from Colorado last night. I spoke to Ms. Kathy Hughes of Loveland, who lost her husband. David succumbed to lung cancer. Again, the latter years of his life were dedicated to combating the dangers of secondhand smoke.

Just as my colleague from California, Ms. HARMAN, shared her own family experience with this, we too in my family have direct experience. My partner Marlin's late mother, Wendy Klein Reiss, passed away from lung cancer 2 years ago. It was a very painful thing to go through; and, of course, her wish and her dying breaths were that she never started smoking.

Americans across all political, demographic, and geographic lines have expressed overwhelming support for this legislation. The strong endorsement of hundreds of public health organizations for this bipartisan bill sends a powerful message.

The bill simply gives the FDA the long overdue authority to regulate tobacco products and reduce their devastating harm, just as they enjoy today for pet food and lettuce and cosmetics.

Today, we have an opportunity to protect millions of children across this Nation and to safeguard their future and prevent them from starting smoking. We have an opportunity to do the right thing, to save lives and to strengthen American families.

I urge a ''yes'' vote on the previous question and the rule.

Mr. Speaker, I yield back the balance of my time, and I move the previous question on the resolution.

The previous question was ordered.

The resolution was agreed to.

A motion to reconsider was laid on the table.

REPORT ON RESOLUTION PROVIDING FOR FURTHER CONSIDERATION OF H. CON. RES. 85, CONCURRENT RESOLUTION ON THE BUDGET FOR FISCAL YEAR 2010

Mr. POLIS (during consideration of H. Res. 307), from the Committee on Rules, submitted a privileged report (Rept. No. 111–73) on the resolution (H. Res. 316) providing for further consideration of the concurrent resolution (H. Con. Res. 85) setting forth the congressional budget for the United States Government for fiscal year 2010 and including the appropriate budgetary levels for fiscal years 2009 and 2011 through 2014, which was referred to the House Calendar and ordered to be printed.

FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT

Mr. WAXMAN. Mr. Speaker, pursuant to House Resolution 307, I call up the bill (H.R. 1256) to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, and ask for its immediate consideration.

The Clerk read the title of the bill.

The SPEAKER pro tempore. Pursuant to House Resolution 307, the amendment printed in part A of House Report 111–72 is adopted, and the bill, as amended, is considered read.

The text of the bill, as amended, is as follows:

H.R. 1256

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Family Smoking Prevention and Tobacco Control Act''.

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

SEC. 2. FINDINGS.

The Congress finds the following:

(1) The use of tobacco products by the Nation's children is a pediatric disease of considerable proportions that results in new generations of tobacco-dependent children and adults.

(2) A consensus exists within the scientific and medical communities that tobacco products are inherently dangerous and cause cancer, heart disease, and other serious adverse health effects.

(3) Nicotine is an addictive drug.

(4) Virtually all new users of tobacco products are under the minimum legal age to purchase such products.

(5) Tobacco advertising and marketing contribute significantly to the use of nicotine-containing tobacco products by adolescents.

(6) Because past efforts to restrict advertising and marketing of tobacco products have failed adequately to curb tobacco use by adolescents, comprehensive restrictions on the sale, promotion, and distribution of such products are needed.

(7) Federal and State governments have lacked the legal and regulatory authority and resources they need to address comprehensively the public health and societal problems caused by the use of tobacco products.

(8) Federal and State public health officials, the public health community, and the public at large recognize that the tobacco industry should be subject to ongoing oversight.

(9) Under article I, section 8 of the Constitution, the Congress is vested with the responsibility for regulating interstate commerce and commerce with Indian tribes.

(10) The sale, distribution, marketing, advertising, and use of tobacco products are activities in and substantially affecting interstate commerce because they are sold, marketed, advertised, and distributed in interstate commerce on a nationwide basis, and have a substantial effect on the Nation's economy.

(11) The sale, distribution, marketing, advertising, and use of such products substantially affect interstate commerce through the health care and other costs attributable to the use of tobacco products.

(12) It is in the public interest for Congress to enact legislation that provides the Food and Drug Administration with the authority to regulate tobacco products and the advertising and promotion of such products. The benefits to the American people from enacting such legislation would be significant in human and economic terms.

(13) Tobacco use is the foremost preventable cause of premature death in America. It causes over 400,000 deaths in the United States each year, and approximately 8,600,000 Americans have chronic illnesses related to smoking.

(14) Reducing the use of tobacco by minors by 50 percent would prevent well over 10,000,000 of today's children from becoming regular, daily smokers, saving over 3,000,000 of them from premature death due to tobacco-induced disease. Such a reduction in youth smoking would also result in approximately $75,000,000,000 in savings attributable to reduced health care costs.

(15) Advertising, marketing, and promotion of tobacco products have been especially directed to attract young persons to use tobacco products, and these efforts have resulted in increased use of such products by youth. Past efforts to oversee these activities have not been successful in adequately preventing such increased use.

(16) In 2005, the cigarette manufacturers spent more than $13,000,000,000 to attract new users, retain current users, increase current consumption, and generate favorable long-term attitudes toward smoking and tobacco use.

(17) Tobacco product advertising often misleadingly portrays the use of tobacco as socially acceptable and healthful to minors.

(18) Tobacco product advertising is regularly seen by persons under the age of 18, and persons under the age of 18 are regularly exposed to tobacco product promotional efforts.

(19) Through advertisements during and sponsorship of sporting events, tobacco has become strongly associated with sports and has become portrayed as an integral part of sports and the healthy lifestyle associated with rigorous sporting activity.

(20) Children are exposed to substantial and unavoidable tobacco advertising that leads to favorable beliefs about tobacco use, plays a role in leading young people to overestimate the prevalence of tobacco use, and increases the number of young people who begin to use tobacco.

(21) The use of tobacco products in motion pictures and other mass media glamorizes its use for young people and encourages them to use tobacco products.

(22) Tobacco advertising expands the size of the tobacco market by increasing consumption of tobacco products including tobacco use by young people.

(23) Children are more influenced by tobacco marketing than adults: more than 80 percent of youth smoke three heavily marketed brands, while only 54 percent of adults, 26 and older, smoke these same brands.

(24) Tobacco company documents indicate that young people are an important and often crucial segment of the tobacco market. Children, who tend to be more price sensitive than adults, are influenced by advertising and promotion practices that result in drastically reduced cigarette prices.

(25) Comprehensive advertising restrictions will have a positive effect on the smoking rates of young people.

(26) Restrictions on advertising are necessary to prevent unrestricted tobacco advertising from undermining legislation prohibiting access to young people and providing for education about tobacco use.

(27) International experience shows that advertising regulations that are stringent and comprehensive have a greater impact on overall tobacco use and young people's use than weaker or less comprehensive ones.

(28) Text only requirements, although not as stringent as a ban, will help reduce underage use of tobacco products while preserving the informational function of advertising.

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

(30) The final regulations promulgated by the Secretary of Health and Human Services in the August 28, 1996, issue of the Federal Register (61 Fed. Reg. 44615–44618) for inclusion as part 897 of title 21, Code of Federal Regulations, are consistent with the first amendment to the United States Constitution and with the standards set forth in the amendments made by this subtitle for the regulation of tobacco products by the Food and Drug Administration, and the restriction on the sale and distribution of, including access to and the advertising and promotion of, tobacco products contained in such regulations are substantially related to accomplishing the public health goals of this Act.

(31) The regulations described in paragraph (30) will directly and materially advance the Federal Government's substantial interest in reducing the number of children and adolescents who use cigarettes and smokeless tobacco and in preventing the life-threatening health consequences associated with tobacco use. An overwhelming majority of Americans who use tobacco products begin using such products while they are minors and become addicted to the nicotine in those products before reaching the age of 18. Tobacco advertising and promotion play a crucial role in the decision of these minors to begin using tobacco products. Less restrictive and less comprehensive approaches have not and will not be effective in reducing the problems addressed by such regulations. The reasonable restrictions on the advertising and promotion of tobacco products contained in such regulations will lead to a significant decrease in the number of minors using and becoming addicted to those products.

(32) The regulations described in paragraph (30) impose no more extensive restrictions on communication by tobacco manufacturers and sellers than are necessary to reduce the number of children and adolescents who use cigarettes and smokeless tobacco and to prevent the life-threatening health consequences associated with tobacco use. Such regulations are narrowly tailored to restrict those advertising and promotional practices which are most likely to be seen or heard by youth and most likely to entice them into tobacco use, while affording tobacco manufacturers and sellers ample opportunity to convey information about their products to adult consumers.

(33) Tobacco dependence is a chronic disease, one that typically requires repeated interventions to achieve long-term or permanent abstinence.

(34) Because the only known safe alternative to smoking is cessation, interventions should target all smokers to help them quit completely.

(35) Tobacco products have been used to facilitate and finance criminal activities both domestically and internationally. Illicit trade of tobacco products has been linked to organized crime and terrorist groups.

(36) It is essential that the Food and Drug Administration review products sold or distributed for use to reduce risks or exposures associated with tobacco products and that it be empowered to review any advertising and labeling for such products. It is also essential that manufacturers, prior to marketing such products, be required to demonstrate that such products will meet a series of rigorous criteria, and will benefit the health of the population as a whole, taking into account both users of tobacco products and persons who do not currently use tobacco products.

(37) Unless tobacco products that purport to reduce the risks to the public of tobacco use actually reduce such risks, those products can cause substantial harm to the public health to the extent that the individuals, who would otherwise not consume tobacco products or would consume such products less, use tobacco products purporting to reduce risk. Those who use products sold or distributed as modified risk products that do not in fact reduce risk, rather than quitting or reducing their use of tobacco products, have a substantially increased likelihood of suffering disability and premature death. The costs to society of the widespread use of products sold or distributed as modified risk products that do not in fact reduce risk or that increase risk include thousands of unnecessary deaths and injuries and huge costs to our health care system.

(38) As the National Cancer Institute has found, many smokers mistakenly believe that ''low tar'' and ''light'' cigarettes cause fewer health problems than other cigarettes. As the National Cancer Institute has also found, mistaken beliefs about the health consequences of smoking ''low tar'' and ''light'' cigarettes can reduce the motivation to quit smoking entirely and thereby lead to disease and death.

(39) Recent studies have demonstrated that there has been no reduction in risk on a population-wide basis from ''low tar'' and ''light'' cigarettes, and such products may actually increase the risk of tobacco use.

(40) The dangers of products sold or distributed as modified risk tobacco products that do not in fact reduce risk are so high that there is a compelling governmental interest in ensuring that statements about modified risk tobacco products are complete, accurate, and relate to the overall disease risk of the product.

(41) As the Federal Trade Commission has found, consumers have misinterpreted advertisements in which one product is claimed to be less harmful than a comparable product, even in the presence of disclosures and advisories intended to provide clarification.

(42) Permitting manufacturers to make unsubstantiated statements concerning modified risk tobacco products, whether express or implied, even if accompanied by disclaimers would be detrimental to the public health.

(43) The only way to effectively protect the public health from the dangers of unsubstantiated modified risk tobacco products is to empower the Food and Drug Administration to require that products that tobacco manufacturers sold or distributed for risk reduction be reviewed in advance of marketing, and to require that the evidence relied on to support claims be fully verified.

(44) The Food and Drug Administration is a regulatory agency with the scientific expertise to identify harmful substances in products to which consumers are exposed, to design standards to limit exposure to those substances, to evaluate scientific studies supporting claims about the safety of products, and to evaluate the impact of labels, labeling, and advertising on consumer behavior in order to reduce the risk of harm and promote understanding of the impact of the product on health. In connection with its mandate to promote health and reduce the risk of harm, the Food and Drug Administration routinely makes decisions about whether and how products may be marketed in the United States.

(45) The Federal Trade Commission was created to protect consumers from unfair or deceptive acts or practices, and to regulate unfair methods of competition. Its focus is on those marketplace practices that deceive or mislead consumers, and those that give some competitors an unfair advantage. Its mission is to regulate activities in the marketplace. Neither the Federal Trade Commission nor any other Federal agency except the Food and Drug Administration possesses the scientific expertise needed to implement effectively all provisions of the Family Smoking Prevention and Tobacco Control Act.

(46) If manufacturers state or imply in communications directed to consumers through the media or through a label, labeling, or advertising, that a tobacco product is approved or inspected by the Food and Drug Administration or complies with Food and Drug Administration standards, consumers are likely to be confused and misled. Depending upon the particular language used and its context, such a statement could result in consumers being misled into believing that the product is endorsed by the Food and Drug Administration for use or in consumers being misled about the harmfulness of the product because of such regulation, inspection, approval, or compliance.

(47) In August 2006 a United States district court judge found that the major United States cigarette companies continue to target and market to youth. USA v. Philip Morris, USA, Inc., et al. (Civil Action No. 99–2496 (GK), August 17, 2006).

(48) In August 2006 a United States district court judge found that the major United States cigarette companies dramatically increased their advertising and promotional spending in ways that encourage youth to start smoking subsequent to the signing of the Master Settlement Agreement in 1998. USA v. Philip Morris, USA, Inc., et al. (Civil Action No. 99–2496 (GK), August 17, 2006).

(49) In August 2006 a United States district court judge found that the major United States cigarette companies have designed their cigarettes to precisely control nicotine delivery levels and provide doses of nicotine sufficient to create and sustain addiction while also concealing much of their nicotine-related research. USA v. Philip Morris, USA, Inc., et al. (Civil Action No. 99–2496 (GK), August 17, 2006).

SEC. 3. PURPOSE.

The purposes of this Act are—

(1) to provide authority to the Food and Drug Administration to regulate tobacco products under the Federal Food, Drug, and

Cosmetic Act (21 U.S.C. 301 et seq.), by recognizing it as the primary Federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products as provided for in this Act;

(2) to ensure that the Food and Drug Administration 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 Food and Drug Administration 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 Food and Drug Administration with the authority to regulate the levels of tar, nicotine, and other harmful components of tobacco products;

(6) in order to ensure that consumers are better informed, to require tobacco product manufacturers to disclose research which has not previously been made available, as well as research generated in the future, relating to the health and dependency effects or safety of tobacco products;

(7) to continue to permit 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 cessation to reduce disease risk and the social costs associated with tobacco-related diseases; and

(10) to strengthen legislation against 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; or

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

(b) AGRICULTURAL ACTIVITIES.—The provisions of this Act (or an amendment made by this Act) which authorize the Secretary 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 Secretary 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.

TITLE I—AUTHORITY OF THE FOOD AND DRUG ADMINISTRATION

SEC. 101. AMENDMENT OF FEDERAL FOOD, DRUG, AND COSMETIC ACT.

(a) DEFINITION OF TOBACCO PRODUCTS.—Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following:

''(rr)(1) The term 'tobacco product' means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).

''(2) The term 'tobacco product' does not mean an article that is a drug under subsection (g)(1), a device under subsection (h), or a combination product described in section 503(g).

''(3) The products described in paragraph (2) shall be subject to chapter V of this Act.

''(4) A tobacco product shall not be marketed in combination with any other article or product regulated under this Act (including a drug, biologic, food, cosmetic, medical device, or a dietary supplement).''.

(b) FDA AUTHORITY OVER TOBACCO PRODUCTS.—The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is amended—

(1) by redesignating chapter IX as chapter X;

(2) by redesignating sections 901 through 910 as sections 1001 through 1010; and

(3) by inserting after chapter VIII the following:

''CHAPTER IX—TOBACCO PRODUCTS

''SEC. 900. DEFINITIONS.

''In this chapter:

''(1) ADDITIVE.—The term 'additive' means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), except that such term does not include tobacco or a pesticide chemical residue in or on raw tobacco or a pesticide chemical.

''(2) BRAND.—The term 'brand' means a variety of tobacco product distinguished by the tobacco used, tar content, nicotine content, flavoring used, size, filtration, packaging, logo, registered trademark, brand name, identifiable pattern of colors, or any combination of such attributes.

''(3) CIGARETTE.—The term 'cigarette'—

''(A) means a product that—

''(i) is a tobacco product; and

''(ii) meets the definition of the term 'cigarette' in section 3(1) of the Federal Cigarette Labeling and Advertising Act; and

''(B) includes tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco.

''(4) CIGARETTE TOBACCO.—The term 'cigarette tobacco' means any product that consists of loose tobacco that is intended for use by consumers in a cigarette. Unless otherwise stated, the requirements applicable to cigarettes under this chapter shall also apply to cigarette tobacco.

''(5) COMMERCE.—The term 'commerce' has the meaning given that term by section 3(2) of the Federal Cigarette Labeling and Advertising Act.

''(6) COUNTERFEIT TOBACCO PRODUCT.—The term 'counterfeit tobacco product' means a tobacco product (or the container or labeling of such a product) that, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a tobacco product listed in a registration under section 905(i)(1).

''(7) DISTRIBUTOR.—The term 'distributor' as regards a tobacco product means any person who furthers the distribution of a tobacco product, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Common carriers are not considered distributors for purposes of this chapter.

''(8) ILLICIT TRADE.—The term 'illicit trade' means any practice or conduct prohibited by law which relates to production, shipment, receipt, possession, distribution, sale, or purchase of tobacco products including any practice or conduct intended to facilitate such activity.

''(9) INDIAN COUNTRY.—The term 'Indian country' has the meaning given such term in section 1151 of title 18, United States Code.

''(10) INDIAN TRIBE.—The term 'Indian tribe' has the meaning given such term in section 4(e) of the Indian Self-Determination and Education Assistance Act.

''(11) LITTLE CIGAR.—The term 'little cigar' means a product that—

''(A) is a tobacco product; and

''(B) meets the definition of the term 'little cigar' in section 3(7) of the Federal Cigarette Labeling and Advertising Act.

''(12) NICOTINE.—The term 'nicotine' means the chemical substance named 3-(1-Methyl-2-pyrrolidinyl) pyridine or C[10]H[14]N[2], including any salt or complex of nicotine.

''(13) PACKAGE.—The term 'package' means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers.

''(14) RETAILER.—The term 'retailer' means any person, government, or entity who sells tobacco products to individuals for personal consumption, or who operates a facility where self-service displays of tobacco products are permitted.

''(15) ROLL-YOUR-OWN TOBACCO.—The term 'roll-your-own tobacco' means any tobacco product which, because of its appearance, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco for making cigarettes.

''(16) SMALL TOBACCO PRODUCT MANUFACTURER.—The term 'small tobacco product manufacturer' means a tobacco product manufacturer that employs fewer than 350 employees. For purposes of determining the number of employees of a manufacturer under the preceding sentence, the employees of a manufacturer are deemed to include the employees of each entity that controls, is controlled by, or is under common control with such manufacturer.

''(17) SMOKE CONSTITUENT.—The term 'smoke constituent' means any chemical or chemical compound in mainstream or sidestream tobacco smoke that either transfers from any component of the cigarette to the smoke or that is formed by the combustion or heating of tobacco, additives, or other component of the tobacco product.

''(18) SMOKELESS TOBACCO.—The term 'smokeless tobacco' means any tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity.

''(19) STATE; TERRITORY.—The terms 'State' and 'Territory' shall have the meanings given to such terms in section 201.

''(20) TOBACCO PRODUCT MANUFACTURER.—The term 'tobacco product manufacturer' means any person, including any repacker or relabeler, who—

''(A) manufactures, fabricates, assembles, processes, or labels a tobacco product; or

''(B) imports a finished tobacco product for sale or distribution in the United States.

''(21) TOBACCO WAREHOUSE.—

''(A) Subject to subparagraphs (B) and (C), the term 'tobacco warehouse' includes any person—

''(i) who—

''(I) removes foreign material from tobacco leaf through nothing other than a mechanical process;

''(II) humidifies tobacco leaf with nothing other than potable water in the form of steam or mist; or

''(III) de-stems, dries, and packs tobacco leaf for storage and shipment;

''(ii) who performs no other actions with respect to tobacco leaf; and

''(iii) who provides to any manufacturer to whom the person sells tobacco all information related to the person's actions described in clause (i) that is necessary for compliance with this Act.

''(B) The term 'tobacco warehouse' excludes any person who—

''(i) reconstitutes tobacco leaf;

''(ii) is a manufacturer, distributor, or retailer of a tobacco product; or

''(iii) applies any chemical, additive, or substance to the tobacco leaf other than potable water in the form of steam or mist.

''(C) The definition of the term 'tobacco warehouse' in subparagraph (A) shall not apply to the extent to which the Secretary determines, through rulemaking, that regulation under this chapter of the actions described in such subparagraph is appropriate for the protection of the public health.

''(22) UNITED STATES.—The term 'United States' means the 50 States of the United States of America and the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, Johnston Atoll, the Northern Mariana Islands, and any other trust territory or possession of the United States.

"SEC. 901. FDA 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 911, shall be regulated by the Secretary under this chapter and shall not be subject to the provisions of chapter V.

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

''(c) SCOPE.—

''(1) IN GENERAL.—Nothing in this chapter, or any policy issued or regulation promulgated thereunder, or in sections 101(a), 102, or 103 of title I, title II, or title III of the Family Smoking Prevention and Tobacco Control Act, shall be construed to affect, expand, or limit the Secretary's authority over (including the authority to determine whether products may be regulated), or the regulation of, products under this Act that are not tobacco products under chapter V or any other chapter.

''(2) LIMITATION OF AUTHORITY.—

''(A) IN GENERAL.—The provisions of this chapter 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 Food and Drug Administration have any authority to enter onto a farm owned by a producer of tobacco leaf without the written consent of such producer.

''(B) EXCEPTION.—Notwithstanding subparagraph (A), 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 chapter 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.

''(C) RULE OF CONSTRUCTION.—Nothing in this chapter shall be construed to grant the Secretary authority to promulgate regulations on any matter that involves the production of tobacco leaf or a producer thereof, other than activities by a manufacturer affecting production.

''(d) RULEMAKING PROCEDURES.—Each rulemaking under this chapter shall be in accordance with chapter 5 of title 5, United States Code. This subsection shall not be construed to affect the rulemaking provisions of section 102(a) of the Family Smoking Prevention and Tobacco Control Act.

''(e) CENTER FOR TOBACCO PRODUCTS.—Not later than 90 days after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall establish within the Food and Drug Administration the Center for Tobacco Products, which shall report to the Commissioner of Food and Drugs in the same manner as the other agency centers within the Food and Drug Administration. The Center shall be responsible for the implementation of this chapter and related matters assigned by the Commissioner.

''(f) OFFICE TO ASSIST SMALL TOBACCO PRODUCT MANUFACTURERS.—The Secretary shall establish within the Food and Drug Administration an identifiable office to provide technical and other nonfinancial assistance to small tobacco product manufacturers to assist them in complying with the requirements of this Act.

''(g) CONSULTATION PRIOR TO RULEMAKING.—Prior to promulgating rules under this chapter, the Secretary shall endeavor to consult with other Federal agencies as appropriate.

"SEC. 902. ADULTERATED TOBACCO PRODUCTS.

''A tobacco product shall be deemed to be adulterated if—

''(1) it consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise contaminated by any added poisonous or added deleterious substance that may render the product injurious to health;

''(2) it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health;

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

''(4) the manufacturer or importer of the tobacco product fails to pay a user fee assessed to such manufacturer or importer pursuant to section 919 by the date specified in section 919 or by the 30th day after final agency action on a resolution of any dispute as to the amount of such fee;

''(5) it is, or purports to be or is represented as, a tobacco product which is subject to a tobacco product standard established under section 907 unless such tobacco product is in all respects in conformity with such standard;

''(6)(A) it is required by section 910(a) to have premarket review and does not have an order in effect under section 910(c)(1)(A)(i); or

''(B) it is in violation of an order under section 910(c)(1)(A);

''(7) the methods used in, or the facilities or controls used for, its manufacture, packing, or storage are not in conformity with applicable requirements under section 906(e)(1) or an applicable condition prescribed by an order under section 906(e)(2); or

''(8) it is in violation of section 911.

"SEC. 903. MISBRANDED TOBACCO PRODUCTS.

''(a) IN GENERAL.—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) the name and place of business of the tobacco product manufacturer, packer, or distributor;

''(B) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count;

''(C) an accurate statement of the percentage of the tobacco used in the product that is domestically grown tobacco and the percentage that is foreign grown tobacco; and

''(D) the statement required under section 920(a),

except that under subparagraph (B) reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary;

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

''(4) if it has an established name, unless its label bears, to the exclusion of any other nonproprietary name, its established name prominently printed in type as required by the Secretary by regulation;

''(5) if the Secretary has issued regulations requiring that its labeling bear adequate directions for use, or adequate warnings against use by children, that are necessary for the protection of users unless its labeling conforms in all respects to such regulations;

''(6) if it was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 905(b), 905(c), 905(d), or 905(h), if it was not included in a list required by section 905(i), if a notice or other information respecting it was not provided as required by such section or section 905(j), or if it does not bear such symbols from the uniform system for identification of tobacco products prescribed under section 905(e) as the Secretary by regulation requires;

''(7) if, in the case of any tobacco product distributed or offered for sale in any State—

''(A) its advertising is false or misleading in any particular; or

''(B) it is sold or distributed in violation of regulations prescribed under section 906(d);

''(8) unless, in the case of any tobacco product distributed or offered for sale in any State, the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that tobacco product—

''(A) a true statement of the tobacco product's established name as described in paragraph (4), printed prominently; and

''(B) a brief statement of—

''(i) the uses of the tobacco product and relevant warnings, precautions, side effects, and contraindications; and

''(ii) in the case of specific tobacco products made subject to a finding by the Secretary after notice and opportunity for comment that such action is appropriate to protect the public health, a full description of the components of such tobacco product or the formula showing quantitatively each ingredient of such tobacco product to the extent required in regulations which shall be

issued by the Secretary after an opportunity for a hearing;

''(9) if it is a tobacco product subject to a tobacco product standard established under section 907, unless it bears such labeling as may be prescribed in such tobacco product standard; or

''(10) if there was a failure or refusal—

''(A) to comply with any requirement prescribed under section 904 or 908; or

''(B) to furnish any material or information required under section 909.

''(b) PRIOR APPROVAL OF LABEL STATEMENTS.—The Secretary may, by regulation, require prior approval of statements made on the label of a tobacco product. No regulation issued under this subsection may require prior approval by the Secretary of the content of any advertisement, except for modified risk tobacco products as provided in section 911. No advertisement of a tobacco product published after the date of enactment of the Family Smoking Prevention and Tobacco Control Act shall, with respect to the language of label statements as prescribed under section 4 of the Federal Cigarette Labeling and Advertising Act and section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 or the regulations issued under such sections, be subject to the provisions of sections 12 through 15 of the Federal Trade Commission Act.

''SEC. 904. SUBMISSION OF HEALTH INFORMATION TO THE SECRETARY.

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

''(1) Not later than 6 months after the date of enactment of the Family Smoking Prevention and Tobacco Control 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 subbrand.

''(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 Secretary in accordance with section 4(e) of the Federal Cigarette Labeling and Advertising Act.

''(3) Beginning 3 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, a listing of all constituents, including smoke constituents as applicable, identified by the Secretary as harmful or potentially 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. Effective beginning 3 years after such date of enactment, the manufacturer, importer, or agent shall comply with regulations promulgated under section 915 in reporting information under this paragraph, where applicable.

''(4) Beginning 6 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, all documents developed after such date of enactment that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives.

''(b) DATA SUBMISSION.—At the request of the Secretary, 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, behavioral, 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 reduction in risk to health from tobacco products can occur upon the employment of technology available or known to the manufacturer.

''(3) Any or all documents (including underlying scientific or financial information) relating to marketing research involving the use of tobacco products or marketing practices and the effectiveness of such practices used by tobacco manufacturers and distributors.

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) TIME FOR SUBMISSION.—

''(1) IN GENERAL.—At least 90 days prior to the delivery for introduction into interstate commerce of a tobacco product not on the market on the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the manufacturer of such product shall provide the information required under subsection (a).

''(2) DISCLOSURE OF ADDITIVE.—If at any time a tobacco product manufacturer adds to its tobacco products a new tobacco additive or increases the quantity of an existing tobacco additive, the manufacturer shall, except as provided in paragraph (3), at least 90 days prior to such action so advise the Secretary in writing.

''(3) DISCLOSURE OF OTHER ACTIONS.—If at any time a tobacco product manufacturer eliminates or decreases an existing additive, or adds or increases an additive that has by regulation been designated by the Secretary as an additive that is not a human or animal carcinogen, or otherwise harmful to health under intended conditions of use, the manufacturer shall within 60 days of such action so advise the Secretary in writing.

''(d) DATA LIST.—

''(1) IN GENERAL.—Not later than 3 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, and annually thereafter, the Secretary 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 Secretary) the list established under subsection (e).

''(2) CONSUMER RESEARCH.—The Secretary 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 Family Smoking Prevention and Tobacco Control Act, the Secretary 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.

''(e) DATA COLLECTION.—Not later than 24 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall establish, and periodically revise as appropriate, a list of harmful and potentially harmful constituents, including smoke constituents, to health in each tobacco product by brand and by quantity in each brand and subbrand. The Secretary shall publish a public notice requesting the submission by interested persons of scientific and other information concerning the harmful and potentially harmful constituents in tobacco products and tobacco smoke.

''SEC. 905. ANNUAL REGISTRATION.

''(a) DEFINITIONS.—In this section:

''(1) MANUFACTURE, PREPARATION, COMPOUNDING, OR PROCESSING.—The term 'manufacture, preparation, compounding, or processing' shall include repackaging or otherwise changing the container, wrapper, or labeling of any tobacco product package in furtherance of the distribution of the tobacco product from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user.

''(2) NAME.—The term 'name' shall include in the case of a partnership the name of each partner and, in the case of a corporation, the name of each corporate officer and director, and the State of incorporation.

''(b) REGISTRATION BY OWNERS AND OPERATORS.—On or before December 31 of each year, every person who owns or operates any establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products shall register with the Secretary the name, places of business, and all such establishments of that person. If enactment of the Family Smoking Prevention and Tobacco Control Act occurs in the second half of the calendar year, the Secretary shall designate a date no later than 6 months into the subsequent calendar year by which registration pursuant to this subsection shall occur.

''(c) REGISTRATION BY NEW OWNERS AND OPERATORS.—Every person upon first engaging in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products in any establishment owned or operated in any State by that person shall immediately register with the Secretary that person's name, place of business, and such establishment.

''(d) REGISTRATION OF ADDED ESTABLISHMENTS.—Every person required to register under subsection (b) or (c) shall immediately register with the Secretary any additional establishment which that person owns or operates in any State and in which that person begins the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products.

''(e) UNIFORM PRODUCT IDENTIFICATION SYSTEM.—The Secretary may by regulation prescribe a uniform system for the identification of tobacco products and may require that persons who are required to list such tobacco products under subsection (i) shall list such tobacco products in accordance with such system.

''(f) PUBLIC ACCESS TO REGISTRATION INFORMATION.—The Secretary shall make available for inspection, to any person so requesting, any registration filed under this section.

''(g) BIENNIAL INSPECTION OF REGISTERED ESTABLISHMENTS.—Every establishment registered with the Secretary under this section shall be subject to inspection under section 704 or subsection (h), and every such establishment engaged in the manufacture, compounding, or processing of a tobacco product or tobacco products shall be so inspected by 1 or more officers or employees duly designated by the Secretary at least once in the 2-year period beginning with the date of registration of such establishment under this section and at least once in every successive 2-year period thereafter.

''(h) REGISTRATION BY FOREIGN ESTABLISHMENTS.—Any establishment within any foreign country engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products, shall register under this section under regulations promulgated by the Secretary. Such regulations shall require such establishment to provide the information required by subsection (i) and shall include provisions for registration of any such establishment upon condition that adequate and effective means

are available, by arrangement with the government of such foreign country or otherwise, to enable the Secretary to determine from time to time whether tobacco products manufactured, prepared, compounded, or processed in such establishment, if imported or offered for import into the United States, shall be refused admission on any of the grounds set forth in section 801(a).

''(i) REGISTRATION INFORMATION.—

''(1) PRODUCT LIST.—Every person who registers with the Secretary under subsection (b), (c), (d), or (h) shall, at the time of registration under any such subsection, file with the Secretary a list of all tobacco products which are being manufactured, prepared, compounded, or processed by that person for commercial distribution and which have not been included in any list of tobacco products filed by that person with the Secretary under this paragraph or paragraph (2) before such time of registration. Such list shall be prepared in such form and manner as the Secretary may prescribe and shall be accompanied by—

''(A) in the case of a tobacco product contained in the applicable list with respect to which a tobacco product standard has been established under section 907 or which is subject to section 910, a reference to the authority for the marketing of such tobacco product and a copy of all labeling for such tobacco product;

''(B) in the case of any other tobacco product contained in an applicable list, a copy of all consumer information and other labeling for such tobacco product, a representative sampling of advertisements for such tobacco product, and, upon request made by the Secretary for good cause, a copy of all advertisements for a particular tobacco product; and

''(C) if the registrant filing a list has determined that a tobacco product contained in such list is not subject to a tobacco product standard established under section 907, a brief statement of the basis upon which the registrant made such determination if the Secretary requests such a statement with respect to that particular tobacco product.

''(2) CONSULTATION WITH RESPECT TO FORMS.—The Secretary shall consult with the Secretary of the Treasury in developing the forms to be used for registration under this section to minimize the burden on those persons required to register with both the Secretary and the Tax and Trade Bureau of the Department of the Treasury.

''(3) BIANNUAL REPORT OF ANY CHANGE IN PRODUCT LIST.—Each person who registers with the Secretary under this section shall report to the Secretary once during the month of June of each year and once during the month of December of each year the following:

''(A) A list of each tobacco product introduced by the registrant for commercial distribution which has not been included in any list previously filed by that person with the Secretary under this subparagraph or paragraph (1). A list under this subparagraph shall list a tobacco product by its established 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 that person has discontinued the manufacture, preparation, compounding, or processing for commercial distribution of a tobacco product included in a list filed under subparagraph (A) or paragraph (1), notice of such discontinuance, the date of such discontinuance, and the identity of its established name.

''(C) If since the date the registrant reported under subparagraph (B) a notice of discontinuance that person has resumed the manufacture, preparation, compounding, or processing for commercial distribution of the tobacco product with respect to which such notice of discontinuance was reported, notice of such resumption, the date of such resumption, the identity of such tobacco product by established name, and other information required by paragraph (1), unless the registrant has previously reported such resumption to the Secretary under this subparagraph.

''(D) Any material change in any information previously submitted under this paragraph or paragraph (1).

''(j) REPORT PRECEDING INTRODUCTION OF CERTAIN SUBSTANTIALLY EQUIVALENT PRODUCTS INTO INTERSTATE COMMERCE.—

''(1) IN GENERAL.—Each person who is required to register under this section and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a tobacco product intended for human use that was not commercially marketed (other than for test marketing) in the United States as of February 15, 2007, shall, at least 90 days prior to making such introduction or delivery, report to the Secretary (in such form and manner as the Secretary shall prescribe)—

''(A) the basis for such person's determination that—

''(i) the tobacco product is substantially equivalent, within the meaning of section 910, to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007, or to a tobacco product that the Secretary has previously determined, pursuant to subsection (a)(3) of section 910, is substantially equivalent and that is in compliance with the requirements of this Act; or

''(ii) the tobacco product is modified within the meaning of paragraph (3), the modifications are to a product that is commercially marketed and in compliance with the requirements of this Act, and all of the modifications are covered by exemptions granted by the Secretary pursuant to paragraph (3); and

''(B) action taken by such person to comply with the requirements under section 907 that are applicable to the tobacco product.

''(2) APPLICATION TO CERTAIN POST-FEBRUARY 15, 2007, PRODUCTS.—A report under this subsection for a tobacco product that was first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after February 15, 2007, and prior to the date that is 21 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act shall be submitted to the Secretary not later than 21 months after such date of enactment.

''(3) EXEMPTIONS.—

''(A) IN GENERAL.—The Secretary may exempt from the requirements of this subsection relating to the demonstration that a tobacco product is substantially equivalent within the meaning of section 910, tobacco products that are modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive, if the Secretary determines that—

''(i) such modification would be a minor modification of a tobacco product that can be sold under this Act;

''(ii) a report under this subsection is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for protection of the public health; and

''(iii) an exemption is otherwise appropriate.

''(B) REGULATIONS.—Not later than 15 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall issue regulations to implement this paragraph.

''SEC. 906. GENERAL PROVISIONS RESPECTING CONTROL OF TOBACCO PRODUCTS.

''(a) IN GENERAL.—Any requirement established by or under section 902, 903, 905, or 909 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 907, section 910, section 911, or subsection (d) of this section, and any requirement established by or under section 902, 903, 905, or 909 which is inconsistent with a requirement imposed on such tobacco product under section 907, section 910, section 911, 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 907, 908, 909, 910, or 911 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 Secretary 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 Secretary or the Secretary's representative under section 903, 904, 907, 908, 909, 910, 911, or 704, 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 chapter, or when relevant in any proceeding under this chapter.

''(d) RESTRICTIONS.—

''(1) IN GENERAL.—The Secretary may by regulation require restrictions on the sale and distribution of a tobacco product, including restrictions on the access to, and the advertising and promotion of, the tobacco product, if the Secretary determines that such regulation would be appropriate for the protection of the public health. The Secretary may by regulation impose restrictions on the advertising and promotion of a tobacco product consistent with and to full extent permitted by the first amendment to the Constitution. 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 population as a whole, including users and nonusers of the tobacco product, and taking into account—

''(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

''(B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

No such regulation may require that the sale or distribution of a tobacco product be limited to the written or oral authorization of a practitioner licensed by law to prescribe medical products.

''(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 Secretary may in such regulation prescribe.

''(3) LIMITATIONS.—

''(A) IN GENERAL.—No restrictions under paragraph (1) may—

''(i) prohibit the sale of any tobacco product in face-to-face transactions by a specific category of retail outlets; or

''(ii) establish a minimum age of sale of tobacco products to any person older than 18 years of age.

''(B) MATCHBOOKS.—For purposes of any regulations issued by the Secretary, matchbooks of conventional size containing not more than 20 paper matches, and which are customarily given away for free with the purchase of tobacco products, shall be considered as adult-written publications which shall be permitted to contain advertising. Notwithstanding the preceding sentence, if the Secretary finds that such treatment of matchbooks is not appropriate for the protection of the public health, the Secretary may determine by regulation that matchbooks shall not be considered adult-written publications.

''(4) REMOTE SALES.—

''(A) IN GENERAL.—The Secretary shall—

''(i) within 18 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, promulgate regulations regarding the sale and distribution of tobacco products that occur through means other than a direct, face-to-face exchange between a retailer and a consumer in order to prevent the sale and distribution of tobacco products to individuals who have not attained the minimum age established by applicable law for the purchase of such products, including requirements for age verification; and

''(ii) within 2 years after such date of enactment, issue regulations to address the promotion and marketing of tobacco products that are sold or distributed through means other than a direct, face-to-face exchange between a retailer and a consumer in order to protect individuals who have not attained the minimum age established by applicable law for the purchase of such products.

''(B) RELATION TO OTHER AUTHORITY.—Nothing in this paragraph limits the authority of the Secretary to take additional actions under the other paragraphs of this subsection.

''(e) GOOD MANUFACTURING PRACTICE REQUIREMENTS.—

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

''(A) IN GENERAL.—In applying manufacturing restrictions to tobacco, the Secretary 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 chapter. Such regulations may provide for the testing of raw tobacco for pesticide chemical residues regardless of whether a tolerance for such chemical residues has been established.

''(B) REQUIREMENTS.—The Secretary 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);

''(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; and

''(v) not require any small tobacco product manufacturer to comply with a regulation under subparagraph (A) for at least 4 years following the effective date established by the Secretary for such regulation.

''(2) EXEMPTIONS; VARIANCES.—

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

''(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 Secretary shall prescribe.

''(B) REFERRAL TO THE TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE.—The Secretary 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 Secretary 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 Secretary under subparagraph (A); or

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

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

''(C) APPROVAL.—The Secretary may approve—

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

''(ii) a petition for a variance for a tobacco product from a requirement if the Secretary 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 chapter.

''(D) CONDITIONS.—An order of the Secretary 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 chapter.

''(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 the Family Smoking Prevention and Tobacco Control Act.

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

"SEC. 907. TOBACCO PRODUCT STANDARDS.

''(a) IN GENERAL.—

''(1) SPECIAL RULES.—

''(A) SPECIAL RULE FOR CIGARETTES.—Beginning 3 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, a cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke. Nothing in this subparagraph shall be construed to limit the Secretary's authority to take action under this section or other sections of this Act applicable to menthol or any artificial or natural flavor, herb, or spice not specified in this subparagraph.

''(B) ADDITIONAL SPECIAL RULE.—Beginning 2 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, a tobacco product manufacturer shall not use tobacco, including foreign grown tobacco, that contains a pesticide chemical residue that is at a level greater than is specified by any tolerance applicable under Federal law to domestically grown tobacco.

''(2) REVISION OF TOBACCO PRODUCT STANDARDS.—The Secretary may revise the tobacco product standards in paragraph (1) in accordance with subsection (c).

''(3) TOBACCO PRODUCT STANDARDS.—

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

''(B) DETERMINATIONS.—

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

''(I) the risks and benefits to the population as a whole, including users and nonusers of tobacco products, of the proposed standard;

''(II) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

''(III) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

''(ii) ADDITIONAL CONSIDERATIONS.—In the event that the Secretary makes a determination, set forth in a proposed tobacco product

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 tobacco product because the Secretary has found that the additive, constituent, or other component is or may be 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 Secretary's consideration scientific evidence that demonstrates that the proposed standard will not reduce or eliminate the risk of illness or injury.

''(4) CONTENT OF TOBACCO PRODUCT STANDARDS.—A tobacco product standard established under this section for a tobacco product—

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

''(i) for nicotine yields of the product;

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

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

''(B) shall, 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 tobacco product;

''(ii) provisions for the testing (on a sample basis or, if necessary, on an individual basis) of the tobacco product;

''(iii) provisions for the measurement of the tobacco product characteristics of the tobacco product;

''(iv) provisions requiring that the results of each or of certain of the tests of the tobacco product required to be made under clause (ii) show that the tobacco product is in conformity with the portions of the standard for which the test or tests were required; and

''(v) a provision requiring that the sale and distribution of the tobacco product be restricted but only to the extent that the sale and distribution of a tobacco product may be restricted under a regulation under section 906(d);

''(C) shall, where appropriate, require the use and prescribe the form and content of labeling for the proper use of the tobacco product; and

''(D) shall require tobacco products containing foreign-grown tobacco to meet the same standards applicable to tobacco products containing domestically grown tobacco.

''(5) PERIODIC REEVALUATION OF TOBACCO PRODUCT STANDARDS.—The Secretary shall provide for periodic evaluation of tobacco product standards established under this section to determine whether such standards should be changed to reflect new medical, scientific, or other technological data. The Secretary may provide for testing under paragraph (4)(B) by any person.

''(6) INVOLVEMENT OF OTHER AGENCIES; INFORMED PERSONS.—In carrying out duties under this section, the Secretary 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 Secretary's judgment can make a significant contribution.

''(b) CONSIDERATIONS BY SECRETARY.—

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

''(2) OTHER CONSIDERATIONS.—The Secretary shall consider all other information submitted in connection with a proposed standard, including information concerning the countervailing effects of the tobacco product standard on the health of adolescent tobacco users, adult tobacco users, or nontobacco users, such as the creation of a significant demand for contraband or other tobacco products that do not meet the requirements of this chapter and the significance of such demand.

''(c) PROPOSED STANDARDS.—

''(1) IN GENERAL.—The Secretary shall publish in the Federal Register a notice of proposed rulemaking for the establishment, amendment, or revocation of any tobacco product standard.

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

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

''(B) invite interested persons to submit a draft or proposed tobacco product standard for consideration by the Secretary;

''(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 tobacco product standard.

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

''(4) COMMENT.—The Secretary shall provide for a comment period of not less than 60 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 tobacco product standard and after consideration of comments submitted under subsections (b) and (c) and any report from the Tobacco Products Scientific Advisory Committee, the Secretary shall—

''(A) if the Secretary determines that the standard would be appropriate for the protection of the public health, promulgate a regulation establishing a tobacco product 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 tobacco product 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 Secretary 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 Secretary 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. If the Secretary determines, based on the Secretary's evaluation of submitted comments, that a product standard can be met only by manufacturers requiring substantial changes to the methods of farming the domestically grown tobacco used by the manufacturer, the effective date of that product standard shall be not less than 2 years after the date of publication of the final regulation establishing the standard.

''(3) LIMITATION ON POWER GRANTED TO THE FOOD AND DRUG ADMINISTRATION.—Because of the importance of a decision of the Secretary to issue a regulation—

''(A) banning all cigarettes, all smokeless tobacco products, all little cigars, all cigars other than little cigars, all pipe tobacco, or all roll-your-own tobacco products; or

''(B) requiring the reduction of nicotine yields of a tobacco product to zero,

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

''(4) AMENDMENT; REVOCATION.—

''(A) AUTHORITY.—The Secretary, upon the Secretary'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 tobacco product standard.

''(B) EFFECTIVE DATE.—The Secretary may declare a proposed amendment of a tobacco product 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 Secretary determines that making it so effective is in the public interest.

''(5) REFERRAL TO ADVISORY COMMITTEE.—

''(A) IN GENERAL.—The Secretary may refer a proposed regulation for the establishment, amendment, or revocation of a tobacco product 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 Secretary may make a referral under this paragraph—

''(i) on the Secretary'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 Secretary 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 60 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 Secretary and other data and information before it, submit to the Secretary 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 Secretary shall make a copy of each report and recommendation under subparagraph (D) publicly available.

''(e) MENTHOL CIGARETTES.—

''(1) REFERRAL; CONSIDERATIONS.—Immediately upon the establishment of the Tobacco Products Scientific Advisory Committee under section 917(a), the Secretary shall refer to the Committee for report and recommendation, under section 917(c)(4), the issue of the impact of the use of menthol in cigarettes on the public health, including such use among children, African Americans, Hispanics, and other racial and ethnic minorities. In its review, the Tobacco Products Scientific Advisory Committee shall address the considerations listed in subsections (a)(3)(B)(i) and (b).

''(2) REPORT AND RECOMMENDATION.—Not later than 1 year after its establishment, the Tobacco Product Scientific Advisory Committee shall submit to the Secretary the report and recommendations required pursuant to paragraph (1).

''(3) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to limit the Secretary's authority to take action under this section or other sections of this Act applicable to menthol.

''SEC. 908. NOTIFICATION AND OTHER REMEDIES.

''(a) NOTIFICATION.—If the Secretary 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 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 chapter (other than this section) to eliminate such risk,

the Secretary 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 Secretary may order notification by any appropriate means, including public service announcements. Before issuing an order under this subsection, the Secretary 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 Secretary 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, adverse health consequences or death, the Secretary 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 Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary 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 Secretary determines that the order should be amended to include a recall of the tobacco product with respect to which the order was issued, the Secretary shall, except as provided in subparagraph (B), amend the order to require a recall. The Secretary shall specify a timetable in which the tobacco product recall will occur and shall require periodic reports to the Secretary 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 Secretary 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 Secretary 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. 909. RECORDS AND REPORTS ON TOBACCO PRODUCTS.

''(a) IN GENERAL.—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 Secretary may by regulation reasonably require to assure that such tobacco product is not adulterated or misbranded and to otherwise protect public health. Regulations prescribed under the preceding sentence—

''(1) may require a tobacco product manufacturer or importer to report to the Secretary whenever the manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed tobacco products may have caused or contributed to a serious unexpected adverse experience associated with the use of the product or any significant increase in the frequency of a serious, expected adverse product experience;

''(2) shall require reporting of other significant adverse tobacco product experiences as determined by the Secretary to be necessary to be reported;

''(3) shall not impose requirements unduly burdensome to a tobacco product manufacturer or importer, taking into account the cost of complying with such requirements and the need for the protection of the public health and the implementation of this chapter;

''(4) when prescribing the procedure for making requests for reports or information, shall require that each request made under such regulations for submission of a report or information to the Secretary state the reason or purpose for such request and identify to the fullest extent practicable such report or information;

''(5) when requiring submission of a report or information to the Secretary, shall state the reason or purpose for the submission of such report or information and identify to the fullest extent practicable such report or information; and

''(6) may not require that the identity of any patient or user be disclosed in records, reports, or information required under this subsection unless required for the medical welfare of an individual, to determine risks to public health of a tobacco product, or to verify a record, report, or information submitted under this chapter.

In prescribing regulations under this subsection, the Secretary shall have due regard for the professional ethics of the medical profession and the interests of patients. The prohibitions of paragraph (6) continue to apply to records, reports, and information concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

''(b) REPORTS OF REMOVALS AND CORRECTIONS.—

''(1) IN GENERAL.—Except as provided in paragraph (2), the Secretary shall by regulation require a tobacco product manufacturer or importer of a tobacco product to report promptly to the Secretary any corrective action taken or removal from the market of a tobacco product undertaken by such manufacturer or importer if the removal or correction was undertaken—

''(A) to reduce a risk to health posed by the tobacco product; or

''(B) to remedy a violation of this chapter caused by the tobacco product which may present a risk to health.

A tobacco product manufacturer or importer of a tobacco product who undertakes a corrective action or removal from the market of a tobacco product which is not required to be reported under this subsection shall keep a record of such correction or removal.

''(2) EXCEPTION.—No report of the corrective action or removal of a tobacco product may be required under paragraph (1) if a report of the corrective action or removal is required and has been submitted under subsection (a).

''SEC. 910. APPLICATION FOR REVIEW OF CERTAIN TOBACCO PRODUCTS.

''(a) IN GENERAL.—

''(1) NEW TOBACCO PRODUCT DEFINED.—For purposes of this section the term 'new tobacco product' means—

''(A) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or

''(B) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

''(2) PREMARKET REVIEW REQUIRED.—

''(A) NEW PRODUCTS.—An order under subsection (c)(1)(A)(i) for a new tobacco product is required unless—

''(i) the manufacturer has submitted a report under section 905(j); and the Secretary has issued an order that the tobacco product—

''(I) is substantially equivalent to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007; and

''(II) is in compliance with the requirements of this Act; or

''(ii) the tobacco product is exempt from the requirements of section 905(j) pursuant to a regulation issued under section 905(j)(3).

''(B) APPLICATION TO CERTAIN POST-FEBRUARY 15, 2007, PRODUCTS.—Subparagraph (A) shall not apply to a tobacco product—

''(i) that was first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after February 15, 2007, and prior to the date that is 21 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act; and

''(ii) for which a report was submitted under section 905(j) within such 21-month period,

except that subparagraph (A) shall apply to the tobacco product if the Secretary issues an order that the tobacco product is not substantially equivalent.

''(3) SUBSTANTIALLY EQUIVALENT DEFINED.—

''(A) IN GENERAL.—In this section and section 905(j), the term 'substantially equivalent' or 'substantial equivalence' means, with respect to the tobacco product being compared to the predicate tobacco product, that the Secretary by order has found that the tobacco product—

''(i) has the same characteristics as the predicate tobacco product; or

''(ii) has different characteristics and the information submitted contains information, including clinical data if deemed necessary by the Secretary, 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.

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

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

''(4) HEALTH INFORMATION.—

''(A) SUMMARY.—As part of a submission under section 905(j) respecting a tobacco product, the person required to file a premarket notification under such section shall provide an adequate summary of any health information related to the tobacco product or state that such information will be made available upon request by any person.

''(B) REQUIRED INFORMATION.—Any summary under subparagraph (A) respecting a tobacco product shall contain detailed information regarding data concerning adverse health effects and shall be made available to the public by the Secretary within 30 days of the issuance of a determination that such tobacco product is substantially equivalent to another tobacco product.

''(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 tobacco product and whether such tobacco product presents less risk than other tobacco products;

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

''(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 tobacco product;

''(D) an identifying reference to any tobacco product standard under section 907 which would be applicable to any aspect of such tobacco product, and either adequate information to show that such aspect of such tobacco product fully meets such tobacco product standard or adequate information to justify any deviation from such standard;

''(E) such samples of such tobacco product and of components thereof as the Secretary may reasonably require;

''(F) specimens of the labeling proposed to be used for such tobacco product; and

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

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

''(A) may, on the Secretary'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 Secretary 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.—

''(A) IN GENERAL.—As promptly as possible, but in no event later than 180 days after the receipt of an application under subsection (b), the Secretary, after considering the report and recommendation submitted under subsection (b)(2), shall—

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

''(ii) issue an order that the new product may not be introduced or delivered for introduction into interstate commerce if the Secretary 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.

''(B) RESTRICTIONS ON SALE AND DISTRIBUTION.—An order under subparagraph (A)(i) may require that the sale and distribution of the tobacco product be restricted but only to the extent that the sale and distribution of a tobacco product may be restricted under a regulation under section 906(d).

''(2) DENIAL OF APPLICATION.—The Secretary shall deny an application submitted under subsection (b) if, upon the basis of the information submitted to the Secretary as part of the application and any other information before the Secretary with respect to such tobacco product, the Secretary finds that—

''(A) there is a lack of a showing that permitting such tobacco product 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 tobacco product do not conform to the requirements of section 906(e);

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

''(D) such tobacco product is not shown to conform in all respects to a tobacco product standard in effect under section 907, 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 Secretary 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 Secretary).

''(4) BASIS FOR FINDING.—For purposes of this section, the finding as to whether the marketing of a tobacco product 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 population as a whole, including users and nonusers of the tobacco product, and taking into account—

''(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

''(B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

''(5) BASIS FOR ACTION.—

''(A) INVESTIGATIONS.—For purposes of paragraph (2)(A), whether permitting a tobacco product to be marketed would be appropriate for the protection of the public health shall, when appropriate, be determined on the basis of well-controlled investigations, which may include 1 or more clinical investigations by experts qualified by training and experience to evaluate the tobacco product.

''(B) OTHER EVIDENCE.—If the Secretary determines that there exists valid scientific evidence (other than evidence derived from investigations described in subparagraph (A)) which is sufficient to evaluate the tobacco product, the Secretary may authorize that the determination for purposes of paragraph (2)(A) be made on the basis of such evidence.

''(d) WITHDRAWAL AND TEMPORARY SUSPENSION.—

''(1) IN GENERAL.—The Secretary 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 tobacco product for which an order was issued under subsection (c)(1)(A)(i), issue an order withdrawing the order if the Secretary finds—

''(A) that the continued marketing of such tobacco product 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 909;

''(ii) has refused to permit access to, or copying or verification of, such records as required by section 704; or

''(iii) has not complied with the requirements of section 905;

''(D) on the basis of new information before the Secretary with respect to such tobacco product, evaluated together with the evidence before the Secretary 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 tobacco product do not conform with the requirements of section 906(e) and were not brought into conformity with such requirements within a reasonable time after receipt of written notice from the Secretary of nonconformity;

''(E) on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when the application was reviewed, that the labeling of such tobacco product, 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 Secretary of such fact; or

''(F) on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when such order was issued, that such tobacco product is not shown to conform in all respects to a tobacco product standard which is in effect under section 907, 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)(i) 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 912.

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

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

''(1) in person by any officer or employee of the department designated by the Secretary; 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 Secretary.

''(f) RECORDS.—

''(1) ADDITIONAL INFORMATION.—In the case of any tobacco product for which an order issued pursuant to subsection (c)(1)(A)(i) for an application filed under subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, as the Secretary 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 Secretary 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 Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

''(g) INVESTIGATIONAL TOBACCO PRODUCT EXEMPTION FOR INVESTIGATIONAL USE.—The Secretary may exempt tobacco products intended for investigational use from the provisions of this chapter under such conditions as the Secretary may by regulation prescribe.

''SEC. 911. 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', or 'low' or similar descriptors; 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 Family Smoking Prevention and Tobacco Control 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' solely because its label, labeling, or advertising uses the following phrases to describe such product and its use: 'smokeless tobacco', 'smokeless tobacco product', 'not consumed by smoking', 'does not produce smoke', 'smokefree', 'smoke-free', 'without smoke', 'no smoke', or 'not smoke'.

''(3) EFFECTIVE DATE.—The provisions of paragraph (2)(A)(ii) shall take effect 12 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act for those products whose label, labeling, or advertising contains the terms described in such paragraph on such date of enactment. The 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 paragraph (2)(A)(ii).

''(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 Food and Drug Administration and is subject to the requirements of chapter V.

''(d) FILING.—Any person may file with the Secretary 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 Secretary may require.

''(e) PUBLIC AVAILABILITY.—The Secretary 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 Secretary 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 Secretary.

''(g) MARKETING.—

''(1) MODIFIED RISK PRODUCTS.—Except as provided in paragraph (2), the Secretary 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 Secretary 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) benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.

''(2) SPECIAL RULE FOR CERTAIN PRODUCTS.—

''(A) IN GENERAL.—The Secretary 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 Secretary 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 products 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 less harmful; or

''(II) presents or has been demonstrated to present less of a risk of disease than 1 or more other commercially marketed tobacco products; and

''(iv) issuance of an order with respect to the application is expected to benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.

''(C) CONDITIONS OF MARKETING.—

''(i) IN GENERAL.—Applications subject to an order under this paragraph shall be limited to a term of not more than 5 years, but may be renewed upon a finding by the Secretary that the requirements of this paragraph continue to be satisfied based on the filing of a new application.

''(ii) AGREEMENTS BY APPLICANT.—An order under this paragraph shall be conditioned on the applicant's agreement to conduct postmarket surveillance and studies and to submit to the Secretary the results of such surveillance and studies to determine the impact of the order on consumer perception, behavior, and health and to enable the Secretary to review the accuracy of the determinations upon which the order was based in accordance with a protocol approved by the Secretary.

''(iii) ANNUAL SUBMISSION.—The results of such postmarket surveillance and studies described in clause (ii) shall be submitted annually.

''(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 Secretary.

''(4) BENEFIT TO HEALTH OF INDIVIDUALS AND OF POPULATION AS A WHOLE.—In making the determinations under paragraphs (1) and (2), the Secretary shall take into account—

''(A) the relative health risks to individuals of the tobacco product that is the subject of the application;

''(B) the increased or decreased likelihood that existing users of tobacco products who would otherwise stop using such products will switch to the tobacco product that is the subject of the application;

''(C) the increased or decreased likelihood that persons who do not use tobacco products will start using the tobacco product that is the subject of the application;

''(D) the risks and benefits to persons from the use of the tobacco product that is the subject of the application as compared to the use of products for smoking cessation approved under chapter V to treat nicotine dependence; and

''(E) comments, data, and information submitted by interested persons.

''(h) ADDITIONAL CONDITIONS FOR MARKETING.—

''(1) MODIFIED RISK PRODUCTS.—The Secretary 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 Secretary may require for the marketing of a product under this subsection that a claim comparing a tobacco product to 1 or more 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 Secretary 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.

''(3) LABEL DISCLOSURE.—

''(A) IN GENERAL.—The Secretary may require the disclosure on the label of other substances in the tobacco product, or substances that may be produced by the consumption of that tobacco product, that may affect a disease or health-related condition or may increase the risk of other diseases or health-related conditions associated with the use of tobacco products.

''(B) CONDITIONS OF USE.—If the conditions of use of the tobacco product may affect the risk of the product to human health, the Secretary may require the labeling of conditions of use.

''(4) TIME.—An order issued under subsection (g)(1) shall be effective for a specified period of time.

''(5) ADVERTISING.—The Secretary may require, with respect to a product for which an applicant obtained an order under subsection (g)(1), that the product comply with requirements relating to advertising and promotion of the tobacco product.

''(i) POSTMARKET SURVEILLANCE AND STUDIES.—

''(1) IN GENERAL.—The Secretary 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 Secretary to review the accuracy of the determinations upon which the order was based, and to provide information that the Secretary 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 Secretary 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 Secretary, a protocol for the required surveillance. The Secretary, within 60 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 Secretary as necessary to protect the public health.

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

''(1) the applicant, based on new information, can no longer make the demonstrations required under subsection (g), or the Secretary 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 907;

''(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 Secretary has issued an order pursuant to subsection (g) shall not be subject to chapter IV or V.

''(l) IMPLEMENTING REGULATIONS OR GUIDANCE.—

''(1) SCIENTIFIC EVIDENCE.—Not later than 2 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary 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 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;

''(E) require that data from the required studies and surveillance be made available to the Secretary prior to the decision on renewal of a modified risk tobacco product; and

''(F) establish a reasonable timetable for the Secretary to review an application under this section.

''(2) CONSULTATION.—The regulations or guidance issued under paragraph (1) shall 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 Family Smoking Prevention and Tobacco Control Act, the Secretary 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 910 and which the applicant seeks to commercially market under this section.

''(m) DISTRIBUTORS.—Except as provided in this section, no distributor may take any action, after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, with respect to a tobacco product that would reasonably be 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.

''SEC. 912. JUDICIAL REVIEW.

''(a) RIGHT TO REVIEW.—

''(1) IN GENERAL.—Not later than 30 days after—

''(A) the promulgation of a regulation under section 907 establishing, amending, or revoking a tobacco product standard; or

''(B) a denial of an application under section 910(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 Secretary.

''(B) RECORD OF PROCEEDINGS.—On receipt of a petition under subparagraph (A), the Secretary 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 Secretary 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 Secretary, 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 906, 907, 908, 909, 910, or 916 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. 913. EQUAL TREATMENT OF RETAIL OUTLETS.

''The Secretary shall issue regulations to require that retail establishments for which the predominant business is the sale of tobacco products comply with any advertising restrictions applicable to retail establishments accessible to individuals under the age of 18.

''SEC. 914. JURISDICTION OF AND COORDINATION WITH THE FEDERAL TRADE COMMISSION.

''(a) JURISDICTION.—

''(1) IN GENERAL.—Except where expressly provided in this chapter, nothing in this chapter 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.

''(2) ENFORCEMENT.—Any advertising that violates this chapter or a provision of the regulations referred to in section 102 of the Family Smoking Prevention and Tobacco Control Act, is an unfair or deceptive act or practice under section 5(a) of the Federal Trade Commission Act and shall be considered a violation of a rule promulgated under section 18 of that Act.

''(b) COORDINATION.—With respect to the requirements of section 4 of the Federal Cigarette Labeling and Advertising Act and section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986—

''(1) the Chairman of the Federal Trade Commission shall coordinate with the Secretary concerning the enforcement of such Act as such enforcement relates to unfair or deceptive acts or practices in the advertising of cigarettes or smokeless tobacco; and

''(2) the Secretary shall consult with the Chairman of such Commission in revising the label statements and requirements under such sections.

''SEC. 915. REGULATION REQUIREMENT.

''(a) TESTING, REPORTING, AND DISCLOSURE.—Not later than 36 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary 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 testing and reporting of tobacco product constituents, ingredients, and additives, including smoke constituents, by brand and subbrand that the Secretary 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; 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 or other appropriate means, and make disclosures regarding the results of the testing of other constituents, including smoke constituents, ingredients, or additives, that the Secretary determines should be disclosed to the public to protect the public health and will not mislead consumers about the risk of tobacco-related disease.

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

''(d) SMALL TOBACCO PRODUCT MANUFACTURERS.—

''(1) FIRST COMPLIANCE DATE.—The initial regulations promulgated under subsection (a) shall not impose requirements on small tobacco product manufacturers before the later of—

''(A) the end of the 2-year period following the final promulgation of such regulations; and

''(B) the initial date set by the Secretary for compliance with such regulations by manufacturers that are not small tobacco product manufacturers.

''(2) TESTING AND REPORTING INITIAL COMPLIANCE PERIOD.—

''(A) 4-YEAR PERIOD.—The initial regulations promulgated under subsection (a) shall give each small tobacco product manufacturer a 4-year period over which to conduct testing and reporting for all of its tobacco products. Subject to paragraph (1), the end of the first year of such 4-year period shall coincide with the initial date of compliance under this section set by the Secretary with respect to manufacturers that are not small tobacco product manufacturers or the end of the 2-year period following the final promulgation of such regulations, as described in paragraph (1)(A). A small tobacco product manufacturer shall be required—

''(i) to conduct such testing and reporting for 25 percent of its tobacco products during each year of such 4-year period; and

''(ii) to conduct such testing and reporting for its largest-selling tobacco products (as determined by the Secretary) before its other tobacco products, or in such other order of priority as determined by the Secretary.

''(B) CASE-BY-CASE DELAY.—Notwithstanding subparagraph (A), the Secretary may, on a case-by-case basis, delay the date by which an individual small tobacco product manufacturer must conduct testing and reporting for its tobacco products under this section based upon a showing of undue hardship to such manufacturer. Notwithstanding the preceding sentence, the Secretary shall not extend the deadline for a small tobacco product manufacturer to conduct testing and reporting for all of its tobacco products beyond a total of 5 years after the initial date of compliance under this section set by the Secretary with respect to manufacturers that are not small tobacco product manufacturers.

''(3) SUBSEQUENT AND ADDITIONAL TESTING AND REPORTING.—The regulations promulgated under subsection (a) shall provide that, with respect to any subsequent or additional testing and reporting of tobacco products required under this section, such testing and reporting by a small tobacco product manufacturer shall be conducted in accordance with the timeframes described in paragraph (2)(A), except that, in the case of a new product, or if there has been a modification described in section 910(a)(1)(B) of any product of a small tobacco product manufacturer since the last testing and reporting required under this section, the Secretary shall require that any subsequent or additional testing and reporting be conducted in accordance with the same timeframe applicable to manufacturers that are not small tobacco product manufacturers.

''(4) JOINT LABORATORY TESTING SERVICES.—The Secretary shall allow any 2 or more small 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 small tobacco product manufacturer shall not be considered to be in violation of this section before the deadline applicable under paragraphs (3) and (4), if—

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

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

''(2) CONDITIONS.—Notwithstanding the requirements of this section, the Secretary may delay the date by which a small 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 small tobacco product manufacturer provides evidence to the Secretary 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 Secretary, taking into account the laboratory testing capacity that is available to tobacco product manufacturers, shall review and verify the evidence submitted by a small tobacco product manufacturer in accordance with paragraph (2). If the Secretary finds that the conditions described in such paragraph are met, the Secretary shall notify the small tobacco product manufacturer that the manufacturer shall not be considered to be in violation of the testing and reporting 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 Secretary has not made a finding before the reporting deadline, the manufacturer shall not be considered to be in violation of such requirements until the Secretary 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 Secretary may provide further extensions of time, in increments of no more than 1 year, for required testing and reporting to occur if the Secretary determines, based on evidence properly and timely submitted by a small 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 or the Family Smoking Prevention and Tobacco Control Act other than this section.

''SEC. 916. PRESERVATION OF STATE AND LOCAL AUTHORITY.

''(a) IN GENERAL.—

''(1) PRESERVATION.—Except as provided in paragraph (2)(A), nothing in this chapter, or rules promulgated under this chapter, 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, or more stringent than, requirements established under this chapter, including a law, rule, regulation, or other measure relating to or prohibiting the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of tobacco products by individuals of any age, information reporting to the State, or measures relating to fire safety standards for tobacco products. No provision of this chapter 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 chapter 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, exposure to, access to, the advertising and promotion of, or use of, tobacco products by individuals of any age, or relating to fire safety standards for tobacco products. 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 chapter 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. 917. TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE.

''(a) ESTABLISHMENT.—Not later than 6 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall establish a 12-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 Secretary shall appoint as members of the Tobacco Products Scientific 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) 7 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) 1 individual who is an officer or employee of a State or local government or of the Federal Government;

''(iii) 1 individual as a representative of the general public;

''(iv) 1 individual as a representative of the interests of the tobacco manufacturing industry;

''(v) 1 individual as a 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; and

''(vi) 1 individual as a representative of the interests of the tobacco growers.

''(B) NONVOTING MEMBERS.—The members of the committee appointed under clauses (iv), (v), and (vi) of subparagraph (A) shall serve as consultants to those described in clauses (i) through (iii) of subparagraph (A) and shall be nonvoting representatives.

''(C) 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.

''(2) LIMITATION.—The Secretary may not appoint to the Advisory Committee any individual who is in the regular full-time employ of the Food and Drug Administration or any agency responsible for the enforcement of this Act. The Secretary may appoint Federal officials as ex officio members.

''(3) CHAIRPERSON.—The Secretary 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 Secretary—

''(1) as provided in this chapter;

''(2) on the effects of the alteration of the nicotine yields from tobacco products;

''(3) on whether there is a threshold level below which nicotine yields do not produce dependence on the tobacco product involved; and

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

''(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 Secretary, 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 Secretary 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. 918. DRUG PRODUCTS USED TO TREAT TOBACCO DEPENDENCE.

''(a) IN GENERAL.—The Secretary shall—

''(1) at the request of the applicant, consider designating products for smoking cessation, including nicotine replacement products as fast track research and approval products within the meaning of section 506;

''(2) consider approving the extended use of nicotine replacement products (such as nicotine patches, nicotine gum, and nicotine lozenges) for the treatment of tobacco dependence; and

''(3) review and consider the evidence for additional indications for nicotine replacement products, such as for craving relief or relapse prevention.

''(b) REPORT ON INNOVATIVE PRODUCTS.—

''(1) IN GENERAL.—Not later than 3 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary, 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 regulate, promote, and encourage the development of innovative 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.

''(2) RECOMMENDATIONS.—The report under paragraph (1) shall include the recommendations of the Secretary on how the Food and Drug Administration should coordinate and facilitate the exchange of information on such innovative products and treatments among relevant offices and centers within the Administration and within the National Institutes of Health, the Centers for Disease Control and Prevention, and other relevant agencies.

''SEC. 919. USER FEES.

''(a) ESTABLISHMENT OF QUARTERLY FEE.—Beginning on the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall in accordance with this section assess user fees on, and collect such fees from, each manufacturer and importer of tobacco products subject to this chapter. The fees shall be assessed and collected with respect to each quarter of each fiscal year, and the total amount assessed and collected for a fiscal year shall be the amount specified in subsection (b)(1) for such year, subject to subsection (c).

''(b) ASSESSMENT OF USER FEE.—

''(1) AMOUNT OF ASSESSMENT.—The total amount of user fees authorized to be assessed and collected under subsection (a) for a fiscal year is the following, as applicable to the fiscal year involved:

''(A) For fiscal year 2009, $85,000,000 (subject to subsection (e)).

''(B) For fiscal year 2010, $235,000,000.

''(C) For fiscal year 2011, $450,000,000.

''(D) For fiscal year 2012, $477,000,000.

''(E) For fiscal year 2013, $505,000,000.

''(F) For fiscal year 2014, $534,000,000.

''(G) For fiscal year 2015, $566,000,000.

''(H) For fiscal year 2016, $599,000,000.

''(I) For fiscal year 2017, $635,000,000.

''(J) For fiscal year 2018, $672,000,000.

''(K) For fiscal year 2019 and each subsequent fiscal year, $712,000,000.

''(2) ALLOCATIONS OF ASSESSMENT BY CLASS OF TOBACCO PRODUCTS.—

''(A) IN GENERAL.—The total user fees assessed and collected under subsection (a) each fiscal year with respect to each class of tobacco products shall be an amount that is equal to the applicable percentage of each class for the fiscal year multiplied by the amount specified in paragraph (1) for the fiscal year.

''(B) APPLICABLE PERCENTAGE.—

''(i) IN GENERAL.—For purposes of subparagraph (A), the applicable percentage for a fiscal year for each of the following classes of tobacco products shall be determined in accordance with clause (ii):

''(I) Cigarettes.

''(II) Cigars, including small cigars and cigars other than small cigars.

''(III) Snuff.

''(IV) Chewing tobacco.

''(V) Pipe tobacco.

''(VI) Roll-your-own tobacco.

''(ii) ALLOCATIONS.—The applicable percentage of each class of tobacco product described in clause (i) for a fiscal year shall be the percentage determined under section 625(c) of Public Law 108–357 for each such class of product for such fiscal year.

''(iii) REQUIREMENT OF REGULATIONS.—Notwithstanding clause (ii), no user fees shall be assessed on a class of tobacco products unless such class of tobacco products is listed in section 901(b) or is deemed by the Secretary in a regulation under section 901(b) to be subject to this chapter.

''(iv) REALLOCATIONS.—In the case of a class of tobacco products that is not listed in section 901(b) or deemed by the Secretary in a regulation under section 901(b) to be subject to this chapter, the amount of user fees that would otherwise be assessed to such class of tobacco products shall be reallocated to the classes of tobacco products that are subject to this chapter in the same manner and based on the same relative percentages otherwise determined under clause (ii).

''(3) DETERMINATION OF USER FEE BY COMPANY.—

''(A) IN GENERAL.—The total user fee to be paid by each manufacturer or importer of a particular class of tobacco products shall be determined for each quarter by multiplying—

''(i) such manufacturer's or importer's percentage share as determined under paragraph (4); by

''(ii) the portion of the user fee amount for the current quarter to be assessed on all manufacturers and importers of such class of tobacco products as determined under paragraph (2).

''(B) NO FEE IN EXCESS OF PERCENTAGE SHARE.—No manufacturer or importer of tobacco products shall be required to pay a user fee in excess of the percentage share of such manufacturer or importer.

''(4) ALLOCATION OF ASSESSMENT WITHIN EACH CLASS OF TOBACCO PRODUCT.—The percentage share of each manufacturer or importer of a particular class of tobacco products of the total user fee to be paid by all manufacturers or importers of that class of tobacco products shall be the percentage determined for purposes of allocations under subsections (e) through (h) of section 625 of Public Law 108–357.

''(5) ALLOCATION FOR CIGARS.—Notwithstanding paragraph (4), if a user fee assessment is imposed on cigars, the percentage share of each manufacturer or importer of cigars shall be based on the excise taxes paid by such manufacturer or importer during the prior fiscal year.

''(6) TIMING OF ASSESSMENT.—The Secretary shall notify each manufacturer and importer of tobacco products subject to this section of the amount of the quarterly assessment imposed on such manufacturer or importer under this subsection for each quarter of each fiscal year. Such notifications shall occur not later than 30 days prior to the end of the quarter for which such assessment is made, and payments of all assessments shall be made by the last day of the quarter involved.

''(7) MEMORANDUM OF UNDERSTANDING.—

''(A) IN GENERAL.—The Secretary shall request the appropriate Federal agency to enter into a memorandum of understanding that provides for the regular and timely transfer from the head of such agency to the Secretary of the information described in paragraphs (2)(B)(ii) and (4) and all necessary information regarding all tobacco product manufacturers and importers required to pay user fees. The Secretary shall maintain all disclosure restrictions established by the head of such agency regarding the information provided under the memorandum of understanding.

''(B) ASSURANCES.—Beginning not later than fiscal year 2015, and for each subsequent fiscal year, the Secretary shall ensure that the Food and Drug Administration is able to determine the applicable percentages described in paragraph (2) and the percentage shares described in paragraph (4). The Secretary may carry out this subparagraph by entering into a contract with the head of the Federal agency referred to in subparagraph (A) to continue to provide the necessary information.

''(c) CREDITING AND AVAILABILITY OF FEES.—

''(1) IN GENERAL.—Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation.

''(2) AVAILABILITY.—

''(A) IN GENERAL.—Fees appropriated under paragraph (3) are available only for the purpose of paying the costs of the activities of the Food and Drug Administration related to the regulation of tobacco products under this chapter and the Family Smoking Prevention and Tobacco Control Act. No fees collected under subsection (a) may be used for any other costs.

''(B) PROHIBITION AGAINST USE OF OTHER FUNDS.—

''(i) IN GENERAL.—Except as provided in clause (ii), fees collected under subsection (a) are the only funds authorized to be made available for the purpose described in subparagraph (A).

''(ii) STARTUP COSTS.—Clause (i) does not apply until the date on which the Secretary has collected fees under subsection (a) for 2 fiscal year quarters. Until such date, other amounts available to the Food and Drug Administration (excluding fees collected under subsection (a)) are authorized to be made available to pay the costs described in subparagraph (A), provided that such amounts are reimbursed through fees collected under subsection (a).

''(3) AUTHORIZATION OF APPROPRIATIONS.—For fiscal year 2009 and each subsequent fiscal year, there is authorized to be appropriated for fees under this section an amount equal to the amount specified in subsection (b)(1) for the fiscal year.

''(d) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

''(e) APPLICABILITY TO FISCAL YEAR 2009.—If the date of enactment of the Family Smoking Prevention and Tobacco Control

Act occurs during fiscal year 2009, the following applies, subject to subsection (c):

''(1) The Secretary shall determine the fees that would apply for a single quarter of such fiscal year according to the application of subsection (b) to the amount specified in paragraph (1)(A) of such subsection (referred to in this subsection as the 'quarterly fee amounts').

''(2) For the quarter in which such date of enactment occurs, the amount of fees assessed shall be a pro rata amount, determined according to the number of days remaining in the quarter (including such date of enactment) and according to the daily equivalent of the quarterly fee amounts. Fees assessed under the preceding sentence shall not be collected until the next quarter.

''(3) For the quarter following the quarter to which paragraph (2) applies, the full quarterly fee amounts shall be assessed and collected, in addition to collection of the pro rata fees assessed under paragraph (2).''.

SEC. 102. FINAL RULE.

(a) CIGARETTES AND SMOKELESS TOBACCO.—

(1) IN GENERAL.—On the first day of publication of the Federal Register that is 180 days or more after the date of enactment of this Act, the Secretary of Health and Human Services shall publish in the Federal Register a final rule regarding cigarettes and smokeless tobacco, which—

(A) is deemed to be issued under chapter 9 of the Federal Food, Drug, and Cosmetic Act, as added by section 101 of this Act; and

(B) shall be deemed to be in compliance with all applicable provisions of chapter 5 of title 5, United States Code, and all other provisions of law relating to rulemaking procedures.

(2) CONTENTS OF RULE.—Except as provided in this subsection, the final rule published under paragraph (1), shall be identical in its provisions to part 897 of the regulations promulgated by the Secretary of Health and Human Services in the August 28, 1996, issue of the Federal Register (61 Fed. Reg., 44615–44618). Such rule shall—

(A) provide for the designation of jurisdictional authority that is in accordance with this subsection in accordance with this Act and the amendments made by this Act;

(B) strike Subpart C—Labels and section 897.32(c);

(C) strike paragraphs (a), (b), and (i) of section 897.3 and insert definitions of the terms ''cigarette'', ''cigarette tobacco,'', and ''smokeless tobacco'' as defined in section 900 of the Federal Food, Drug, and Cosmetic Act;

(D) insert ''or roll-your-own paper'' in section 897.34(a) after ''other than cigarettes or smokeless tobacco'';

(E) become effective on the date that is 1 year after the date of enactment of this Act; and

(F) amend paragraph (d) of section 897.16 to read as follows:

''(d)(1) Except as provided in subparagraph (2), no manufacturer, distributor, or retailer may distribute or cause to be distributed any free samples of cigarettes, smokeless tobacco, or other tobacco products (as such term is defined in section 201 of the Federal Food, Drug, and Cosmetic Act).

''(2)(A) Subparagraph (1) does not prohibit a manufacturer, distributor, or retailer from distributing or causing to be distributed free samples of smokeless tobacco in a qualified adult-only facility.

''(B) This subparagraph does not affect the authority of a State or local government to prohibit or otherwise restrict the distribution of free samples of smokeless tobacco.

''(C) For purposes of this paragraph, the term 'qualified adult-only facility' means a facility or restricted area that—

''(i) requires each person present to provide to a law enforcement officer (whether on or off duty) or to a security guard licensed by a governmental entity government-issued identification showing a photograph and at least the minimum age established by applicable law for the purchase of smokeless tobacco;

''(ii) does not sell, serve, or distribute alcohol;

''(iii) is not located adjacent to or immediately across from (in any direction) a space that is used primarily for youth-oriented marketing, promotional, or other activities;

''(iv) is a temporary structure constructed, designated, and operated as a distinct enclosed area for the purpose of distributing free samples of smokeless tobacco in accordance with this subparagraph; and

''(v) is enclosed by a barrier that—

''(I) is constructed of, or covered with, an opaque material (except for entrances and exits);

''(II) extends from no more than 12 inches above the ground or floor (which area at the bottom of the barrier must be covered with material that restricts visibility but may allow airflow) to at least 8 feet above the ground or floor (or to the ceiling); and

''(III) prevents persons outside the qualified adult-only facility from seeing into the qualified adult-only facility, unless they make unreasonable efforts to do so; and

''(vi) does not display on its exterior—

''(I) any tobacco product advertising;

''(II) a brand name other than in conjunction with words for an area or enclosure to identify an adult-only facility; or

''(III) any combination of words that would imply to a reasonable observer that the manufacturer, distributor, or retailer has a sponsorship that would violate section 897.34(c).

''(D) Distribution of samples of smokeless tobacco under this subparagraph permitted to be taken out of the qualified adult-only facility shall be limited to 1 package per adult consumer containing no more than 0.53 ounces (15 grams) of smokeless tobacco. If such package of smokeless tobacco contains individual portions of smokeless tobacco, the individual portions of smokeless tobacco shall not exceed 8 individual portions and the collective weight of such individual portions shall not exceed 0.53 ounces (15 grams). Any manufacturer, distributor, or retailer who distributes or causes to be distributed free samples also shall take reasonable steps to ensure that the above amounts are limited to one such package per adult consumer per day.

''(3) Notwithstanding subparagraph (2), no manufacturer, distributor, or retailer may distribute or cause to be distributed any free samples of smokeless tobacco—

''(A) to a sports team or entertainment group; or

''(B) at any football, basketball, baseball, soccer, or hockey event or any other sporting or entertainment event determined by the Secretary to be covered by this subparagraph.

''(4) The Secretary shall implement a program to ensure compliance with this paragraph and submit a report to the Congress on such compliance not later than 18 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act.

''(5) Nothing in this paragraph shall be construed to authorize any person to distribute or cause to be distributed any sample of a tobacco product to any individual who has not attained the minimum age established by applicable law for the purchase of such product.''.

(3) AMENDMENTS TO RULE.—Prior to making amendments to the rule published under paragraph (1), the Secretary shall promulgate a proposed rule in accordance with chapter 5 of title 5, United States Code.

(4) RULE OF CONSTRUCTION.—Except as provided in paragraph (3), nothing in this section shall be construed to limit the authority of the Secretary to amend, in accordance with chapter 5 of title 5, United States Code, the regulation promulgated pursuant to this section, including the provisions of such regulation relating to distribution of free samples.

(5) ENFORCEMENT OF RETAIL SALE PROVISIONS.—The Secretary of Health and Human Services shall ensure that the provisions of this Act, the amendments made by this Act, and the implementing regulations (including such provisions, amendments, and regulations relating to the retail sale of tobacco products) are enforced with respect to the United States and Indian tribes.

(6) QUALIFIED ADULT-ONLY FACILITY.—A qualified adult-only facility (as such term is defined in section 897.16(d) of the final rule published under paragraph (1)) that is also a retailer and that commits a violation as a retailer shall not be subject to the limitations in section 103(q) and shall be subject to penalties applicable to a qualified adult-only facility.

(7) CONGRESSIONAL REVIEW PROVISIONS.—Section 801 of title 5, United States Code, shall not apply to the final rule published under paragraph (1).

(b) LIMITATION ON ADVISORY OPINIONS.—As of the date of enactment of this Act, the following documents issued by the Food and Drug Administration shall not constitute advisory opinions under section 10.85(d)(1) of title 21, Code of Federal Regulations, except as they apply to tobacco products, and shall not be cited by the Secretary of Health and Human Services or the Food and Drug Administration as binding precedent:

(1) The preamble to the proposed rule in the document titled ''Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents'' (60 Fed. Reg. 41314–41372 (August 11, 1995)).

(2) The document titled ''Nicotine in Cigarettes and Smokeless Tobacco Products is a Drug and These Products Are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act'' (60 Fed. Reg. 41453–41787 (August 11, 1995)).

(3) The preamble to the final rule in the document titled ''Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents'' (61 Fed. Reg. 44396–44615 (August 28, 1996)).

(4) The document titled ''Nicotine in Cigarettes and Smokeless Tobacco is a Drug and These Products are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act; Jurisdictional Determination'' (61 Fed. Reg. 44619–45318 (August 28, 1996)).

SEC. 103. CONFORMING AND OTHER AMENDMENTS TO GENERAL PROVISIONS.

(a) AMENDMENT OF FEDERAL FOOD, DRUG, AND COSMETIC ACT.—Except as otherwise expressly provided, whenever in this section an amendment is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference is to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(b) SECTION 301.—Section 301 (21 U.S.C. 331) is amended—

(1) in subsection (a), by inserting ''tobacco product,'' after ''device,'';

(2) in subsection (b), by inserting ''tobacco product,'' after ''device,'';

(3) in subsection (c), by inserting ''tobacco product,'' after ''device,'';

(4) in subsection (e)—

(A) by striking the period after ''572(i)''; and

(B) by striking ''or 761 or the refusal to permit access to'' and inserting ''761, 909, or 920 or the refusal to permit access to'';

(5) in subsection (g), by inserting ''tobacco product,'' after ''device,'';

(6) in subsection (h), by inserting ''tobacco product,'' after ''device,'';

(7) in subsection (j)—

(A) by striking the period after ''573''; and

(B) by striking ''708, or 721'' and inserting ''708, 721, 904, 905, 906, 907, 908, 909, or 920(b)'';

(8) in subsection (k), by inserting ''tobacco product,'' after ''device,'';

(9) by striking subsection (p) and inserting the following:

''(p) The failure to register in accordance with section 510 or 905, the failure to provide any information required by section 510(j), 510(k), 905(i), or 905(j), or the failure to provide a notice required by section 510(j)(2) or 905(i)(3).'';

(10) by striking subsection (q)(1) and inserting the following:

''(q)(1) The failure or refusal—

''(A) to comply with any requirement prescribed under section 518, 520(g), 903(b), 907, 908, or 916;

''(B) to furnish any notification or other material or information required by or under section 519, 520(g), 904, 909, or 920; or

''(C) to comply with a requirement under section 522 or 913.'';

(11) in subsection (q)(2), by striking ''device,'' and inserting ''device or tobacco product,'';

(12) in subsection (r), by inserting ''or tobacco product'' after the term ''device'' each time that such term appears; and

(13) by adding at the end the following:

''(oo) The sale of tobacco products in violation of a no-tobacco-sale order issued under section 303(f).

''(pp) The introduction or delivery for introduction into interstate commerce of a tobacco product in violation of section 911.

''(qq)(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp (including tax stamp), tag, label, or other identification device upon any tobacco product or container or labeling thereof so as to render such tobacco product a counterfeit tobacco product.

''(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other item that is designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any tobacco product or container or labeling thereof so as to render such tobacco product a counterfeit tobacco product.

''(3) The doing of any act that causes a tobacco product to be a counterfeit tobacco product, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit tobacco product.

''(rr) The charitable distribution of tobacco products.

''(ss) The failure of a manufacturer or distributor to notify the Attorney General and the Secretary of the Treasury of their knowledge of tobacco products used in illicit trade.

''(tt) With respect to a tobacco product, any statement directed to consumers through the media or through the label, labeling, or advertising that would reasonably be expected to result in consumers believing that the product is regulated, inspected or approved by the Food and Drug Administration, or that the product complies with the requirements of the Food and Drug Administration, including a statement or implication in the label, labeling, or advertising of such product, and that could result in consumers believing that the product is endorsed for use by the Food and Drug Administration or in consumers being misled about the harmfulness of the product because of such regulation, inspection, or compliance.''.

(c) SECTION 303.—Section 303(f) (21 U.S.C. 333(f)) is amended—

(1) in paragraph (1)(A), by inserting ''or tobacco products'' after the term ''devices'' each place such term appears;

(2) in paragraph (5)—

(A) in subparagraph (A)—

(i) by striking ''assessed'' the first time it appears and inserting ''assessed, or a no-tobacco-sale order may be imposed,''; and

(ii) by striking ''penalty'' the second time it appears and inserting ''penalty, or upon whom a no-tobacco-sale order is to be imposed,'';

(B) in subparagraph (B)—

(i) by inserting after ''penalty,'' the following: ''or the period to be covered by a no-tobacco-sale order,''; and

(ii) by adding at the end the following: ''A no-tobacco-sale order permanently prohibiting an individual retail outlet from selling tobacco products shall include provisions that allow the outlet, after a specified period of time, to request that the Secretary compromise, modify, or terminate the order.''; and

(C) by adding at the end the following:

''(D) The Secretary may compromise, modify, or terminate, with or without conditions, any no-tobacco-sale order.'';

(3) in paragraph (6)—

(A) by inserting ''or the imposition of a no-tobacco-sale order'' after the term ''penalty'' each place such term appears; and

(B) by striking ''issued.'' and inserting ''issued, or on which the no-tobacco-sale order was imposed, as the case may be.''; and

(4) by adding at the end the following:

''(8) If the Secretary finds that a person has committed repeated violations of restrictions promulgated under section 906(d) at a particular retail outlet then the Secretary may impose a no-tobacco-sale order on that person prohibiting the sale of tobacco products in that outlet. A no-tobacco-sale order may be imposed with a civil penalty under paragraph (1). Prior to the entry of a no-sale order under this paragraph, a person shall be entitled to a hearing pursuant to the procedures established through regulations of the Food and Drug Administration for assessing civil money penalties, including at a retailer's request a hearing by telephone, or at the nearest regional or field office of the Food and Drug Administration, or at a Federal, State, or county facility within 100 miles from the location of the retail outlet, if such a facility is available.''.

(d) SECTION 304.—Section 304 (21 U.S.C. 334) is amended—

(1) in subsection (a)(2)—

(A) by striking ''and'' before ''(D)''; and

(B) by striking ''device.'' and inserting the following: ''device, and (E) Any adulterated or misbranded tobacco product.'';

(2) in subsection (d)(1), by inserting ''tobacco product,'' after ''device,'';

(3) in subsection (g)(1), by inserting ''or tobacco product'' after the term ''device'' each place such term appears; and

(4) in subsection (g)(2)(A), by inserting ''or tobacco product'' after ''device''.

(e) SECTION 505.—Section 505(n)(2) (21 U.S.C. 355(n)(2)) is amended by striking ''section 904'' and inserting ''section 1004''.

(f) SECTION 523.—Section 523(b)(2)(D) (21 U.S.C. 360m(b)(2)(D)) is amended by striking ''section 903(g)'' and inserting ''section 1003(g)''.

(g) SECTION 702.—Section 702(a)(1) (U.S.C. 372(a)(1)) is amended—

(1) by striking ''(a)(1)'' and inserting ''(a)(1)(A)''; and

(2) by adding at the end the following:

''(B)(i) For a tobacco product, to the extent feasible, the Secretary shall contract with the States in accordance with this paragraph to carry out inspections of retailers within that State in connection with the enforcement of this Act.

''(ii) The Secretary shall not enter into any contract under clause (i) with the government of any of the several States to exercise enforcement authority under this Act on Indian country without the express written consent of the Indian tribe involved.''.

(h) SECTION 703.—Section 703 (21 U.S.C. 373) is amended—

(1) by inserting ''tobacco product,'' after the term ''device,'' each place such term appears; and

(2) by inserting ''tobacco products,'' after the term ''devices,'' each place such term appears.

(i) SECTION 704.—Section 704 (21 U.S.C. 374) is amended—

(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'';

(2) in subsection (b), by inserting ''tobacco product,'' after ''device,''; and

(3) in subsection (g)(13), by striking ''section 903(g)'' and inserting ''section 1003(g)''.

(j) SECTION 705.—Section 705(b) (21 U.S.C. 375(b)) is amended by inserting ''tobacco products,'' after ''devices,''.

(k) SECTION 709.—Section 709 (21 U.S.C. 379a) is amended by inserting ''tobacco product,'' after ''device,''.

(l) SECTION 801.—Section 801 (21 U.S.C. 381) is amended—

(1) in subsection (a)—

(A) by inserting ''tobacco products,'' after the term ''devices,'' ;

(B) by inserting ''or section 905(h)'' after ''section 510''; and

(C) by striking the term ''drugs or devices'' each time such term appears and inserting ''drugs, devices, or tobacco products'';

(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—'';

(3) by adding at the end the following:

''(p)(1) Not later than 36 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report regarding—

''(A) the nature, extent, and destination of United States tobacco product exports that do not conform to tobacco product standards established pursuant to this Act;

''(B) the public health implications of such exports, including any evidence of a negative public health impact; and

''(C) recommendations or assessments of policy alternatives available to Congress and the executive branch to reduce any negative public health impact caused by such exports.

''(2) The Secretary is authorized to establish appropriate information disclosure requirements to carry out this subsection.''.

(m) SECTION 1003.—Section 1003(d)(2)(C) (as redesignated by section 101(b)) is amended—

(1) by striking ''and'' after ''cosmetics,''; and

(2) inserting '', and tobacco products'' after ''devices''.

(n) SECTION 1009.—Section 1009(b) (as redesignated by section 101(b)) is amended by striking ''section 908'' and inserting ''section 1008''.

(o) SECTION 409 OF THE FEDERAL MEAT INSPECTION ACT.—Section 409(a) of the Federal Meat Inspection Act (21 U.S.C. 679(a)) is amended by striking ''section 902(b)'' and inserting ''section 1002(b)''.

(p) RULE OF CONSTRUCTION.—Nothing in this section is intended or shall be construed to expand, contract, or otherwise modify or amend the existing limitations on State government authority over tribal restricted fee or trust lands.

(q) GUIDANCE AND EFFECTIVE DATES.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall issue guidance—

(A) defining the term ''repeated violation'', as used in section 303(f)(8) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)(8)) as amended by subsection (c), as including at least 5 violations of particular requirements over a 36-month period at a particular retail outlet that constitute a repeated violation and providing for civil penalties in accordance with paragraph (2);

(B) providing for timely and effective notice by certified or registered mail or personal delivery to the retailer of each alleged violation at a particular retail outlet prior to conducting a followup compliance check, such notice to be sent to the location specified on the retailer's registration or to the retailer's registered agent if the retailer has provider such agent information to the Food and Drug Administration prior to the violation;

(C) providing for a hearing pursuant to the procedures established through regulations of the Food and Drug Administration for assessing civil money penalties, including at a retailer's request a hearing by telephone or at the nearest regional or field office of the Food and Drug Administration, and providing for an expedited procedure for the administrative appeal of an alleged violation;

(D) providing that a person may not be charged with a violation at a particular retail outlet unless the Secretary has provided notice to the retailer of all previous violations at that outlet;

(E) establishing that civil money penalties for multiple violations shall increase from one violation to the next violation pursuant to paragraph (2) within the time periods provided for in such paragraph;

(F) providing that good faith reliance on the presentation of a false government-issued photographic identification that contains a date of birth does not constitute a violation of any minimum age requirement for the sale of tobacco products if the retailer has taken effective steps to prevent such violations, including—

(i) adopting and enforcing a written policy against sales to minors;

(ii) informing its employees of all applicable laws;

(iii) establishing disciplinary sanctions for employee noncompliance; and

(iv) requiring its employees to verify age by way of photographic identification or electronic scanning device; and

(G) providing for the Secretary, in determining whether to impose a no-tobacco-sale order and in determining whether to compromise, modify, or terminate such an order, to consider whether the retailer has taken effective steps to prevent violations of the minimum age requirements for the sale of tobacco products, including the steps listed in subparagraph (F).

(2) PENALTIES FOR VIOLATIONS.—

(A) IN GENERAL.—The amount of the civil penalty to be applied for violations of restrictions promulgated under section 906(d), as described in paragraph (1), shall be as follows:

(i) With respect to a retailer with an approved training program, the amount of the civil penalty shall not exceed—

(I) in the case of the first violation, $0.00 together with the issuance of a warning letter to the retailer;

(II) in the case of a second violation within a 12-month period, $250;

(III) in the case of a third violation within a 24-month period, $500;

(IV) in the case of a fourth violation within a 24-month period, $2,000;

(V) in the case of a fifth violation within a 36-month period, $5,000; and

(VI) in the case of a sixth or subsequent violation within a 48-month period, $10,000 as determined by the Secretary on a case-by-case basis.

(ii) With respect to a retailer that does not have an approved training program, the amount of the civil penalty shall not exceed—

(I) in the case of the first violation, $250;

(II) in the case of a second violation within a 12-month period, $500;

(III) in the case of a third violation within a 24-month period, $1,000;

(IV) in the case of a fourth violation within a 24-month period, $2,000;

(V) in the case of a fifth violation within a 36-month period, $5,000; and

(VI) in the case of a sixth or subsequent violation within a 48-month period, $10,000 as determined by the Secretary on a case-by-case basis.

(B) TRAINING PROGRAM.—For purposes of subparagraph (A), the term ''approved training program'' means a training program that complies with standards developed by the Food and Drug Administration for such programs.

(C) CONSIDERATION OF STATE PENALTIES.—The Secretary shall coordinate with the States in enforcing the provisions of this Act and, for purposes of mitigating a civil penalty to be applied for a violation by a retailer of any restriction promulgated under section 906(d), shall consider the amount of any penalties paid by the retailer to a State for the same violation.

(3) GENERAL EFFECTIVE DATE.—The amendments made by paragraphs (2), (3), and (4) of subsection (c) shall take effect upon the issuance of guidance described in paragraph (1) of this subsection.

(4) SPECIAL EFFECTIVE DATE.—The amendment made by subsection (c)(1) shall take effect on the date of enactment of this Act.

(5) PACKAGE LABEL REQUIREMENTS.—The package label requirements of paragraphs (2), (3), and (4) of section 903(a) of the Federal Food, Drug, and Cosmetic Act (as amended by this Act) shall take effect on the date that is 12 months after the date of enactment of this Act. The 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 903(a)(2), (3), and (4) and section 920(a) of the Federal Food, Drug, and Cosmetic Act.

(6) ADVERTISING REQUIREMENTS.—The advertising requirements of section 903(a)(8) of the Federal Food, Drug, and Cosmetic Act (as amended by this Act) shall take effect on the date that is 12 months after the date of enactment of this Act.

SEC. 104. STUDY ON RAISING THE MINIMUM AGE TO PURCHASE TOBACCO PRODUCTS.

The Secretary of Health and Human Services shall—

(1) convene an expert panel to conduct a study on the public health implications of raising the minimum age to purchase tobacco products; and

(2) not later than 5 years after the date of enactment of this Act, submit a report to the Congress on the results of such study.

SEC. 105. ENFORCEMENT ACTION PLAN FOR ADVERTISING AND PROMOTION RESTRICTIONS.

(a) ACTION PLAN.—

(1) DEVELOPMENT.—Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall develop and publish an action plan to enforce restrictions adopted pursuant to section 906 of the Federal Food, Drug, and Cosmetic Act, as added by section 101(b) of this Act, or pursuant to section 102(a) of this Act, on promotion and advertising of menthol and other cigarettes to youth.

(2) CONSULTATION.—The action plan required by paragraph (1) shall be developed in consultation with public health organizations and other stakeholders with demonstrated expertise and experience in serving minority communities.

(3) PRIORITY.—The action plan required by paragraph (1) shall include provisions designed to ensure enforcement of the restrictions described in paragraph (1) in minority communities.

(b) STATE AND LOCAL ACTIVITIES.—

(1) INFORMATION ON AUTHORITY.—Not later than 3 months after the date of enactment of this Act, the Secretary shall inform State, local, and tribal governments of the authority provided to such entities under section 5(c) of the Federal Cigarette Labeling and Advertising Act, as added by section 203 of this Act, or preserved by such entities under section 916 of the Federal Food, Drug, and Cosmetic Act, as added by section 101(b) of this Act.

(2) COMMUNITY ASSISTANCE.—At the request of communities seeking assistance to prevent underage tobacco use, the Secretary shall provide such assistance, including assistance with strategies to address the prevention of underage tobacco use in communities with a disproportionate use of menthol cigarettes by minors.

TITLE II—TOBACCO PRODUCT 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 upper portion of the front and rear panels of the package, directly on the package underneath the cellophane or other clear wrapping. Each label statement shall comprise at least the top 30 percent of the front and rear panels 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 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) 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 top of each advertisement within the trim area. The Secretary may revise the required type sizes in such area in such manner as the Secretary determines appropriate. 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 tobacco products, each label statement required by subsection (a) may be printed on the inside cover of the matchbook.

''(4) ADJUSTMENT BY SECRETARY.—The Secretary may, through a rulemaking under section 553 of title 5, United States Code, adjust the format and type sizes for the label statements required by this section; the text, format, and type sizes of any required tar, nicotine yield, or other constituent (including smoke constituent) disclosures; or the text, format, and type sizes for any other disclosures required under the Federal Food, Drug, and Cosmetic Act. The text of any such label statements or disclosures shall be required to appear only within the 20 percent area of cigarette advertisements provided by paragraph (2). The Secretary shall promulgate regulations which provide for adjustments in the format and type sizes of any text required to appear in such area to ensure that the total text required to appear by law will fit within such area.

''(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 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 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 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 12 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. AUTHORITY TO REVISE CIGARETTE WARNING LABEL STATEMENTS.

(a) PREEMPTION.—Section 5(a) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1334(a)) is amended by striking ''No'' and inserting ''Except to the extent the Secretary requires additional or different statements on any cigarette package by a regulation, by an order, by a standard, by an authorization to market a product, or by a condition of marketing a product, pursuant to the Family Smoking Prevention and Tobacco Control Act (and the amendments made by that Act), or as required under section 903(a)(2) or section 920(a) of the Federal Food, Drug, and Cosmetic Act, no''.

(b) CHANGE IN REQUIRED STATEMENTS.—Section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333), as amended by section 201, is further amended by adding at the end the following:

''(d) CHANGE IN REQUIRED STATEMENTS.—The Secretary may, by a rulemaking conducted under section 553 of title 5, United States Code, adjust the format, type size, and text of any of the label requirements, require color graphics to accompany the text, increase the required label area from 30 percent up to 50 percent of the front and rear panels of the package, or establish the format, type size, and text of any other disclosures required under the Federal Food, Drug, and Cosmetic Act, if the Secretary finds that such a change would promote greater public understanding of the risks associated with the use of tobacco products.''.

SEC. 203. STATE REGULATION OF CIGARETTE ADVERTISING AND PROMOTION.

Section 5 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1334) is amended by adding at the end the following:

''(c) EXCEPTION.—Notwithstanding subsection (b), a State or locality may enact statutes and promulgate regulations, based on smoking and health, that take effect after the effective date of the Family Smoking Prevention and Tobacco Control Act, imposing specific bans or restrictions on the time, place, and manner, but not content, of the advertising or promotion of any cigarettes.''.

SEC. 204. 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 is not a safe alternative to cigarettes.

''WARNING: Smokeless tobacco is addictive.

''(2) Each label statement required by paragraph (1) shall be—

''(A) located on the 2 principal display panels of the package, and each label statement shall comprise at least 30 percent of each such display panel; and

''(B) in 17-point conspicuous and legible type and in black text on a white background, or white text 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 (b)(3), except that if the text of a label statement would occupy more than 70 percent of the area specified by subparagraph (A), such text may appear in a smaller type size, so long as at least 60 percent of such warning area is occupied by the label statement.

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

''(4) The provisions of this subsection do not apply to a 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.

''(5) 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 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 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 requirements 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 tar, 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 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 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 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.

''(4) The Secretary may, through a rulemaking under section 553 of title 5, United States Code, adjust the format and type sizes for the label statements required by this section; the text, format, and type sizes of any required tar, nicotine yield, or other constituent disclosures; or the text, format, and type sizes for any other disclosures required under the Federal Food, Drug, and Cosmetic Act. The text of any such label statements or disclosures shall be required to appear only within the 20 percent area of advertisements provided by paragraph (2). The Secretary shall promulgate regulations which provide for adjustments in the format and type sizes of any text required to appear in such area to ensure that the total text required to appear by law will fit within such area.

''(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 12 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)

SEC. 205. AUTHORITY TO REVISE SMOKELESS TOBACCO PRODUCT WARNING LABEL STATEMENTS.

(a) IN GENERAL.—Section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4402), as amended by section 204, is further amended by adding at the end the following:

''(d) AUTHORITY TO REVISE WARNING LABEL STATEMENTS.—The Secretary may, by a rulemaking conducted under section 553 of title 5, United States Code, adjust the format, type size, and text of any of the label requirements, require color graphics to accompany the text, increase the required label area from 30 percent up to 50 percent of the front and rear panels of the package, or establish the format, type size, and text of any other disclosures required under the Federal Food, Drug, and Cosmetic Act, if the Secretary finds that such a change would promote greater public understanding of the risks associated with the use of smokeless tobacco products.''.

(b) PREEMPTION.—Section 7(a) of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4406(a)) is amended by striking ''No'' and inserting ''Except as provided in the Family Smoking Prevention and Tobacco Control Act (and the amendments made by that Act), no''.

SEC. 206. TAR, NICOTINE, AND OTHER SMOKE CONSTITUENT DISCLOSURE TO THE PUBLIC.

Section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333), as amended by sections 201 and 202, is further amended by adding at the end the following:

''(e) TAR, NICOTINE, AND OTHER SMOKE CONSTITUENT DISCLOSURE.—

''(1) IN GENERAL.—The Secretary shall, by a rulemaking conducted under section 553 of title 5, United States Code, determine (in the Secretary's sole discretion) whether cigarette and other tobacco product manufacturers shall be required to include in the area of each cigarette advertisement specified by subsection (b) of this section, or on the package label, or both, the tar and nicotine yields of the advertised or packaged brand. Any such disclosure shall be in accordance with the methodology established under such regulations, shall conform to the type size requirements of subsection (b) of this section, and shall appear within the area specified in subsection (b) of this section.

''(2) RESOLUTION OF DIFFERENCES.—Any differences between the requirements established by the Secretary under paragraph (1) and tar and nicotine yield reporting requirements established by the Federal Trade Commission shall be resolved by a memorandum of understanding between the Secretary and the Federal Trade Commission.

''(3) CIGARETTE AND OTHER TOBACCO PRODUCT CONSTITUENTS.—In addition to the disclosures required by paragraph (1), the Secretary may, under a rulemaking conducted under section 553 of title 5, United States Code, prescribe disclosure requirements regarding the level of any cigarette or other tobacco product constituent including any smoke constituent. Any such disclosure may be required if the Secretary determines that disclosure would be of benefit to the public health, or otherwise would increase consumer awareness of the health consequences of the use of tobacco products, except that no such prescribed disclosure shall be required on the face of any cigarette package or advertisement. Nothing in this section shall prohibit the Secretary from requiring such prescribed disclosure through a cigarette or other tobacco product package or advertisement insert, or by any other means under the Federal Food, Drug, and Cosmetic Act.

''(4) RETAILERS.—This subsection applies to a retailer only if that retailer is responsible

for or directs the label statements required under this section.''.

TITLE III—PREVENTION OF ILLICIT TRADE IN TOBACCO PRODUCTS

SEC. 301. LABELING, RECORDKEEPING, RECORDS INSPECTION.

Chapter IX of the Federal Food, Drug, and Cosmetic Act, as added by section 101, is further amended by adding at the end the following:

''SEC. 920. LABELING, RECORDKEEPING, RECORDS INSPECTION.

''(a) ORIGIN LABELING.—

''(1) REQUIREMENT.—Beginning 1 year after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the label, packaging, and shipping containers of tobacco products for introduction or delivery for introduction into interstate commerce in the United States shall bear the statement 'sale only allowed in the United States'.

''(2) EFFECTIVE DATE.—The effective date specified in paragraph (1) 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 such paragraph.

''(b) REGULATIONS CONCERNING RECORDKEEPING FOR TRACKING AND TRACING.—

''(1) IN GENERAL.—The Secretary shall promulgate regulations regarding the establishment and maintenance of records by any person who manufactures, processes, transports, distributes, receives, packages, holds, exports, or imports tobacco products.

''(2) INSPECTION.—In promulgating the regulations described in paragraph (1), the Secretary shall consider which records are needed for inspection to monitor the movement of tobacco products from the point of manufacture through distribution to retail outlets to assist in investigating potential illicit trade, smuggling, or counterfeiting of tobacco products.

''(3) CODES.—The Secretary may require codes on the labels of tobacco products or other designs or devices for the purpose of tracking or tracing the tobacco product through the distribution system.

''(4) SIZE OF BUSINESS.—The Secretary shall take into account the size of a business in promulgating regulations under this section.

''(5) RECORDKEEPING BY RETAILERS.—The Secretary shall not require any retailer to maintain records relating to individual purchasers of tobacco products for personal consumption.

''(c) RECORDS INSPECTION.—If the Secretary has a reasonable belief that a tobacco product is part of an illicit trade or smuggling or is a counterfeit product, each person who manufactures, processes, transports, distributes, receives, holds, packages, exports, or imports tobacco products shall, at the request of an officer or employee duly designated by the Secretary, permit such officer or employee, at reasonable times and within reasonable limits and in a reasonable manner, upon the presentation of appropriate credentials and a written notice to such person, to have access to and copy all records (including financial records) relating to such article that are needed to assist the Secretary in investigating potential illicit trade, smuggling, or counterfeiting of tobacco products. The Secretary shall not authorize an officer or employee of the government of any of the several States to exercise authority under the preceding sentence on Indian country without the express written consent of the Indian tribe involved.

''(d) KNOWLEDGE OF ILLEGAL TRANSACTION.—

''(1) NOTIFICATION.—If the manufacturer or distributor of a tobacco product has knowledge which reasonably supports the conclusion that a tobacco product manufactured or distributed by such manufacturer or distributor that has left the control of such person may be or has been—

''(A) imported, exported, distributed, or offered for sale in interstate commerce by a person without paying duties or taxes required by law; or

''(B) imported, exported, distributed, or diverted for possible illicit marketing,

the manufacturer or distributor shall promptly notify the Attorney General and the Secretary of the Treasury of such knowledge.

''(2) KNOWLEDGE DEFINED.—For purposes of this subsection, the term 'knowledge' as applied to a manufacturer or distributor means—

''(A) the actual knowledge that the manufacturer or distributor had; or

''(B) the knowledge which a reasonable person would have had under like circumstances or which would have been obtained upon the exercise of due care.

''(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.''.

SEC. 302. STUDY AND REPORT.

(a) STUDY.—The Comptroller General of the United States shall conduct a study of cross-border trade in tobacco products to—

(1) collect data on cross-border trade in tobacco products, including illicit trade and trade of counterfeit tobacco products and make recommendations on the monitoring of such trade;

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

(3) collect data on the health effects (particularly with respect to individuals under 18 years of age) resulting from cross-border trade in tobacco products, including the health effects resulting from—

(A) the illicit trade of tobacco products and the trade of counterfeit tobacco products; and

(B) the differing tax rates applicable to tobacco products.

(b) REPORT.—Not later than 18 months after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the study described in subsection (a).

(c) DEFINITION.—In this section:

(1) The term ''cross-border trade'' means trade across a border of the United States, a State or Territory, or Indian country.

(2) The term ''Indian country'' has the meaning given to such term in section 1151 of title 18, United States Code.

(3) The terms ''State'' and ''Territory'' have the meanings given to those terms in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

The SPEAKER pro tempore. After 1 hour of debate on the bill, as amended, it shall be in order to consider the amendment in the nature of a substitute printed in part B of the report, if ordered by the gentleman from Indiana (Mr. BUYER) or his designee, which shall be in order without intervention of any point of order, shall be considered read, and shall be debatable for 30 minutes equally divided and controlled by the proponent and an opponent.

The gentleman from California (Mr. WAXMAN) and the gentleman from Indiana (Mr. BUYER) each will control 30 minutes.

The Chair recognizes the gentleman from California.

Mr. WAXMAN. Mr. Speaker, I yield myself such time as I may consume in debating this legislation.

Mr. Speaker, and my colleagues, we have come to what I hope will be an historic occasion, and that is finally doing something about the harm that tobacco does to thousands and thousands of Americans who die each year, and to stop the attempt to get our children to smoke. But it has taken us far too long to get to this point.

In 1994, the tobacco executives stood up before my subcommittee, they raised their hand, and they said they were going to tell the truth. They swore under oath, though, that nicotine was not addictive. They also said cigarettes were not harmful. They also said they didn't manipulate nicotine. They also said that they would never target kids. And, it turned out, they were not telling us the truth.

In 1996, the Food and Drug Administration tried to regulate tobacco products, but the Supreme Court told them that they needed Congress to give them specific legal authority. Now, 13 years later, here we are finally giving FDA that authority to regulate the leading preventable cause of death in America.

Every one of us has seen the devastating effects of tobacco through losing someone we love, watching others grow sick, or even feeling the grip of addiction firsthand. Worst of all is watching our children and grandchildren be targeted as the next wave of casualties.

Regulating tobacco is the single most important thing we can do right now to curb this deadly toll, and FDA is the only agency with the right combination of scientific expertise, regulatory experience, and public health mission to oversee these products effectively.

This legislation will direct the Food and Drug Administration to end the marketing and sales of tobacco to kids; to prevent manufacturers from calling cigarettes ''light'' or ''less dangerous'' when in fact they are not; and to require changes to what is in cigarettes, like toxic ingredients such as formaldehyde, benzene, radioactive elements, and other deadly chemicals.

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Some have objected that this bill is too big a challenge for an already overburdened FDA. But it is clear to me that FDA's recent struggles are primarily a result of years of chronic underfunding. This does not mean that FDA, with strong and committed leadership, cannot take on the critical role of protecting the country against the harms of tobacco. It simply means that when we give the agency this new responsibility, we also must give it the

resources necessary to do the job and to do it well.

We have ensured that this will happen. The tobacco program will be fully funded through a new user fee paid for by the industry. That money will go exclusively to the new tobacco center and will be enough for FDA to handle this task well. Furthermore, by doing so, we will ensure that the new tobacco program will have no impact on other missions at the Food And Drug Administration.

In short, we have everything we need to take this historic step: A comprehensive and flexible set of new authorities and full, certain funding. All we need now is the political will to do the right thing.

The breadth of support for this bill, from the AARP to the American Academy of Pediatrics, from the Southern Baptist Convention to the Islamic Society of North America, shows just how critical this issue is to all Americans. It is also supported by the American Lung Association, the American Heart Association and the American Cancer Society, the groups that are best situated to understand the damage caused by tobacco.

I also want to note that we have worked hard to accommodate specific concerns that we have heard about this bill. In committee consideration of the bill last year, we made changes to ensure fairness and flexibility for convenience stores, tobacco growers and small manufacturers, and we worked with the minority to incorporate their suggestions. We also worked with members of the Congressional Black Caucus to ensure that menthol cigarettes will be an early focus of the agency's attention and the agency has the authority to deal with these and other products.

I want to thank my colleague, TODD PLATTS, for his strong leadership and dedication to working on this legislation, as well as JOHN DINGELL and FRANK PALLONE for their diligent work in moving this bill forward over the years. I also want to thank ED TOWNS, STEPHEN LYNCH and IKE SKELTON, all of whom were critical in getting us to this point. Each of these individuals has made this possible and produced a great victory for all Americans, especially our children.

I urge the passage of this legislation.

I reserve the balance of my time.

Mr. BUYER. I yield myself such time as I may consume.

I would note that the gentleman read a list of individuals that supports his bill. But what he left off the list and the prior speaker under the rule, the gentleman from Colorado, was very critical of the tobacco companies. But Altria supports the Waxman bill. Now what is interesting about this is I would ask the gentleman from Colorado, he was so critical of tobacco, but obviously he didn't know that a tobacco company was supporting the Waxman bill.

I truly believe in my heart, since I had written Altria, and they have sent me a letter here in response to the substitute, H.R. 1261, I truly believe that had they not endorsed the Waxman bill 8 years ago that they would be endorsing this bill. And the reason I say that, I just find it in my heart, they let me know in their bill dated to me by the chairman and chief executive of Altria, he says, ''We specifically support H.R. 1266 and supported its predecessor bills for more than 8 years.'' That is the Waxman bill. But he goes on further in his letter, and he says, ''Your letter seeks our input on several aspects of tobacco regulation. You recently introduced H.R. 1261, including harm reduction, product design standards and the appropriate public health standard for tobacco regulation. Before addressing these topics more specifically,'' and they do that in the letter, he said, ''I want to commend your thoughtful leadership on the topic of comprehensive tobacco regulation. Your focus on H.R. 1261 on harm reduction strategies will, we believe, encourage further meaningful conversation about how Federal regulators should exercise authority over tobacco products. We especially appreciate the focus you are bringing in the public policy debate in an important principle that regulation should ensure and certainly not discourage adult consumers access to accurate, objective and non-misleading information about the relative risks of all tobacco products. We have consistently expressed our view that it would be wrong for the Federal regulatory framework to deny adult tobacco consumers access to information about potential benefits to products that could ultimately reduce the harm caused by smoking.''

Now that is the harm-reduction strategy that we have incorporated in this bipartisan bill. And so I wanted to bring that to everyone's attention that this harm-reduction strategy is extremely important. We should not have this abstinence approach that is in the Waxman bill. Now this was an approach that was drafted many, many years ago, and a lot of things have taken place since Mr. WAXMAN drafted this bill. And he is not taking these things into account. I respect the gentleman. I respect his efforts. I respect his tenacity and his persistence. And hopefully we will have a meeting of the minds one day, and we can incorporate both of our dual-tracked efforts here to move people to stop smoking.

The supporters of the Waxman bill, as I noted from some of the speakers, they claim that it is designed to protect children from the dangers of smoking. But H.R. 1256 does not include any provision that actually protects minors from tobacco use. The American Association of Public Health Physicians wrote on March 3, 2009, ''The current bill, the bill which is before us and being debated, referred to as the Waxman bill, H.R. 1256, in its current form would ensure current levels of tobacco-related deaths while doing nothing of significance to reduce the number of teens who would initiate tobacco use with no bill at all.''

You see, those of whom are supporting the substitute, we support steps to require the States to use more of their Master Settlement Agreement funds to combat underage smoking and promote smoking cessation while also strengthening the Synar amendment which prevents the underage purchasing of cigarettes. Unfortunately, H.R. 1256 does not contain these important public health provisions.

With that, I reserve the balance of my time.

Mr. WAXMAN. Mr. Speaker, I yield to the gentleman from North Carolina (Mr. ETHERIDGE).

Mr. ETHERIDGE. I thank the gentleman. I would like to engage the chairman in a colloquy to address the issue of FDA and tobacco farmers.

I represent one of the largest tobacco-producing districts in the Nation, so naturally I have a lot of farmers who are very concerned about how they might be affected by this legislation.

Mr. Chairman, my question to you is, does this bill in any way authorize the FDA to regulate tobacco farms?

Mr. WAXMAN. I thank you for the question, Mr. ETHERIDGE. This is an important question, especially for those who represent tobacco-growing districts. There has been some confusion about this point, so let me be clear. It is not the intent of this bill to allow FDA on the farm. The bill gives FDA the authority to regulate tobacco products but not tobacco leaf.

Mr. ETHERIDGE. I thank you for that.

And does the bill specifically state that FDA's regulatory authority would only apply to manufactured tobacco products and not the traditional production and harvest methods on the farm?

Mr. WAXMAN. The gentleman is correct.

Mr. ETHERIDGE. I thank the chairman.

Mr. WAXMAN, I thank you for that, and I thank you for the clarification that this is a bill intended to protect our children and not to regulate tobacco farmers. Tobacco is a critical crop in North Carolina's economy and has been for a long time. I look forward to continuing to working with you to help North Carolina farmers preserve their jobs and their livelihood.

Mr. WAXMAN. I reserve the balance of my time.

Mr. BUYER. I yield myself such time as I may consume.

The gentleman just spoke about his concern with regard to product standards. It is one of the chief concerns in the Waxman bill. The provisions on product standards allow the FDA to impose any requirements or prohibitions it sees fit, except that it may not ban the product or reduce nicotine delivery to zero. FDA need not consider the cost or feasibility of imposing a standard. FDA does have to consider

the possibility of a black market, but can impose a standard even if it will lead to the creation or expansion of a black market. That should concern everyone with regard to illicit trade.

The Waxman bill also prevents communication about significant differences among levels of risk presented by different types of tobacco products, and it clamps down on any effects to develop and market modified-risk tobacco products. Modified-risk tobacco products are defined as any existing or new product that bears a claim or where the manufacturer conveys to consumers through media or otherwise that: It presents a lower risk or is less harmful than other tobacco products; has a reduced level of substance or reduced exposure to a substance; is free of or does not contain a substance; or uses the descriptor ''light,'' ''mild'' or ''low'' or a similar descriptor.

Approval of a modified-risk product requires under the Waxman bill that the product will significantly reduce harm and the risk of disease to the individual users and that approval benefits the health of the population as a whole. You see, this is a two-tier standard and is almost impossible or nearly impossible to satisfy. So I completely understand why the gentleman came to the floor concerned about product standards. So if you want to embrace a harm-reduction strategy to migrate people from smoking down the continuum of risk to eventually quitting, the Waxman bill does not permit that. We don't permit the innovation of science to drive people to lower-risk products. And that is what the substitute tries to do.

With that, I will yield to the gentleman, the ranking Republican, LAMAR SMITH of Texas, such time as he may consume.

Mr. SMITH of Texas. Mr. Speaker, I thank my colleague from Indiana for yielding me time.

Mr. Speaker, H.R. 1256 directs the Secretary of HHS to promulgate an interim final rule that is identical to the FDA's 1996 rule, which legal experts from across the political spectrum have stated would violate the first amendment.

While these experts' views should carry great weight, even more persuasive is the fact that the U.S. Supreme Court also has weighed in on various provisions of the rule, finding them unconstitutional. In Lorillard Tobacco v. Reilly, the U.S. Supreme Court struck down a Massachusetts statute that was similar in many ways to the FDA's proposed rule. The statute banned outdoor ads within 1,000 feet of schools, parks and playgrounds and also restricted point-of-sale advertising for tobacco products.

The Court held that this regulation ran afoul of the test established in the Central Hudson case, which defines the protection afforded commercial speech under the first amendment, as it was not sufficiently narrowly tailored and would have disparate impacts from community to community.

The Court then noted that since the Massachusetts statute was based on the FDA's rule, the FDA rule would have similar constitutional problems. As Justice Sandra Day O'Connor wrote for the court, ''The uniformly broad sweep of the geographical limitation demonstrates a lack of tailoring.''

Additionally, the proposed rule in H.R. 1256 would require ads to use only black text on a white background. The U.S. Supreme Court found a similar provision unconstitutional in Zauderer v. Office of Disciplinary Counsel. In that case, dealing with advertising for legal services, the Court held that the use of colors and illustrations in ads is entitled to the same first amendment protections given verbal commercial speech.

Justice Byron White, in his opinion for the Court, wrote that pictures and illustrations in ads cannot be banned ''simply on the strength of the general argument that the visual content of advertisements may, under some circumstances, be deceptive or manipulative.''

So there are numerous speech restrictions in this legislation that raise serious first amendment concerns. This will create a swarm of lawsuits that will only divert us from trying to develop more effective approaches to tobacco use in the United States.

To include speech restrictions that a broad range of legal experts have stated are almost certain to be unconstitutional fatally taints this bill.

□ 1945

I know the bill is well-intentioned, but I hope my colleagues will support the alternative offered by the gentleman from Indiana (Mr. BUYER).

Mr. BUYER. I reserve the balance of my time.

Mr. WAXMAN. I am including in the RECORD an exchange of letters on H.R. 1256 between the chairman of the Committee on the Judiciary and myself.

COMMITTEE ON THE JUDICIARY,
Washington, DC, March 24, 2009.

Hon. HENRY A. WAXMAN,
Chairman, Committee on Energy and Commerce, House of Representatives, Washington, DC.

DEAR CHAIRMAN WAXMAN: This is to advise you that, as a result of your having worked with us to appropriately craft provisions in H.R. 1256, the ''Family Smoking Prevention and Tobacco Control Act,'' that fall within the rule X jurisdiction of the Committee on the Judiciary, we are able to agree to discharging our committee from further consideration of the bill in order that it may proceed without delay to the House floor for consideration.

The Judiciary Committee takes this action with the understanding that by foregoing further consideration of H.R. 1256 at this time, we do not waive any jurisdiction over subject matter contained in this or similar legislation. We also reserve the right to seek appointment of an appropriate number of conferees to any House-Senate conference involving this important legislation, and request your support if such a request is made.

I would appreciate your including this letter in the Congressional Record during consideration of the bill on the House floor. Thank you for your attention to this request, and for the cooperative relationship between our two committees.

Sincerely,

JOHN CONYERS, JR.,
Chairman.

CONGRESS OF THE UNITED STATES,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC, March 25, 2009.

Hon. JOHN CONYERS,
Chairman, Committee on the Judiciary, Washington, DC.

DEAR CHAIRMAN CONYERS: Thank you for your letter regarding H.R. 1256, the ''Family Smoking Prevention and Tobacco Control Act.'' The letter noted that certain provisions of the bill are within the jurisdiction of the Committee on the Judiciary under rule X of the Rules of the House.

The Committee on Energy and Commerce recognizes the jurisdictional interest of the Committee on the Judiciary in these provisions. We further appreciate your agreement to forgo action on the bill, and I concur that the agreement does not in any way prejudice the Committee on the Judiciary with respect to the appointment of conferees or its jurisdictional prerogatives on this bill or similar legislation in the future.

I will include our letters in the Congressional Record during consideration of the bill on the House floor. Again I appreciate your cooperation regarding this important legislation.

Sincerely,

HENRY A. WAXMAN

I reserve the balance of my time.

Mr. BUYER. I would yield now 3 minutes to Dr. Gingrey, the gentleman from Georgia.

Mr. GINGREY of Georgia. Mr. Speaker, I thank the gentleman for yielding. And I certainly want to pay tribute to Chairman WAXMAN in regard to the work that he has done over these many years, 10, at least, in regard to trying to help our society rid themselves of, really, the scourge of smoking cigarettes and many health care problems that that leads to. I don't think that there's any question in anybody's mind about that. And certainly the Surgeon General's warning, very profound, clear warning on a package of cigarettes, should bring their attention to that every time they light up, whether we're talking about young adults or at any age group. And leading to lung cancer and chronic obstructive pulmonary disease, maybe better known as emphysema. So I commend Chairman WAXMAN very much. I think his heart is in the right place, and what he's trying to do is very credible.

But I do feel that Representative BUYER, from Indiana, and his substitute amendment, will be presented shortly. I really feel, Mr. Speaker, that this is very likely a better way. And so I do rise in strong support of the Buyer amendment in the nature of a substitute.

Despite decades of intense efforts to eradicate the practice, still more than 40 million American adults continue to smoke cigarettes, and that is likely to remain the case, unfortunately, for decades to come.

All tobacco products are harmful, but the health risks associated with cigarettes are significantly greater than those associated with the use of smoke-

free tobacco and nicotine-only products.

So, given these facts, an increasing number of public health experts advocate adopting a tobacco ''harm-reduction'' approach like that proposed in the Buyer amendment that will lower the health risks associated with using tobacco or nicotine.

A growing body of science shows that smokers who switch to smokeless tobacco products can significantly decrease their risk of tobacco-related illness and death.

A World Health Organization Study Group wrote last year that: ''Smokeless tobacco products do not cause the lung diseases causally associated with the use of combusted tobacco products such as cigarettes, pipes and cigars.''

Scientific studies show that even the risk for cancers of the mouth and the throat are higher for smokers than for those who use tobacco products that do not burn. Year after year, this body has considered tobacco regulation that fails to recognize the significant progress that can be achieved by adding this harm-reduction component to tobacco-control efforts.

An article last year, Mr. Speaker, in the Journal of Health Care Law and Policy correctly concluded that, and this is a quote, ''Ignoring harm reduction is simply not a viable option as there is no question that it is possible to provide massively less toxic alternative products.''

The SPEAKER pro tempore. The time of the gentleman has expired.

Mr. BUYER. I yield to the gentleman of Georgia an additional minute.

Mr. GINGREY of Georgia. Mr. Speaker, a 2007 article in the International Journal of Drug Policy noted that ''A pragmatic, public health approach to tobacco control would recognize a continuum of risk and encourage nicotine users to move themselves down the risk spectrum by choosing safer alternatives to smoking, without demanding abstinence.''

The Buyer amendment presents us with the opportunity to institute that type of pragmatic approach. It offers a stringent regime under which harm-reduction strategies can augment and leverage continued efforts to prevent tobacco use, and to encourage current smokers to quit.

So, as a physician who deeply cares about the health and the welfare of our citizens, I urge you, my colleagues on both sides of the aisle, to adopt the amendment as our Nation's best option for fighting the disease and the death caused by tobacco in the 21st century.

Mr. BUYER. I reserve my time.

Mr. WAXMAN. Mr. Speaker, I have no further requests for time. Although some Members may join us shortly, I ask the gentleman how many other speakers he wishes to call on before we close the debate.

Mr. BUYER. We have two speakers that I'm aware of that are on their way.

Mr. WAXMAN. I'll reserve my time and let you go forward. I see there are some of your Members there if they're going to speak on the bill.

Mr. BUYER. To the gentleman's question, you wanted to know how many more speakers do I have. I was not prepared that you would not have speakers in support of your bill, so I thought that we'd be going back and forth, so I have Members coming from their offices to the floor. But I would be more than happy to take some of my time.

May I ask, Mr. Speaker—actually, we're on your time, I guess, at the moment. I guess, on your time. May I ask how much time both of us may have remaining?

The SPEAKER pro tempore. The gentleman from Indiana has 16 minutes remaining. The gentleman from California has 23½ minutes remaining.

Mr. WAXMAN. We're going to reserve the balance of our time.

Mr. BUYER. I yield myself such time as I may consume.

We've had a discussion here on the floor, Mr. Speaker, with regard to other concerns over the Food and Drug Administration and its ability to regulate tobacco products, products that will never qualify as safe and effective, and could have significant negative impacts on all Americans.

Congress has spent a great deal of time investigating the ways in which the FDA has been unable to fulfill its core mission. Burdening the FDA with additional responsibilities outside the agency's expertise and core missions at this time will have dire consequences for the American people and the FDA's ability to ensure the safety and efficacy of our Nation's food, drugs and medical devices.

H.R. 1256 allows the FDA to divert resources from its core mission, including funds from food safety inspections and drugs and devices approvals to fund the startup costs of a newer tobacco center. At a time when FDA is struggling to perform many of its core functions, diversion of its limited resources will negatively impact the safety of the American public.

Now, in a bipartisan manner, we share the concerns of many in the public health community that effectively giving FDA's stamp of approval on cigarettes will improperly lead people to believe that these products are safe, and they really aren't. So there actually could be this perception, when people see that the FDA has approved it, there could be this public perception that there's an FDA approval of a particular nicotine delivery device.

Now, what we seek to do is to turn this over to a different agency, whereby we can learn about the different relative risks among that continuum of risk, so that people can make, then, informed decisions and choices relative to the use of tobacco products.

Now, I agree with the American Association of Public Health Physicians, which wrote on March 3, 2009, in regard to H.R. 1256, ''The current bill, in its current form, would assure current levels of tobacco-related deaths, while doing nothing of significance to reduce the number of teens who would initiate tobacco use with no bill at all.''

Now, I read that earlier, but it's so important I had to read it again. Now, Congressman MCINTYRE and I have authored this bipartisan alternative to establish the Tobacco Harm Reduction Center under the Department of Health and Human Services. The alternative is based on public health policies that acknowledge a continuum of risk among all tobacco products, and referenced scientific literature which shows that smokeless tobacco products are 90 to even 99 percent less hazardous than cigarettes in their risks of causing tobacco-related illnesses and death.

Now, why wouldn't we embrace that as a form of public policy?

Unlike H.R. 1256, the alternative substitute would have insured adult tobacco users are given complete, accurate and truthful information about the risks and relative risks of all tobacco products so that they can make informed health decisions, while providing incentives to develop reduced-risk tobacco products.

See, that's really one of the chief concerns I have about Mr. WAXMAN's legislation is that when he creates a two-tier product standard with the implementation of new products, how can we ever migrate people to a lesser-harm nicotine delivery device in our efforts to get them to quit? That's why we have this position by Mr. WAXMAN, either you smoke or you die. And that's not what we should be embracing.

The alternative substitute, which Members will have a chance to vote on, strengthens prevention against minors' tobacco use, ensures that States properly fund anti-tobacco education and smoking-cessation programs, and protects American jobs.

Now, this alternative legislation will significantly improve the public health, while also protecting the already overburdened FDA from new responsibilities that take away from its ability to protect, once again, our Nation's food and drug supply.

In 2001 the Institute of Medicine noted, ''The potential for reduction in morbidity and mortality that could result from the use of less toxic products by those who do not stop using tobacco, justifies the inclusion of harm reduction as a component in a broad program of tobacco control.'' That was my appeal to Chairman WAXMAN as to why the harm reduction strategy should be endorsed.

You see, if enacted, H.R. 1256, Mr. WAXMAN's bill, significantly curtails, if not entirely eliminates, incentives for manufacturers to develop and market products that reduce exposure to tobacco toxic substances. In order to obtain approval of a modified risk product, an applicant must demonstrate that the marketing and the labeling of the product will not mislead consumers into believing that the product is or

has been demonstrated to be less harmful than current products.

Further, it has to be demonstrated that the product reduces risk for both the individual and for the population as a whole. This is the two-tiered standard I keep referring to. It is unlikely that such a standard could ever be proven. You see, that is what is so clever about Mr. WAXMAN's legislation. He puts in a standard that can never be achieved. And if you want to move people down a continuum of risk and improve public health, it cannot be done under Mr. WAXMAN's approach.

Now, those of us that support the substitute are concerned that such disincentives will effectively freeze the current tobacco market and prevent innovation that could lead to significantly less harmful tobacco products and improve the Nation's health. That is the exact position that Altria took in their letter to me.

Mr. Speaker, H.R. 1256 directs the Secretary of HHS to promulgate an interim final rule that is identical to the FDA's 1996 rule, which legal experts from across the political spectrum have stated would violate the First Amendment. While these experts' views should carry great weight, even more dispositive is the fact that the U.S. Supreme Court has also weighed in on various provisions of the rule, finding them unconstitutional.

In Lorillard Tobacco Co. v. Reilly, the U.S. Supreme Court struck down a Massachusetts statute that was similar in many ways to the FDA's proposed rule. The statute banned outdoor ads within 1,000 feet of schools, parks and playgrounds and also restricted point-of-sale advertising for tobacco products. The Court held that this regulation ran afoul of the test established in the Central Hudson case, which defines the protection afforded commercial speech under the First Amendment, as it was not sufficiently narrowly tailored, and would have disparate impacts from community to community.

The Court then noted that since the Massachusetts statute was based on the FDA's rule, the FDA rule would have similar unconstitutional effects on a nationwide basis. As Justice Sandra Day O'Connor wrote for the Court, ''the uniformly broad sweep of the geographical limitation demonstrates a lack of tailoring.''

Additionally, the proposed rule in H.R. 1256 would require ads to use only black text on a white background. Again, the U.S. Supreme Court found a similar provision unconstitutional in Zauderer v. Office of Disciplinary Counsel. In that case, dealing with advertising for legal services, the Court held that the use of colors and illustrations in ads are entitled to the same First Amendment protections given verbal commercial speech. Justice Byron White, in his opinion for the Court, wrote that pictures and illustrations in ads cannot be banned ''simply on the strength of the general argument that the visual content of advertisements may, under some circumstances, be deceptive or manipulative.''

There are numerous other speech restrictions in this legislation that raise serious First Amendment issues and will create a swarm of lawsuits that will only divert us from trying to develop more effective approaches to tobacco use in the United States. To put forward speech restrictions that a broad range of experts have stated are almost certain to be struck down would be highly counterproductive, and the only winners in this effort will be the litigants' constitutional lawyers rather than the American public.

I reserve the balance of my time.

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Mr. WAXMAN. Mr. Speaker, I am ready to move on to the Buyer substitute, and if the gentleman from Indiana is ready to yield back his time, I will yield back my time, and we can go to the substitute, itself.

Mr. BUYER. You would not rob me of the opportunity to put my chart on display, would you, Mr. Chairman?

Mr. WAXMAN. I wouldn't deny you any opportunity to make any points or to show any charts.

Mr. BUYER. Thank you.

Mr. WAXMAN. Is the gentleman ready to offer his amendment?

Mr. BUYER. I am prepared to show a chart on my debate time.

Mr. WAXMAN. Oh. Well then, I'll reserve the balance of my time.

Mr. BUYER. I thank the gentleman.

How much time do I have, Mr. Speaker?

The SPEAKER pro tempore. The gentleman has 9½ minutes remaining.

Mr. BUYER. I yield 3 minutes to the gentleman from Texas, Dr. BURGESS.

Mr. BURGESS. I thank the gentleman for yielding.

This bill is certainly a misplaced priority. Mr. Speaker, I lost both parents to tobacco-related illness. I know of the seriousness of this illness. I saw it virtually every day in the 25 years I practiced medicine. Tobacco is a scourge upon our society.

It is for Congress to meet then. In the bill in front of us this evening, the Food and Drug Administration, a Federal agency that right now is essentially a beleaguered agency that cannot do what we require it to do with regulating food and drugs, is now going to be given a completely new mission.

The mission of the Food and Drug Administration is to ensure that we have drugs that are safe and effective. Tobacco, when used as directed, kills 400,000 people a year. Tobacco certainly could be regarded as effective when used as directed, but it could never be regarded as safe.

Last night, in the Rules Committee, I attempted to offer an amendment which would have allowed the Food and Drug Administration to at least require that a cigarette be manufactured that contains zero milligrams of nicotine. In fact, there is explicit language in the bill that prohibits the Food and Drug Administration from requiring a zero-milligram nicotine cigarette. Why is this important?

Well, I told the Rules Committee last night that this was essentially the anti-hypocrisy amendment. If we were serious about what we were trying to do for public health, we would allow the Food and Drug Administration to eliminate nicotine in the cigarette because, after all, a tobacco cigarette is a drug-delivery device. Its sole purpose is to deliver nicotine to the user. In fact, if you do not have nicotine with its addictive powers, cigarette smoking is, itself, so unpleasant that no one would willingly smoke a cigarette. They do so to satisfy the addiction to nicotine.

In some of Chairman WAXMAN's hearings that he did in the last decade, he had tobacco executives admit that they manipulated levels of nicotine. Why? Because the nicotine is required to addict a smoker so he will continue to smoke. Eliminate the nicotine, and you have eliminated the smoking as a habit. As a consequence, the enormous public health debt that we're piling up in treating smoking-related illnesses suddenly becomes a much more realistic figure.

I, frankly, do not understand why we would have a bill on the floor to allow the Food and Drug Administration to regulate tobacco usage when we will not allow them to have the one tool that would actually do some good in this legislation, which is to allow the Food and Drug Administration to require a zero-milligram nicotine cigarette.

In other words, we're going to allow nicotine to continue to be in cigarettes, allow the level to continue to be manipulated and continue to allow the youth of this country to be addicted to this pernicious habit. If we were really serious, if it weren't just the fact that we're addicted to tobacco money, we would allow the FDA the ability to exclude nicotine from cigarette products.

Mr. WAXMAN. Mr. Speaker, we have put in this bill that the FDA has the power to lower the levels of nicotine to a level that would be appropriate for the protection of the public health. We did not allow the FDA, under the legislation, to eliminate nicotine from cigarettes because we're all aware that, if cigarettes were not permitted to contain nicotine at all, that would be tantamount to an outright ban on cigarettes. I would not like to see people smoking cigarettes at all, but I'm not for prohibition, and therefore, we did not give the FDA that power to ban cigarettes in effect.

Now, it's odd to find that we're criticized for not doing enough and then are criticized for doing too much. You can't have it both ways. I think the FDA is in the position to regulate. We ought to give them that power, and that's why I would urge support for the legislation.

At this time, I would like to yield 5 minutes to the gentleman from Pennsylvania (Mr. PLATTS), and if he needs more time, I'll yield more to him.

Mr. PLATTS. Mr. Speaker, I rise in support of H.R. 1256, the Family Smoking Prevention and Tobacco Control Act. My good friend and former colleague, Congressman Tom Davis, helped to champion this effort with Chairman WAXMAN for many years. With Congressman Davis' retirement last year, I'm honored to have taken

his place as the lead Republican sponsor of this important legislation and to have the privilege of working with Chairman WAXMAN and his staff on this important effort.

Mr. Speaker, tobacco is one of the deadliest consumer products on the market today. It kills over 400,000 Americans every year. Yet it is one of the least regulated of all consumer products. In other words, while the FDA has the authority to regulate seemingly harmless products such as lipstick, hair spray and shaving cream, to name just three, the FDA does not have the authority it needs to regulate one of the deadliest, if not the deadliest, products available for sale to our citizens. It is long past time when tobacco products should be subject to serious regulation to protect the public's health. This bill would finally accomplish this important goal.

First, this legislation would ensure that tobacco products are not advertised to or sold to children. Addiction to tobacco begins almost universally in childhood and in adolescence. Every day, almost 4,000 children try their first cigarette, and over 1,000 become daily smokers. Tobacco companies have long taken advantage of this vulnerability by promoting their products through such tactics as cartoon advertisements, free tobacco-themed merchandise that appeals to kids and through sponsorships of sports and entertainment events.

With health care costs spiraling out of control every year, the cost of treating these smokers later in life is fast becoming prohibitively expensive. Prohibiting advertising to children would go a long way in preventing young people in America from starting to smoke, and it would save billions of dollars and countless lives in the years to come.

Second, this legislation would require that tobacco products marketed as safer than other tobacco products are, in fact, demonstrated to be safer. The history of low-tar cigarettes illustrates the grave danger to public health caused by fooling consumers into believing unsubstantiated claims that one kind of cigarette is safer than another. Millions of Americans switched to low-tar cigarettes, believing they were reducing their risk of lung cancer. Many were convinced to switch instead of to quit. It was not until decades later that we learned through the deaths of those smoking low-tar cigarettes that low-tar cigarettes were just as dangerous as full-tar cigarettes. Under this legislation, we will not have to wait for the deaths of millions of more Americans to learn whether a so-called ''safer'' cigarette is what it claims to be.

This bill does not ban tobacco products. H.R. 1256 would allow the FDA to scientifically evaluate the health benefits and risks posed by ingredients in cigarettes, and it would take steps to reduce the harm caused by tobacco products. This legislation preserves an adult's choice to smoke. Even though I don't believe we want anyone to, it preserves that choice, and we make sure that those tobacco products that are marketed as safe alternatives to cigarettes are, in fact, scientifically proven to be safer.

Finally, I understand that some individuals have concerns with placing such authority under the FDA. I think it's important to note that the FDA already regulates products that people use to help quit smoking, such as nicotine gums and patches. In addition, this legislation does provide an entirely separate funding stream for the FDA's regulation of tobacco products to ensure that other important efforts carried out by this agency are not diminished.

I hope my colleagues will join me in supporting the Family Smoking Prevention and Tobacco Control Act.

For the record, I believe there was reference that the reason we're not completely banning it is because of the influence of tobacco funds in campaigns. If I understand that correctly, I want to be on the record as one who doesn't accept any political action committee funds, including tobacco funds, and I've not received any such funds. Never have. Never will. This is about doing right for American citizens. It's about the health of our citizens. It's especially about the health of our children.

Vote ''yes'' and oppose this substitute. Support the underlying bill.

Mr. BUYER. I want to thank both gentlemen—Mr. PLATTS and the chairman—for his bill. As I've said, I complimented you earlier about your persistence and about your tenacity, about your drive and your sincerity. I don't question it at all. I have a different approach on how we can improve public policy, and this has been a good debate. I want to thank the chairman for allowing this debate to occur. It was a healthy debate at the committee during the markup. I think it's a healthy debate for us to have.

Over 100 countries around the world are struggling with how they answer these public health questions on how to deal with individuals who become addicted to nicotine. When you look at this approach of, ''Well, let's just quit. Stop smoking and just quit,'' I just take a simple look at this. I say there are 45 million smokers, and then there are 2 million who are trying to stop smoking. Yet there's only a 7 percent success rate. Something is not working. To me, that's a rate of failure.

So that's why Mr. MCINTYRE and I came up with a different approach. We came up with a harm-reduction approach, and what we seek to do is to put our arms around everything. Not only are we trying to accomplish some of the similar goals of Mr. WAXMAN and Mr. PLATTS and of others who support Mr. WAXMAN's approach, but we wanted to include everything. We could include abstinence. We could include cessation programs and prevention and education. We seek to do that because we have a harm-reduction strategy to do that, and we want to move people down a continuum of risk.

When you look at the 45 million smokers, 85 percent of them are smoking light or ultralight cigarettes. Now, the reason they do that is they make a subconscious decision that somehow it's a healthier or a safer cigarette. The reality is it's not. It's not.

So Mr. PLATTS is absolutely correct, but what we seek to do in the substitute is we want to regulate tobacco. That's what Mr. MCINTYRE and I seek to do. We want to regulate tobacco. We don't want to do it under the FDA. We want to do it in a harm-reduction center, and we want the tobacco companies to come forward. We'll regulate that tobacco, but we want to migrate smokers into other forms of products. I'm going to talk about that in greater detail on the substitute.

At this point, Mr. WAXMAN, I don't have any other speakers, so we can proceed to the substitute.

Mr. DINGELL. Mr. Speaker, I rise in strong support of H.R. 1256, the Family Smoking Prevention and Tobacco Control Act. This historic legislation will grant the Food and Drug Administration the authority to regulate tobacco products. Aside from a few technical changes, H.R. 1256 is identical to the legislation Chairman WAXMAN and I worked hard together to pass in the House last year.

This legislation is long overdue:

In 1957, Surgeon General Leroy Burney declared the causal link between smoking and lung cancer.

In 1964, Surgeon General Luther Terry's Report proclaimed that cigarette smoking is a health hazard of sufficient importance in the United States to warrant appropriate remedial action.

Today, fifty-two years after the cancer link was established, forty-five years after the call for remedial action, we are finally poised to regulate this lethal product.

H.R. 1256 creates a fully-funded separate tobacco center at FDA to regulate tobacco products. The FDA is the appropriate scientific and regulatory agency to provide this oversight. Through a user fee on tobacco products, FDA will have the resources to implement this legislation and the legislation segregates the tobacco center and its funding from other FDA programs.

The FDA needs more resources and greater authority to meet its other obligations with respect to food, drugs, devices and cosmetics. My colleagues, Mr. PALLONE and Mr. STUPAK, and I have introduced legislation to address this need. To my colleagues who are concerned with FDA's lack of resources, I invite you to join us in this effort.

Each year, tobacco use kills more than 400,000 people. The American people need assurance that their food and medical products are safe. But they also need meaningful oversight of tobacco products. This Congress can deliver both.

I urge my colleagues to vote in favor of H.R. 1256.

Mr. VAN HOLLEN. Madam Speaker, as an original cosponsor, I rise in strong support of the bipartisan Family Smoking Prevention and Tobacco Control Act. I want to thank Chairman WAXMAN and so many others for their

leadership in bringing this legislation to the floor after so many years and so many battles. This is an important day for the American people.

Granting the Food and Drug Administration authority to regulate tobacco products is long overdue and is a critical step in the protection of the public's health. As we know, the FDA has the power to regulate and oversee all sorts of products that are sold today. Many products that they regulate are not addictive. Yet we do not have the FDA's regulatory authority when it came to the very addictive products of tobacco and nicotine.

Because of the lack of regulatory authority on tobacco products, the FDA has been sidelined and the result is that the big tobacco companies have taken advantage of that opportunity and exploited it by marketing their deadly products to young people. For far too long, the tobacco companies have been targeting our kids, deceiving all of us about the harmful effects of their products and manipulating the ingredients in their products—all to ensure that their profit levels remained high. In order for them to continue to make their profits, they had to continue getting one generation after another hooked on tobacco products.

Let's make sure that future generations of young people do not get addicted. Addiction to tobacco products has had a huge cost to our society in terms of lives and money with over 400,000 American deaths every year. We have a chance today to put an end to that cycle.

In my home State of Maryland, I am very proud of the steps we have taken to curb the effects of tobacco use. We increased the tobacco tax and youth smoking has declined. We also passed a comprehensive smokefree indoor air law in 2007. But we can't have every State fighting alone to have a successful national program to curb tobacco use. We need one entity that has this power to help protect the American people, especially the young people of our country, from the deadly effects of tobacco products.

Mr. Speaker, this bill is a crucial step in protecting the health and well-being of our constituents from the deadly effects of tobacco use. It will save lives and money. I urge my colleagues to join me in a yes vote on this much-needed legislation.

Mr. LUCAS. Mr. Speaker, I am appalled at the blatant disregard for the public policy process. What kind of trick is being played out on the American people when half of H.R. 1256—the half that pays for FDA legislation—comes on suspension of the rules and the other half, the part that burdens American companies with more taxes and regulation, comes under a closed rule?

This bill gives FDA broad statutory authority to regulate the manufacturing, distribution, advertising, promotion, sale, and use of cigarettes and smokeless tobacco. And, it will ultimately result in FDA being on the farm micromanaging our farmers.

FDA has clearly proven it is severely overburdened with its current authority. Just look to the recent examples of salmonella found in peanut and pistachio products. Why would we give a huge new expansion of authority to an agency that has proven it can't handle the load it has? Can you honestly tell the American people to have confidence in the FDA to protect them?

How will this new authority be paid for? New taxes, of course. The bill taxes companies and importers to pay for the cost of regulation. The bill sets the amount of the assessments each year, which will increase to $712 million per year.

Also, this bill calls for using funds from the Thrift Savings Plan. Do we really want to use the savings portion of the bill to pay for more Washington bureaucracy?

Tobacco producers, small convenience stores, and tobacco warehouseman, which are the backbones of commerce across poor and rural districts, will be put out of business under this bill.

And, farmers—beware—FDA will come directly on your farm and tell you how to operate. Producers will bear the brunt of this legislation. FDA will tell producers what type of seeds they can plant, the methods in which they cultivate those seeds, the records they must keep and on and on and on.

I ask for a "no" vote on this classic tax and regulate bill.

Mr. BUYER. I yield back the balance of my time.

Mr. WAXMAN. Mr. Speaker, I also yield back my time.

The SPEAKER pro tempore. All time for debate on the bill has expired.

AMENDMENT OFFERED BY MR. BUYER

Mr. BUYER. Mr. Speaker, I have an amendment at the desk.

The SPEAKER pro tempore. The Clerk will designate the amendment.

The text of the amendment is as follows:

Amendment in the nature of a substitute printed in part B of House Report 111–72 offered by Mr. BUYER:

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 smoke-free 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 tobacco 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 establishments 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 appropriate 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 products 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 reporting 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 requirements 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 manufacturer 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.''.

The SPEAKER pro tempore. Pursuant to House Resolution 307, the gentleman from Indiana (Mr. BUYER) and a Member opposed each will control 15 minutes.

The Chair recognizes the gentleman from Indiana.

Mr. BUYER. Thank you.

Mr. Speaker, I have a parliamentary inquiry: Because this is my substitute, do I speak last on the substitute?

The SPEAKER pro tempore. A manager in opposition will have the right to close.

Mr. BUYER. Thank you.

With that, I will yield to the cosponsor of this bipartisan substitute, Mr. MCINTYRE of North Carolina.

Mr. MCINTYRE. Mr. Speaker, I rise this evening in support of the Youth Prevention and Harm Reduction Act, which is embodied in the substitute that Mr. BUYER is describing and offering and on which he and I have worked together, which is a bipartisan bill.

I have worked with Mr. BUYER to craft a practical approach to government regulation of tobacco that protects health while preserving a vital economic engine for many communities, not only throughout my district in southeastern North Carolina and across the great Tar Heel State, but also across the country.

The underlying bill will grant the Food and Drug Administration wide authority to dictate to manufacturers and growers dramatic changes in product design and leaf cultivation, a concern that has been raised repeatedly by the tobacco growers in my district and tobacco growers throughout the States that are affected. The last thing we want, of course, is to have any government bureaucrat coming on the farm or dictating to farmers about how they grow their crops. This is the part that we want to be abundantly clear about.

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The tobacco industry contributes over $36 billion to the U.S. economy each year employing over 19,000 individuals nationwide. In my home State of North Carolina, over 8,600 people are employed by the industry with a Statewide economic impact of nearly $24 billion. The manufacturing provisions and

the concern about the FDA and its involvement on the farm in the underlying bill would put many companies and growers out of business. And in this time of economic uncertainty, the last thing that any of us can afford is to lose more jobs. Our substitute specifically protects growers by preventing any government agency from requiring changes to traditional farming practices, including standard cultivization practices, curing processes, seed composition, tobacco-type fertilization, soil, record keeping or any other requirement affecting farming practices.

In addition, this bill is about public health and prevents minors from smoking. Our substitute considers cutting-edge scientific research, as Mr. BUYER has indicated a little while ago, which would promote a harm-reduction strategy to move smokers to less harmful tobacco products.

So we're talking about here about protecting public health, definitely protecting minors, and making sure that our growers and farmers are not put out of business.

According to applied economics, the use of these reduced tobacco products increases the average probability of smoking cessation by over 10 percent. The Buyer-McIntyre substitute specifically addresses youth tobacco by encouraging States to penalize minors for purchasing and possessing tobacco products. Under current law, retailers are prohibited from selling tobacco products to minors, but unlike with the purchase of alcohol, minors are not penalized for underage purchase and possession of tobacco products.

This also calls upon the States to increase their percentage of the Master Settlement Agreement dollars to fund tobacco cessation and public health programs. In the past 10 years, States have spent just 3.2 percent of their total tobacco-generated revenue on tobacco prevention and cessation programs.

We take this concern about our youth seriously. I had a son. Back when he was in high school he was part of the Tobacco Free Kids Program and we understand, appreciate, and respect that; and, in fact, our bill has even stronger provisions dealing with that.

The Buyer-McIntyre substitute is a commonsense way to help protect public health and protect our vital tobacco economy and the jobs that we cannot afford to lose, especially in this time of economic crisis in our country.

I urge my colleagues to vote ''yes'' on the Buyer-McIntyre substitute, a bipartisan support, which provides a reasonable and pragmatic way to deal with tobacco regulation and help protect our minors from the harms of tobacco.

I reserve my time.

Mr. WAXMAN. Mr. Speaker, at this time, I rise to claim the time in opposition to the amendment.

The SPEAKER pro tempore. The gentleman from California is recognized.

Mr. WAXMAN. Mr. Speaker, I am pleased at this time to yield 3 minutes to a very important member of the Energy and Commerce Committee and its Subcommittee on Health, the gentlelady from California (Mrs. CAPPS).

Mrs. CAPPS. Mr. Speaker, I thank my colleague and chairman of our committee and a real pioneer and hero in this area.

I rise to give strong opposition to the Buyer amendment.

The Buyer amendment would undermine the precise goals of this underlying bill, that is to prevent kids from smoking. There is nothing in the Buyer amendment that would restrict tobacco marketing to youth, yet we know that marketing to our kids is a persistent tobacco company tactic. They do it to draw in new smokers at a very early age to replace their dwindling client base because of people finally being able to quit or, unfortunately, dying as a complication of smoking.

As a grandmother, I am horrified that my teenage granddaughters are the target of disgusting adds like this very one. Dressed to the Nines, this title was featured repeatedly in many magazines read frequently by young women and girls. The add highlights the latest fashion trends. It tells kids how to ''update your closet,'' and it directs them, of all things, to the Camel cigarettes Web site.

Under the Waxman-Platts bill, however, we specifically eliminate this kind of marketing to kids that depict smoking as cool or glamorous. And that's because it is not. Smoking is not cool. It isn't glamorous. It's an expensive ticket to an early death, and the tobacco companies and the magazines that run these adds, they know it, and they should be ashamed of themselves. But these days, corporate shame is in short supply, and we cannot rely on it to protect our kids.

In addition, this bill gives the FDA the authority to respond to the inevitable attempts by tobacco companies to circumvent new restrictions.

So I urge my colleagues to reject this Buyer substitute amendment because it lacks critical provisions that are so important to prevent children, our youth, from smoking.

I urge everyone to support the Waxman-Platts bill.

Mr. BUYER. I would say to the gentlelady who just spoke in the well that Mr. WAXMAN's bill was drafted years ago, and it was drafted prior to the Master Settlement Agreement. And it is the Master Settlement Agreement itself that has great restrictions upon advertisers. So there is a reason that I don't have it—I say to the gentlelady, there is a reason I don't have that part in the bill because the Master Settlement Agreement that is now administered by the attorneys general in 46 States, including the District of Columbia, who work in concert not only with the FDA but also with the Federal Trade Commission. These tobacco companies are not even advertising today in these types of magazines.

But one of the reasons I didn't go further in advertising is that when we work in concert with the Harm Reduction Center under Health and Human Services, what we seek to do is to inform the public with regard to the relative risks among different types of tobacco product, and that's what we seek to do. We seek to migrate people from the smoking to other types of products.

If I could, I would like to show exactly what I am about to share.

What I would like to share here with you is a chart, and what is important about this chart is about the continuum of risk and about all of the different types of products that are available in the marketplace today.

So when you think about this and you think about the continuum of risk, what I did is I sought to say, All right. Let's think about the products that are presently available out there.

So when you think about that, we have non-filtered cigarettes. That's the worse. I mean, you get those toxins. You get them right into your body and substance, and that's really bad. Non-filtered cigarettes.

Then you've got filtered cigarettes. We know that's a little bit better—all of these tobacco products are harmful. So we go from non-filtered cigarettes to a filtered cigarette.

Then I have a vented filtered cigarette, but those are really bad, too, because people try to gain access to that nicotine so they suck a little harder on that cigarette and they draw it deeper into their lungs. That's not a good thing.

Then we have tobacco-heated cigarettes like the Accord. Now, we know that that reduces a lot of the toxic substances, but we're really not sure where on the continuum of risk does it lie along with the electronic cigarette because there isn't sufficient science yet to back that up.

And these are products that—innovation that is coming out in the marketplace because people every day are making conscious decisions about what we eat, what we drink on a risk assessment, and that's what we are trying to do here in the statute.

So after electronic cigarettes, we have smokeless tobacco products. Now, when I think about this, we can go from a non-filtered cigarette and go all the way down 90 percent down the health risk chart, 90 percent, to get to a U.S. smokeless product.

Let's talk about the difference between a U.S. smokeless product and a Swedish Snus. The U.S. smokeless tobacco product is fermented. So through that fermentation and the natural processing of tobacco and the nitrosamines, you still have some serious carcinogens and some toxic substances. But it is still scientifically shown to be a much better and safer tobacco product than that of smoking.

You see, it is not the nicotine that is killing people. It's the smoke. It's the

smoke. It's the smoke. That's killing people.

So to get away from that—I heard somebody coughing. It was the smoke, I am telling you.

If we can pull them away from the smoke and move them down the continuum of risk chart—actually if we could get them into a Swedish snus, get them into a pasteurized product, we take away 98 percent of the health risk. And then if we can get them to—actually they are now called dissolvable tobacco products. These are orbs or strips that you can lay on your tongue or a stick that's a little like an oversized toothpick that you can stick in your mouth. These are tobacco products that contain no nitrosamines, and you can eliminate 99 percent of the health risk, but an individual can still gain their access to nicotine if they like.

And what we're trying to do, though, is move then down the continuum of risk, make informed decisions in order for them to be healthier but still gain access to their nicotine.

Then you have therapeutic nicotine devices, which are your gum, your patches, your lozenges.

And then we have pharmaceuticals. We want people to quit smoking. But in order to do this, what we've done—not only Mr. MCINTYRE but Mr. SHULER and others here in a bipartisan effort—is to create a harm-reduction strategy. And we embrace—so not only the goals of Mr. WAXMAN on abstinence, but we also embrace the goals of education, prevention and cessation activities as we try to move people and make informed choices along this continuum of risk.

Now, what is so, to me, unconscionable is that if, in fact, Mr. WAXMAN's bills were to pass, is that these new innovative types of nicotine delivery devices could not make their access to the market. Now as I said—I will say it for the umpteenth time—I respect Mr. WAXMAN and his desire to try to get people to eliminate smoking. We just recognized that today only 7 percent success rate with regard to these type of nicotine replacement therapies, and that's a failure rate, and we shouldn't do that.

I reserve the balance of my time.

Mr. WAXMAN. Mr. Speaker, may I inquire how much time each side has remaining?

The SPEAKER pro tempore. The gentleman from California has 13 minutes remaining. The gentleman from Indiana has 7½ minutes remaining.

Mr. WAXMAN. Well, I plan to close the debate, and I know that Mr. BUYER has another speaker on his side, so I want to reserve the balance of my time.

Mr. BUYER. Mr. Speaker, I would yield to one of the cosponsors of this substitute, Mr. SHULER of North Carolina, for as much time as he might consume.

Mr. SHULER. Mr. Chairman, I want to commend you for your hard work, and although we may disagree on legislation, I want to commend you for your hard work in the prevention of smoking and trying to get children off smoking as well.

So, Mr. Speaker, I strongly support the commonsense amendment proposed by the gentleman from Indiana. And I strongly oppose the underlying bill.

Putting a dangerous, overworked FDA in charge of tobacco is a threat to public safety. Last year, the FDA commissioner testified that he had serious concerns that this bill could undermine the public health role of the FDA. And the FDA Science Board said the FDA's inability to keep up with scientific advancements means that Americans' lives will be at risk.

What are these risks? Well, let me talk about three areas that just happened last year.

Last summer, 1,400 people were sickened by peppers from Mexico, but we shut down the entire tomato industry. Just last month, more than 100 people become sick because of salmonella and alfalfa sprouts. And in January, more than 500 people became sick because of salmonella from Peanut Corporation of America. Amazingly enough, this plant had never been inspected even after Canada rejected a shipment of peanuts. That's right. The FDA is overworked. We have to rely on the Canadians to inspect our food now.

Instead of putting our food and drug supply at greater risk, let's deal with the underage smoking head on. This amendment does that by putting more resources into prevention and harm-reduction programs that have helped reduce youth smoking by over 50 percent for the last 10 years.

Let's pass this amendment so that we can keep our kids safe from cigarettes and keep our children safe with the food that they eat.

□ 2030

I ask my colleagues to support the passage of the Buyer amendment.

Mr. WAXMAN. Mr. Speaker, I am going to reserve my time to close the debate, so I will allow the gentleman from Indiana (Mr. BUYER) to continue.

Mr. BUYER. Mr. Speaker, I yield 3 minutes to the gentlewoman from Tennessee (Mrs. BLACKBURN).

Mrs. BLACKBURN. Mr. Speaker, I thank the gentleman from Indiana for the excellent work that he has done on a substitute, for addressing this issue the way it should be addressed.

We are all concerned about cigarette smoke and the effects of tobacco on our health, and I don't think that is the debate that is here. But one of the things that concerns me in this debate is that there are some pieces that have kind of been left out, that are not being addressed.

Well, we all are concerned about what has happened with teen smoking, with the effects of tobacco on an individual's health. One of the things that has happened is the Synar amendment and the good work that the Synar language has done in reducing teen smoking has been left out, and what we are having brought forward is this bill that will actually give the FDA stamp of approval to some tobacco processes and uses. And for someone as a wife, a mother, a grandmother, a community volunteer that has actually worked to address school health curriculums, to address smoking, to fight and work with smoking cessation programs, I know that that is a dangerous step to give the FDA stamp of approval to tobacco usage.

In addition to that, this is legislation that is going to build a bureaucracy. It is going to pull the government into our farms, into our manufacturers, into our retailers further and further.

But, Mr. Speaker, I think that actually that's a lot of what is going on in this entire Congress, growing the bureaucracy. We're hearing it's going to take 250,000 new Federal employees to implement the stimulus and this massive budget that is before us; new Federal employees, 250,000 new Federal employees. It is building bureaucracies, taking power away from individuals, taking power away from the House and handing it over to a bureaucracy that continues to grow every single day.

And the steps that are being taken with moving tobacco to the FDA is another part of that. We know the FDA can't do the job in front of them now when it comes to dealing with policing drugs, looking at contaminated food, addressing the issues that we have had with everything from peanut butter to pistachios. They are not getting the job done, and now we want to pull them on to our farms and into our manufacturing facilities addressing tobacco, and we have processes that already work. But it's not about funding and keeping attention on processes that work.

What we know is this is all about growing a bureaucracy. I encourage my colleagues to vote against this bill.

Mr. BUYER. I yield myself such time as I may consume.

According to the Journal of Health Care Law and Policy, dated 2008, ''There is a very strong basis in science for believing that the harm caused by current cigarettes can be massively reduced by alternative nicotine delivery systems. Anti-tobacco campaigners who refuse to discuss harm reduction will merely be ensuring that they are not part of the ongoing dialogue that will shape this key area of policy.''

I also would like to cite Britton and Edwards in The Lancet, 2007. ''The risk of adverse effects associated with Snus use is lower than that associated with smoking, overall by an estimated 90 percent. Whatever the true overall hazard, use of low nitrosamine smokeless products is clearly substantially less harmful than tobacco smoking.''

Also citing the Scientific Committee on Emerging and Newly Identified

Health Risks, dated 2007, ''The magnitude of the overall reduction in hazard,'' meaning switching from cigarettes to smokeless, ''is difficult to estimate.'' But as outlined in their paper, for cardiovascular disease, it is at least a 50 percent reduction; for pancreatic cancer, it is at least 30 percent; for oral and other GI cancer, it is at least 50 percent reduction and probably more; and for lung cancer and chronic obstructive pulmonary disease, it's possibly even 100 percent.

Now, what I'm hopeful is that at some point, I'm going to make this quest that Mr. WAXMAN and I can somehow come together, because according to CBO the reduction in the rates of smoking in the Waxman bill is two-tenths of 1 percent per year. So we're going to take over $6 billion to reduce smoking rates under Mr. WAXMAN's approach by two-tenths of 1 percent per year. Which means over a 10-year time frame, the total that we're going to reduce for smoking in the entire country is 2 percent. We are going to reduce smoking rates in the country under Mr. WAXMAN by 2 percent.

We can do much better than that, and that's why we have this substitute is that we want to move people from smoking down the continuum of risk to eventually quitting, and I think that's exactly what the chairman embraces.

Please support the substitute.

The SPEAKER pro tempore. The gentleman's time has expired.

Mr. WAXMAN. Mr. Speaker, I strongly oppose this substitute amendment offered by Mr. BUYER.

The bill before us, the Waxman-Platts bill, has been carefully crafted over more than a decade, in close consultation with the public health community. It's been endorsed by over 1,000 different public health, scientific, medical, faith, and community organizations. It is also supported by a prestigious and bipartisan group of former public health officials, including former Secretaries of Health and Human Services, Tommy Thompson and Donna Shalala; former Surgeons General, David Satcher and Richard Carmona; former CDC Director, Julie Gerberding; and former FDA Commissioner, David Kessler. It reflects a strong, reasonable, and comprehensive approach to addressing the tobacco epidemic.

Now, this Buyer substitute is deeply flawed. It represents an inadequate response for the greatest preventable cause of death and disease in the United States.

One of the biggest problems in this substitute is that it places oversight of tobacco under a totally new, untested agency. They create a new government agency that lacks any experience in protecting the public health. FDA is our Nation's primary protector of the public health, and it has both the regulatory and scientific expertise to handle the complex task of regulating tobacco. The agency devoted 10 years to investigating tobacco in the 1990s. It has over 100 years of experience in setting science-based standards to protect and promote the public health.

Mr. BUYER's substitute would ignore all of this expertise, would ignore the whole record of all of the public health organizations, and set up a new agency. And the premise of his new agency would be tobacco harm reduction, and he showed us a chart. That chart in effect said that what we should do is try to encourage people to reduce the harm from tobacco by using other tobacco products.

There's no evidence to support his approach. He is basing his assumption that current smokers will use smokeless tobacco to quit, but there's no evidence to support this assumption. In fact, the U.S. Public Health Service's clinical practice guidelines finds no evidence to suggest that smokeless tobacco is effective in helping smokers quit. Rather than have smokers quit, it's just as likely that smokeless tobacco can be used to introduce youth to tobacco use and to discourage smokers from quitting. I would submit that what his proposal would do would be to do everything but get smokers to quit, and it does not focus on getting people not to start smoking in the first place. The only evidence one can cite for using smokeless tobacco to quit is inadequate. It's not based on science, and I'm sure it will be a tremendous boon to the smokeless tobacco industry.

A second major problem with the substitute is that it fails to provide any dedicated funding for tobacco regulation. Instead, it relies on a future appropriation that may or may not ever come along, and then this new agency is supposed to do something to reduce smoking in this country.

It fails to create effective Federal enforcement to prevent tobacco sales to minors. The Buyer amendment would not punish individual retail clerks. Instead, it would fine kids for possession rather than making sure that they don't have access to cigarettes in the first place. The Waxman-Platts bill would instead create a strong Federal enforcement system to ensure that retailers do not sell to minors, while providing adequate procedural protections for retailers.

Another flaw, it allows tobacco companies to keep targeting the kids. One of the most critical goals of our bill is to stop tobacco industry targeting of our children. This bill that's being offered as a substitute does nothing to address the problem. It leaves companies free to continue pushing their products on kids and teenagers, and I would submit that that is not a good substitute for the bill that is before us.

I'm also extremely concerned that it effectively exempts smokeless tobacco products such as chewing tobacco from any oversight. It assumes that those products are safe. Well, there's no evidence for that. It ignores the range of harm-reduction options that pose far less risk such as nicotine replacement therapies, which, by the way, are already being approved as safe by the FDA, and instead, he wants to substitute smokeless tobacco for smoking cigarettes.

The substitute fails to protect consumers from false and misleading claims about reduced harm. It would allow tobacco companies to market products as safer or posing less risk without providing scientific evidence that those claims are actually true. This means that consumers would still be vulnerable to false and misleading claims, and we know those claims: cigarettes are light, cigarettes are low tar. Those are the claims we've heard over the years, and they're wrong, they're dangerous, they're misleading, and nothing would be done to stop those kinds of claims under this substitute. Our bill would allow products to be marketed as less hazardous only when those claims are based on sound science and only when the health of the entire population is considered.

And finally, the substitute gives the tobacco industry a vote in advising the agency on scientific decisions. This flies in the face of everything we know about the industry. Big Tobacco has shown repeatedly that it will distort and discard scientific evidence in service of its business objectives without regard to the public health. We don't give drug or device manufacturers a vote in advising the FDA, and we shouldn't do that here. Giving the tobacco industry voting representation on a scientific advisory committee has no precedent.

I would submit you can choose between a substitute that's just been offered only in the last month or so or you can vote for a bill that has been reviewed by and approved by the Heart Association, the Lung Association, the Cancer Society, the Campaign for Tobacco-Free Kids, the American Public Health Association, the American Academy of Pediatrics, the New England Journal of Medicine, and the AARP, just to mention a few of the thousand groups that oppose the Buyer amendment and support the underlying bill.

This tobacco harm-reduction act proposal is no substitute. In fact, it seems to me that the only harm it reduces is harm to the tobacco industry.

I urge a ''no'' vote on the Buyer substitute.

I yield back the balance of my time.

The SPEAKER pro tempore. All time for debate has expired.

Pursuant to clause 1(c) of rule XIX, further proceedings on this measure are postponed.

□ 2045

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, the Chair will postpone further proceedings today on motions to suspend the rules on which a recorded vote or the yeas