ordinance that (A) was in effect on tribal lands on
3 the date of introduction of the Youth Prevention and
4 Tobacco Harm Reduction Act, and (B) covers the
5 same subject matter as the law described in sub-
6 section (e)(1). Any law or ordinance that meets the
7 conditions of this paragraph shall also be deemed to
8 meet the requirement described in subsection (k)(1),
9 if such law or ordinance is at least as stringent as
10 the law described in subsection (e)(1).
11 "(6) For purposes of this subsection—
12 "(A) 'Administrator' means the Adminis-
13 trator of the Tobacco Harm Reduction Center.
14 "(B) 'Indian tribe' has the meaning as-
15 signed that term in section 4(e) of the Indian
16 Self Determination and Education Assistance
17 Act, section 450b(e) of title 25, United States
18 Code.
19 "(C) 'Tribal lands' means all lands within
20 the exterior boundaries of any Indian reserva-
21 tion, all lands the title to which is held by the
22 United States in trust for an Indian tribe, or
23 lands the title to which is held by an Indian
24 tribe subject to a restriction by the United

1 States against alienation, and all dependent In-
2 dian communities.
3 "(D) 'tribal organization' has the meaning
4 assigned that term in section 4(l) of the Indian
5 Self Determination and Education Assistance
6 Act, section 450b(l) of title 25, United States
7 Code.".

8 **SEC. 403. ESTABLISHMENT OF RANKINGS.**

9 (a) STANDARDS AND PROCEDURES FOR
10 RANKINGS.—Within 24 months after the effective date of
11 this Act, the Administrator shall, by regulation, after con-
12 sultation with an Advisory Committee established for such
13 purpose, establish the standards and procedures for pro-
14 mulgating rankings, comprehensible to consumers of to-
15 bacco products, of the following categories of tobacco
16 products and also nicotine-containing products on the
17 basis of the relative risks of serious or chronic tobacco-
18 related diseases and adverse health conditions those cat-
19 egories of tobacco products and also nicotine-containing
20 products respectively present—
21 (1) cigarettes;
22 (2) loose tobacco for roll-your-own tobacco
23 products;
24 (3) little cigars;
25 (4) cigars;

1 (5) pipe tobacco;
2 (6) moist snuff;
3 (7) dry snuff;
4 (8) chewing tobacco;
5 (9) other forms of tobacco products, including
6 pelletized tobacco and compressed tobacco, treated
7 collectively as a single category; and
8 (10) other nicotine-containing products, treated
9 collectively as a single category.
10 The Administrator shall not have authority or discretion
11 to establish a relative-risk ranking of any category or sub-
12 category of tobacco products or any category or sub-
13 category of nicotine-containing products other than the
14 ten categories specified in this subsection.
15 (b) CONSIDERATIONS IN PROMULGATING REGULA-
16 TIONS.—In promulgating regulations under this section,
17 the Administrator—
18 (1) shall take into account relevant epidemio-
19 logic studies and other relevant competent and reli-
20 able scientific evidence; and
21 (2) in assessing the risks of serious or chronic
22 tobacco-related diseases and adverse health condi-
23 tions presented by a particular category, shall con-
24 sider the range of tobacco products or nicotine-con-
25 taining products within the category, and shall give

1 appropriate weight to the market shares of the re-
2 spective products in the category.
3 (c) PROMULGATION OF RANKINGS OF CAT-
4 EGORIES.—Once the initial regulations required by sub-
5 section (a) are in effect, the Administrator shall promptly,
6 by order, after notice and an opportunity for comment,
7 promulgate to the general public rankings of the cat-
8 egories of tobacco products and nicotine-containing prod-
9 ucts in accordance with those regulations. The Adminis-
10 trator shall promulgate the initial rankings of those cat-
11 egories of tobacco products and nicotine-containing prod-
12 ucts to the general public not later than January 1, 2010.
13 Thereafter, on an annual basis, the Administrator shall,
14 by order, promulgate to the general public updated
15 rankings that are (1) in accordance with those regulations,
16 and (2) reflect the scientific evidence available at the time
17 of promulgation. The Administrator shall open and main-
18 tain an ongoing public docket for receipt of data and other
19 information submitted by any person with respect to such
20 annual promulgation of rankings.

21 TITLE V—ENFORCEMENT
22 PROVISIONS

23 **SEC. 501. PROHIBITED ACTS.**

24 The following acts and the causing thereof are hereby
25 prohibited—

1 (1) the introduction or delivery for introduction
2 into interstate commerce of any tobacco product that
3 is adulterated or misbranded;
4 (2) the adulteration or misbranding of any to-
5 bacco product in interstate commerce;
6 (3) the receipt in interstate commerce of any
7 tobacco product that is known to be adulterated or
8 misbranded, and the delivery or proffered delivery
9 thereof for pay or otherwise;
10 (4) the failure to establish or maintain any
11 record, or make any report or other submission, or
12 to provide any notice required by or under this Act;
13 or the refusal to permit access to, verification of, or
14 copying of any record as required by this Act;
15 (5) the refusal to permit entry or inspection as
16 authorized by this Act;
17 (6) the making to the Administrator of a state-
18 ment, report, certification or other submission re-
19 quired by this Act, with knowledge that such state-
20 ment, report, certification, or other submission is
21 false in a material aspect;
22 (7) the manufacturing, shipping, receiving, stor-
23 ing, selling, distributing, possession, or use of any
24 tobacco product with knowledge that it is an illicit
25 tobacco product;

1 (8) the forging, simulating without proper per-
2 mission, falsely representing, or without proper au-
3 thority using any brand name;
4 (9) the using by any person to his or her own
5 advantage, or revealing, other than to the Adminis-
6 trator or officers or employees of the Agency, or to
7 the courts when relevant in any judicial proceeding
8 under this Act, any information acquired under au-
9 thority of this Act concerning any item which as a
10 trade secret is entitled to protection; except that the
11 foregoing does not authorize the withholding of in-
12 formation from either House of Congress or from, to
13 the extent of matter within its jurisdiction, any com-
14 mittee or subcommittee of such committee or any
15 joint committee of Congress or any subcommittee of
16 such joint committee;
17 (10) the alteration, mutilation, destruction, ob-
18 literation, or removal of the whole or any part of the
19 labeling of, or the doing of any other act with re-
20 spect to, a tobacco product, if such act is done while
21 such tobacco product is held for sale (whether or not
22 the first sale) after shipment in interstate commerce,
23 and results in such tobacco product being adulter-
24 ated or misbranded;

1 (11) the importation of any tobacco product
2 that is adulterated, misbranded, or otherwise not in
3 compliance with this Act; and
4 (12) the commission of any act prohibited by
5 section 201 of this Act.

6 **SEC. 502. INJUNCTION PROCEEDINGS.**

7 (a) The district courts of the United States shall have
8 jurisdiction, for cause shown, to restrain violations of this
9 Act, except for violations of section 701(k).
10 (b) In case of an alleged violation of an injunction
11 or restraining order issued under this section, which also
12 constitutes a violation of this Act, trial shall be by the
13 court, or upon demand of the defendant, by a jury.

14 **SEC. 503. PENALTIES.**

15 (a) CRIMINAL PENALTIES.—Any person who willfully
16 violates a provision of section 501 of this Act shall be im-
17 prisoned for not more than one year or fined not more
18 than $25,000, or both.
19 (b) CIVIL PENALTIES FOR VIOLATION OF SECTION
20 803.—
21 (1) Any person who knowingly distributes or
22 sells, other than through retail sale or retail offer for
23 sale, any cigarette brand style in violation of section
24 803(a)—

1 (A) for a first offense shall be liable for a
2 civil penalty not to exceed $10,000 for each dis-
3 tribution or sale, or
4 (B) for a second offense shall be liable for
5 a civil penalty not to exceed $25,000 for each
6 distribution or sale,
7 except that the penalty imposed against any person
8 with respect to violations during any 30-day period
9 shall not exceed $100,000.
10 (2) Any retailer who knowingly distributes, sells
11 or offers for sale any cigarette brand style in viola-
12 tion of section 803(a) shall—
13 (A) for a first offense for each sale or offer
14 for sale of cigarettes, if the total number of
15 packages of cigarettes sold or offered for sale—
16 (i) does not exceed 50 packages of
17 cigarettes, be liable for a civil penalty not
18 to exceed $500 for each sale or offer for
19 sale, and
20 (ii) exceeds 50 packages of cigarettes,
21 be liable for a civil penalty not to exceed
22 $1,000 for each sale or offer for sale;
23 (B) for each subsequent offense for each
24 sale or offer for sale of cigarettes, if the total
25 number of cigarettes sold or offered for sale—

1 (i) does not exceed 50 packages of
2 cigarettes, be liable for a civil penalty not
3 to exceed $2,000 for each sale or offer for
4 sale, and
5 (ii) exceeds 50 packages of cigarettes,
6 be liable for a civil penalty not to exceed
7 $5,000 for each sale or offer for sale;
8 except that the penalty imposed against any
9 person during any 30-day period shall not ex-
10 ceed $25,000.

11 **SEC. 504. SEIZURE.**

12 (a) ARTICLES SUBJECT TO SEIZURE.—
13 (1) Any tobacco product that is adulterated or
14 misbranded when introduced into or while in inter-
15 state commerce or while held for sale (whether or
16 not the first sale) after shipment in interstate com-
17 merce, or which may not, under the provisions of
18 this Act, be introduced into interstate commerce,
19 shall be liable to be proceeded against while in inter-
20 state commerce, or at any time thereafter, on libel
21 of information and condemned in any district court
22 of the United States within the jurisdiction of which
23 the tobacco product is found. No libel for condemna-
24 tion shall be instituted under this Act for any al-
25 leged misbranding if there is pending in any court

1 a libel for condemnation proceeding under this Act
2 based upon the same alleged misbranding, and not
3 more than one such proceeding shall be instituted if
4 no such proceeding is so pending, except that such
5 limitations shall not apply—
6 (A) when such misbranding has been the
7 basis of a prior judgment in favor of the United
8 States, in a criminal, injunction, or libel for
9 condemnation proceeding under this Act, or
10 (B) when the Administrator has probable
11 cause to believe from facts found, without hear-
12 ing, by the Administrator or any officer or em-
13 ployee of the Agency that the misbranded to-
14 bacco product is dangerous to health beyond
15 the inherent danger to health posed by tobacco,
16 or that the labeling of the misbranded tobacco
17 product is fraudulent, or would be in a material
18 respect misleading to the injury or damage of
19 the purchaser or consumer. In any case where
20 the number of libel for condemnation pro-
21 ceedings is limited as above provided, the pro-
22 ceeding pending or instituted shall, on applica-
23 tion of the claimant, seasonably made, be re-
24 moved for trial to any district agreed upon by
25 stipulation between the parties, or, in case of

1 failure to so stipulate within a reasonable time,
2 the claimant may apply to the court of the dis-
3 trict in which the seizure has been made, and
4 such court (after giving the United States at-
5 torney for such district reasonable notice and
6 opportunity to be heard) shall by order, unless
7 good cause to the contrary is shown, specify a
8 district of reasonable proximity to the claim-
9 ant's principal place of business, to which the
10 case shall be removed for trial.
11 (2) The following shall be liable to be proceeded
12 against at any time on libel of information and con-
13 demned in any district court of the United States
14 within the jurisdiction of which they are found—
15 (A) any tobacco product that is an illicit
16 tobacco product;
17 (B) any container of an illicit tobacco
18 product;
19 (C) any equipment or thing used in mak-
20 ing an illicit tobacco product; and
21 (D) any adulterated or misbranded tobacco
22 product.
23 (3)(A) Except as provided in subparagraph (B),
24 no libel for condemnation may be instituted under

1 paragraph (1) or (2) against any tobacco product
2 which—
3 (i) is misbranded under this Act be-
4 cause of its advertising, and
5 (ii) is being held for sale to the ulti-
6 mate consumer in an establishment other
7 than an establishment owned or operated
8 by a manufacturer, packer, or distributor
9 of the tobacco product.
10 (B) A libel for condemnation may be insti-
11 tuted under paragraph (1) or (2) against a to-
12 bacco product described in subparagraph (A) if
13 the tobacco product's advertising which resulted
14 in the tobacco product being misbranded was
15 disseminated in the establishment in which the
16 tobacco product is being held for sale to the ul-
17 timate consumer—
18 (i) such advertising was disseminated
19 by, or under the direction of, the owner or
20 operator of such establishment, or
21 (ii) all or part of the cost of such ad-
22 vertising was paid by such owner or oper-
23 ator.
24 (b) PROCEDURES.—The tobacco product, equipment,
25 or other thing proceeded against shall be liable to seizure

1 by process pursuant to the libel, and the procedure in
2 cases under this section shall conform, as nearly as may
3 be, to the procedure in admiralty; except that on demand
4 of either party any issue of fact joined in any such case
5 shall be tried by jury. When libel for condemnation pro-
6 ceedings under this section, involving the same claimant
7 and the same issues of adulteration or misbranding, are
8 pending in two or more jurisdictions, such pending pro-
9 ceedings, upon application of the claimant seasonably
10 made to the court of one such jurisdiction, shall be consoli-
11 dated for trial by order of such court, and tried in (1)
12 any district selected by the claimant where one of such
13 proceedings is pending; or (2) a district agreed upon by
14 stipulation between the parties. If no order for consolida-
15 tion is so made within a reasonable time, the claimant may
16 apply to the court of one such jurisdiction and such court
17 (after giving the United States attorney for such district
18 reasonable notice and opportunity to be heard) shall by
19 order, unless good cause to the contrary is shown, specify
20 a district of reasonable proximity to the claimant's prin-
21 cipal place of business, in which all such pending pro-
22 ceedings shall be consolidated for trial and tried. Such
23 order of consolidation shall not apply so as to require the
24 removal of any case the date for trial of which has been
25 fixed. The court granting such order shall give prompt no-

1 tification thereof to the other courts having jurisdiction
2 of the cases covered thereby.
3 (c) SAMPLES AND ANALYSES.—The court at any time
4 after seizure up to a reasonable time before trial shall by
5 order allow any party to a condemnation proceeding, the
6 party's attorney or agent, to obtain a representative sam-
7 ple of the article seized and a true copy of the analysis,
8 if any, on which the proceeding is based and the identi-
9 fying marks or numbers, if any, of the packages from
10 which the samples analyzed were obtained.
11 (d) DISPOSITION OF CONDEMNED TOBACCO PROD-
12 UCTS.—(1) Any tobacco product condemned under this
13 section shall, after entry of the decree, be disposed of by
14 destruction or sale as the court may, in accordance with
15 the provisions of this section, direct; and the proceeds
16 thereof, if sold, less the legal costs and charges, shall be
17 paid into the Treasury of the United States; but such to-
18 bacco product shall not be sold under such decree contrary
19 to the provisions of this Act or the laws of the jurisdiction
20 in which sold. After entry of the decree and upon the pay-
21 ment of the costs of such proceedings and the execution
22 of a good and sufficient bond conditioned that such article
23 shall not be sold or disposed of contrary to the provisions
24 of this Act or the laws of any State in which sold, the
25 court may by order direct that such tobacco product be

1 delivered to the owner thereof to be destroyed or brought
2 into compliance with the provisions of this Act, under the
3 supervision of an officer or employee duly designated by
4 the Administrator; and the expenses of such supervision
5 shall be paid by the person obtaining release of the tobacco
6 product under bond. If the tobacco product was imported
7 into the United States and the person seeking its release
8 establishes (A) that the adulteration, misbranding, or vio-
9 lation did not occur after the tobacco product was im-
10 ported, and (B) that the person seeking the release of the
11 tobacco product had no cause for believing that it was
12 adulterated, misbranded, or in violation before it was re-
13 leased from customs custody, the court may permit the
14 tobacco product to be delivered to the owner for expor-
15 tation under section 709 in lieu of destruction upon a
16 showing by the owner that there is a reasonable certainty
17 that the tobacco product will not be re-imported into the
18 United States.

19 (2) The provisions of paragraph (1) of this subsection
20 shall, to the extent deemed appropriate by the court, apply
21 to any equipment or other thing which is not otherwise
22 within the scope of such paragraph and which is referred
23 to in paragraph (2) of subsection (a).

24 (3) Whenever in any proceeding under this section,
25 involving paragraph (2) of subsection (a), the condemna-

1 tion of any equipment or thing (other than a tobacco prod-
2 uct) is decreed, the court shall allow the claim of any
3 claimant, to the extent of such claimant's interest, for re-
4 mission or mitigation of such forfeiture if such claimant
5 proves to the satisfaction of the court (A) that such claim-
6 ant has not caused the equipment or thing to be within
7 one of the categories referred to in such paragraph (2)
8 and has no interest in any tobacco product referred to
9 therein, (B) that such claimant has an interest in such
10 equipment or other thing as owner or lienor or otherwise,
11 acquired by such claimant in good faith, and (C) that such
12 claimant at no time had any knowledge or reason to be-
13 lieve that such equipment or other thing was being or
14 would be used in, or to facilitate, the violation of laws of
15 the United States relating to any illicit tobacco product.
16 (e) COSTS AND FEES.—When a decree of condemna-
17 tion is entered against the tobacco product or other article,
18 court costs and fees, and storage and other proper ex-
19 penses shall be awarded against the person, if any, inter-
20 vening as claimant of the tobacco product or other article.
21 (f) REMOVAL FOR TRIAL.—In the case of removal for
22 trial of any case as provided by subsection (a) or (b)—
23 (1) The clerk of the court from which removal
24 is made shall promptly transmit to the court in
25 which the case is to be tried all records in the case

1 necessary in order that such court may exercise ju-
2 risdiction.
3 (2) The court to which such case was removed
4 shall have the powers and be subject to the duties,
5 for purposes of such case, which the court from
6 which removal was made would have had, or to
7 which such court would have been subject, if such
8 case had not been removed.
9 (g) ADMINISTRATIVE DETENTION OF TOBACCO
10 PRODUCTS.—
11 (1) DETENTION AUTHORITY.—
12 (A) IN GENERAL.—An officer or qualified
13 employee of the Agency may order the deten-
14 tion, in accordance with this subsection, of any
15 tobacco product that is found during an inspec-
16 tion, examination, or investigation under this
17 Act conducted by such officer or qualified em-
18 ployee, if the officer or qualified employee has
19 credible evidence or information indicating that
20 such article presents a threat of serious adverse
21 health consequences beyond those normally in-
22 herent in the use of tobacco products.
23 (B) ADMINISTRATOR'S APPROVAL.—A to-
24 bacco product or component thereof may be or-
25 dered detained under subparagraph (A) if, but

1 only if, the Administrator or an official des-
2 ignated by the Administrator approves the
3 order. An official may not be so designated un-
4 less the official is an officer with supervisory re-
5 sponsibility for the inspection, examination, or
6 investigation that led to the order.

7 (2) PERIOD OF DETENTION.—A tobacco prod-
8 uct may be detained under paragraph (1) for a rea-
9 sonable period, not to exceed 20 days, unless a
10 greater period, not to exceed 30 days, is necessary,
11 to institute an action under subsection (a) or section
12 702.

13 (3) SECURITY OF DETAINED TOBACCO PROD-
14 UCT.—An order under paragraph (1) may require
15 that the tobacco product to be detained be labeled
16 or marked as detained, and shall require that the to-
17 bacco product be maintained in or removed to a se-
18 cure facility, as appropriate. A tobacco product sub-
19 ject to such an order shall not be transferred by any
20 person from the place at which the tobacco product
21 is ordered detained, or from the place to which the
22 tobacco product is so removed, as the case may be,
23 until released by the Administrator or until the expi-
24 ration of the detention period applicable under such
25 order, whichever occurs first. This subsection may

1 not be construed as authorizing the delivery of the
2 tobacco product pursuant to the execution of a bond
3 while the tobacco product is subject to the order,
4 and section 709 does not authorize the delivery of
5 the tobacco product pursuant to the execution of a
6 bond while the article is subject to the order.

7 (4) APPEAL OF DETENTION ORDER.—

8 (A) IN GENERAL.—With respect to a to-
9 bacco product ordered detained under para-
10 graph (1), any person who would be entitled to
11 be a claimant of such tobacco product if the to-
12 bacco product were seized under subsection (a)
13 may appeal the order to the Administrator.
14 Within five days after such an appeal is filed,
15 the Administrator, after providing opportunity
16 for an informal hearing, shall confirm or termi-
17 nate the order involved, and such confirmation
18 by the Administrator shall be considered a final
19 agency action for purposes of section 702 of
20 title 5, United States Code. If during such five-
21 day period the Administrator fails to provide
22 such an opportunity, or to confirm or terminate
23 such order, the order is deemed to be termi-
24 nated.

1 (B) EFFECT OF INSTITUTING COURT AC-
2 TION.—The process under subparagraph (A)
3 for the appeal of an order under paragraph (1)
4 terminates if the Administrator institutes an
5 action under subsection (a) or section 702 re-
6 garding the tobacco product involved.

7 **SEC. 505. REPORT OF MINOR VIOLATIONS.**

8 Nothing in this Act shall be construed as requiring
9 the Administrator to report for prosecution, or for institu-
10 tion of libel or injunction proceedings, minor violations of
11 this Act whenever the Administrator believes that the pub-
12 lic interest will be adequately served by a suitable written
13 notice or warning.

14 **SEC. 506. INSPECTION.**

15 (a) AUTHORITY TO INSPECT.—The Administrator
16 shall have the power to inspect the premises of a tobacco
17 product manufacturer for purposes of determining compli-
18 ance with this Act, or the regulations promulgated under
19 it. Officers of the Agency designated by the Administrator,
20 upon presenting appropriate credentials and a written no-
21 tice to the person in charge of the premises, are authorized
22 to enter, at reasonable times, without a search warrant,
23 any factory, warehouse, or other establishment in which
24 tobacco products are manufactured, processed, packaged,
25 or held for domestic distribution. Any such inspection shall

1 be conducted within reasonable limits and in a reasonable
2 manner, and shall be limited to examining only those
3 things, including but not limited to records, relevant to
4 determining whether violations of this Act, or regulations
5 under it, have occurred. No inspection authorized by this
6 section shall extend to financial data, sales data other than
7 shipment data, pricing data, personnel data (other than
8 data as to qualifications of technical and professional per-
9 sonnel performing functions subject to this Act), or re-
10 search data. A separate notice shall be given for each such
11 inspection, but a notice shall not be required for each
12 entry made during the period covered by the inspection.
13 Each such inspection shall be commenced and completed
14 with reasonable promptness.

15 (b) REPORT OF OBSERVATIONS.—Before leaving the
16 premises, the officer of the Agency who has supervised or
17 conducted the inspection shall give to the person in charge
18 of the premises a report in writing setting forth any condi-
19 tions or practices that appear to manifest a violation of
20 this Act, or the regulations under it.

21 (c) SAMPLES.—If the officer has obtained any sample
22 in the course of inspection, prior to leaving the premises
23 that officer shall give to the person in charge of the prem-
24 ises a receipt describing the samples obtained. As to each
25 sample obtained, the officer shall furnish promptly to the

1 person in charge of the premises a copy of the sample and
2 of any analysis made upon the sample.

3 **SEC. 507. EFFECT OF COMPLIANCE.**

4 Compliance with the provisions of this Act and the
5 regulations promulgated under it shall constitute a com-
6 plete defense to any civil action, including but not limited
7 to any products liability action, that seeks to recover dam-
8 ages, whether compensatory or punitive, based upon an
9 alleged defect in the labeling or advertising of any tobacco
10 product distributed for sale domestically.

11 **SEC. 508. IMPORTS.**

12 (a) IMPORTS; LIST OF REGISTERED FOREIGN ES-
13 TABLISHMENTS; SAMPLES FROM UNREGISTERED FOR-
14 EIGN ESTABLISHMENTS; EXAMINATION AND REFUSAL OF
15 ADMISSION.—The Secretary of Homeland Security shall
16 deliver to the Administrator, upon request by the Adminis-
17 trator, samples of tobacco products that are being im-
18 ported or offered for import into the United States, giving
19 notice thereof to the owner or consignee, who may appear
20 before the Administrator and have the right to introduce
21 testimony. The Administrator shall furnish to the Sec-
22 retary of Homeland Security a list of establishments reg-
23 istered pursuant to subsection (d) of section 109 of this
24 Act, and shall request that, if any tobacco products manu-
25 factured, prepared, or processed in an establishment not

1 so registered are imported or offered for import into the
2 United States, samples of such tobacco products be deliv-
3 ered to the Administrator, with notice of such delivery to
4 the owner or consignee, who may appear before the Ad-
5 ministrator and have the right to introduce testimony. If
6 it appears from the examination of such samples or other-
7 wise that (1) such tobacco product is forbidden or re-
8 stricted in sale in the country in which it was produced
9 or from which it was exported, or (2) such tobacco product
10 is adulterated, misbranded, or otherwise in violation of
11 this Act, then such tobacco product shall be refused ad-
12 mission, except as provided in subsection (b) of this sec-
13 tion. The Secretary of Homeland Security shall cause the
14 destruction of any such tobacco product refused admission
15 unless such tobacco product is exported, under regulations
16 prescribed by the Secretary of Homeland Security, within
17 ninety days of the date of notice of such refusal or within
18 such additional time as may be permitted pursuant to such
19 regulations.

20 (b) DISPOSITION OF REFUSED TOBACCO PROD-
21 UCTS.—Pending decision as to the admission of a tobacco
22 product being imported or offered for import, the Sec-
23 retary of Homeland Security may authorize delivery of
24 such tobacco product to the owner or consignee upon the
25 execution by such consignee of a good and sufficient bond

1 providing for the payment of such liquidated damages in
2 the event of default as may be required pursuant to regu-
3 lations of the Secretary of Homeland Security. If it ap-
4 pears to the Administrator that a tobacco product in-
5 cluded within the provisions of clause (3) of subsection
6 (a) of this section can, by relabeling or other action, be
7 brought into compliance with this Act or rendered other
8 than a tobacco product, final determination as to admis-
9 sion of such tobacco product may be deferred and, upon
10 filing of timely written application by the owner or con-
11 signee and the execution by such consignee of a bond as
12 provided in the preceding provisions of this subsection, the
13 Administrator may, in accordance with regulations, au-
14 thorize the applicant to perform such relabeling or other
15 action specified in such authorization (including destruc-
16 tion or export of rejected tobacco products or portions
17 thereof, as may be specified in the Administrator's author-
18 ization). All such relabeling or other action pursuant to
19 such authorization shall in accordance with regulations be
20 under the supervision of an officer or employee of the
21 Agency designated by the Administrator, or an officer or
22 employee of the Department of Homeland Security des-
23 ignated by the Secretary of Homeland Security.
24 (c) CHARGES CONCERNING REFUSED TOBACCO
25 PRODUCTS.—All expenses (including travel, per diem or

1 subsistence, and salaries of officers or employees of the
2 United States) in connection with the destruction provided
3 for in subsection (a) of this section and the supervision
4 of the relabeling or other action authorized under the pro-
5 visions of subsection (b) of this section, the amount of
6 such expenses to be determined in accordance with regula-
7 tions, and all expenses in connection with the storage,
8 cartage, or labor with respect to any tobacco product re-
9 fused admission under subsection (a) of this section, shall
10 be paid by the owner or consignee and, in default of such
11 payment, shall constitute a lien against any future impor-
12 tations made by such owner or consignee.

13 **SEC. 509. TOBACCO PRODUCTS FOR EXPORT.**

14 (a) EXEMPTION FOR TOBACCO PRODUCTS EX-
15 PORTED.—Except as provided in subsection (b), a tobacco
16 product intended for export shall be exempt from this Act
17 if—

18 (1) it is not in conflict with the laws of the
19 country to which it is intended fore export, as shown
20 by either (A) a document issued by the government
21 of that country or (B) a document provided by a
22 person knowledgeable with respect to the relevant
23 laws of that country and qualified by training and
24 experience to opine on whether the tobacco product
25 is or is not in conflict with such laws;

1 (2) it is labeled on the outside of the shipping
2 package that it is intended for export; and
3 (3) the particular units of tobacco product in-
4 tended for export have not been sold or offered for
5 sale in domestic commerce.
6 (b) PRODUCTS FOR U.S. ARMED FORCES OVER-
7 SEAS.—A tobacco product intended for export shall not
8 be exempt from this Act if it is intended for sale or dis-
9 tribution to members or units of the Armed Forces of the
10 United States located outside of the United States.
11 (c) This Act shall not apply to a person that manu-
12 factures and/or distributes tobacco products solely for ex-
13 port under subsection (a), except to the extent such to-
14 bacco products are subject to subsection (b).

15 TITLE VI—MISCELLANEOUS 16 PROVISIONS

17 SEC. 601. USE OF PAYMENTS UNDER THE MASTER SETTLE- 18 MENT AGREEMENT AND INDIVIDUAL STATE 19 SETTLEMENT AGREEMENTS.

20 (a) REDUCTION OF GRANT AMOUNTS.—(1) For fiscal
21 year 2010 and each subsequent fiscal year, the Secretary
22 shall reduce, as provided in subsection (b), the amount
23 of any grant under section 1921 of the Public Health
24 Service Act (42 U.S.C. § 300x–21) for any State that
25 spends on tobacco control programs from the funds re-

1 ceived by such State pursuant to the Master Settlement
2 Agreement, the Florida Settlement Agreement, the Min-
3 nesota Settlement Agreement, the Mississippi Memo-
4 randum of Understanding, or the Texas Settlement Agree-
5 ment, as applicable, less than 20 percent of the amounts
6 received by that State from settlement payments.

7 (2) In the case of a State whose legislature does not
8 convene a regular session in fiscal year 2009 or 2010, and
9 in the case of a State whose legislature does not convene
10 a regular session in fiscal year 2010, the requirement de-
11 scribed in subsection (a)(1) as a condition of receipt of
12 a grant under section 1921 of the Public Health Service
13 Act shall apply only for fiscal year 2009 and subsequent
14 fiscal years.

15 (b) DETERMINATION OF STATE SPENDING.—Before
16 making a grant under section 1921 of the Public Health
17 Service Act, section 300x–21 of title 42, United States
18 Code, to a State for the first applicable fiscal year or any
19 subsequent fiscal year, the Secretary shall make a deter-
20 mination of whether, during the immediately preceding fis-
21 cal year, the State has spent on tobacco control programs,
22 from the funds received by such State pursuant to the
23 Master Settlement Agreement, the Florida Settlement
24 Agreement, the Minnesota Settlement Agreement, the
25 Mississippi Memorandum of Understanding, or the Texas

1 Settlement Agreement, as applicable, at least the amount
2 referenced in (a)(1). If, after notice to the State and an
3 opportunity for a hearing, the Secretary determines that
4 the State has spent less than such amount, the Secretary
5 shall reduce the amount of the allotment under section
6 300x–21 of title 42, United States Code, for the State for
7 the fiscal year involved by an amount equal to—
8 (1) in the case of the first applicable fiscal year,
9 10 percent of the amount determined under section
10 300x–33 of title 42, United States Code, for the
11 State for the fiscal year;
12 (2) in the case of the first fiscal year following
13 such applicable fiscal year, 20 percent of the amount
14 determined under section 300x–33 of title 42,
15 United States Code, for the State for the fiscal year;
16 (3) in the case of the second such fiscal year,
17 30 percent of the amount determined under section
18 300x–33 of title 42, United States Code, for the
19 State for the fiscal year; and
20 (4) in the case of the third such fiscal year or
21 any subsequent fiscal year, 40 percent of the amount
22 determined under section 300x–33 of title 42,
23 United States Code, for the State for the fiscal year.

1 The Secretary shall not have authority or discretion to
2 grant to any State a waiver of the terms and requirements
3 of this subsection or subsection (a).
4 (c) DEFINITIONS.—For the purposes of this sec-
5 tion—
6 (1) The term "first applicable fiscal year"
7 means—
8 (A) fiscal year 2011, in the case of any
9 State described in subsection (a)(2) of this sec-
10 tion; and
11 (B) fiscal year 2010, in the case of any
12 other State.
13 (2) The term "Florida Settlement Agreement"
14 means the Settlement Agreement, together with the
15 exhibits thereto, entered into on August 25, 1997,
16 between the State of Florida and signatory tobacco
17 product manufacturers, as specified therein.
18 (3) The term "Master Settlement Agreement"
19 means the Master Settlement Agreement, together
20 with the exhibits thereto, entered into on November
21 23, 1998, between the signatory States and signa-
22 tory tobacco product manufacturers, as specified
23 therein.
24 (4) The term "Minnesota Settlement Agree-
25 ment" means the Settlement Agreement, together

1 with the exhibits thereto, entered into on May 8,
2 1998, between the State of Minnesota and signatory
3 tobacco product manufacturers, as specified therein.
4 (5) The term "Mississippi Memorandum of Un-
5 derstanding" means the Memorandum of Under-
6 standing, together with the exhibits thereto and Set-
7 tlement Agreement contemplated therein, entered
8 into on July 2, 1997, between the State of Mis-
9 sissippi and signatory tobacco product manufactur-
10 ers, as specified therein.
11 (6) The term "Secretary" means the Secretary
12 of Health and Human Services.
13 (7) The term "Texas Settlement Agreement"
14 means the Settlement Agreement, together with the
15 exhibits thereto, entered into on January 16, 1998,
16 between the State of Texas and signatory tobacco
17 product manufacturers, as specified therein.

18 **SEC. 602. PREEMPTION OF STATE LAWS IMPLEMENTING**
19 **FIRE SAFETY STANDARD FOR CIGARETTES.**

20 (a) IN GENERAL.—With respect to fire safety stand-
21 ards for cigarettes, no State or political subdivision shall—
22 (1) require testing of cigarettes that would be
23 in addition to, or different from, the testing pre-
24 scribed in subsection (b); or

1 (2) require a performance standard that is in
2 addition to, or different from, the performance
3 standard set forth in subsection (b).
4 (b) TEST METHOD AND PERFORMANCE STAND-
5 ARD.—
6 (1) To the extent a State or political subdivi-
7 sion enacts or has enacted legislation or a regulation
8 setting a fire safety standard for cigarettes, the test
9 method employed shall be—
10 (A) the American Society of Testing and
11 Materials ("ASTM") standard E2187–4, enti-
12 tled "Standard Test Method for Measuring the
13 Ignition Strength of Cigarettes";
14 (B) for each cigarette on 10 layers of filter
15 paper;
16 (C) so that a replicate test of 40 cigarettes
17 for each brand style of cigarettes comprises a
18 complete test trial for that brand style; and
19 (D) in a laboratory that has been accred-
20 ited in accordance with ISO/IEC 17205 of the
21 International Organization for Standardization
22 ("ISO") and that has an implemented quality
23 control and quality assurance program that in-
24 cludes a procedure capable of determining the

1 repeatability of the testing results to a repeat-
2 ability value that is no greater than 0.19.
3 (2) To the extent a State or political subdivi-
4 sion enacts or has enacted legislation or a regulation
5 setting a fire safety standard for cigarettes, the per-
6 formance standard employed shall be that no more
7 than 25 percent of the cigarettes of that brand style
8 tested in a complete test in accordance with para-
9 graph (1) exhibit full-length burns
10 (c) EXCEPTION TO SUBSECTION (b).—In the event
11 that a manufacturer of a cigarette that a State or political
12 subdivision or its respective delegated agency determines
13 cannot be tested in accordance with the test method pre-
14 scribed in subsection (b)(1)(A), the manufacturer shall
15 propose a test method and performance standard for the
16 cigarette to the State or political subdivision. Upon ap-
17 proval of the proposed test method and a determination
18 by the State or political division that the performance
19 standard proposed by the manufacturer is equivalent to
20 the performance standard prescribed in subsection (b)(2),
21 the manufacturer may employ such test method and per-
22 formance standard to certify such cigarette pursuant to
23 this subsection notwithstanding subsection (b).

1 **SEC. 603. INSPECTION BY THE ALCOHOL AND TOBACCO**
2 **TAX TRADE BUREAU OF RECORDS OF CER-**
3 **TAIN CIGARETTE AND SMOKELESS TOBACCO**
4 **SELLERS.**

5 (a) IN GENERAL.—Any officer of the Bureau of the
6 Alcohol and Tobacco Tax Trade Bureau may, during nor-
7 mal business hours, enter the premises of any person de-
8 scribed in subsection (b) for the purposes of inspecting—

9 (1) any records or information required to be
10 maintained by such person under the provisions of
11 law referred to in subsection (d); or

12 (2) any cigarettes or smokeless tobacco kept or
13 stored by such person at such premises.

14 (b) COVERED PERSONS.—Subsection (a) applies to
15 any person who engages in a delivery sale, and who ships,
16 sells, distributes, or receives any quantity in excess of
17 10,000 cigarettes, or any quantity in excess of 500 single-
18 unit consumer-sized cans or packages of smokeless to-
19 bacco, within a single month.

20 (c) RELIEF.—

21 (1) IN GENERAL.—The district courts of the
22 United States shall have the authority in a civil ac-
23 tion under this subsection to compel inspections au-
24 thorized by subsection (a).

25 (2) VIOLATIONS.—Whoever violates subsection
26 (a) or an order issued pursuant to paragraph (1)

1 shall be subject to a civil penalty in an amount not
2 to exceed $10,000 for each violation.
3 (d) COVERED PROVISIONS OF LAW.—The provisions
4 of law referred to in this subsection are—
5 (1) the Act of October 19, 1949 (15 U.S.C.
6 375; commonly referred to as the "Jenkins Act");
7 (2) chapter 114 of title 18, United States Code;
8 and
9 (3) this Act.
10 (e) DELIVERY SALE DEFINED.—In this section, the
11 term "delivery sale" has the meaning given that term in
12 2343(e) of title 18, United States Code, as amended by
13 this Act.
14 **SEC. 604. SEVERABILITY.**
15 If any provision of this Act, the amendments made
16 by this Act, or the application of any provision of this Act
17 to any person or circumstance is held to be invalid, the
18 remainder of this Act, the amendments made by this Act,
19 and the application of the provisions of this Act to any
20 other person or circumstance shall not be affected, and
21 shall continue to be enforced to the fullest extent possible.

1 # TITLE VII—TOBACCO GROWER
2 # PROTECTION

3 **SEC. 701. TOBACCO GROWER PROTECTION.**

4 No provision in this Act shall allow the Administrator
5 or any other person to require changes to traditional farm-
6 ing practices, including standard cultivation practices, cur-
7 ing processes, seed composition, tobacco type, fertilization,
8 soil, record keeping, or any other requirement affecting
9 farming practices.

Amend the title so as to read: "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.".