111TH CONGRESS } HOUSE OF REPRESENTATIVES { REPORT
1st Session } { 111–72

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

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

R E P O R T

[To accompany H. Res. 307]

The Committee on Rules, having had under consideration House Resolution 307, by a nonrecord 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.

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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 Members: McGovern—Nay; Hastings—Nay; Arcuri—Nay; Perlmutter—Nay; Pingree—Nay; Polis—Nay; Dreier—Yea; 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 Members: McGovern—Nay; Hastings—Nay; Arcuri—Nay; Perlmutter—Nay; Pingree—Nay; Polis—Nay; Dreier—Yea; 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 car-

rying 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

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 520(g), or chapter IX and data relating to 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:

(2) in subsection (e)(1)—

(A) by inserting "tobacco product" after "drug, device,"; and

(B) by inserting ", and a tobacco product intended for export shall not be deemed to be in violation of section 906(e), 907, 911, or 920(a)," before "if it—";

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

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

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. 2. FINDINGS.

The Congress finds the following:

(1) Cigarette smoking is a leading cause of preventable deaths in the United States. Cigarette smoking significantly increases the risk of developing lung cancer, heart disease, chronic bronchitis, emphysema and other serious diseases with adverse health conditions.

(2) The risk for serious diseases is significantly affected by the type of tobacco product and the frequency, duration and manner of use.

(3) No tobacco product has been shown to be safe and without risks. The health risks associated with cigarettes are significantly greater than those associated with the use of smokefree tobacco and nicotine products.

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

(5) It is the smoke inhaled from burning tobacco which poses the most significant risk of serious diseases.

(6) Quitting cigarette smoking significantly reduces the risk for serious diseases.

(7) Adult tobacco consumers have a right to be fully and accurately informed about the risks of serious diseases, the significant differences in the comparative risks of different tobacco and nicotine-based products, and the benefits of quitting. This information should be based on sound science.

(8) Governments, public health officials, tobacco manufacturers and others share a responsibility to provide adult tobacco consumers with accurate information about the various health risks and comparative risks associated with the use of different tobacco and nicotine products.

(9) Tobacco products should be regulated in a manner that is designed to achieve significant and measurable reductions in the morbidity and mortality associated with tobacco use. Regulations should enhance the information available to adult consumers to permit them to make informed choices, and encourage the development of tobacco and nicotine products with lower risks than cigarettes currently sold in the United States.

(10) The form of regulation should be based on the risks and comparative risks of tobacco and nicotine products and their respective product categories.

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

(12) Reducing the diseases and deaths associated with the use of cigarettes serves public health goals and is in the best interest of consumers and society. Harm reduction should be the critical element of any comprehensive public policy surrounding the health consequences of tobacco use.

(13) Significant reductions in the harm associated with the use of cigarettes can be achieved by providing accurate information regarding the comparative risks of tobacco products to adult tobacco consumers, thereby encouraging smokers to migrate to the use of smoke-free tobacco and nicotine products, and by developing new smoke-free tobacco and nicotine products and other actions.

(14) Governments, public health officials, manufacturers, tobacco producers and consumers should support the development, production, and commercial introduction of tobacco leaf, and tobacco and nicotine-based products that are scientifically shown to reduce the risks associated with the use of existing tobacco products, particularly cigarettes.

(15) Adult tobacco consumers should have access to a range of commercially viable tobacco and nicotine-based products.

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

(17) Transitioning smokers to selected smokeless tobacco products will eliminate environmental tobacco smoke and fire-related hazards.

(18) Current "abstain, quit, or die" tobacco control policies in the United States may have reached their maximum possible public health benefit because of the large number of cigarette smokers either unwilling or unable to discontinue their addiction to nicotine.

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

(20) Health-related agencies and organizations, both within the United States and abroad have already gone on record endorsing Harm Reduction as an approach to further reducing tobacco related illness and death.

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

SEC. 3. PURPOSE.

The purposes of this Act are—

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

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

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

(4) to provide new and flexible enforcement authority to ensure that there is effective oversight of the tobacco industry's efforts to develop, introduce, and promote less harmful tobacco products;

(5) to vest the Center with the authority to regulate the levels of tar, nicotine, and other harmful components of tobacco products;

(6) to ensure that consumers are better informed regarding the relative risks for death and disease between categories of tobacco products;

(7) to continue to allow the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage purchasers;

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

(9) to promote prevention, cessation, and harm reduction policies and regulations to reduce disease risk and the social costs associated with tobacco-related diseases;

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

(11) to establish national policies that effectively reduce disease and death associated with cigarette smoking and other tobacco use;

(12) to establish national policies that encourage prevention, cessation, and harm reduction measures regarding the use of tobacco products;

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

(14) to establish national policies that accurately and consistently inform adult tobacco consumers of significant differences in risk between respective tobacco products;

(15) to establish national policies that encourage and assist the development and awareness of noncombustible tobacco and nicotine products;

(16) to coordinate national and State prevention, cessation, and harm reduction programs;

(17) to impose measures to ensure tobacco products are not sold or accessible to underage purchasers; and

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

SEC. 4. SCOPE AND EFFECT.

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

(1) establish a precedent with regard to any other industry, situation, circumstance, or legal action;

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

(3) be applicable to tobacco products or component parts manufactured in the United States for export.

(b) AGRICULTURAL ACTIVITIES.—The provisions of this Act (or an amendment made by this Act) which authorize the Administrator to take certain actions with regard to tobacco and tobacco products shall not be construed to affect any authority of the Secretary of Agriculture under existing law regarding the growing, cultivation, or curing of raw tobacco.

(c) REVENUE ACTIVITIES.—The provisions of this Act (or an amendment made by this Act) which authorize the Administrator

to take certain actions with regard to tobacco products shall not be construed to affect any authority of the Secretary of the Treasury under chapter 52 of the Internal Revenue Code of 1986.

SEC. 5. SEVERABILITY.

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

SEC. 6. EFFECTIVE DATE.

Except as otherwise specifically provided, the effective date of this Act shall be the date of its enactment.

TITLE I—AUTHORITY OF THE TOBACCO HARM REDUCTION CENTER

SEC. 100. DEFINITIONS.

In this Act:

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

(2) The term "adult" means any individual who has attained the minimum age under applicable State law to be an individual to whom tobacco products may lawfully be sold.

(3) The term "adult-only facility" means a facility or restricted area, whether open-air or enclosed, where the operator ensures, or has a reasonable basis to believe, that no youth is present. A facility or restricted area need not be permanently restricted to adults in order to constitute an adult-only facility, if the operator ensures, or has a reasonable basis to believe, that no youth is present during any period of operation as an adult-only facility.

(4) The term "affiliate" means a person that directly or indirectly owns or controls, is owned or controlled by, or is under common ownership or control with, another person. The terms "owns," "is owned", and "ownership" refer to ownership of an equity interest, or the equivalent thereof, of 50 percent or more.

(5) The term "annual report" means a tobacco product manufacturer's annual report to the Center, which provides ingredient information and nicotine yield ratings for each brand style that tobacco product manufacturer manufactures for commercial distribution domestically.

(6) The term "brand name" means a brand name of a tobacco product distributed or sold domestically, alone, or in conjunction with any other word, trademark, logo, symbol, motto, selling message, recognizable pattern of colors, or any other indicium of product identification identical or similar to, or identifiable with, those used for any domestic brand of tobacco product. The term shall not include the corporate name of any tobacco product manufacturer that does not, after the effective

date of this Act, sell a brand style of tobacco product in the United States that includes such corporate name.

(7) The term "brand style" means a tobacco product having a brand name, and distinguished by the selection of the tobacco, ingredients, structural materials, format, configuration, size, package, product descriptor, amount of tobacco, or yield of "tar" or nicotine.

(8) The term "Center" means the Tobacco Harm Reduction Center.

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

(10) The term "cigarette" means—

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

(B) any roll of tobacco wrapped in any substance containing tobacco which, because of the appearance of the roll of tobacco, the type of tobacco used in the filler, or its package or labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in paragraph (1).

(11) The term "competent and reliable scientific evidence" means evidence based on tests, analyses, research, or studies, conducted and evaluated in an objective manner by individuals qualified to do so, using procedures generally accepted in the relevant scientific disciplines to yield accurate and reliable results.

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

(13) The terms "domestic" and "domestically" mean within the United States, including activities within the United States involving advertising, marketing, distribution, or sale of tobacco products that are intended for consumption within the United States.

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

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

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

(C) that is counterfeit; or

(D) that has or had a label, labeling, or packaging stating, or that stated, that the product is or was for export only, or that it is or was at any time restricted by section 5704 of title 26, United States Code.

(15) The term "illicit trade" means any transfer, distribution, or sale in interstate commerce of any illicit tobacco product.

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

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

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

(19) The term "International Organization for Standardization (ISO) testing regimen" means the methods for measuring cigarette smoke yields, as set forth in the most recent version of ISO 3308, entitled "Routine analytical cigarette-smoking machine—Definition of standard conditions"; ISO 4387, entitled "Cigarettes—Determination of total and nicotine-free dry particulate matter using a routine analytical smoking machine"; ISO 10315, entitled "Cigarettes—Determination of nicotine in smoke condensates—Gas-chromatographic method"; ISO 10362–1, entitled "Cigarettes—Determination of water in smoke condensates—Part 1: Gas-chromatographic method"; and ISO 8454, entitled "Cigarettes—Determination of carbon monoxide in the vapour phase of cigarette smoke—NDIR method". A cigarette that does not burn down in accordance with the testing regimen standards may be measured under the same puff regimen using the number of puffs that such a cigarette delivers before it extinguishes, plus an additional three puffs, or with such other modifications as the Administrator may approve.

(20) The term "interstate commerce" means all trade, traffic, or other commerce—

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

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

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

(D) over which the United States has jurisdiction.

(21) The term "label" means a display of written, printed, or graphic matter upon or applied securely to the immediate container of a tobacco product.

(22) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon or applied securely to any tobacco product or any of its containers or wrappers, or (2) accompanying a tobacco product.

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

(24) The term "loose tobacco" means any form of tobacco, alone or in combination with any other ingredient or material, that, because of its appearance, form, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco for making or assembling cigarettes, incorporation into pipes, or otherwise used by consumers to make any tobacco product.

(25) The term "manufacture" means to design, manufacture, fabricate, assemble, process, package, or repackage, label, or relabel, import, or hold or store in a commercial quantity, but does not include—

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

(B) the holding, storing or transporting of a tobacco product by a common carrier for hire, a public warehouse, a testing laboratory, a distributor, or a retailer.

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

(A) synthetically produced, or

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

(27) The term "package" means a pack, box, carton, pouch, or container of any kind in which a tobacco product or tobacco products are offered for sale, sold, or otherwise distributed to consumers. The term "package" does not include an outer container used solely for shipping one or more packages of a tobacco product or tobacco products.

(28) The term "person" means any individual, partnership, corporation, committee, association, organization or group of persons, or other legal or business entity.

(29) The term "proof of age" means a driver's license or other form of identification that is issued by a governmental authority and includes a photograph and a date of birth of the individual.

(30) The term "raw tobacco" means tobacco in a form that is received by a tobacco product manufacturer as an agricultural commodity, whether in a form that is natural, stem, or leaf, cured or aged, or as parts or pieces, but not in a reconstituted form, extracted pulp form, or extract form.

(31) The term "reduced-exposure claim" means a statement in advertising or labeling intended for one or more consumers of tobacco products, that a tobacco product provides a reduced exposure of users of that tobacco product to one or more toxicants, as compared to an appropriate reference tobacco product or category of tobacco products. A statement or representation that a tobacco product or the tobacco in a tobacco product contains "no additives" or is "natural" or that uses a substantially similar term is not a reduced-exposure claim if the advertising or labeling that contains such statement or representation also contains the disclosure required by section 108(h) of this Act.

(32) The term "reduced-risk claim" means a statement in advertising or labeling intended for one or more consumers of smoking articles, that a smoking article provides to users of that product a reduced risk of morbidity or mortality resulting from one or more chronic diseases or serious adverse health conditions associated with tobacco use, as compared to an appropriate reference smoking article or category of smoking articles, even if it is not stated, represented, or implied that all health risks associated with using that smoking article have been reduced or eliminated. A statement or representation that a smoking article or the tobacco in a smoking article contains "no additives," or is "natural," or that uses a substantially similar term is not a reduced-risk claim if the advertising or labeling that contains such statement or representation also contains the disclosure required by section 108(h).

(33) The term "retailer" means any person that—

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

(B) operates a facility where the sale of tobacco products to individuals for personal consumption is permitted.

(34) The term "small business" means a tobacco product manufacturer that—

(A) has 150 or fewer employees; and

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

(35) The term "smokeless tobacco product" means any form of finely cut, ground, powdered, reconstituted, processed or shaped tobacco, leaf tobacco, or stem tobacco, whether or not combined with any other ingredient, whether or not in extract or extracted form, and whether or not incorporated within any carrier or construct, that is intended to be placed in the oral or nasal cavity, including dry snuff, moist snuff, and chewing tobacco.

(36) The term "smoking article" means any tobacco-containing article that is intended, when used by a consumer, to be burned or otherwise to employ heat to produce a vapor, aerosol or smoke that—

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

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

(37) The term "State" means any State of the United States and, except as otherwise specifically provided, includes any Indian tribe or tribal organization, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Island, Kingman Reef, Johnston Atoll, the Northern Marianas, and any other trust territory or possession of the United States.

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

(39) The term "tobacco" means a tobacco plant or any part of a harvested tobacco plant intended for use in the production of a tobacco product, including leaf, lamina, stem, or stalk, whether in green, cured, or aged form, whether in raw, treated, or processed form, and whether or not combined with other materials, including any by-product, extract, extracted pulp material, or any other material (other than purified nicotine) derived from a tobacco plant or any component thereof, and including strip, filler, stem, powder, and granulated, blended, or reconstituted forms of tobacco.

(40) The term "tobacco product" means—

(A) the singular of "tobacco products" as defined in section 5702(c) of the Internal Revenue Code of 1986;

(B) any other product that contains tobacco as a principal ingredient and that, because of its appearance, type, or the tobacco used in the product, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a tobacco product as described in subparagraph (A); and

(C) any form of tobacco or any construct incorporating tobacco, intended for human consumption, whether by—

(i) placement in the oral or nasal cavity;

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

(iii) any other means.

(41) The term "tobacco product category" means a type of tobacco product characterized by its composition, components, and intended use, and includes tobacco products classified as cigarettes, loose tobacco for roll-your-own tobacco products, little cigars, cigars, pipe tobacco, moist snuff, dry snuff, chewing tobacco, and other forms of tobacco products (which are treated in this Act collectively as a single category).

(42) The term "tobacco product communication" means any means, medium, or manner for providing information relating to any tobacco product, including face-to-face interaction, mailings by postal service or courier to an individual who is an addressee, and electronic mail to an individual who is an addressee.

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

(A) manufactures anywhere a tobacco product that is intended to be distributed commercially in the United States, including a tobacco product intended to be distributed commercially in the United States through an importer;

(B) is the first purchaser for resale in the United States of tobacco products manufactured outside the United States for distribution commercially in the United States; or

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

(44) The term "toxicant" means a chemical or physical agent that produces an adverse biological effect.

(45) The term "tribal organization" has the meaning assigned that term in section 4(1) of the Indian Self Determination and Education Assistance Act.

(46) The term "United States" means the several States, as defined in this Act.

(47) The term "youth" means any individual who in not an adult.

SEC. 101. CENTER AUTHORITY OVER TOBACCO PRODUCTS.

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

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

(c) CENTER.—The Secretary of Health and Human Services shall establish within the Department of Health and Human Services the Tobacco Harm Reduction Center. The head of the Center shall be an Administrator, who shall assume the statutory authority conferred by this Act, perform the functions that relate to the subject matter of this Act, and have the authority to promulgate regulations for the efficient enforcement of this Act. In promulgating any

regulations under such authority, in whole or in part or any regulation that is likely to have an annual effect on the economy of $50,000,000 or more or have a material adverse effect on adult users of tobacco products, tobacco product manufacturers, distributors, or retailers, the Administrator shall—

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

(2) consider experience gained under any relevantly similar regulations at the Federal or State level;

(3) determine the reasonableness of the relationship between the costs of complying with such regulation and the public health benefits to be achieved by such regulation;

(4) determine the reasonable likelihood of measurable and substantial reductions in morbidity and mortality among individual tobacco users;

(5) determine the impact to United States tobacco producers and farm operations;

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

(7) determine the impact on illicit trade of tobacco products.

(d) LIMITATION OF AUTHORITY.—

(1) IN GENERAL.—The provisions of this Act shall not apply to tobacco leaf that is not in the possession of a manufacturer of tobacco products, or to the producers of tobacco leaf, including tobacco growers, tobacco warehouses, and tobacco grower cooperatives, nor shall any employee of the Center have any authority to enter onto a farm owned by a producer of tobacco leaf without the written consent of such producer.

(2) EXCEPTION.—Notwithstanding paragraph (1), if a producer of tobacco leaf is also a tobacco product manufacturer or controlled by a tobacco product manufacturer, the producer shall be subject to this Act in the producer's capacity as a manufacturer. The exception in this subparagraph shall not apply to a producer of tobacco leaf who grows tobacco under a contract with a tobacco product manufacturer and who is not otherwise engaged in the manufacturing process.

(3) RULE OF CONSTRUCTION.—Nothing in this Act shall be construed to grant the Administrator authority to promulgate regulations on any matter that involves the production of tobacco leaf or a producer thereof.

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

(f) CONSULTATION PRIOR TO RULEMAKING.—Prior to promulgating rules under this Act, the Administrator shall endeavor to consult with other Federal agencies as appropriate.

SEC. 102. EXCLUSION OF OTHER REGULATORY PROGRAMS.

(a) EXCLUSION OF TOBACCO PRODUCTS AND NICOTINE-CONTAINING PRODUCTS FROM THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.—No tobacco product and no nicotine-containing product shall be regulated as a food, drug, or device in accordance with section 201 (f), (g) or (h) or Chapter IV or V of the Federal Food, Drug, and Cosmetic Act, except that any tobacco product commercially distributed domestically and any nicotine-containing product commercially distributed domestically shall be subject to Chapter V of the

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

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

(1) establish a precedent with regard to any other industry, situation, circumstance, or legal action; or

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

(c) EXCLUSIONS FROM AUTHORITY OF ADMINISTRATOR.—The authority granted to the Administrator under this Act shall not apply to—

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

(2) raw tobacco that is grown for a tobacco product manufacturer by a grower, and that is in the possession of that grower or of a person that is not a tobacco product manufacturer and is within the scope of subparagraphs (A) through(F) of paragraph (3); or

(3) the activities, materials, facilities, or practices of persons that are not tobacco product manufacturers and that are—

(A) producers of raw tobacco, including tobacco growers;

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

(C) tobacco grower cooperatives;

(D) persons that cure raw tobacco;

(E) persons that process raw tobacco; and

(F) persons that store raw tobacco for aging.

If a producer of raw tobacco is also a tobacco product manufacturer, an affiliate of a tobacco product manufacturer, or a person producing raw tobacco for a tobacco product manufacturer, then that producer shall be subject to this Act only to the extent of that producer's capacity as a tobacco product manufacturer.

SEC. 103. EXISTING FEDERAL STATUTES MAINTAINED.

Except as amended or repealed by this Act, all Federal statutes in effect as of the effective date of this Act that regulate tobacco, tobacco products, or tobacco product manufacturers shall remain in full force and effect. Such statutes include, without limitation—

(1) the Federal Cigarette Labeling and Advertising Act, sections 1331–1340 of title 15, United States Code, except that section 1335 of title 15, United States Code, is repealed;

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

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

(4) those statutes authorizing regulation of tobacco, tobacco products, or tobacco product manufacturers by the Federal Trade Commission, the Department of Agriculture, the Environmental Protection Agency, the Internal Revenue Service,

and the Alcohol and Tobacco Tax and Trade Bureau of the Department of the Treasury.

SEC. 104. PROCEEDINGS IN THE NAME OF THE UNITED STATES; SUBPOENAS; PREEMPTION OF STATE AND LOCAL LAW; NO PRIVATE RIGHT OF ACTION.

In furtherance of this Act:

(1) All proceedings for the enforcement, or to restrain violations, of this Act shall be by and in the name of the United States. Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any proceeding under this section. No State, or political subdivision thereof, may proceed or intervene in any Federal or State court under this Act or under any regulation promulgated under it, or allege any violation thereof except a violation by the Administrator. Nothing in this Act shall be construed to create a right of action by any private person for any violation of any provision of this Act or of any regulation promulgated under it.

(2) With respect to any subject matter addressed by this Act or by any regulation promulgated under it, no requirement or prohibition shall be imposed under State or local law upon any tobacco product manufacturer or distributor.

(3) Paragraph (2) shall not apply to any requirement or prohibition imposed under State or local law before the date of introduction of the bill that was enacted as this Act.

SEC. 105. ILLICIT TRADE.

The Administrator shall not promulgate any regulation or take any other action that has the effect of—

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

(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, by the Environmental Protection Agency for use on tobacco in the United States) that may render it injurious to health; but, in case the substance is not an added substance, such to-

bacco product shall not be considered adulterated under this subsection if the quantity of such substance in such tobacco product does not ordinarily render it injurious to health;

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

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

(B) if such product was not distributed commercially domestically on that date, by comparable tobacco products of the same style and within the same category that were commercially distributed domestically on that date;

(3) if it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth;

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

(5) if its "tar" yield is in violation of section 111.

SEC. 107. MISBRANDED TOBACCO PRODUCTS.

A tobacco product shall be deemed to be misbranded—

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

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

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

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

(C) the name and place of business of the tobacco product manufacturer, packer, or distributor; and

(D) the information required by section 201(c) and (e) or section 202(c) and (e), as applicable;

(3) if any word, statement, or other information required by or under authority of this Act to appear on the label, labeling, or advertising is not prominently placed thereon with such conspicuousness (as compared with other words, statements, or designs on the label, labeling, or advertising, as applicable) and in such terms as to render it reasonably likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(4) if any word, statement, or other information is required by or under this Act to appear on the label, unless such word, statement, or other information also appears on the outside container or wrapper, if any, of the retail package of such tobacco product, or is easily legible through the outside container or wrapper;

(5) if it was manufactured, prepared, or processed in an establishment not duly registered under section 109, if it was not included in a list required by section 109, or if a notice or other information respecting it was not provided as required by section 109;

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

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

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

(A) containing "no additives," or any substantially similar term, unless the labeling or advertising, as applicable, also contains, clearly and prominently, the following disclosure: "No additives in our tobacco does NOT mean safer."; or

(B) being "natural," or any substantially similar term, unless the labeling or advertising, as applicable, also contains, clearly and prominently, the following disclosure: "Natural does NOT mean safer.";

(9) if in its labeling or advertising a term descriptive of the tobacco in the tobacco product is used otherwise than in accordance with a sanction or approval granted by a Federal agency;

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

(11) if with respect to such tobacco product a certification required by section 803 was not submitted or is materially false or misleading; or

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

SEC. 108. SUBMISSION OF HEALTH INFORMATION TO THE ADMINISTRATOR.

(a) REQUIREMENT.—Each tobacco product manufacturer or importer, or agents thereof, shall submit to the Administrator the following information:

(1) Not later than 18 months after the date of enactment of the Act, a listing of all ingredients, including tobacco, substances, compounds, and additives that are, as of such date, added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand and by quantity in each brand and brand style.

(2) A description of the content, delivery, and form of nicotine in each tobacco product measured in milligrams of nicotine in accordance with regulations promulgated by the Administrator in accordance with section 4(e) of the Federal Cigarette Labeling and Advertising Act.

(3) Beginning 4 years after the date of enactment of this Act, a listing of all constituents, including smoke constituents as applicable, identified by the Administrator as harmful to health in each tobacco product, and as applicable in the smoke of each tobacco product, by brand and by quantity in each brand and subbrand.

(b) DATA SUBMISSION.—At the request of the Administrator, each tobacco product manufacturer or importer of tobacco products, or agents thereof, shall submit the following:

(1) Any or all documents (including underlying scientific information) relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer

(or agents thereof) on the health, toxicological, or physiologic effects of tobacco products and their constituents (including smoke constituents), ingredients, components, and additives.

(2) Any or all documents (including underlying scientific information) relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer (or agents thereof) that relate to the issue of whether a significant reduction in risk to health from tobacco products can occur upon the employment of technology available to the manufacturer.

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

(c) DATA LIST.—

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

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

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

SEC. 109. REGISTRATION AND LISTING.

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

(1) The term "manufacture, preparation, or processing" shall include repackaging or otherwise changing the container, wrapper, or label of any tobacco product package other than the carton in furtherance of the distribution of the tobacco product from the original place of manufacture to the person that makes final delivery or sale to the ultimate consumer or user, but shall not include the addition of a tax marking or other marking required by law to an already packaged tobacco product.

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

(b) ANNUAL REGISTRATION.—Commencing one year after enactment, on or before December 31 of each year, every person that owns or operates any establishment in any State engaged in the manufacture, preparation, or processing of a tobacco product or products for commercial distribution domestically shall register with the Administrator its name, places of business, and all such establishments.

(c) NEW PRODUCERS.—Every person upon first engaging, for commercial distribution domestically, in the manufacture, preparation, or processing of a tobacco product or products in any establishment that it owns or operates in any State shall immediately register with the Administrator its name, places of business, and such establishment.

(d) REGISTRATION OF FOREIGN ESTABLISHMENTS.—

(1) Commencing one year after enactment of this Act, on or before December 31 of each year, the person that, within any foreign country, owns or operates any establishment engaged in the manufacture, preparation, or processing of a tobacco product that is imported or offered for import into the United States shall, through electronic means or other means permitted by the Administrator, register with the Administrator the name and place of business of each such establishment, the name of the United States agent for the establishment, and the name of each importer of such tobacco product in the United States that is known to such person.

(2) Such person also shall provide the information required by subsection (j), including sales made by mail, or through the Internet, or other electronic means.

(3) The Administrator is authorized to enter into cooperative arrangements with officials of foreign countries to ensure that adequate and effective means are available for purposes of determining, from time to time, whether tobacco products manufactured, prepared, or processed by an establishment described in paragraph (1), if imported or offered for import into the United States, shall be refused admission on any of the grounds set forth in section 708.

(e) ADDITIONAL ESTABLISHMENTS.—Every person duly registered in accordance with the foregoing subsections of this section shall immediately register with the Administrator any additional establishment that it owns or operates and in which it begins the manufacture, preparation, or processing of a tobacco product or products for commercial distribution domestically or for import into the United States.

(f) EXCLUSIONS FROM APPLICATION OF THIS SECTION.—The foregoing subsections of this section shall not apply to—

(1) persons that manufacture, prepare, or process tobacco products solely for use in research, teaching, chemical or biological analysis, or export; or

(2) such other classes of persons as the Administrator may by regulation exempt from the application of this section upon a finding that registration by such classes of persons in accordance with this section is not necessary for the protection of the public health.

(g) INSPECTION OF PREMISES.—Every establishment registered with the Administrator pursuant to this section shall be subject to inspection pursuant to section 706; and every such establishment engaged in the manufacture, preparation, or processing of a tobacco product or products shall be so inspected by one or more officers or employees duly designated by the Administrator at least once in the two-year period beginning with the date of registration of such establishment pursuant to this section and at least once in every successive two-year period thereafter, except that inspection of es-

tablishments outside the United States may be conducted by other personnel pursuant to a cooperative arrangement under subsection (d)(3).

(h) FILING OF LISTS OF TOBACCO PRODUCTS MANUFACTURED, PREPARED, OR PROCESSED BY REGISTRANTS; STATEMENTS; ACCOMPANYING DISCLOSURES.—

(1) Every person that registers with the Administrator under subsection (b), (c), (d), or (e) shall, at the time of registration under any such subsection, file with the Administrator a list of all brand styles (with each brand style in each list listed by the common or usual name of the tobacco product category to which it belongs and by any proprietary name) that are being manufactured, prepared, or processed by such person for commercial distribution domestically or for import into the United States, and that such person has not included in any list of tobacco products filed by such person with the Administrator under this paragraph or paragraph (2) before such time of registration. Such list shall be prepared in such form and manner as the Administrator may prescribe, and shall be accompanied by the label for each such brand style and a representative sampling of any other labeling and advertising for each;

(2) Each person that registers with the Administrator under this section shall report to the Administrator each August for the preceding six-month period from January through June, and each February for the preceding six-month period form July through December, following information:

(A) A list of each brand style introduced by the registrant for commercial distribution domestically or for import into the United States that has not been included in any list previously filed by such registrant with the Administrator under this subparagraph or paragraph (1). A list under this subparagraph shall list a brand style by the common or usual name of the tobacco product category to which it belongs and by any proprietary name, and shall be accompanied by the other information required by paragraph (1).

(B) If since the date the registrant last made a report under this paragraph (or if such registrant has not previously made a report under this paragraph, since the effective date of this Act) such registrant has discontinued the manufacture, preparation, or processing for commercial distribution domestically or for import into the United States of a brand style included in a list filed by such registrant under subparagraph (A) or paragraph (1), notice of such discontinuance, the date of such discontinuance, and the identity (by the common or usual name of the tobacco product category to which it belongs and by any proprietary name) of such tobacco product.

(C) If, since the date the registrant reported pursuant to subparagraph (B) a notice of discontinuance of a tobacco product, the registrant has resumed the manufacture, preparation, or processing for commercial distribution domestically or for import into the United States of that brand style, notice of such resumption, the date of such resumption, the identity of such brand style (by the common

or usual name of the tobacco product category to which it belongs and by any proprietary name), and the other information required by paragraph (1), unless the registrant has previously reported such resumption to the Administrator pursuant to this subparagraph.

(D) Any material change in any information previously submitted pursuant to this paragraph (2) or paragraph (1).

(i) ELECTRONIC REGISTRATION.—Registrations under subsections (b), (c), (d), and (e) (including the submission of updated information) shall be submitted to the Administrator by electronic means, unless the Administrator grants a request for waiver of such requirement because use of electronic means is not reasonable for the person requesting such waiver.

SEC. 110. GENERAL PROVISIONS RESPECTING CONTROL OF TOBACCO PRODUCTS.

(a) IN GENERAL.—Any requirement established by or under section 106, 107, or 113 applicable to a tobacco product shall apply to such tobacco product until the applicability of the requirement to the tobacco product has been changed by action taken under section 111, section 114, section 115, or subsection (d) of this section, and any requirement established by or under section 106, 107, or 113 which is inconsistent with a requirement imposed on such tobacco product under section 111, section 114, section 115, or subsection (d) of this section shall not apply to such tobacco product.

(b) INFORMATION ON PUBLIC ACCESS AND COMMENT.—Each notice of proposed rulemaking or other notification under section 111, 112, 113, 114, or 115 or under this section, any other notice which is published in the Federal Register with respect to any other action taken under any such section and which states the reasons for such action, and each publication of findings required to be made in connection with rulemaking under any such section shall set forth—

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

(2) the period within which interested persons may present their comments on the notice or findings (including the need therefore) orally or in writing, which period shall be at least 60 days but may not exceed 90 days unless the time is extended by the Administrator by a notice published in the Federal Register stating good cause therefore.

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

(d) RESTRICTIONS.—

(1) IN GENERAL.—The Administrator may issue regulations, consistent with this Act, regarding tobacco products if the Administrator determines that such regulation would be appro-

priate for the protection of the public health. The finding as to whether such regulation would be appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the users of the tobacco product, and taking into account that the standard is reasonably likely to result in measurable and substantial reductions in morbidly and mortality among individual tobacco users.

(2) LABEL STATEMENTS.—The label of a tobacco product shall bear such appropriate statements of the restrictions required by a regulation under subsection (a) as the Administrator may in such regulation prescribe.

(e) GOOD MANUFACTURING PRACTICE REQUIREMENTS.—

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

(A) IN GENERAL.—In applying manufacturing restrictions to tobacco, the Administrator shall, in accordance with subparagraph (B), prescribe regulations (which may differ based on the type of tobacco product involved) requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation (including a process to assess the performance of a tobacco product), packing, and storage of a tobacco product conform to current good manufacturing practice, or hazard analysis and critical control point methodology, as prescribed in such regulations to assure that the public health is protected and that the tobacco product is in compliance with this Act. Such regulations may provide for the testing of raw tobacco for pesticide chemical residues after a tolerance for such chemical residues has been established.

(B) REQUIREMENTS.—The Administrator shall—

(i) before promulgating any regulation under subparagraph (A), afford the Tobacco Products Scientific Advisory Committee an opportunity to submit recommendations with respect to the regulation proposed to be promulgated;

(ii) before promulgating any regulation under subparagraph (A), afford opportunity for an oral hearing;

(iii) provide the Tobacco Products Scientific Advisory Committee a reasonable time to make its recommendation with respect to proposed regulations under subparagraph (A); and

(iv) in establishing the effective date of a regulation promulgated under this subsection, take into account the differences in the manner in which the different types of tobacco products have historically been produced, the financial resources of the different tobacco product manufacturers, and the state of their existing manufacturing facilities, and shall provide for a reasonable period of time for such manufacturers to conform to good manufacturing practices but no earlier than four years from date of enactment.

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

(i) was knowingly grown or processed using a pesticide chemical that is not approved under applicable

Federal law for use in domestic tobacco farming and processing; or

(ii) in the case of a pesticide chemical that is so approved, was grown or processed using the pesticide chemical in a manner inconsistent with the approved labeling for use of the pesticide chemical in domestic tobacco farming and processing.

(D) EXCLUSION.—Subparagraph (C)(ii) shall not apply to tobacco products manufactured with foreign-grown flue-cured or burley tobacco so long as that foreign grown tobacco was either—

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

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

(E) SETTING OF MAXIMUM RESIDUE LIMITS.—The Administrator shall adopt the following pesticide residue standards:

Pesticide residue standards

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

CHLORDANE.....3.0
DIBROMOCHLOROPROPANE (DBCP).....1.0
DICAMBA (Temporary).... 5.0
ENDRIN....0.1
ETHYLENE DIBROMIDE (EDB)....0.1
FORMOTHION.....0.5
HEXACHLOROBENZENE (HCB)....0.1
METHOXYCHLOR.....0.1
TOXAPHENE.....0.3
2,4-D (Temporary).....5.0
2,4,5-T.....0.1
Sum of ALDRIN and DIELDRIN.....0.1
Sum of CYPERMETHRIN and PERMETHRIN (Temporary).....3.0
Sum of DDT, TDE (DDD), and DDE 0.4
Sum of HEPTACHLOR and HEPTACHLOR EPOXIDE.....0.1

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

(2) EXEMPTIONS; VARIANCES.—

(A) PETITION.—Any person subject to any requirement prescribed under paragraph (1) may petition the Administrator for a permanent or temporary exemption or variance from such requirement. Such a petition shall be submitted to the Administrator in such form and manner as the Administrator shall prescribe and shall—

(i) in the case of a petition for an exemption from a requirement, set forth the basis for the petitioner's determination that compliance with the requirement is not required to assure that the tobacco product will be in compliance with this Act;

(ii) in the case of a petition for a variance from a requirement, set forth the methods proposed to be used in, and the facilities and controls proposed to be used for, the manufacture, packing, and storage of the tobacco product in lieu of the methods, facilities, and controls prescribed by the requirement; and

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

(B) REFERRAL TO THE TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE.—The Administrator may refer to the Tobacco Products Scientific Advisory Committee any petition submitted under subparagraph (A). The Tobacco Products Scientific Advisory Committee shall report its recommendations to the Administrator with respect to a petition referred to it within 60 days after the date of the petition's referral. Within 60 days after—

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

(ii) the day after the petition was referred to the Tobacco Products Scientific Advisory Committee,

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

(C) APPROVAL.—The Administrator may approve—

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

(ii) a petition for a variance for a tobacco product from a requirement if the Administrator determines that the methods to be used in, and the facilities and controls to be used for, the manufacture, packing, and storage of the tobacco product in lieu of the methods, facilities, and controls prescribed by the requirement are sufficient to assure that the tobacco product will be in compliance with this Act.

(D) CONDITIONS.—An order of the Administrator approving a petition for a variance shall prescribe such conditions respecting the methods used in, and the facilities and controls used for, the manufacture, packing, and storage of the tobacco product to be granted the variance under the petition as may be necessary to assure that the tobacco product will be in compliance with this Act.

(E) HEARING.—After the issuance of an order under subparagraph (B) respecting a petition, the petitioner shall have an opportunity for an informal hearing on such order.

(3) COMPLIANCE.—Compliance with requirements under this subsection shall not be required before the end of the 3-year period following the date of enactment of this Act.

(f) RESEARCH AND DEVELOPMENT.—The Administrator may enter into contracts for research, testing, and demonstrations respecting tobacco products and may obtain tobacco products for research, testing, and demonstration purposes.

SEC. 111. SMOKING ARTICLE STANDARDS.

(a) IN GENERAL.—

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

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

(i) the name of any candy or fruit;

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

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

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

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

(D) DEFINITIONS.—In this section:

(i) The term "candy" means a confection made from sugar or sugar substitute, including any confection identified generically or by brand, and shall include the words "cacao," "chocolate," "cinnamon," "cocoa," "honey," "licorice," "maple," "mocha," and "vanilla."

(ii) The term "fruit" means any fruit identified by generic name, type, or variety, including but not limited to "apple," "banana," "cherry," and "orange." The term "fruit" does not include words that identify seeds, nuts or peppers, or types or varieties thereof or words that are extensions or variations of such words.

(2) SMOKING ARTICLE STANDARDS.—

(A) IN GENERAL.—The Administrator may adopt smoking article standards in addition to those in paragraph (1) if the Administrator finds that a smoking article standard is appropriate for the protection of the public health.

(B) DETERMINATIONS.—

(i) CONSIDERATIONS.—In making a finding described in subparagraph (A), the Administrator shall consider scientific evidence concerning—

(I) the risks and benefits to the users of smoking articles of the proposed standard; and

(II) that the standard is reasonably likely to result in measurable and substantial reductions in

morbidity and mortality among individual tobacco users.

(ii) ADDITIONAL CONSIDERATIONS.—In the event that the Administrator makes a determination, set forth in a proposed smoking article standard in a proposed rule, that it is appropriate for the protection of public health to require the reduction or elimination of an additive, constituent (including a smoke constituent), or other component of a smoking article because the Administrator has found that the additive, constituent, or other component is harmful, any party objecting to the proposed standard on the ground that the proposed standard will not reduce or eliminate the risk of illness or injury may provide for the Administrator's consideration scientific evidence that demonstrates that the proposed standard will not reduce or eliminate the risk of illness or injury.

(3) CONTENT OF SMOKING ARTICLE STANDARDS.—A smoking article standard established under this section for a smoking article—

(A) may include provisions that are appropriate for the protection of the public health, including provisions, where appropriate—

(i) for "tar" and nicotine yields of the product;

(ii) for the reduction of other constituents, including smoke constituents, or harmful components of the product; or

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

(B) may, where appropriate for the protection of the public health, include—

(i) provisions respecting the construction, components, ingredients, additives, constituents, including smoke constituents, and properties of the smoking article;

(ii) provisions for the testing (on a sample basis or, if necessary, on an individual basis) of the smoking article;

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

(iv) provisions requiring that the results of each or of certain of the tests of the smoking article required to be made under clause (ii) show that the smoking article is in conformity with the portions of the standard for which the test or tests were required.

(4) PERIODIC REEVALUATION OF SMOKING ARTICLE STANDARDS.—The Administrator may provide for periodic evaluation of smoking article standards established under this section to determine whether such standards should be changed to reflect new medical, scientific, or other technological data.

(5) CIGARETTE "TAR" LIMITS.—

(A) NO INCREASE IN "TAR" YIELDS.—No cigarette manufacturer shall distribute for sale domestically a brand style of cigarettes that generates a "tar" yield greater than the "tar" yield of that brand style of cigarettes on the date of

introduction of this Act, as determined by the ISO smoking regimen and its associated tolerances. The "tar" tolerances for cigarettes with ISO "tar" yields in the range of 1 to 20 milligrams per cigarette, based on variations arising from sampling procedure, test method, and sampled product, itself, are the greater of plus or minus—

(i) 15 percent; or

(ii) 1 milligram per cigarette.

(B) LIMIT ON NEW CIGARETTES.—After the effective date of this Act, no cigarette manufacturer shall manufacture for commercial distribution domestically a brand style of cigarettes that both—

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

(ii) generates a "tar" yield of greater than 20 milligrams per cigarette as determined by the ISO smoking regimen and its associated tolerances.

(C) LIMIT ON ALL CIGARETTES.—After December 31, 2010, no cigarette manufacturer shall manufacture for commercial distribution domestically a brand style of cigarettes that generates a "tar" yield greater than 20 milligrams per cigarette as determined by the ISO smoking regimen and its associated tolerances.

(D) REVIEW BY ADMINISTRATOR.—After the effective date of this Act, the Administrator shall evaluate the available scientific evidence addressing the potential relationship between historical "tar" yield values and risk of harm to smokers. If upon a review of that evidence, and after consultation with technical experts of the Tobacco Harm Reduction Center and the Centers for Disease Control and Prevention and notice and an opportunity for public comment, the Administrator determines, that a reduction in "tar" yield may reasonably be expected to provide a meaningful reduction of the risk or risks of harm to smokers, the Administrator shall issue an order that—

(i) provides that no cigarette manufacturer shall manufacture for commercial distribution domestically a cigarette that generates a "tar" yield that exceeds 14 milligrams as determined by the ISO smoking regimen and its associated tolerances; and

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

(6) INVOLVEMENT OF OTHER AGENCIES; INFORMED PERSONS.—In carrying out duties under this section, the Administrator shall endeavor to—

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

(B) consult with other Federal agencies concerned with standard setting and other nationally or internationally recognized standard-setting entities; and

(C) invite appropriate participation, through joint or other conferences, workshops, or other means, by informed persons representative of scientific, professional, industry, agricultural, or consumer organizations who in the Administrator's judgment can make a significant contribution.

(b) CONSIDERATIONS BY ADMINISTRATOR.—

(1) TECHNICAL ACHIEVABILITY.—The Administrator shall consider information submitted in connection with a proposed standard regarding the technical achievability of compliance with such standard.

(2) OTHER CONSIDERATIONS.—The Administrator shall consider all other information submitted in connection with a proposed standard, such as the creation of a significant demand for contraband or other tobacco products that do not meet the requirements of this Act and the significance of such demand.

(c) PROPOSED STANDARDS.—

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

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

(A) set forth a finding with supporting justification that the smoking article standard is appropriate for the protection of the public health;

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

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

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

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

(4) COMMENT.—The Administrator shall provide for a comment period of not less than 90 days.

(d) PROMULGATION.—

(1) IN GENERAL.—After the expiration of the period for comment on a notice of proposed rulemaking published under subsection (c) respecting a standard and after consideration of comments submitted under subsections (b) and (c) and any report from the Tobacco Products Scientific Advisory Committee, if the Administrator determines that the standard would be appropriate for the protection of the public health, the Administrator shall—

(A) promulgate a regulation establishing a smoking article standard and publish in the Federal Register findings on the matters referred to in subsection (c); or

(B) publish a notice terminating the proceeding for the development of the standard together with the reasons for such termination.

(2) EFFECTIVE DATE.—A regulation establishing a smoking article standard shall set forth the date or dates upon which the standard shall take effect, but no such regulation may take

effect before 1 year after the date of its publication unless the Administrator determines that an earlier effective date is necessary for the protection of the public health. Such date or dates shall be established so as to minimize, consistent with the public health, economic loss to, and disruption or dislocation of, domestic and international trade. In establishing such effective date or dates, the Administrator shall consider information submitted in connection with a proposed product standard by interested parties, including manufacturers and tobacco growers, regarding the technical achievability of compliance with the standard, and including information concerning the existence of patents that make it impossible to comply in the timeframe envisioned in the proposed standard.

(3) LIMITATION ON POWER GRANTED.—Because of the importance of a decision of the Administrator to issue a regulation—

(A) banning cigarettes, smokeless smoking articles, little cigars, cigars other than little cigars, pipe tobacco, or roll-your-own smoking articles;

(B) requiring the reduction of "tar" or nicotine yields of a smoking article to zero;

(C) prohibiting the sale of any smoking article in face-to-face transactions by a specific category of retail outlets;

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

(E) requiring that the sale or distribution of a smoking article be limited to the written or oral authorization of a practitioner licensed by law to prescribe medical products,

the Administrator is prohibited from taking such actions under this Act.

(4) MATCHBOOKS.—For purposes of any regulations issued by the Administrator under this Act, matchbooks of conventional size containing not more than 20 paper matches, and which are customarily given away for free with the purchase of smoking articles, shall be considered as adult-written publications which shall be permitted to contain advertising.

(5) AMENDMENT; REVOCATION.—

(A) AUTHORITY.—The Administrator, upon the Administrator's own initiative or upon petition of an interested person, may by a regulation, promulgated in accordance with the requirements of subsection (c) and paragraph (2), amend or revoke a smoking article standard.

(B) EFFECTIVE DATE.—The Administrator may declare a proposed amendment of a smoking article standard to be effective on and after its publication in the Federal Register and until the effective date of any final action taken on such amendment if the Administrator determines that making it so effective is in the public interest.

(6) REFERRAL TO ADVISORY COMMITTEE.—

(A) IN GENERAL.—The Administrator shall refer a proposed regulation for the establishment, amendment, or revocation of a smoking article standard to the Tobacco Products Scientific Advisory Committee for a report and recommendation with respect to any matter involved in the proposed regulation which requires the exercise of scientific judgment.

(B) INITIATION OF REFERRAL.—The Administrator shall make a referral under this paragraph—

(i) on the Administrator's own initiative; or

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

(I) demonstrates good cause for the referral; and

(II) is made before the expiration of the period for submission of comments on the proposed regulation.

(C) PROVISION OF DATA.—If a proposed regulation is referred under this paragraph to the Tobacco Products Scientific Advisory Committee, the Administrator shall provide the Advisory Committee with the data and information on which such proposed regulation is based.

(D) REPORT AND RECOMMENDATION.—The Tobacco Products Scientific Advisory Committee shall, within 90 days after the referral of a proposed regulation under this paragraph and after independent study of the data and information furnished to it by the Administrator and other data and information before it, submit to the Administrator a report and recommendation respecting such regulation, together with all underlying data and information and a statement of the reason or basis for the recommendation.

(E) PUBLIC AVAILABILITY.—The Administrator shall make a copy of each report and recommendation under subparagraph (D) publicly available.

SEC. 112. NOTIFICATION AND OTHER REMEDIES.

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

(1) a tobacco product which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm materially above the risk for death and disease of tobacco products currently in interstate commerce, to the public health; and

(2) notification under this subsection is necessary to eliminate the unreasonable risk of such harm and no more practicable means is available under the provisions of this Act (other than this section) to eliminate such risk,

the Administrator may issue such order as may be necessary to assure that adequate notification is provided in an appropriate form, by the persons and means best suited under the circumstances involved, to all persons who should properly receive such notification in order to eliminate such risk. The Administrator may order notification by any appropriate means, including public service announcements. Before issuing an order under this subsection, the Administrator shall consult with the persons who are to give notice under the order.

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

(c) RECALL AUTHORITY.—

(1) IN GENERAL.—If the Administrator finds that there is a reasonable probability that a tobacco product contains a manufacturing or other defect not ordinarily contained in tobacco

products on the market that would cause serious, acute adverse health consequences or death, the Administrator shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the tobacco product) to immediately cease distribution of such tobacco product. The order shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order and on whether the order should be amended to require a recall of such tobacco product. If, after providing an opportunity for such a hearing, the Administrator determines that inadequate grounds exist to support the actions required by the order, the Administrator shall vacate the order.

(2) AMENDMENT OF ORDER TO REQUIRE RECALL.—

(A) IN GENERAL.—If, after providing an opportunity for an informal hearing under paragraph (1), the Administrator determines that the order should be amended to include a recall of the tobacco product with respect to which the order was issued, the Administrator shall, except as provided in subparagraph (B), amend the order to require a recall. The Administrator shall specify a timetable in which the tobacco product recall will occur and shall require periodic reports to the Administrator describing the progress of the recall.

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

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

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

In providing the notice required by clause (ii), the Administrator may use the assistance of retailers and other persons who distributed such tobacco product. If a significant number of such persons cannot be identified, the Administrator shall notify such persons under section 705(b).

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

SEC. 113. RECORDS AND REPORTS ON TOBACCO PRODUCTS.

Every person who is a tobacco product manufacturer or importer of a tobacco product shall establish and maintain such records, make such reports, and provide such information, as the Administrator may by regulation reasonably require to assure that such tobacco product is not adulterated or misbranded.

SEC. 114. APPLICATION FOR REVIEW OF CERTAIN SMOKING ARTICLES.

(a) IN GENERAL.—

(1) NEW SMOKING ARTICLE DEFINED.—For purposes of this section the term "new smoking article" means—

(A) any smoking article that was not commercially marketed in the United States as of the date of enactment of this Act; and

(B) any smoking article that incorporates a significant modification (including changes in design, component, part, or constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or other additive or ingredient) of a smoking article where the modified product was commercially marketed in the United States after the date of enactment of this Act.

(2) PREMARKET REVIEW REQUIRED.—

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

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

(ii) is in compliance with the requirements of this Act.

(B) CONSUMER TESTING.—This section shall not apply to smoking articles that are provided to adult tobacco consumers for purposes of consumer testing. For purposes of this section, the term "consumer testing" means an assessment of smoking articles that is conducted by or under the control and direction of a manufacturer for the purpose of evaluating consumer acceptance of such smoking articles, utilizing only the quantity of cigarettes that is reasonably necessary for such assessment

(3) SUBSTANTIALLY EQUIVALENT DEFINED.—

(A) IN GENERAL.—In this section, the term "substantially equivalent" or "substantial equivalence" means, with respect to the smoking article being compared to the predicate smoking article, that the Administrator by order has found that the smoking article—

(i) has the same general characteristics as the predicate smoking article; or

(ii) has different characteristics and the information submitted contains information, including clinical data if deemed necessary by the Administrator, that demonstrates that it is not appropriate to regulate the product under this section because the product does not raise different questions of public health for the consumer of the product.

(B) CHARACTERISTICS.—In subparagraph (A), the term "characteristics" means the materials, ingredients, design, composition, heating source, or other features of a smoking article.

(C) LIMITATION.—A smoking article may not be found to be substantially equivalent to a predicate smoking article that has been removed from the market at the initiative of the Administrator or that has been determined by a judicial order to be misbranded or adulterated.

(4) HEALTH INFORMATION.—As part of a submission respecting a smoking article, the person required to file a premarket notification shall provide an adequate summary of any health information related to the smoking article or state that such information will be made available upon request by any person.

(b) APPLICATION.—

(1) CONTENTS.—An application under this section shall contain—

(A) full reports of all information, published or known to, or which should reasonably be known to, the applicant, concerning investigations which have been made to show the health risks of such smoking article and whether such smoking article presents less risk than other smoking articles;

(B) a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such smoking article;

(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such smoking article;

(D) an identifying reference to any smoking article standard under section 111 which would be applicable to any aspect of such smoking article, and either adequate information to show that such aspect of such smoking article fully meets such smoking article standard or adequate information to justify any deviation from such standard;

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

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

(G) such other information relevant to the subject matter of the application as the Administrator may require.

(2) REFERRAL TO TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE.—Upon receipt of an application meeting the requirements set forth in paragraph (1), the Administrator—

(A) may, on the Administrator's own initiative; or

(B) may, upon the request of an applicant,

refer such application to the Tobacco Products Scientific Advisory Committee for reference and for submission (within such period as the Administrator may establish) of a report and recommendation respecting the application, together with all underlying data and the reasons or basis for the recommendation.

(c) ACTION ON APPLICATION.—

(1) DEADLINE.—As promptly as possible, but in no event later than 90 days after the receipt of an application under subsection (b), the Administrator, after considering the report and recommendation submitted under subsection (b)(2), shall—

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

(B) issue an order that the new product may not be introduced or delivered for introduction into interstate commerce if the Administrator finds (and sets forth the basis for such finding as part of or accompanying such denial) that 1 or more grounds for denial specified in paragraph (2) of this subsection apply.

(2) DENIAL OF APPLICATION.—The Administrator shall deny an application submitted under subsection (b) if, upon the

basis of the information submitted to the Administrator as part of the application and any other information before the Administrator with respect to such smoking article, the Administrator finds that—

(A) there is a lack of a showing that permitting such smoking article to be marketed would be appropriate for the protection of the public health;

(B) the methods used in, or the facilities or controls used for, the manufacture, processing, or packing of such smoking article do not conform to the requirements of section 110(e);

(C) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; or

(D) such smoking article is not shown to conform to a smoking article standard in effect under section 111, and there is a lack of adequate information to justify the deviation from such standard.

(3) DENIAL INFORMATION.—Any denial of an application shall, insofar as the Administrator determines to be practicable, be accompanied by a statement informing the applicant of the measures required to remove such application from deniable form (which measures may include further research by the applicant in accordance with 1 or more protocols prescribed by the Administrator).

(4) BASIS FOR FINDING.—For purposes of this section, the finding as to whether the commercial introduction of a smoking article for which an application has been submitted is appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the users of the smoking article, and taking into account whether such commercial introduction is reasonably likely to increase the morbidly and mortality among individual tobacco users.

(d) WITHDRAWAL AND TEMPORARY SUSPENSION.—

(1) IN GENERAL.—The Administrator shall, upon obtaining, where appropriate, advice on scientific matters from the Tobacco Products Scientific Advisory Committee, and after due notice and opportunity for informal hearing for a smoking article for which an order was issued under subsection (c)(1)(A), issue an order withdrawing the order if the Administrator finds—

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

(B) that the application contained or was accompanied by an untrue statement of a material fact;

(C) that the applicant—

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

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

(D) on the basis of new information before the Administrator with respect to such smoking article, evaluated together with the evidence before the Administrator when the application was reviewed, that the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or installation of such smoking article do not conform with the requirements of section 110(e) and were not brought into conformity with such requirements within a reasonable time after receipt of written notice from the Administrator of nonconformity;

(E) on the basis of new information before the Administrator, evaluated together with the evidence before the Administrator when the application was reviewed, that the labeling of such smoking article, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Administrator of such fact; or

(F) on the basis of new information before the Administrator, evaluated together with the evidence before the Administrator when such order was issued, that such smoking article is not shown to conform in all respects to a smoking article standard which is in effect under section 111, compliance with which was a condition to the issuance of an order relating to the application, and that there is a lack of adequate information to justify the deviation from such standard.

(2) APPEAL.—The holder of an application subject to an order issued under paragraph (1) withdrawing an order issued pursuant to subsection (c)(1)(A) may, by petition filed on or before the 30th day after the date upon which such holder receives notice of such withdrawal, obtain review thereof in accordance with section 116.

(3) TEMPORARY SUSPENSION.—If, after providing an opportunity for an informal hearing, the Administrator determines there is reasonable probability that the continuation of distribution of a smoking article under an order would cause serious, adverse health consequences or death, that is greater than ordinarily caused by smoking articles on the market, the Administrator shall by order temporarily suspend the authority of the manufacturer to market the product. If the Administrator issues such an order, the Administrator shall proceed expeditiously under paragraph (1) to withdraw such application.

(e) SERVICE OF ORDER.—An order issued by the Administrator under this section shall be served—

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

(2) by mailing the order by registered mail or certified mail addressed to the applicant at the applicant's last known address in the records of the Administrator.

(f) RECORDS.—

(1) ADDITIONAL INFORMATION.—In the case of any smoking article for which an order issued pursuant to subsection (c)(1)(A) for an application filed under subsection (b) is in effect, the applicant shall establish and maintain such records,

and make such reports to the Administrator, as the Administrator may by regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Administrator to determine, or facilitate a determination of, whether there is or may be grounds for withdrawing or temporarily suspending such order.

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

(g) INVESTIGATIONAL SMOKING ARTICLE EXEMPTION FOR INVESTIGATIONAL USE.—The Administrator may exempt smoking articles intended for investigational use from the provisions of this Act under such conditions as the Administrator may by regulation prescribe.

SEC. 115. MODIFIED RISK TOBACCO PRODUCTS.

(a) IN GENERAL.—No person may introduce or deliver for introduction into interstate commerce any modified risk tobacco product unless an order issued pursuant to subsection (g) is effective with respect to such product.

(b) DEFINITIONS.—In this section:

(1) MODIFIED RISK TOBACCO PRODUCT.—The term "modified risk tobacco product" means any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products.

(2) SOLD OR DISTRIBUTED.—

(A) IN GENERAL.—With respect to a tobacco product, the term "sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products" means a tobacco product—

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

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

(II) the tobacco product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance; or

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

(ii) the label, labeling, or advertising of which uses the descriptors "light", "mild", "low", "medium", "ultra light", "low tar" or "ultra low tar"; or

(iii) the tobacco product manufacturer of which has taken any action directed to consumers through the media or otherwise, other than by means of the tobacco product's label, labeling, or advertising, after the date of enactment of the Act, respecting the product that would be reasonably expected to result in consumers believing that the tobacco product or its smoke

may present a lower risk of disease or is less harmful than one or more commercially marketed tobacco products, or presents a reduced exposure to, or does not contain or is free of, a substance or substances.

(B) LIMITATION.—No tobacco product shall be considered to be "sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products", except as described in subparagraph (A).

(C) SMOKELESS TOBACCO PRODUCT.—No smokeless tobacco product shall be considered to be "sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products".

(3) EFFECTIVE DATE.—The provisions of paragraph (2)(A)(ii) shall take effect 12 months after the date of enactment of the Act.

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

(d) FILING.—Any person may file with the Administrator an application for a modified risk tobacco product. Such application shall include—

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

(2) the conditions for using the product;

(3) the formulation of the product;

(4) sample product labels and labeling;

(5) all documents (including underlying scientific information) relating to research findings conducted, supported, or possessed by the tobacco product manufacturer relating to the effect of the product on tobacco-related diseases and health-related conditions, including information both favorable and unfavorable to the ability of the product to reduce risk or exposure and relating to human health;

(6) data and information on how consumers actually use the tobacco product; and

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

(e) PUBLIC AVAILABILITY.—The Administrator shall make the application described in subsection (d) publicly available (except matters in the application which are trade secrets or otherwise confidential, commercial information) and shall request comments by interested persons on the information contained in the application and on the label, labeling, and advertising accompanying such application.

(f) ADVISORY COMMITTEE.—

(1) IN GENERAL.—The Administrator shall refer to the Tobacco Products Scientific Advisory Committee any application submitted under this section.

(2) RECOMMENDATIONS.—Not later than 60 days after the date an application is referred to the Tobacco Products Scientific Advisory Committee under paragraph (1), the Advisory

Committee shall report its recommendations on the application to the Administrator.

(g) MARKETING.—

(1) MODIFIED RISK PRODUCTS.—Except as provided in paragraph (2), the Administrator shall, with respect to an application submitted under this section, issue an order that a modified risk product may be commercially marketed only if the Administrator determines that the applicant has demonstrated that such product, as it is actually used by consumers, will—

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

(B) is reasonably likely to result in measurable and substantial reductions in morbidity and mortality among individual tobacco users.

(2) SPECIAL RULE FOR CERTAIN PRODUCTS.—

(A) IN GENERAL.—The Administrator may issue an order that a tobacco product may be introduced or delivered for introduction into interstate commerce, pursuant to an application under this section, with respect to a tobacco product that may not be commercially marketed under paragraph (1) if the Secretary makes the findings required under this paragraph and determines that the applicant has demonstrated that—

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

(ii) any aspect of the label, labeling, and advertising for such product that would cause the tobacco product to be a modified risk tobacco product under subsection (b) is limited to an explicit or implicit representation that such tobacco product or its smoke does not contain or is free of a substance or contains a reduced level of a substance, or presents a reduced exposure to a substance in tobacco smoke;

(iii) scientific evidence is not available and, using the best available scientific methods, cannot be made available without conducting long-term epidemiological studies for an application to meet the standards set forth in paragraph (1); and

(iv) the scientific evidence that is available without conducting long-term epidemiological studies demonstrates that a measurable and substantial reduction in morbidity or mortality among individual tobacco users is reasonably likely in subsequent studies.

(B) ADDITIONAL FINDINGS REQUIRED.—To issue an order under subparagraph (A) the Administrator must also find that the applicant has demonstrated that—

(i) the magnitude of the overall reductions in exposure to the substance or substances which are the subject of the application is substantial, such substance or substances are harmful, and the product as actually used exposes consumers to the specified reduced level of the substance or substances;

(ii) the product as actually used by consumers will not expose them to higher levels of other harmful substances compared to the similar types of tobacco prod-

ucts then on the market unless such increases are minimal and the reasonably likely overall impact of use of the product remains a substantial and measurable reduction in overall morbidity and mortality among individual tobacco users;

(iii) testing of actual consumer perception shows that, as the applicant proposes to label and market the product, consumers will not be misled into believing that the product—

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

(II) presents or has been demonstrated to present significant less of a risk of disease than other commercially marketed tobacco products; and

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

(3) BASIS.—The determinations under paragraphs (1) and (2) shall be based on—

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

(B) scientific evidence and other information that is made available to the Administrator.

(h) ADDITIONAL CONDITIONS FOR MARKETING.—

(1) MODIFIED RISK PRODUCTS.—The Administrator shall require for the marketing of a product under this section that any advertising or labeling concerning modified risk products enable the public to comprehend the information concerning modified risk and to understand the relative significance of such information in the context of total health and in relation to all of the diseases and health-related conditions associated with the use of tobacco products.

(2) COMPARATIVE CLAIMS.—

(A) IN GENERAL.—The Administrator may require for the marketing of a product under this subsection that a claim comparing a tobacco product to other commercially marketed tobacco products shall compare the tobacco product to a commercially marketed tobacco product that is representative of that type of tobacco product on the market (for example the average value of the top 3 brands of an established regular tobacco product).

(B) QUANTITATIVE COMPARISONS.—The Administrator may also require, for purposes of subparagraph (A), that the percent (or fraction) of change and identity of the reference tobacco product and a quantitative comparison of the amount of the substance claimed to be reduced shall be stated in immediate proximity to the most prominent claim.

(i) POSTMARKET SURVEILLANCE AND STUDIES.—

(1) IN GENERAL.—The Administrator shall require, with respect to a product for which an applicant obtained an order under subsection (g)(1), that the applicant conduct postmarket surveillance and studies for such a tobacco product to determine the impact of the order issuance on consumer perception,

behavior, and health, to enable the Administrator to review the accuracy of the determinations upon which the order was based, and to provide information that the Administrator determines is otherwise necessary regarding the use or health risks involving the tobacco product. The results of postmarket surveillance and studies shall be submitted to the Administrator on an annual basis.

(2) SURVEILLANCE PROTOCOL.—Each applicant required to conduct a surveillance of a tobacco product under paragraph (1) shall, within 30 days after receiving notice that the applicant is required to conduct such surveillance, submit, for the approval of the Administrator, a protocol for the required surveillance. The Administrator, within 30 days of the receipt of such protocol, shall determine if the principal investigator proposed to be used in the surveillance has sufficient qualifications and experience to conduct such surveillance and if such protocol will result in collection of the data or other information designated by the Administrator as necessary to protect the public health.

(j) WITHDRAWAL OF AUTHORIZATION.—The Administrator, after an opportunity for an informal hearing, shall withdraw an order under subsection (g) if the Administrator determines that—

(1) the applicant, based on new information, can no longer make the demonstrations required under subsection (g), or the Administrator can no longer make the determinations required under subsection (g);

(2) the application failed to include material information or included any untrue statement of material fact;

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

(A) a tobacco product standard is established pursuant to section 111;

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

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

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

(5) the applicant failed to meet a condition imposed under subsection (h).

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

(l) IMPLEMENTING REGULATIONS OR GUIDANCE.—

(1) SCIENTIFIC EVIDENCE.—Not later than 2 years after the date of enactment of the Act, the Administrator shall issue regulations or guidance (or any combination thereof) on the scientific evidence required for assessment and ongoing review of modified risk tobacco products. Such regulations or guidance shall—

(A) to the extent that adequate scientific evidence exists, establish minimum standards for scientific studies needed prior to issuing an order under subsection (g) to show a reasonable likelihood that a substantial reduction in morbidity or mortality among individual tobacco users occurs for products described in subsection (g)(1) or is reasonably likely for products described in subsection (g)(2);

(B) include validated biomarkers, intermediate clinical endpoints, and other feasible outcome measures, as appropriate;

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

(D) establish minimum standards for required postmarket surveillance, including ongoing assessments of consumer perception; and

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

(2) CONSULTATION.—The regulations or guidance issued under paragraph (1) may be developed in consultation with the Institute of Medicine, and with the input of other appropriate scientific and medical experts, on the design and conduct of such studies and surveillance.

(3) REVISION.—The regulations or guidance under paragraph (1) shall be revised on a regular basis as new scientific information becomes available.

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

SEC. 116. JUDICIAL REVIEW.

(a) RIGHT TO REVIEW.—

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

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

(B) a denial of an application under section 114(c),

any person adversely affected by such regulation or denial may file a petition for judicial review of such regulation or denial with the United States Court of Appeals for the District of Columbia or for the circuit in which such person resides or has their principal place of business.

(2) REQUIREMENTS.—

(A) COPY OF PETITION.—A copy of the petition filed under paragraph (1) shall be transmitted by the clerk of the court involved to the Administrator.

(B) RECORD OF PROCEEDINGS.—On receipt of a petition under subparagraph (A), the Administrator shall file in the court in which such petition was filed—

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

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

(C) DEFINITION OF RECORD.—In this section, the term "record" means—

(i) all notices and other matter published in the Federal Register with respect to the regulation or order reviewed;

(ii) all information submitted to the Administrator with respect to such regulation or order;

(iii) proceedings of any panel or advisory committee with respect to such regulation or order;

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

(v) any other information identified by the Administrator, in the administrative proceeding held with respect to such regulation or order, as being relevant to such regulation or order.

(b) STANDARD OF REVIEW.—Upon the filing of the petition under subsection (a) for judicial review of a regulation or order, the court shall have jurisdiction to review the regulation or order in accordance with chapter 7 of title 5, United States Code, and to grant appropriate relief, including interim relief, as provided for in such chapter. A regulation or denial described in subsection (a) shall be reviewed in accordance with section 706(2)(A) of title 5, United States Code.

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

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

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

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

Except where expressly provided in this Act, nothing in this Act shall be construed as limiting or diminishing the authority of the Federal Trade Commission to enforce the laws under its jurisdiction with respect to the advertising, sale, or distribution of tobacco products.

SEC. 118. REGULATION REQUIREMENT.

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

(b) CONTENTS OF RULES.—The regulations promulgated under subsection (a)—

(1) shall require annual testing and reporting of tobacco product constituents, ingredients, and additives, including smoke constituents, by brand style that the Administrator determines should be tested to protect the public health, provided that, for purposes of the testing requirements of this paragraph, tobacco products manufactured and sold by a single tobacco product manufacturer that are identical in all respects except the labels, packaging design, logo, trade dress, trademark, brand name, or any combination thereof, shall be considered as a single brand style; and

(2) may require that tobacco product manufacturers, packagers, or importers make disclosures relating to the results of the testing of tar and nicotine through labels or advertising.

(c) AUTHORITY.—The Administrator shall have the authority under this Act to conduct or to require the testing, reporting, or disclosure of tobacco product constituents, including smoke constituents.

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

(e) EXTENSIONS FOR LIMITED LABORATORY CAPACITY.—

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

(A) the tobacco products of such manufacturer are in compliance with all other requirements of this Act; and

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

(2) CONDITIONS.—Notwithstanding the requirements of this section, the Administrator may delay the date by which a tobacco product manufacturer must be in compliance with the testing and reporting required by this section until such time as the testing is reported if, not later than 90 days before the deadline for reporting in accordance with this section, a tobacco product manufacturer provides evidence to the Administrator demonstrating that—

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

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

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

(3) EXTENSION.—The Administrator, taking into account the laboratory testing capacity that is available to tobacco product manufacturers, shall review and verify the evidence submitted by a tobacco product manufacturer in accordance with paragraph (2). If the Administrator finds that the conditions described in such paragraph are met, the Administrator shall notify the tobacco product manufacturer that the manufacturer shall not be considered to be in violation of the testing and re-

porting requirements of this section until the testing is reported or until 1 year after the reporting deadline has passed, whichever occurs sooner. If, however, the Administrator has not made a finding before the reporting deadline, the manufacturer shall not be considered to be in violation of such requirements until the Administrator finds that the conditions described in paragraph (2) have not been met, or until 1 year after the reporting deadline, whichever occurs sooner.

(4) ADDITIONAL EXTENSION.—In addition to the time that may be provided under paragraph (3), the Administrator may provide further extensions of time, in increments of no more than 1 year, for required testing and reporting to occur if the Administrator determines, based on evidence properly and timely submitted by a tobacco product manufacturer in accordance with paragraph (2), that a lack of available laboratory capacity prevents the manufacturer from completing the required testing during the period described in paragraph (3).

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

SEC. 119. PRESERVATION OF STATE AND LOCAL AUTHORITY.

(a) IN GENERAL.—

(1) PRESERVATION.—Except as provided in paragraph (2)(A), nothing in this Act, or rules promulgated under this Act, shall be construed to limit the authority of a Federal agency (including the Armed Forces), a State or political subdivision of a State, or the government of an Indian tribe to enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products that is in addition to requirements established under this Act, including a law, rule, regulation, or other measure relating to or prohibiting the sale, distribution, possession, or use of tobacco products by individuals of any age, information reporting to the State. No provision of this Act shall limit or otherwise affect any State, Tribal, or local taxation of tobacco products.

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

(A) IN GENERAL.—No State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this Act relating to tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products.

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

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

SEC. 120. TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE.

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

(b) MEMBERSHIP.—

(1) IN GENERAL.—

(A) MEMBERS.—The Administrator shall appoint as members of the Tobacco Harm Reduction Advisory Committee individuals who are technically qualified by training and experience in medicine, medical ethics, science, or technology involving the manufacture, evaluation, or use of tobacco products, who are of appropriately diversified professional backgrounds. The committee shall be composed of—

(i) 6 individuals who are physicians, dentists, scientists, or health care professionals practicing in the area of oncology, pulmonology, cardiology, toxicology, pharmacology, addiction, or any other relevant specialty;

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

(iii) 2 representatives of the general public;

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

(v) 1 representative of the interests of the small business tobacco manufacturing industry, which position may be filled on a rotating, sequential basis by representatives of different small business tobacco manufacturers based on areas of expertise relevant to the topics being considered by the Advisory Committee;

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

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

(B) CONFLICTS OF INTEREST.—No members of the committee, other than members appointed pursuant to clauses (iv), (v), and (vi) of subparagraph (A) shall, during the member's tenure on the committee or for the 18-month period prior to becoming such a member, receive any salary, grants, or other payments or support from any business that manufactures, distributes, markets, or sells cigarettes or other tobacco products or government agency with any form of jurisdiction over tobacco products.

(2) LIMITATION.—The Administrator may not appoint to the Advisory Committee any individual who is in the regular full-time employ of the Tobacco Harm Reduction Center or any

agency responsible for the enforcement of this Act. The Administrator may appoint Federal officials as ex officio members.

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

(c) DUTIES.—The Tobacco Products Scientific Advisory Committee shall provide advice, information, and recommendations to the Administrator—

(1) as provided in this Act;

(2) on the implementation of prevention, cessation, and harm reduction policies;

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

(4) on its review of other safety, dependence, or health issues relating to tobacco products as requested by the Administrator.

(d) COMPENSATION; SUPPORT; FACA.—

(1) COMPENSATION AND TRAVEL.—Members of the Advisory Committee who are not officers or employees of the United States, while attending conferences or meetings of the committee or otherwise engaged in its business, shall be entitled to receive compensation at rates to be fixed by the Administrator, which may not exceed the daily equivalent of the rate in effect under the Senior Executive Schedule under section 5382 of title 5, United States Code, for each day (including travel time) they are so engaged; and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5, United States Code, for persons in the Government service employed intermittently.

(2) ADMINISTRATIVE SUPPORT.—The Administrator shall furnish the Advisory Committee clerical and other assistance.

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

(e) PROCEEDINGS OF ADVISORY PANELS AND COMMITTEES.—The Advisory Committee shall make and maintain a transcript of any proceeding of the panel or committee. Each such panel and committee shall delete from any transcript made under this subsection information which is exempt from disclosure under section 552(b) of title 5, United States Code.

SEC. 121. DRUG PRODUCTS USED TO TREAT TOBACCO DEPENDENCE.

(a) REPORT ON INNOVATIVE PRODUCTS.—

(1) IN GENERAL.—Not later than 3 years after the date of enactment of this Act, the Administrator, after consultation with recognized scientific, medical, and public health experts (including both Federal agencies and nongovernmental entities, the Institute of Medicine of the National Academy of Sciences, and the Society for Research on Nicotine and Tobacco), shall submit to the Congress a report that examines how best to promote, and encourage the development and use by current tobacco users of innovative tobacco and nicotine products and treatments (including nicotine-based and non-nicotine-based products and treatments) to better achieve, in a manner that best protects and promotes the public health—

(A) total abstinence from tobacco use;
(B) reductions in consumption of tobacco; and
(C) reductions in the harm associated with continued tobacco use by moving current users to noncombustible tobacco products.

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

SEC. 122. ADVERTISING AND MARKETING OF TOBACCO PRODUCTS.

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

(b) The Administrator shall specify in the report constitutional free speech implications for each recommended restriction or prohibition.

(c) The Administrator shall also specify the class of tobacco products to which the prohibition or restriction would be applicable and the impact of such actions on harm reduction policies, practices, and accurate information available to tobacco users.

(d) The Administrator shall establish and consult with an advisory committee consisting of experts in constitutional law, harm reduction policies, marketing practices, 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.
"WARNING: Smoking during pregnancy can harm your baby.

"WARNING: Smoking can kill you.

"WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.

"WARNING: Quitting smoking now greatly reduces serious risks to your health.

"(2) PLACEMENT; TYPOGRAPHY; ETC.—Each label statement required by paragraph (1) shall be located in the lower portion of the front panel of the package, directly on the package underneath the cellophane or other clear wrapping. Each label statement shall comprise at least the bottom 25 percent of the front panel of the package. The word 'WARNING' shall appear in capital letters and all text shall be in conspicuous and legible 17-point type, unless the text of the label statement would occupy more than 70 percent of such area, in which case the text may be in a smaller conspicuous and legible type size, provided that at least 60 percent of such area is occupied by required text. The text shall be black on a white background, or white on a black background, in a manner that contrasts, by typography, layout, or color, with all other printed material on the package, in an alternating fashion under the plan submitted under subsection (c).

"(3) DOES NOT APPLY TO FOREIGN DISTRIBUTION.—The provisions of this subsection do not apply to a tobacco product manufacturer or distributor of cigarettes which does not manufacture, package, or import cigarettes for sale or distribution within the United States.

"(4) APPLICABILITY TO RETAILERS.—A retailer of cigarettes shall not be in violation of this subsection for packaging that—

"(A) contains a warning label;

"(B) is supplied to the retailer by a license- or permit-holding smoking article manufacturer, importer, or distributor; and

"(C) is not altered by the retailer in a way that is material to the requirements of this subsection.

"(b) ADVERTISING REQUIREMENTS.—

"(1) IN GENERAL.—It shall be unlawful for any tobacco product manufacturer, importer, distributor, or retailer of cigarettes to advertise or cause to be advertised within the United States any cigarette unless its advertising bears, in accordance with the requirements of this section, one of the labels specified in subsection (a).

"(2) TYPOGRAPHY, ETC.—Each label statement required by subsection (a) in cigarette advertising shall comply with the standards set forth in this paragraph. For press and poster advertisements, each such statement and (where applicable) any required statement relating to tar, nicotine, or other constituent (including a smoke constituent) yield shall comprise at least 20 percent of the area of the advertisement and shall appear in a conspicuous and prominent format and location at the bottom of each advertisement within the trim area. The word 'WARNING' shall appear in capital letters, and each label statement shall appear in conspicuous and legible type. The text of the label statement shall be black if the background is white and white if the background is black, under the plan submitted under subsection (c). The label statements

shall be enclosed by a rectangular border that is the same color as the letters of the statements and that is the width of the first downstroke of the capital 'W' of the word 'WARNING' in the label statements. The text of such label statements shall be in a typeface pro rata to the following requirements: 45-point type for a whole-page broadsheet newspaper advertisement; 39-point type for a half-page broadsheet newspaper advertisement; 39-point type for a whole-page tabloid newspaper advertisement; 27-point type for a half-page tabloid newspaper advertisement; 31.5-point type for a double page spread magazine or whole-page magazine advertisement; 22.5-point type for a 28 centimeter by 3 column advertisement; and 15-point type for a 20 centimeter by 2 column advertisement. The label statements shall be in English, except that—

"(A) in the case of an advertisement that appears in a newspaper, magazine, periodical, or other publication that is not in English, the statements shall appear in the predominant language of the publication; and

"(B) in the case of any other advertisement that is not in English, the statements shall appear in the same language as that principally used in the advertisement.

"(3) MATCHBOOKS.—Notwithstanding paragraph (2), for matchbooks (defined as containing not more than 20 matches) customarily given away with the purchase of smokeless tobacco products, each label statement required by subsection (a) may be printed on the inside cover of the matchbook.

"(c) MARKETING REQUIREMENTS.—

"(1) RANDOM DISPLAY.—The label statements specified in subsection (a)(1) shall be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the smokeless tobacco product manufacturer, importer, distributor, or retailer and approved by the Secretary.

"(2) ROTATION.—The label statements specified in subsection (a)(1) shall be rotated quarterly in alternating sequence in advertisements for each brand of cigarettes in accordance with a plan submitted by the smokeless tobacco product manufacturer, importer, distributor, or retailer to, and approved by, the Secretary.

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

"(A) will provide for the equal distribution and display on packaging and the rotation required in advertising under this subsection; and

"(B) assures that all of the labels required under this section will be displayed by the smokeless tobacco product manufacturer, importer, distributor, or retailer at the same time.

"(4) APPLICABILITY TO RETAILERS.—This subsection and subsection (b) apply to a retailer only if that retailer is responsible for or directs the label statements required under this section except that this paragraph shall not relieve a retailer of liability if the retailer displays, in a location open to the public, an

advertisement that does not contain a warning label or has been altered by the retailer in a way that is material to the requirements of this subsection and subsection (b).".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect 24 months after the date of enactment of this Act. Such effective date shall be with respect to the date of manufacture, provided that, in any case, beginning 30 days after such effective date, a manufacturer shall not introduce into the domestic commerce of the United States any product, irrespective of the date of manufacture, that is not in conformance with section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333), as amended by subsection (a).

SEC. 202. SMOKELESS TOBACCO LABELS AND ADVERTISING WARNINGS.

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

"SEC. 3. SMOKELESS TOBACCO WARNING.

"(a) GENERAL RULE.—

"(1) 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 smokeless tobacco product unless the product package bears, in accordance with the requirements of this Act, one of the following labels:

"WARNING: This product can cause mouth cancer.

"WARNING: This product can cause gum disease and tooth loss.

"WARNING: This product has significantly lower risks for diseases associated with cigarettes.

"WARNING: Smokeless tobacco is addictive.

"(2) The label statements required by paragraph (1) shall be introduced by each smokeless tobacco product manufacturer, packager, importer, distributor, or retailer of smokeless tobacco products concurrently into the distribution chain of such products.

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

"(4) A retailer of smokeless tobacco products shall not be in violation of this subsection for packaging that—

"(A) contains a warning label;

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

"(C) is not altered by the retailer in a way that is material to the requirements of this subsection.

"(b) REQUIRED LABELS.—

"(1) It shall be unlawful for any smokeless tobacco product manufacturer, packager, importer, distributor, or retailer of smokeless tobacco products to advertise or cause to be advertised within the United States any smokeless tobacco product unless its advertising bears, in accordance with the require-

ments of this section, one of the labels specified in subsection (a).

"(2)(A) Each label statement required by subsection (a) in smokeless tobacco advertising shall comply with the standards set forth in this paragraph.

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

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

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

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

"(F) The text of such label statements shall be in a typeface pro rata to the following requirements: 45-point type for a whole-page broadsheet newspaper advertisement; 39-point type for a half-page broadsheet newspaper advertisement; 39-point type for a whole-page tabloid newspaper advertisement; 27-point type for a half-page tabloid newspaper advertisement; 31.5-point type for a double page spread magazine or whole-page magazine advertisement; 22.5-point type for a 28 centimeter by 3 column advertisement; and 15-point type for a 20 centimeter by 2 column advertisement.

"(G) The label statements shall be in English, except that—

"(i) in the case of an advertisement that appears in a newspaper, magazine, periodical, or other publication that is not in English, the statements shall appear in the predominant language of the publication; and

"(ii) in the case of any other advertisement that is not in English, the statements shall appear in the same language as that principally used in the advertisement.

"(3)(A) The label statements specified in subsection (a)(1) shall be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the smokeless tobacco product manufacturer, importer, distributor, or retailer and approved by the Secretary.

"(B) The label statements specified in subsection (a)(1) shall be rotated quarterly in alternating sequence in advertisements for each brand of smokeless tobacco product in accordance with a plan submitted by the smokeless tobacco product manufacturer, importer, distributor, or retailer to, and approved by, the Secretary.

"(C) The Secretary shall review each plan submitted under subparagraphs (A) and (B) and approve it if the plan—

"(i) will provide for the equal distribution and display on packaging and the rotation required in advertising under this subsection; and

"(ii) assures that all of the labels required under this section will be displayed by the smokeless tobacco product manufacturer, importer, distributor, or retailer at the same time.

"(D) This paragraph applies to a retailer only if that retailer is responsible for or directs the label statements under this section, unless the retailer displays, in a location open to the public, an advertisement that does not contain a warning label or has been altered by the retailer in a way that is material to the requirements of this subsection.

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

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect 24 months after the date of enactment of this Act. Such effective date shall be with respect to the date of manufacture, provided that, in any case, beginning 30 days after such effective date, a manufacturer shall not introduce into the domestic commerce of the United States any product, irrespective of the date of manufacture, that is not in conformance with section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4402), as amended by subsection (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

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

(b) REQUIRED INFORMATION ON BACK FACE.—Not later than 24 months after the effective date of this Act, the bottom 50 percent of the back face of a package of a tobacco product shall be available solely for disclosures required by or under this Act, the Federal Cigarette Labeling and Advertising Act, sections 1331–1340 of title

15, United States Code, and any other Federal statute. Such disclosures shall include—

(1) the printed name and address of the manufacturer, packer, or distributor, and any other identification associated with the manufacturer, packer, or distributor or with the tobacco product that the Administrator may require;

(2) a list of ingredients as required by subsection (e); and

(3) the appropriate tax registration number.

(c) PACKAGE DISCLOSURE OF INGREDIENTS.—Not later than 24 months after the effective date of this Act, the package of a tobacco product shall bear a list of the common or usual names of the ingredients present in the tobacco product in an amount greater than 0.1 percent of the total dry weight of the tobacco (including all ingredients), that shall comply with the following:

(1) Such listing of ingredients shall appear under, or be conspicuously accompanied by, the heading "Tobacco and principal tobacco ingredients".

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

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

(4) Spices and natural and artificial flavors may be listed, respectively, as "spices" and "natural and artificial flavors" without naming each.

(5) Preservatives may be listed as "preservatives" without naming each.

(6) The disclosure of any ingredient in accordance with this section may, at the option of the tobacco product manufacturer, designate the functionality or purpose of that ingredient.

(7) The package say state "Not for sale to minors".

(8) In the case of a package of cigarettes, the package shall state that smokeless tobacco has significantly lower risks for disease and death than cigarettes.

SEC. 302. DISCLOSURES ON PACKAGES OF SMOKELESS TOBACCO.

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

(1) the principal face of a package of smokeless tobacco 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 two principal faces;

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

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

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

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

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

(b) REQUIRED INFORMATION ON BACK OR BOTTOM FACE.—50 percent of the back or bottom face of a package of smokeless tobacco shall be available solely for disclosures required by or under this Act, the Comprehensive Smokeless Tobacco Health Education Act of 1986, sections 4401–4408 of title 15, United States Code, and any other Federal statute. Such disclosures shall include a list of ingredients as required by subsection (e).

(c) PACKAGE DISCLOSURE OF INGREDIENTS.—Commencing 24 months after the effective date of this Act, a package of smokeless tobacco shall bear a list of the common or usual names of the ingredients present in the smokeless tobacco in an amount greater than 0.1 percent of the total dry weight of the tobacco (including all ingredients).

(1) Such listing of ingredients shall appears under, or be conspicuously accompanied by, the heading "Tobacco and principal tobacco ingredients".

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

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

(4) Spices and natural and artificial flavors may be listed, respectively, as "spices" and "natural and artificial flavors" without naming each.

(5) Preservatives may be listed as "preservatives" without naming each.

(6) The disclosure of any ingredient in accordance with this section may, at the option of the tobacco product manufacturer, designate the functionality or purpose of that ingredient.

(7) Not for sale to minors.

SEC. 303. PUBLIC DISCLOSURE OF INGREDIENTS.

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

(1) a list of the ingredients it uses in each brand style it manufactures for commercial distribution domestically, as provided in subsection (b); and

(2) a composite list of all the ingredients it uses in any of the brand styles it manufactures for commercial distribution domestically, as provided in subsection (c).

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

(1) IN GENERAL.—With respect to the public disclosure required by subsection (a)(1), as to each brand style, the tobacco product manufacture shall disclose the common or usual name of each ingredient present in the brand style in an amount greater than 0.1 percent of the total dry weight of the tobacco (including all ingredients).

(2) REQUIREMENTS.—Disclosure under paragraph (1) shall comply with the following:

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

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

(C) Spices and natural and artificial flavors may be listed, respectively, as "spices" and "natural and artificial flavors" without naming each.

(D) Preservatives may be listed as "preservatives" without naming each.

(E) The disclosure of any ingredient in accordance with this section may, at the option of the tobacco product manufacturer, designate the functionality or purpose of that ingredient.

(c) AGGREGATE DISCLOSURE OF INGREDIENTS.—

(1) IN GENERAL.—The public disclosure required of a tobacco product manufacturer by subsection (a)(2) shall consist of a single list of all ingredients used in any brand style a tobacco product manufacturer manufactures for commercial distribution domestically, without regard to the quantity used, and including, separately, each spice, each natural or artificial flavoring, and each preservative.

(2) LISTING.—The ingredients shall be listed by their respective common or usual names in descending order of predominance by the total weight used annually by the tobacco product manufacturer in manufacturing tobacco products for commercial distribution domestically.

(d) NO REQUIRED DISCLOSURE OF QUANTITIES.—The Administrator shall not require any public disclosure of quantitative information about any ingredient in a tobacco product.

(e) DISCLOSURE ON WEBSITE.—The public disclosures required by subsection (a) of this section may be by posting on an Internet-accessible website, or other location electronically accessible to the public, which is identified on all packages of a tobacco product manufacturer's tobacco products.

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

TITLE IV—PREVENTION OF ILLICIT TRADE IN TOBACCO PRODUCTS

SEC. 401. STUDY AND REPORT ON ILLICIT TRADE.

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

(1) collect data on such trade in tobacco products, including illicit trade involving tobacco products, and make recommendations on the monitoring and enforcement of such trade;

(2) collect data on any advertising intended to be broadcast, transmitted, or distributed from or to the United States from or to another country and make recommendations on how to prevent or eliminate, and what technologies could help facilitate the elimination of, such advertising; and

(3) collect data on such trade in tobacco products by person that is not—

(A) a participating manufacturer (as that term is defined in section II(jj) of the Master Settlement Agreement of November 23, 1998, between certain of the States and certain tobacco product manufacturers); or

(B) an affiliate or subsidiary of a participating manufacturer.

(b) Not later than 18 months after the effective date of this Act, the Administrator shall submit to the Secretary, and committees of relevant jurisdiction in Congress, a report the recommendations of the study conducted under subsection (a).

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

Section 1926 of the Public Health Service Act (42 U.S.C. § 300x–26) is amended by adding at the end thereof the following:

"(e)(1) Subject to paragraphs (2) and (3), for the first fiscal year after enactment and each subsequent fiscal year, the Secretary shall reduce, as provided in subsection (h), the amount of any grant under section 300x–21 of this title for any State that does not have in effect a statute with substantially the following provisions:

"'SEC. 1. DISTRIBUTION TO MINORS.

"'(a) No person shall distribute a tobacco product to an individual under 18 years of age or a different minimum age established under State law. A person who violates this subsection is liable for a civil money penalty of not less than $25 nor more than $125 for each violation of this subsection;

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

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

"'(1) the defendant—

"'(A) relied upon proof of age that appeared on its face to be valid in accordance with the Federal Tobacco Act of 2007;

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

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

"'(2) the individual to whom the tobacco product was distributed was at the time of the distribution used in violation of subsection 8(b).

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

"'(a) An individual under 18 years of age or a different minimum age established under State law shall not purchase or attempt to purchase, receive or attempt to receive, possess or attempt to possess, a tobacco product. An individual who violates this subsection is liable for a civil money penalty of not less than $25 nor more than $125 for each such violation, and shall be required to perform not less than four hours nor more than ten hours of community

service. Upon the second or each subsequent violation of this subsection, such individual shall be required to perform not less than eight hours nor more than twenty hours of community service.

"'(b) A law enforcement agency, upon determining that an individual under 18 years of age or a different minimum age established under State law allegedly purchased, received, possessed, or attempted to purchase, receive, or possess, a tobacco product in violation of subsection (a) shall notify the individual's parent or parents, custodian, or guardian as to the nature of the alleged violation if the name and address of a parent or parents, guardian, or custodian is reasonably ascertainable by the law enforcement agency. The notice required by this subsection shall be made not later than 48 hours after the individual who allegedly violated subsection (a) is cited by such agency for the violation. The notice may be made by any means reasonably calculated to give prompt actual notice, including notice in person, by telephone, or by first-class mail.

"'(c) Subsection (a) does not prohibit an individual under 18 years of age or a different minimum age established under State law from possessing a tobacco product during regular working hours and in the course of such individual's employment if the tobacco product is not possessed for such individual's consumption.

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

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

"'SEC. 4. SIGNAGE.

"'It shall be unlawful for any person who sells tobacco products over-the-counter to fail to post conspicuously on the premises where such person sells tobacco products over-the-counter a sign communicating that—

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

"'(2) the purchase of tobacco products by individuals under 18 years of age or a different minimum age established under State law is prohibited by law; and

"'(3) proof of age may be demanded before tobacco products are sold.

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

"'SEC. 5. NOTIFICATION OF EMPLOYEES.

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

"'(1) the sale or other distribution of tobacco products to any individual under 18 years of age or a different minimum age

established under State law, and the purchase, receipt, or possession of tobacco products in a place open to the public by any individual under 18 years of age or a different minimum age established under State law, is prohibited; and

"'(2) out-of-package distribution of cigarettes and smokeless tobacco products is prohibited.

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

"'(b) It shall be a defense to a charge that an employer violated subsection (a) of this section that the employee acknowledged receipt, either in writing or by electronic means, prior to the alleged violation, of a statement in substantially the following form:

"I understand that State law prohibits the distribution of tobacco products to individuals under 18 years of age or a different minimum age established under State law and out-of-package distribution of cigarettes and smokeless tobacco products, and permits a defense based on evidence that a prospective purchaser's proof of age was reasonably relied upon and appeared on its face to be valid. I understand that if I sell, give, or voluntarily provide a tobacco product to an individual under 18 years of age or a different minimum age established under State law, I may be found responsible for a civil money penalty of not less than $25 nor more than $125 for each violation. I promise to comply with this law."

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

"'SEC. 6. SELF-SERVICE DISPLAYS.

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

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

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

"'(a) It shall be unlawful to distribute or sell tobacco products directly to consumers by mail or courier, unless the person receiving purchase requests for tobacco products takes reasonable action to prevent delivery to individuals who are not adults by—

"'(1) requiring that addressees of the tobacco products be age-verified adults;

"'(2) making good faith efforts to verify that such addressees have attained the minimum age for purchase of tobacco products established by the respective States wherein the addresses of the addressees are located; and

"'(3) addressing the tobacco products delivered by mail or courier to a physical addresses and not to post office boxes.

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

"'SEC. 8. RANDOM UNANNOUNCED INSPECTIONS; REPORTING; AND COMPLIANCE.

"'(a) The State Police, or a local law enforcement authority duly designated by the State Police, shall enforce this Act in a manner that can reasonably be expected to reduce the extent to which tobacco products are distributed to individuals under 18 years of age or a different minimum age established under State law and shall conduct random, unannounced inspections in accordance with the procedures set forth in this Act and in regulations issued under section 1926 of the Federal Public Health Service Act (42 U.S.C. § 300x–26).

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

"'(1) Prior to use of any individual under 18 years of age or a different minimum age established under State law in a random, unannounced inspection, written consent shall be obtained from a parent, custodian, or guardian of such individual;

"'(2) An individual under 18 years of age or a different minimum age established under State law shall act solely under the supervision and direction of the State Police or a local law enforcement authority duly designated by the State Police during a random, unannounced inspection;

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

"'(4) If an individual under 18 years of age or a different minimum age established under State law participating in random, unannounced inspections is questioned during such an inspection about such individual's age, such individual shall state his or her actual age and shall present a true and correct proof of age if requested at any time during the inspection to present it.

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

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

"'SEC. 9. LICENSURE.

"'(a) Each person engaged in the over-the-counter distribution at retail of tobacco products shall hold a license issued under this section. A separate license shall be required for each place of business where tobacco products are distributed at retail. A license issued under this section is not assignable and is valid only for the person

in whose name it is issued and for the place of business designated in the license.

"'(b) The annual license fee is $25 for each place of business where tobacco products are distributed at retail.

"'(c) Every application for a license, including renewal of a license, under this section shall be made upon a form provided by the appropriate State agency or department, and shall set forth the name under which the applicant transacts or intends to transact business, the location of the place of business for which the license is to be issued, the street address to which all notices relevant to the license are to be sent (in this Act referred to as "notice address"), and any other identifying information that the appropriate State agency or department may require.

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

"'(e) Every license issued by the appropriate State agency or department pursuant to this section shall be valid for 1 year from the date of issuance and shall be renewed upon application except as otherwise provided in this Act.

"'(f) Upon notification of a change of address for a place of business for which a license has been issued, a license shall be reissued for the new address without the filing of a new application.

"'(g) The appropriate State agency or department shall notify every person in the State who is engaged in the distribution at retail of tobacco products of the license requirements of this section and of the date by which such person should have obtained a license.

"'(h)(1) Except as provided in paragraph (2), any person who engages in the distribution at retail of tobacco products without a license required by this section is liable for a civil money penalty in an amount equal to (i) two times the applicable license fee, and (ii) $50 for each day that such distribution continues without a license.

"'(2) Any person who engages in the distribution at retail of tobacco products after a license issued under this section has been suspended or revoked is liable for a civil money penalty of $100 per day for each day on which such distribution continues after the date such person received notice of such suspension or revocation.

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

"'SEC. 10. SUSPENSION, REVOCATION, DENIAL, AND NONRENEWAL OF LICENSES.

"'(a) Upon a finding that a licensee has been determined by a court of competent jurisdiction to have violated this Act during the license term, the State shall notify the licensee in writing, served personally or by registered mail at the notice address, that any subsequent violation of this Act at the same place of business may

result in an administrative action to suspend the license for a period determined by the specify the appropriate State agency or department.

"'(b) Upon finding that a further violation by this Act has occurred involving the same place of business for which the license was issued and the licensee has been served notice once under subsection (a), the appropriate State agency or department may initiate an administrative action to suspend the license for a period to be determined by the appropriate State agency or department but not to exceed six months. If an administrative action to suspend a license is initiated, the appropriate State agency or department shall immediately notify the licensee in writing at the notice address of the initiation of the action and the reasons therefor and permit the licensee an opportunity, at least 30 days after written notice is served personally or by registered mail upon the licensee, to show why suspension of the license would be unwarranted or unjust.

"'(c) The appropriate State agency or department may initiate an administrative action to revoke a license that previously has been suspended under subsection (b) if, after the suspension and during the one-year period for which the license was issued, the licensee committed a further violation of this Act, at the same place of business for which the license was issued. If an administrative action to revoke a license is initiated, the appropriate State agency or department shall immediately notify the licensee in writing at the notice address of the initiation of the action and the reasons therefor and permit the licensee an opportunity, at least 30 days after written notice is served personally or by registered mail upon the licensee, to show why revocation of the license would be unwarranted or unjust.

"'(d) A person whose license has been suspended or revoked with respect to a place of business pursuant to this section shall pay a fee of $50 for the renewal or reissuance of the license at that same place of business, in addition to any applicable annual license fees.

"'(e) Revocation of a license under subsection (c) with respect to a place of business shall not be grounds to deny an application by any person for a new license with respect to such place of business for more than 12 months subsequent to the date of such revocation. Revocation or suspension of a license with respect to a particular place of business shall not be grounds to deny an application for a new license, to refuse to renew a license, or to revoke or suspend an existing license at any other place of business.

"'(f) A licensee may seek judicial review of an action of the appropriate State agency or department suspending, revoking, denying, or refusing to renew a license under this section by filing a complaint in a court of competent jurisdiction. Any such complaint shall be filed within 30 days after the date on which notice of the action is received by the licensee. The court shall review the evidence de novo.

"'(g) The State shall not report any action suspending, revoking, denying, or refusing to renew a license under this section to the Federal Secretary of Health and Human Services, unless the opportunity for judicial review of the action pursuant to subsection (f), if any, has been exhausted or the time for seeking such judicial review has expired.

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

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

"'SEC. 12. JURISDICTION AND VENUE.

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

"'SEC. 13. REPORT.

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

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

"(3) Subsection (e)(1) shall not affect any State or local law that (A) was in effect on the date of introduction of the Federal Tobacco Act of 2007, and (B) covers the same subject matter as the law described in subsection (e)(1). Any State law that meets the conditions of this paragraph shall also be deemed to meet the requirement described in subsection (e)(1) as a condition of a receipt of a grant under section 300x–21 of this title, if such State law is at least as stringent as the law described in subsection (e)(1).

"(f)(1) For the first applicable fiscal year and for each subsequent fiscal year, a funding agreement for a grant under section 300x–21 of this title is a funding agreement under which the State involved will enforce the law described in subsection (e)(1) of this section in a manner that can reasonably be expected to reduce the extent to which tobacco products are available to individuals under the age of 18 or a different minimum age established under State law for the purchase of tobacco products.

"(2) For the first applicable fiscal year and for each subsequent fiscal year, a funding agreement for a grant under section 300x–21 of this title is a funding agreement under which the State involved will—

"(A) conduct random, unannounced inspections to ensure compliance with the law described in subsection (e)(1); and

"(B) annually submit to the Secretary a report describing—

"(i) the activities carried out by the State to enforce such law during the fiscal year preceding the fiscal year for which the State is seeking the grant;

"(ii) the extent of success the State has achieved in reducing the availability of tobacco products to individuals under 18 years of age or a different minimum age established under State law, including the results of the inspections conducted under subparagraph (A); and

"(iii) the strategies to be utilized by the State for enforcing such law during the fiscal year for which the grant is sought.

"(g) The law specified in subsection (e)(1) may be administered and enforced by a State using—

"(1) any amounts made available to the State through a grant under section 300x–21 of this title;

"(2) any amounts made available to the State under section 300w of this title;

"(3) any fees collected for licenses issued pursuant to the law described in subsection (e)(1);

"(4) any fines or penalties assessed for violations of the law specified in subsection (e)(1); or

"(5) any other funding source that the legislature of the State may prescribe by statute.

"(h) Before making a grant under section 300x–21 of this title to a State for the first applicable fiscal year or any subsequent fiscal year, the Secretary shall make a determination of whether the State has maintained compliance with subsections (e) and (f) of this section. If, after notice to the State and an opportunity for a hearing, the Secretary determines that the State is not in compliance with such subsections, the Secretary shall reduce the amount of the allotment under section 300x–21 of this title for the State for the fiscal year involved by an amount equal to—

"(1) In the case of the first applicable fiscal year, 10 percent of the amount determined under section 300x–33 for the State for the fiscal year;

"(2) In the case of the first fiscal year following such applicable fiscal year, 20 percent of the amount determined under section 300x–33 for the State for the fiscal year;

"(3) In the case of the second such fiscal year, 30 percent of the amount determined under section 300x–33 for the State for the fiscal year; and

"(4) In the case of the third such fiscal year or any subsequent fiscal year, 40 percent of the amount determined under section 300x–33 for the State for the fiscal year.

The Secretary shall not have authority or discretion to grant to any State a waiver of the terms and requirements of this subsection or subsection (e) or (f).

"(i) For the purposes of subsections (e) through (h) of this section the term 'first applicable fiscal year' means—

"(1) fiscal year 2009, in the case of any State described in subsection (e)(2) of this section; and

"(2) fiscal year 2008, in the case of any other State.

"(j) For purposes of subsections (e) through (h) of this section, references to section 300x–21 shall include any successor grant programs."

"(k) As required by paragraph (1), and subject to paragraph (4), an Indian tribe shall satisfy the requirements of subsection (e)(1) of this section by enacting a law or ordinance with substantially the same provisions as the law described in subsection (e)(1).

"(1) An Indian tribe shall comply with subsection (e)(1) of this section within 180 days after the Administrator finds, in accordance with this paragraph, that—

"(A) the Indian tribe has a governing body carrying out substantial governmental powers and duties;

"(B) the functions to be exercised by the Indian tribe under this Act pertain to activities on trust land within the jurisdiction of the tribe; and

"(C) the Indian tribe is reasonably expected to be capable of carrying out the functions required under this section.

Within 2 years of the date of enactment of the Federal Tobacco Act of 2007, as to each Indian tribe in the United States, the Administrator shall make the findings contemplated by this paragraph or determine that such findings cannot be made, in accordance with the procedures specified in paragraph (4).

"(2) As to Indian tribes subject to subsection (e)(1) of this section, the Administrator shall promulgate regulations that—

"(A) provide whether and to what extent, if any, the law described in subsection (e)(1) may be modified as adopted by Indian tribes; and

"(B) ensure, to the extent possible, that each Indian tribe's retailer licensing program under subsection (e)(1) is no less stringent than the program of the State or States in which the Indian tribe is located.

"(3) If with respect to any Indian tribe the Administrator determines that compliance with the requirements of subsection (e)(1) is inappropriate or administratively infeasible, the Administrator shall specify other means for the Indian tribe to achieve the purposes of the law described in subsection (e)(1) with respect to persons who engage in the distribution at retail of tobacco products on tribal lands.

"(4) The findings and regulations promulgated under paragraphs (1) and (2) shall be promulgated in conformance with section 553 of title 5, United States Code, and shall comply with the following provisions:

"(A) In making findings as provided in paragraph (1), and in drafting and promulgating regulations as provided in paragraph (2) (including drafting and promulgating any revised regulations), the Administrator shall confer with, and allow for active participation by, representatives and members of Indian tribes, and tribal organizations.

"(B) In carrying out rulemaking processes under this subsection, the Administrator shall follow the guidance of subchapter III of chapter 5 of title 5, United States Code, commonly known as the 'Negotiated Rulemaking Act of 1990.'

"(C) The tribal participants in the negotiation process referred to in subparagraph (B) shall be nominated by and shall represent the groups described in this subsection and shall include tribal representatives from all geographic regions.

"(D) The negotiations conducted under this paragraph (4) shall be conducted in a timely manner.

"(E) If the Administrator determines that an extension of the deadlines under subsection (k)(1) of this section is appropriate, the Secretary may submit proposed legislation to Congress for the extension of such deadlines.

"(5) This subsection shall not affect any law or ordinance that (A) was in effect on tribal lands on the date of introduction of the Youth Prevention and Tobacco Harm Reduction Act, and (B) covers the same subject matter as the law described in subsection (e)(1). Any law or ordinance that meets the conditions of this paragraph shall also be deemed to meet the requirement described in subsection (k)(1), if such law or ordinance is at least as stringent as the law described in subsection (e)(1).

"(6) For purposes of this subsection—

"(A) 'Administrator' means the Administrator of the Tobacco Harm Reduction Center.

"(B) 'Indian tribe' has the meaning assigned that term in section 4(e) of the Indian Self Determination and Education Assistance Act, section 450b(e) of title 25, United States Code.

"(C) 'Tribal lands' means all lands within the exterior boundaries of any Indian reservation, all lands the title to which is held by the United States in trust for an Indian tribe, or lands the title to which is held by an Indian tribe subject to a restriction by the United States against alienation, and all dependent Indian communities.

"(D) 'tribal organization' has the meaning assigned that term in section 4(l) of the Indian Self Determination and Education Assistance Act, section 450b(l) of title 25, United States Code.".

SEC. 403. ESTABLISHMENT OF RANKINGS.

(a) STANDARDS AND PROCEDURES FOR RANKINGS.—Within 24 months after the effective date of this Act, the Administrator shall, by regulation, after consultation with an Advisory Committee established for such purpose, establish the standards and procedures for promulgating rankings, comprehensible to consumers of tobacco products, of the following categories of tobacco products and also nicotine-containing products on the basis of the relative risks of serious or chronic tobacco-related diseases and adverse health conditions those categories of tobacco products and also nicotine-containing products respectively present—

(1) cigarettes;

(2) loose tobacco for roll-your-own tobacco products;

(3) little cigars;

(4) cigars;

(5) pipe tobacco;

(6) moist snuff;

(7) dry snuff;

(8) chewing tobacco;

(9) other forms of tobacco products, including pelletized tobacco and compressed tobacco, treated collectively as a single category; and

(10) other nicotine-containing products, treated collectively as a single category.

The Administrator shall not have authority or discretion to establish a relative-risk ranking of any category or subcategory of tobacco products or any category or subcategory of nicotine-containing products other than the ten categories specified in this subsection.

(b) CONSIDERATIONS IN PROMULGATING REGULATIONS.—In promulgating regulations under this section, the Administrator—

(1) shall take into account relevant epidemiologic studies and other relevant competent and reliable scientific evidence; and

(2) in assessing the risks of serious or chronic tobacco-related diseases and adverse health conditions presented by a particular category, shall consider the range of tobacco products or nicotine-containing products within the category, and shall give appropriate weight to the market shares of the respective products in the category.

(c) PROMULGATION OF RANKINGS OF CATEGORIES.—Once the initial regulations required by subsection (a) are in effect, the Administrator shall promptly, by order, after notice and an opportunity for comment, promulgate to the general public rankings of the categories of tobacco products and nicotine-containing products in accordance with those regulations. The Administrator shall promulgate the initial rankings of those categories of tobacco products and nicotine-containing products to the general public not later than January 1, 2010. Thereafter, on an annual basis, the Administrator shall, by order, promulgate to the general public updated rankings that are (1) in accordance with those regulations, and (2) reflect the scientific evidence available at the time of promulgation. The Administrator shall open and maintain an ongoing public docket for receipt of data and other information submitted by any person with respect to such annual promulgation of rankings.

TITLE V—ENFORCEMENT PROVISIONS

SEC. 501. PROHIBITED ACTS.

The following acts and the causing thereof are hereby prohibited—

(1) the introduction or delivery for introduction into interstate commerce of any tobacco product that is adulterated or misbranded;

(2) the adulteration or misbranding of any tobacco product in interstate commerce;

(3) the receipt in interstate commerce of any tobacco product that is known to be adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise;

(4) the failure to establish or maintain any record, or make any report or other submission, or to provide any notice required by or under this Act; or the refusal to permit access to, verification of, or copying of any record as required by this Act;

(5) the refusal to permit entry or inspection as authorized by this Act;

(6) the making to the Administrator of a statement, report, certification or other submission required by this Act, with knowledge that such statement, report, certification, or other submission is false in a material aspect;

(7) the manufacturing, shipping, receiving, storing, selling, distributing, possession, or use of any tobacco product with knowledge that it is an illicit tobacco product;

(8) the forging, simulating without proper permission, falsely representing, or without proper authority using any brand name;

(9) the using by any person to his or her own advantage, or revealing, other than to the Administrator or officers or employees of the Agency, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of this Act concerning any item which as a trade secret is entitled to protection; except that the foregoing does not authorize the withholding of information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee;

(10) the alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a tobacco product, if such act is done while such tobacco product is held for sale (whether or not the first sale) after shipment in interstate commerce, and results in such tobacco product being adulterated or misbranded;

(11) the importation of any tobacco product that is adulterated, misbranded, or otherwise not in compliance with this Act; and

(12) the commission of any act prohibited by section 201 of this Act.

SEC. 502. INJUNCTION PROCEEDINGS.

(a) The district courts of the United States shall have jurisdiction, for cause shown, to restrain violations of this Act, except for violations of section 701(k).

(b) In case of an alleged violation of an injunction or restraining order issued under this section, which also constitutes a violation of this Act, trial shall be by the court, or upon demand of the defendant, by a jury.

SEC. 503. PENALTIES.

(a) CRIMINAL PENALTIES.—Any person who willfully violates a provision of section 501 of this Act shall be imprisoned for not more than one year or fined not more than $25,000, or both.

(b) CIVIL PENALTIES FOR VIOLATION OF SECTION 803.—

(1) Any person who knowingly distributes or sells, other than through retail sale or retail offer for sale, any cigarette brand style in violation of section 803(a)—

(A) for a first offense shall be liable for a civil penalty not to exceed $10,000 for each distribution or sale, or

(B) for a second offense shall be liable for a civil penalty not to exceed $25,000 for each distribution or sale,

except that the penalty imposed against any person with respect to violations during any 30-day period shall not exceed $100,000.

(2) Any retailer who knowingly distributes, sells or offers for sale any cigarette brand style in violation of section 803(a) shall—

(A) for a first offense for each sale or offer for sale of cigarettes, if the total number of packages of cigarettes sold or offered for sale—

(i) does not exceed 50 packages of cigarettes, be liable for a civil penalty not to exceed $500 for each sale or offer for sale, and

(ii) exceeds 50 packages of cigarettes, be liable for a civil penalty not to exceed $1,000 for each sale or offer for sale;

(B) for each subsequent offense for each sale or offer for sale of cigarettes, if the total number of cigarettes sold or offered for sale—

(i) does not exceed 50 packages of cigarettes, be liable for a civil penalty not to exceed $2,000 for each sale or offer for sale, and

(ii) exceeds 50 packages of cigarettes, be liable for a civil penalty not to exceed $5,000 for each sale or offer for sale;

except that the penalty imposed against any person during any 30-day period shall not exceed $25,000.

SEC. 504. SEIZURE.

(a) ARTICLES SUBJECT TO SEIZURE.—

(1) Any tobacco product that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of this Act, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the tobacco product is found. No libel for condemnation shall be instituted under this Act for any alleged misbranding if there is pending in any court a libel for condemnation proceeding under this Act based upon the same alleged misbranding, and not more than one such proceeding shall be instituted if no such proceeding is so pending, except that such limitations shall not apply—

(A) when such misbranding has been the basis of a prior judgment in favor of the United States, in a criminal, injunction, or libel for condemnation proceeding under this Act, or

(B) when the Administrator has probable cause to believe from facts found, without hearing, by the Administrator or any officer or employee of the Agency that the misbranded tobacco product is dangerous to health beyond the inherent danger to health posed by tobacco, or that the labeling of the misbranded tobacco product is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer. In any case where the number of libel for condemnation proceedings is limited as above provided, the proceeding pending or instituted shall, on application of the claimant, seasonably made, be removed for trial to any district agreed upon by stipulation between the parties, or, in case of failure to so stipulate within a reasonable time, the claimant may

apply to the court of the district in which the seizure has been made, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, to which the case shall be removed for trial.

(2) The following shall be liable to be proceeded against at any time on libel of information and condemned in any district court of the United States within the jurisdiction of which they are found—

(A) any tobacco product that is an illicit tobacco product;

(B) any container of an illicit tobacco product;

(C) any equipment or thing used in making an illicit tobacco product; and

(D) any adulterated or misbranded tobacco product.

(3)(A) Except as provided in subparagraph (B), no libel for condemnation may be instituted under paragraph (1) or (2) against any tobacco product which—

(i) is misbranded under this Act because of its advertising, and

(ii) is being held for sale to the ultimate consumer in an establishment other than an establishment owned or operated by a manufacturer, packer, or distributor of the tobacco product.

(B) A libel for condemnation may be instituted under paragraph (1) or (2) against a tobacco product described in subparagraph (A) if the tobacco product's advertising which resulted in the tobacco product being misbranded was disseminated in the establishment in which the tobacco product is being held for sale to the ultimate consumer—

(i) such advertising was disseminated by, or under the direction of, the owner or operator of such establishment, or

(ii) all or part of the cost of such advertising was paid by such owner or operator.

(b) PROCEDURES.—The tobacco product, equipment, or other thing proceeded against shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty; except that on demand of either party any issue of fact joined in any such case shall be tried by jury. When libel for condemnation proceedings under this section, involving the same claimant and the same issues of adulteration or misbranding, are pending in two or more jurisdictions, such pending proceedings, upon application of the claimant seasonably made to the court of one such jurisdiction, shall be consolidated for trial by order of such court, and tried in (1) any district selected by the claimant where one of such proceedings is pending; or (2) a district agreed upon by stipulation between the parties. If no order for consolidation is so made within a reasonable time, the claimant may apply to the court of one such jurisdiction and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify

a district of reasonable proximity to the claimant's principal place of business, in which all such pending proceedings shall be consolidated for trial and tried. Such order of consolidation shall not apply so as to require the removal of any case the date for trial of which has been fixed. The court granting such order shall give prompt notification thereof to the other courts having jurisdiction of the cases covered thereby.

(c) SAMPLES AND ANALYSES.—The court at any time after seizure up to a reasonable time before trial shall by order allow any party to a condemnation proceeding, the party's attorney or agent, to obtain a representative sample of the article seized and a true copy of the analysis, if any, on which the proceeding is based and the identifying marks or numbers, if any, of the packages from which the samples analyzed were obtained.

(d) DISPOSITION OF CONDEMNED TOBACCO PRODUCTS.—(1) Any tobacco product condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, direct; and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States; but such tobacco product shall not be sold under such decree contrary to the provisions of this Act or the laws of the jurisdiction in which sold. After entry of the decree and upon the payment of the costs of such proceedings and the execution of a good and sufficient bond conditioned that such article shall not be sold or disposed of contrary to the provisions of this Act or the laws of any State in which sold, the court may by order direct that such tobacco product be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this Act, under the supervision of an officer or employee duly designated by the Administrator; and the expenses of such supervision shall be paid by the person obtaining release of the tobacco product under bond. If the tobacco product was imported into the United States and the person seeking its release establishes (A) that the adulteration, misbranding, or violation did not occur after the tobacco product was imported, and (B) that the person seeking the release of the tobacco product had no cause for believing that it was adulterated, misbranded, or in violation before it was released from customs custody, the court may permit the tobacco product to be delivered to the owner for exportation under section 709 in lieu of destruction upon a showing by the owner that there is a reasonable certainty that the tobacco product will not be re-imported into the United States.

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

(3) Whenever in any proceeding under this section, involving paragraph (2) of subsection (a), the condemnation of any equipment or thing (other than a tobacco product) is decreed, the court shall allow the claim of any claimant, to the extent of such claimant's interest, for remission or mitigation of such forfeiture if such claimant proves to the satisfaction of the court (A) that such claimant has not caused the equipment or thing to be within one of the categories referred to in such paragraph (2) and has no interest in any tobacco product referred to therein, (B) that such claimant has an

interest in such equipment or other thing as owner or lienor or otherwise, acquired by such claimant in good faith, and (C) that such claimant at no time had any knowledge or reason to believe that such equipment or other thing was being or would be used in, or to facilitate, the violation of laws of the United States relating to any illicit tobacco product.

(e) COSTS AND FEES.—When a decree of condemnation is entered against the tobacco product or other article, court costs and fees, and storage and other proper expenses shall be awarded against the person, if any, intervening as claimant of the tobacco product or other article.

(f) REMOVAL FOR TRIAL.—In the case of removal for trial of any case as provided by subsection (a) or (b)—

(1) The clerk of the court from which removal is made shall promptly transmit to the court in which the case is to be tried all records in the case necessary in order that such court may exercise jurisdiction.

(2) The court to which such case was removed shall have the powers and be subject to the duties, for purposes of such case, which the court from which removal was made would have had, or to which such court would have been subject, if such case had not been removed.

(g) ADMINISTRATIVE DETENTION OF TOBACCO PRODUCTS.—

(1) DETENTION AUTHORITY.—

(A) IN GENERAL.—An officer or qualified employee of the Agency may order the detention, in accordance with this subsection, of any tobacco product that is found during an inspection, examination, or investigation under this Act conducted by such officer or qualified employee, if the officer or qualified employee has credible evidence or information indicating that such article presents a threat of serious adverse health consequences beyond those normally inherent in the use of tobacco products.

(B) ADMINISTRATOR'S APPROVAL.—A tobacco product or component thereof may be ordered detained under subparagraph (A) if, but only if, the Administrator or an official designated by the Administrator approves the order. An official may not be so designated unless the official is an officer with supervisory responsibility for the inspection, examination, or investigation that led to the order.

(2) PERIOD OF DETENTION.—A tobacco product may be detained under paragraph (1) for a reasonable period, not to exceed 20 days, unless a greater period, not to exceed 30 days, is necessary, to institute an action under subsection (a) or section 702.

(3) SECURITY OF DETAINED TOBACCO PRODUCT.—An order under paragraph (1) may require that the tobacco product to be detained be labeled or marked as detained, and shall require that the tobacco product be maintained in or removed to a secure facility, as appropriate. A tobacco product subject to such an order shall not be transferred by any person from the place at which the tobacco product is ordered detained, or from the place to which the tobacco product is so removed, as the case may be, until released by the Administrator or until the expiration of the detention period applicable under such order,

whichever occurs first. This subsection may not be construed as authorizing the delivery of the tobacco product pursuant to the execution of a bond while the tobacco product is subject to the order, and section 709 does not authorize the delivery of the tobacco product pursuant to the execution of a bond while the article is subject to the order.

(4) APPEAL OF DETENTION ORDER.—

(A) IN GENERAL.—With respect to a tobacco product ordered detained under paragraph (1), any person who would be entitled to be a claimant of such tobacco product if the tobacco product were seized under subsection (a) may appeal the order to the Administrator. Within five days after such an appeal is filed, the Administrator, after providing opportunity for an informal hearing, shall confirm or terminate the order involved, and such confirmation by the Administrator shall be considered a final agency action for purposes of section 702 of title 5, United States Code. If during such five-day period the Administrator fails to provide such an opportunity, or to confirm or terminate such order, the order is deemed to be terminated.

(B) EFFECT OF INSTITUTING COURT ACTION.—The process under subparagraph (A) for the appeal of an order under paragraph (1) terminates if the Administrator institutes an action under subsection (a) or section 702 regarding the tobacco product involved.

SEC. 505. REPORT OF MINOR VIOLATIONS.

Nothing in this Act shall be construed as requiring the Administrator to report for prosecution, or for institution of libel or injunction proceedings, minor violations of this Act whenever the Administrator believes that the public interest will be adequately served by a suitable written notice or warning.

SEC. 506. INSPECTION.

(a) AUTHORITY TO INSPECT.—The Administrator shall have the power to inspect the premises of a tobacco product manufacturer for purposes of determining compliance with this Act, or the regulations promulgated under it. Officers of the Agency designated by the Administrator, upon presenting appropriate credentials and a written notice to the person in charge of the premises, are authorized to enter, at reasonable times, without a search warrant, any factory, warehouse, or other establishment in which tobacco products are manufactured, processed, packaged, or held for domestic distribution. Any such inspection shall be conducted within reasonable limits and in a reasonable manner, and shall be limited to examining only those things, including but not limited to records, relevant to determining whether violations of this Act, or regulations under it, have occurred. No inspection authorized by this section shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act), or research data. A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such

inspection shall be commenced and completed with reasonable promptness.

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

(c) SAMPLES.—If the officer has obtained any sample in the course of inspection, prior to leaving the premises that officer shall give to the person in charge of the premises a receipt describing the samples obtained. As to each sample obtained, the officer shall furnish promptly to the person in charge of the premises a copy of the sample and of any analysis made upon the sample.

SEC. 507. EFFECT OF COMPLIANCE.

Compliance with the provisions of this Act and the regulations promulgated under it shall constitute a complete defense to any civil action, including but not limited to any products liability action, that seeks to recover damages, whether compensatory or punitive, based upon an alleged defect in the labeling or advertising of any tobacco product distributed for sale domestically.

SEC. 508. IMPORTS.

(a) IMPORTS; LIST OF REGISTERED FOREIGN ESTABLISHMENTS; SAMPLES FROM UNREGISTERED FOREIGN ESTABLISHMENTS; EXAMINATION AND REFUSAL OF ADMISSION.—The Secretary of Homeland Security shall deliver to the Administrator, upon request by the Administrator, samples of tobacco products that are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may appear before the Administrator and have the right to introduce testimony. The Administrator shall furnish to the Secretary of Homeland Security a list of establishments registered pursuant to subsection (d) of section 109 of this Act, and shall request that, if any tobacco products manufactured, prepared, or processed in an establishment not so registered are imported or offered for import into the United States, samples of such tobacco products be delivered to the Administrator, with notice of such delivery to the owner or consignee, who may appear before the Administrator and have the right to introduce testimony. If it appears from the examination of such samples or otherwise that (1) such tobacco product is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or (2) such tobacco product is adulterated, misbranded, or otherwise in violation of this Act, then such tobacco product shall be refused admission, except as provided in subsection (b) of this section. The Secretary of Homeland Security shall cause the destruction of any such tobacco product refused admission unless such tobacco product is exported, under regulations prescribed by the Secretary of Homeland Security, within ninety days of the date of notice of such refusal or within such additional time as may be permitted pursuant to such regulations.

(b) DISPOSITION OF REFUSED TOBACCO PRODUCTS.—Pending decision as to the admission of a tobacco product being imported or offered for import, the Secretary of Homeland Security may authorize delivery of such tobacco product to the owner or consignee upon the execution by such consignee of a good and sufficient bond providing

for the payment of such liquidated damages in the event of default as may be required pursuant to regulations of the Secretary of Homeland Security. If it appears to the Administrator that a tobacco product included within the provisions of clause (3) of subsection (a) of this section can, by relabeling or other action, be brought into compliance with this Act or rendered other than a tobacco product, final determination as to admission of such tobacco product may be deferred and, upon filing of timely written application by the owner or consignee and the execution by such consignee of a bond as provided in the preceding provisions of this subsection, the Administrator may, in accordance with regulations, authorize the applicant to perform such relabeling or other action specified in such authorization (including destruction or export of rejected tobacco products or portions thereof, as may be specified in the Administrator's authorization). All such relabeling or other action pursuant to such authorization shall in accordance with regulations be under the supervision of an officer or employee of the Agency designated by the Administrator, or an officer or employee of the Department of Homeland Security designated by the Secretary of Homeland Security.

(c) CHARGES CONCERNING REFUSED TOBACCO PRODUCTS.—All expenses (including travel, per diem or subsistence, and salaries of officers or employees of the United States) in connection with the destruction provided for in subsection (a) of this section and the supervision of the relabeling or other action authorized under the provisions of subsection (b) of this section, the amount of such expenses to be determined in accordance with regulations, and all expenses in connection with the storage, cartage, or labor with respect to any tobacco product refused admission under subsection (a) of this section, shall be paid by the owner or consignee and, in default of such payment, shall constitute a lien against any future importations made by such owner or consignee.

SEC. 509. TOBACCO PRODUCTS FOR EXPORT.

(a) EXEMPTION FOR TOBACCO PRODUCTS EXPORTED.—Except as provided in subsection (b), a tobacco product intended for export shall be exempt from this Act if—

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

(2) it is labeled on the outside of the shipping package that it is intended for export; and

(3) the particular units of tobacco product intended for export have not been sold or offered for sale in domestic commerce.

(b) PRODUCTS FOR U.S. ARMED FORCES OVERSEAS.—A tobacco product intended for export shall not be exempt from this Act if it is intended for sale or distribution to members or units of the Armed Forces of the United States located outside of the United States.

(c) This Act shall not apply to a person that manufactures and/or distributes tobacco products solely for export under subsection

(a), except to the extent such tobacco products are subject to subsection (b).

TITLE VI—MISCELLANEOUS PROVISIONS

SEC. 601. USE OF PAYMENTS UNDER THE MASTER SETTLEMENT AGREEMENT AND INDIVIDUAL STATE SETTLEMENT AGREEMENTS.

(a) REDUCTION OF GRANT AMOUNTS.—(1) For fiscal year 2010 and each subsequent fiscal year, the Secretary shall reduce, as provided in subsection (b), the amount of any grant under section 1921 of the Public Health Service Act (42 U.S.C. § 300x–21) for any State that spends on tobacco control programs from the funds received by such State pursuant to the Master Settlement Agreement, the Florida Settlement Agreement, the Minnesota Settlement Agreement, the Mississippi Memorandum of Understanding, or the Texas Settlement Agreement, as applicable, less than 20 percent of the amounts received by that State from settlement payments.

(2) In the case of a State whose legislature does not convene a regular session in fiscal year 2009 or 2010, and in the case of a State whose legislature does not convene a regular session in fiscal year 2010, the requirement described in subsection (a)(1) as a condition of receipt of a grant under section 1921 of the Public Health Service Act shall apply only for fiscal year 2009 and subsequent fiscal years.

(b) DETERMINATION OF STATE SPENDING.—Before making a grant under section 1921 of the Public Health Service Act, section 300x–21 of title 42, United States Code, to a State for the first applicable fiscal year or any subsequent fiscal year, the Secretary shall make a determination of whether, during the immediately preceding fiscal year, the State has spent on tobacco control programs, from the funds received by such State pursuant to the Master Settlement Agreement, the Florida Settlement Agreement, the Minnesota Settlement Agreement, the Mississippi Memorandum of Understanding, or the Texas Settlement Agreement, as applicable, at least the amount referenced in (a)(1). If, after notice to the State and an opportunity for a hearing, the Secretary determines that the State has spent less than such amount, the Secretary shall reduce the amount of the allotment under section 300x–21 of title 42, United States Code, for the State for the fiscal year involved by an amount equal to—

(1) in the case of the first applicable fiscal year, 10 percent of the amount determined under section 300x–33 of title 42, United States Code, for the State for the fiscal year;

(2) in the case of the first fiscal year following such applicable fiscal year, 20 percent of the amount determined under section 300x–33 of title 42, United States Code, for the State for the fiscal year;

(3) in the case of the second such fiscal year, 30 percent of the amount determined under section 300x–33 of title 42, United States Code, for the State for the fiscal year; and

(4) in the case of the third such fiscal year or any subsequent fiscal year, 40 percent of the amount determined under section

300x–33 of title 42, United States Code, for the State for the fiscal year.

The Secretary shall not have authority or discretion to grant to any State a waiver of the terms and requirements of this subsection or subsection (a).

(c) DEFINITIONS.—For the purposes of this section—

(1) The term "first applicable fiscal year" means—

(A) fiscal year 2011, in the case of any State described in subsection (a)(2) of this section; and

(B) fiscal year 2010, in the case of any other State.

(2) The term "Florida Settlement Agreement" means the Settlement Agreement, together with the exhibits thereto, entered into on August 25, 1997, between the State of Florida and signatory tobacco product manufacturers, as specified therein.

(3) The term "Master Settlement Agreement" means the Master Settlement Agreement, together with the exhibits thereto, entered into on November 23, 1998, between the signatory States and signatory tobacco product manufacturers, as specified therein.

(4) The term "Minnesota Settlement Agreement" means the Settlement Agreement, together with the exhibits thereto, entered into on May 8, 1998, between the State of Minnesota and signatory tobacco product manufacturers, as specified therein.

(5) The term "Mississippi Memorandum of Understanding" means the Memorandum of Understanding, together with the exhibits thereto and Settlement Agreement contemplated therein, entered into on July 2, 1997, between the State of Mississippi and signatory tobacco product manufacturers, as specified therein.

(6) The term "Secretary" means the Secretary of Health and Human Services.

(7) The term "Texas Settlement Agreement" means the Settlement Agreement, together with the exhibits thereto, entered into on January 16, 1998, between the State of Texas and signatory tobacco product manufacturers, as specified therein.

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

(a) IN GENERAL.—With respect to fire safety standards for cigarettes, no State or political subdivision shall—

(1) require testing of cigarettes that would be in addition to, or different from, the testing prescribed in subsection (b); or

(2) require a performance standard that is in addition to, or different from, the performance standard set forth in subsection (b).

(b) TEST METHOD AND PERFORMANCE STANDARD.—

(1) To the extent a State or political subdivision enacts or has enacted legislation or a regulation setting a fire safety standard for cigarettes, the test method employed shall be—

(A) the American Society of Testing and Materials ("ASTM") standard E2187–4, entitled "Standard Test Method for Measuring the Ignition Strength of Cigarettes";

(B) for each cigarette on 10 layers of filter paper;

(C) so that a replicate test of 40 cigarettes for each brand style of cigarettes comprises a complete test trial for that brand style; and

(D) in a laboratory that has been accredited in accordance with ISO/IEC 17205 of the International Organization for Standardization ("ISO") and that has an implemented quality control and quality assurance program that includes a procedure capable of determining the repeatability of the testing results to a repeatability value that is no greater than 0.19.

(2) To the extent a State or political subdivision enacts or has enacted legislation or a regulation setting a fire safety standard for cigarettes, the performance standard employed shall be that no more than 25 percent of the cigarettes of that brand style tested in a complete test in accordance with paragraph (1) exhibit full-length burns

(c) EXCEPTION TO SUBSECTION (b).—In the event that a manufacturer of a cigarette that a State or political subdivision or its respective delegated agency determines cannot be tested in accordance with the test method prescribed in subsection (b)(1)(A), the manufacturer shall propose a test method and performance standard for the cigarette to the State or political subdivision. Upon approval of the proposed test method and a determination by the State or political division that the performance standard proposed by the manufacturer is equivalent to the performance standard prescribed in subsection (b)(2), the manufacturer may employ such test method and performance standard to certify such cigarette pursuant to this subsection notwithstanding subsection (b).

SEC. 603. INSPECTION BY THE ALCOHOL AND TOBACCO TAX TRADE BUREAU OF RECORDS OF CERTAIN CIGARETTE AND SMOKELESS TOBACCO SELLERS.

(a) IN GENERAL.—Any officer of the Bureau of the Alcohol and Tobacco Tax Trade Bureau may, during normal business hours, enter the premises of any person described in subsection (b) for the purposes of inspecting—

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

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

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

(c) RELIEF.—

(1) IN GENERAL.—The district courts of the United States shall have the authority in a civil action under this subsection to compel inspections authorized by subsection (a).

(2) VIOLATIONS.—Whoever violates subsection (a) or an order issued pursuant to paragraph (1) shall be subject to a civil penalty in an amount not to exceed $10,000 for each violation.

(d) COVERED PROVISIONS OF LAW.—The provisions of law referred to in this subsection are—

(1) the Act of October 19, 1949 (15 U.S.C. 375; commonly referred to as the "Jenkins Act");

(2) chapter 114 of title 18, United States Code; and

(3) this Act.

(e) DELIVERY SALE DEFINED.—In this section, the term "delivery sale" has the meaning given that term in 2343(e) of title 18, United States Code, as amended by this Act.

SEC. 604. SEVERABILITY.

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

TITLE VII—TOBACCO GROWER PROTECTION

SEC. 701. TOBACCO GROWER PROTECTION.

No provision in this Act shall allow the Administrator or any other person to require changes to traditional farming practices, including standard cultivation practices, curing processes, seed composition, tobacco type, fertilization, soil, record keeping, or any other requirement affecting 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.".

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