provide them with the help they need to kick the habit. Holding up these smoking cessation aids, in an age of bureaucratic red tape, is no longer an option. I believe that that's a concept that's consistent with the harm-reduction strategy that my colleague from Indiana had discussed earlier.

By creating a special category of small tobacco product manufacturers, the bill will ensure that small businesses have the assistance they need from the FDA to comply with the new regulations. Supported by over 1,000 health and faith-based groups from across the country, including the American Cancer Association, the American Heart Association, the American Lung Association, The Campaign for Tobacco Free Kids, and the American Dental Association. This bill also preserves States rights by not preempting State tobacco laws. It's extremely important to respect that many States, including my own home State of Colorado, already recognize the dangers of smoking and the role that regulation can play and have excellent laws on the books that keep cigarettes out of the hands of children and also regulates second-hand smoke.

I'm very proud to say that my home State of Colorado is recognized as a leader in tobacco control, as demonstrated by our leadership in enacting a comprehensive smoke-free law that includes casinos. Additionally, Colorado is working on enacting a youth-access policy statewide. A senator from my district, the State senator, introduced a bill last year that required ID checks for tobacco purchases and prohibited youths from possessing tobacco products.

I would like to highlight, in conclusion, a story of a hero in the cancer awareness movement from my district, a type of heroism that, unfortunately, is all too common.

□ 1015

Susan DeWitt was a typical soccer mom from Superior, Colorado. She made a DVD video about the struggles of her family during her 8-year battle with cancer that ultimately cost her her life. She had earlier worked as a reporter in Boulder County. She had been a light smoker in her teens and continued into her twenties, and she quit in 1992, in her early thirties.

She passed away at the age of 42 from lung cancer. She created ''Through My Children's Eyes'' as a legacy, and her family founded the Susan DeWitt Foundation to continue her work.

How many more Susan DeWitts must there be in this country? This plague has touched almost all American lives. How many of us have lost a friend or relative to lung cancer and to smoking?

This bill is a critical important first step in finally creating a regulatory structure to discourage young people from ever beginning to smoke and regulating the safety of tobacco products.

Madam Speaker, I urge a ''yes'' vote on the rule and the underlying bill.

Madam 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.

FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT

Mr. WAXMAN. Madam Speaker, pursuant to House Resolution 532, I call up from the Speaker's table the bill (H.R. 1256) to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes, with a Senate amendment thereto, and I have a motion at the desk.

The Clerk read the title of the bill.

The SPEAKER pro tempore. The Clerk will designate the Senate amendment.

The text of the Senate amendment is as follows:

Senate amendment:

Strike all after the enacting clause and insert the following:

DIVISION A—FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

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

(b) TABLE OF CONTENTS.—The table of contents of this division 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 division.

(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 division 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 division;

(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 division (or an amendment made by this division) 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 division (or an amendment made by this division) 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 division (or an amendment made by this division) 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 division, of the amendments made by this division, or of the regulations promulgated under this division (or under such amendments), or the application of any such provision to any person or circumstance is held to be invalid, the remainder of this division, such amendments and such regulations, and the application of such provisions to any other person or circumstance shall not be affected and shall continue to be enforced to the fullest extent possible.

SEC. 6. MODIFICATION OF DEADLINES FOR SECRETARIAL ACTION.

(a) DELAYED COMMENCEMENT OF DATES FOR SECRETARIAL ACTION.—

(1) IN GENERAL.—Except as provided in subsection (c), with respect to any time periods specified in this division (or in an amendment made by this division) that begin on the date of enactment of this Act, within which the Secretary of Health and Human Services is required to carry out and complete specified activities, the calculation of such time periods shall commence on the date described in subsection (b).

(2) LIMITATION.—Subsection (a) shall only apply with respect to obligations of the Secretary of Health and Human Services that must be completed within a specified time period and shall not apply to the obligations of any other person or to any other provision of this division (including the amendments made by this division) that do not create such obligations of the Secretary and are not contingent on actions by the Secretary.

(b) DATE DESCRIBED.—The date described in this subsection is the first day of the first fiscal quarter following the initial 2 consecutive fiscal quarters of fiscal year 2010 for which the Secretary of Health and Human Services has collected fees under section 919 of the Federal Food, Drug, and Cosmetic Act (as added by section 101).

(c) EXCEPTION.—Subsection (a) shall not apply to any time period (or date) contained—

(1) in section 102, except that the reference to ''180 days'' in subsection (a)(1) of such section shall be deemed to be ''270 days''; and

(2) in sections 201 through 204 (or the amendments made by any such sections).

(d) ADJUSTMENT.—The Secretary of Health and Human Services may extend or reduce the duration of one or more time periods to which subsection (a) applies if the Secretary determines appropriate, except that no such period shall be extended for more than 90 days.

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 to ensure that such statements do not violate the misbranding provisions of subsection (a) and that such statements comply with other provisions of the Family Smoking Prevention and Tobacco Control Act (including the amendments made by such Act). 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.

''(f) DISSOLVABLE TOBACCO PRODUCTS.—

''(1) REFERRAL; CONSIDERATIONS.—The Secretary shall refer to the Tobacco Products Scientific Advisory Committee for report and recommendation, under section 917(c)(4), the issue of the nature and impact of the use of dissolvable tobacco products on the public health, including such use among children. In its review, the Tobacco Products Scientific Advisory Committee shall address the considerations listed in subsection (a)(3)(B)(i).

''(2) REPORT AND RECOMMENDATION.—Not later than 2 years 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 at any time applicable to any dissolvable tobacco product.

''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 nonnicotine-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, subject to paragraph (2)(D). 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 (referred to in this subsection as 'tobacco regulation activities'), except that such fees may be used for the reimbursement specified in subparagraph (C).

''(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 tobacco regulation activities.

''(ii) STARTUP COSTS.—Clause (i) does not apply until October 1, 2009. Until such date, any amounts available to the Food and Drug Administration (excluding user fees) shall be available and allocated as needed to pay the costs of tobacco regulation activities.

''(C) REIMBURSEMENT OF START-UP AMOUNTS.—

''(i) IN GENERAL.—Any amounts allocated for the start-up period pursuant to subparagraph (B)(ii) shall be reimbursed through any appropriated fees collected under subsection (a), in such manner as the Secretary determines appropriate to ensure that such allocation results in no net change in the total amount of funds otherwise available, for the period from October 1, 2008, through September 30, 2010, for Food and Drug Administration programs and activities (other than tobacco regulation activities) for such period.

''(ii) TREATMENT OF REIMBURSED AMOUNTS.—Amounts reimbursed under clause (i) shall be available for the programs and activities for which funds allocated for the start-up period were available, prior to such allocation, until September 30, 2010, notwithstanding any otherwise applicable limits on amounts for such programs or activities for a fiscal year.

''(D) FEE COLLECTED DURING START-UP PERIOD.—Notwithstanding the first sentence of paragraph (1), fees under subsection (a) may be collected through September 30, 2009 under subparagraph (B)(ii) and shall be available for obligation and remain available until expended. Such offsetting collections shall be credited to the salaries and expenses account of the Food and Drug Administration.

''(E) OBLIGATION OF START-UP COSTS IN ANTICIPATION OF AVAILABLE FEE COLLECTIONS.—Notwithstanding any other provision of law, following the enactment of an appropriation for fees under this section for fiscal year 2010, or any portion thereof, obligations for costs of tobacco regulation activities during the start-up period may be incurred in anticipation of the receipt of offsetting fee collections through procedures specified in section 1534 of title 31, United States Code.

''(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).''.

(c) CONFORMING AMENDMENT.—Section 9(1) of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4408(i)) is amended to read as follows:

''(1) The term 'smokeless tobacco' has the meaning given such term by section 900(18) of the Federal Food, Drug, and Cosmetic Act.''.

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 division; 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 division and the amendments made by this division;

(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) include such modifications to section 897.30(b), if any, that the Secretary determines are appropriate in light of governing First Amendment case law, including the decision of the Supreme Court of the United States in Lorillard Tobacco Co. v. Reilly (533 U.S. 525 (2001));

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

(G) 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;

''(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 division, the amendments made by this division, 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 915;

''(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) Making any express or implied statement or representation directed to consumers with respect to a tobacco product, in a label or labeling or through the media or advertising, that either conveys, or misleads or would mislead consumers into believing, that—

''(1) the product is approved by the Food and Drug Administration;

''(2) the Food and Drug Administration deems the product to be safe for use by consumers;

''(3) the product is endorsed by the Food and Drug Administration for use by consumers; or

''(4) the product is safe or less harmful by virtue of—

''(A) its regulation or inspection by the Food and Drug Administration; or

''(B) its compliance with regulatory requirements set by the Food and Drug Administration; including any such statement or representation rendering the product misbranded under section 903.''.

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

(1) in paragraph (5)—

(A) by striking ''paragraph (1), (2), (3), or (4)'' each place such appears and inserting ''paragraph (1), (2), (3), (4), or (9)'';

(B) 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,'';

(C) 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

(D) by adding at the end the following:

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

(2) 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

(3) 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.

''(9) CIVIL MONETARY PENALTIES FOR VIOLATION OF TOBACCO PRODUCT REQUIREMENTS.—

''(A) IN GENERAL.—Subject to subparagraph (B), any person who violates a requirement of this Act which relates to tobacco products shall be liable to the United States for a civil penalty in an amount not to exceed $15,000 for each such violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding.

''(B) ENHANCED PENALTIES.—

''(i) Any person who intentionally violates a requirement of section 902(5), 902(6), 904, 908(c), or 911(a), shall be subject to a civil monetary penalty of—

''(I) not to exceed $250,000 per violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding; or

''(II) in the case of a violation that continues after the Secretary provides written notice to such person, $250,000 for the first 30-day period (or any portion thereof) that the person continues to be in violation, and such amount shall double for every 30-day period thereafter that the violation continues, not to exceed $1,000,000 for any 30-day period, and not to exceed $10,000,000 for all such violations adjudicated in a single proceeding.

''(ii) Any person who violates a requirement of section 911(g)(2)(C)(ii) or 911(i)(1), shall be subject to a civil monetary penalty of—

''(I) not to exceed $250,000 per violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding; or

''(II) in the case of a violation that continues after the Secretary provides written notice to such person, $250,000 for the first 30-day period (or any portion thereof) that the person continues to be in violation, and such amount shall double for every 30-day period thereafter that the violation continues, not to exceed $1,000,000 for any 30-day period, and not to exceed $10,000,000 for all such violations adjudicated in a single proceeding.

''(iii) In determining the amount of a civil penalty under clause (i)(II) or (ii)(II), the Secretary shall take into consideration whether the person is making efforts toward correcting the violation of the requirements of the section for which such person is subject to such civil penalty.''.

(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''; and

(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—''; and

(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 (3) and (4) of section 903(a) of the Federal Food, Drug, and Cosmetic Act (as amended by this division) shall take effect on the date that is 12 months after the date of enactment of this Act. The package label requirements of paragraph (2) of such section 903(a) for cigarettes shall take effect on the date that is 15 months after the issuance of the regulations required by section 4(d) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333), as amended by section 201 of this division. The package label requirements of paragraph (2) of such section 903(a) for tobacco products other than cigarettes 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 division) 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 division, or pursuant to section 102(a) of this division, 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 division, or preserved by such entities under section 916 of the Federal Food, Drug, and Cosmetic Act, as added by section 101(b) of this division.

(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.

SEC. 106. STUDIES OF PROGRESS AND EFFECTIVENESS.

(a) FDA REPORT.—Not later than 3 years after the date of enactment of this Act, and not less than every 2 years thereafter, the Secretary of Health and Human Services 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 concerning—

(1) the progress of the Food and Drug Administration in implementing this division, including major accomplishments, objective measurements of progress, and the identification of any areas that have not been fully implemented;

(2) impediments identified by the Food and Drug Administration to progress in implementing this division and to meeting statutory timeframes;

(3) data on the number of new product applications received under section 910 of the Federal Food, Drug, and Cosmetic Act and modified risk product applications received under section 911 of such Act, and the number of applications acted on under each category; and

(4) data on the number of full time equivalents engaged in implementing this division.

(b) GAO REPORT.—Not later than 5 years after the date of enactment of this Act, the Comptroller General of the United States shall conduct a study of, and submit to the Committees described in subsection (a) a report concerning—

(1) the adequacy of the authority and resources provided to the Secretary of Health and Human Services for this division to carry out its goals and purposes; and

(2) any recommendations for strengthening that authority to more effectively protect the public health with respect to the manufacture, marketing, and distribution of tobacco products.

(c) PUBLIC AVAILABILITY.—The Secretary of Health and Human Services and the Comptroller General of the United States, respectively, shall make the reports required under subsection (a) and (b) available to the public, including by posting such reports on the respective Internet websites of the Food and Drug Administration and the Government Accountability Office.

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 the top 50 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).

''(d) GRAPHIC LABEL STATEMENTS.—Not later than 24 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall issue regulations that require color graphics depicting the negative health consequences of smoking to accompany the label statements specified in subsection (a)(1). The Secretary may adjust the type size, text and format of the label statements specified in subsections (a)(2) and (b)(2) as the Secretary determines appropriate so that both the graphics and the accompanying label statements are clear, conspicuous, legible and appear within the specified area.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect 15 months after the issuance of the regulations required by subsection (a). 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 through a rulemaking conducted under section 553 of title 5, United States Code, may adjust the format, type size, color graphics, and text of any of the label requirements, 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 other than cigarettes for introduction or delivery for introduction into interstate commerce in the United States shall bear the statement 'sale only allowed in the United States'. Beginning 15 months after the issuance of the regulations required by section 4(d) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333), as amended by section 201 of Family Smoking Prevention and Tobacco Control Act, the label, packaging, and shipping containers of cigarettes 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).

DIVISION B—FEDERAL RETIREMENT REFORM ACT

SEC. 100. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This division may be cited as the ''Federal Retirement Reform Act of 2009''.

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

TITLE I—PROVISIONS RELATING TO FEDERAL EMPLOYEES RETIREMENT

SEC. 101. SHORT TITLE.

This title may be cited as the ''Thrift Savings Plan Enhancement Act of 2009''.

SEC. 102. AUTOMATIC ENROLLMENTS AND IMMEDIATE EMPLOYING AGENCY CONTRIBUTIONS.

(a) IN GENERAL.—Section 8432(b) of title 5, United States Code, is amended by striking paragraphs (2) through (4) and inserting the following:

''(2)(A) The Executive Director shall by regulation provide for an eligible individual to be automatically enrolled to make contributions under subsection (a) at the default percentage of basic pay.

''(B) For purposes of this paragraph, the default percentage shall be equal to 3 percent or such other percentage, not less than 2 percent nor more than 5 percent, as the Board may prescribe.

''(C) The regulations shall include provisions under which any individual who would otherwise be automatically enrolled in accordance with subparagraph (A) may—

''(i) modify the percentage or amount to be contributed pursuant to automatic enrollment, effective not later than the first full pay period following receipt of the election by the appropriate processing entity; or

''(ii) decline automatic enrollment altogether.

''(D)(i) Except as provided in clause (ii), for purposes of this paragraph, the term 'eligible individual' means any individual who, after any regulations under subparagraph (A) first take effect, is appointed, transferred, or reappointed to a position in which that individual becomes eligible to contribute to the Thrift Savings Fund.

''(ii) Members of the uniformed services shall not be eligible individuals for purposes of this paragraph.

''(E) Sections 8351(a)(1), 8440a(a)(1), 8440b(a)(1), 8440c(a)(1), 8440d(a)(1), and 8440e(a)(1) shall be applied in a manner consistent with the purposes of this paragraph.''.

(b) TECHNICAL AMENDMENT.—Section 8432(b)(1) of title 5, United States Code, is amended by striking the parenthetical matter in subparagraph (B).

SEC. 103. QUALIFIED ROTH CONTRIBUTION PROGRAM.

(a) IN GENERAL.—Subchapter III of chapter 84 of title 5, United States Code, is amended by inserting after section 8432c the following:

''§ 8432d. Qualified Roth contribution program

''(a) DEFINITIONS.—For purposes of this section—

''(1) the term 'qualified Roth contribution program' means a program described in paragraph (1) of section 402A(b) of the Internal Revenue Code of 1986 which meets the requirements of paragraph (2) of such section; and

''(2) the terms 'designated Roth contribution' and 'elective deferral' have the meanings given such terms in section 402A of the Internal Revenue Code of 1986.

''(b) AUTHORITY TO ESTABLISH.—The Executive Director shall by regulation provide for the inclusion in the Thrift Savings Plan of a qualified Roth contribution program, under such terms and conditions as the Board may prescribe.

''(c) REQUIRED PROVISIONS.—The regulations under subsection (b) shall include—

''(1) provisions under which an election to make designated Roth contributions may be made—

''(A) by any individual who is eligible to make contributions under section 8351, 8432(a), 8440a, 8440b, 8440c, 8440d, or 8440e; and

''(B) by any individual, not described in subparagraph (A), who is otherwise eligible to make elective deferrals under the Thrift Savings Plan;

''(2) any provisions which may, as a result of enactment of this section, be necessary in order to clarify the meaning of any reference to an 'account' made in section 8432(f), 8433, 8434(d), 8435, 8437, or any other provision of law; and

''(3) any other provisions which may be necessary to carry out this section.''.

(b) CLERICAL AMENDMENT.—The analysis for chapter 84 of title 5, United States Code, is amended by inserting after the item relating to section 8432c the following:

''8432d. Qualified Roth contribution program.''.

SEC. 104. AUTHORITY TO ESTABLISH MUTUAL FUND WINDOW.

(a) IN GENERAL.—Section 8438(b)(1) of title 5, United States Code, is amended—

(1) in subparagraph (D), by striking ''and'' at the end;

(2) in subparagraph (E), by striking the period and inserting ''; and''; and

(3) by adding after subparagraph (E) the following:

''(F) a service that enables participants to invest in mutual funds, if the Board authorizes the mutual fund window under paragraph (5).''.

(b) REQUIREMENTS.—Section 8438(b) of title 5, United States Code, is amended by adding at the end the following:

''(5)(A) The Board may authorize the addition of a mutual fund window under the Thrift Savings Plan if the Board determines that such addition would be in the best interests of participants.

''(B) The Board shall ensure that any expenses charged for use of the mutual fund window are borne solely by the participants who use such window.

''(C) The Board may establish such other terms and conditions for the mutual fund window as the Board considers appropriate to protect the interests of participants, including requirements relating to risk disclosure.

''(D) The Board shall consult with the Employee Thrift Advisory Council (established under section 8473) before authorizing the addition of a mutual fund window or establishing a service that enables participants to invest in mutual funds.''.

(c) TECHNICAL AND CONFORMING AMENDMENT.—Section 8438(d)(1) of title 5, United States Code, is amended by inserting ''and options'' after ''investment funds''.

SEC. 105. REPORTING REQUIREMENTS.

(a) ANNUAL REPORT.—The Board shall, not later than June 30 of each year, submit to Congress an annual report on the operations of the Thrift Savings Plan. Such report shall include, for the prior calendar year, information on the number of participants as of the last day of such prior calendar year, the median balance in participants' accounts as of such last day, demographic information on participants, the percentage allocation of amounts among investment funds or options, the status of the development and implementation of the mutual fund window, the diversity demographics of any company, investment adviser, or other entity retained to invest and manage the assets of the Thrift Savings Fund, and such other information as the Board considers appropriate. A copy of each annual report under this subsection shall be made available to the public through an Internet website.

(b) REPORTING OF FEES AND OTHER INFORMATION.—

(1) IN GENERAL.—The Board shall include in the periodic statements provided to participants under section 8439(c) of title 5, United States Code, the amount of the investment management fees, administrative expenses, and any other fees or expenses paid with respect to each investment fund and option under the Thrift Savings Plan. Any such statement shall also provide a statement notifying participants as to how they may access the annual report described in subsection (a), as well as any other information concerning the Thrift Savings Plan that might be useful.

(2) USE OF ESTIMATES.—For purposes of providing the information required under this subsection, the Board may provide a reasonable and representative estimate of any fees or expenses described in paragraph (1) and shall indicate any such estimate as being such an estimate. Any such estimate shall be based on the previous year's experience.

(c) DEFINITIONS.—For purposes of this section—

(1) the term ''Board'' has the meaning given such term by 8401(5) of title 5, United States Code;

(2) the term ''participant'' has the meaning given such term by section 8471(3) of title 5, United States Code; and

(3) the term ''account'' means an account established under section 8439 of title 5, United States Code.

SEC. 106. ACKNOWLEDGMENT OF RISK.

(a) IN GENERAL.—Section 8439(d) of title 5, United States Code, is amended—

(1) by striking the matter after ''who elects to invest in'' and before ''shall sign an acknowledgment'' and inserting ''any investment fund or option under this chapter, other than the Government Securities Investment Fund,''; and

(2) by striking ''either such Fund'' and inserting ''any such fund or option''.

(b) COORDINATION WITH PROVISIONS RELATING TO FIDUCIARY RESPONSIBILITIES, LIABILITIES, AND PENALTIES.—Section 8477(e)(1)(C) of title 5, United States Code, is amended—

(1) by redesignating subparagraph (C) as subparagraph (C)(i); and

(2) by adding at the end the following:

''(ii) A fiduciary shall not be liable under subparagraph (A), and no civil action may be brought against a fiduciary—

''(I) for providing for the automatic enrollment of a participant in accordance with section 8432(b)(2)(A);

''(II) for enrolling a participant in a default investment fund in accordance with section 8438(c)(2); or

''(III) for allowing a participant to invest through the mutual fund window or for establishing restrictions applicable to participants' ability to invest through the mutual fund window.''.

SEC. 107. SUBPOENA AUTHORITY.

(a) IN GENERAL.—Chapter 84 of title 5, United States Code, is amended by inserting after section 8479 the following:

''§ 8480. Subpoena authority

''(a) In order to carry out the responsibilities specified in this subchapter and subchapter III of this chapter, the Executive Director may issue subpoenas commanding each person to whom the subpoena is directed to produce designated books, documents, records, electronically stored information, or tangible materials in the possession or control of that individual.

''(b) Notwithstanding any Federal, State, or local law, any person, including officers, agents, and employees, receiving a subpoena under this section, who complies in good faith with the subpoena and thus produces the materials sought, shall not be liable in any court of any State or the United States to any individual, domestic or foreign corporation or upon a partnership or other unincorporated association for such production.

''(c) When a person fails to obey a subpoena issued under this section, the district court of the United States for the district in which the investigation is conducted or in which the person failing to obey is found, shall on proper application issue an order directing that person to comply with the subpoena. The court may punish as contempt any disobedience of its order.

''(d) The Executive Director shall prescribe regulations to carry out subsection (a).''.

(b) TECHNICAL AND CONFORMING AMENDMENT.—The table of sections for chapter 84 of title 5, United States Code, is amended by inserting after the item relating to section 8479 the following:

''8480. Subpoena authority.''.

SEC. 108. AMOUNTS IN THRIFT SAVINGS FUNDS SUBJECT TO LEGAL PROCEEDINGS.

Section 8437(e)(3) of title 5, United States Code, is amended in the first sentence by striking ''or relating to the enforcement of a judgment for the physically, sexually, or emotionally abusing a child as provided under section 8467(a)'' and inserting ''the enforcement of an order for restitution under section 3663A of title 18, forfeiture under section 8432(g)(5) of this title, or an obligation of the Executive Director to make a payment to another person under section 8467 of this title''.

SEC. 109. ACCOUNTS FOR SURVIVING SPOUSES.

Section 8433(e) of title 5, United States Code, is amended—

(1) by inserting ''(1)'' after ''(e)''; and

(2) by adding at the end the following:

''(2) Notwithstanding section 8424(d), if an employee, Member, former employee, or former Member dies and has designated as sole or partial beneficiary his or her spouse at the time of death, or, if an employee, Member, former employee, or former Member, dies with no designated beneficiary and is survived by a spouse, the spouse may maintain the portion of the employee's or Member's account to which the spouse is entitled in accordance with the following terms:

''(A) Subject to the limitations of subparagraph (B), the spouse shall have the same withdrawal options under subsection (b) as the employee or Member were the employee or Member living.

''(B) The spouse may not make withdrawals under subsection (g) or (h).

''(C) The spouse may not make contributions or transfers to the account.

''(D) The account shall be disbursed upon the death of the surviving spouse. A beneficiary or surviving spouse of a deceased spouse who has inherited an account is ineligible to maintain the inherited spousal account.

''(3) The Executive Director shall prescribe regulations to carry out this subsection.''.

SEC. 110. TREATMENT OF MEMBERS OF THE UNIFORMED SERVICES UNDER THE THRIFT SAVINGS PLAN.

(a) SENSE OF CONGRESS.—It is the sense of Congress that—

(1) members of the uniformed services should have a retirement system that is at least as generous as the one which is available to Federal civilian employees; and

(2) Federal civilian employees receive matching contributions from their employing agencies for their contributions to the Thrift Savings Fund, but the costs of requiring such a matching contribution from the Department of Defense could be significant.

(b) REPORTING REQUIREMENT.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Defense shall report to Congress on—

(1) the cost to the Department of Defense of providing a matching payment with respect to contributions made to the Thrift Savings Fund by members of the Armed Forces;

(2) the effect that requiring such a matching payment would have on recruitment and retention; and

(3) any other information that the Secretary of Defense considers appropriate.

TITLE II—SPECIAL SURVIVOR INDEMNITY ALLOWANCE FOR SURVIVING SPOUSES OF ARMED FORCES MEMBERS

SEC. 201. INCREASE IN MONTHLY AMOUNT OF SPECIAL SURVIVOR INDEMNITY ALLOWANCE FOR WIDOWS AND WIDOWERS OF DECEASED MEMBERS OF THE ARMED FORCES AFFECTED BY REQUIRED SURVIVOR BENEFIT PLAN ANNUITY OFFSET FOR DEPENDENCY AND INDEMNITY COMPENSATION.

(a) PAYMENT AMOUNT PER FISCAL YEAR.—Paragraph (2) of section 1450(m) of title 10, United States Code, is amended—

(1) in subparagraph (E), by striking ''and'' after the semicolon; and

(2) by striking subparagraph (F) and inserting the following new subparagraphs:

''(F) for months during fiscal year 2014, $150;

''(G) for months during fiscal year 2015, $200;

''(H) for months during fiscal year 2016, $275; and

''(I) for months during fiscal year 2017, $310.''.

(b) DURATION.—Paragraph (6) of such section is amended—

(1) by striking ''February 28, 2016'' and inserting ''September 30, 2017''; and

(2) by striking ''March 1, 2016'' both places it appears and inserting ''October 1, 2017''.

MOTION OFFERED BY MR. WAXMAN

The SPEAKER pro tempore. The Clerk will report the motion.

The Clerk read as follows:

Mr. Waxman moves that the House concur in the Senate amendment.

The SPEAKER pro tempore. Pursuant to House Resolution 532, the motion shall be debatable for 1 hour, equally divided and controlled by the chairman and ranking minority member of the Committee on Energy and Commerce.

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. Madam Speaker, I yield myself such time as I may consume.

It is hard to believe that we have finally reached this day. After more than a decade of effort and with countless delays and defeats along the way, at last we are about to enact truly historic legislation to protect the public health and to end the tobacco epidemic.

I am proud that we have made it to this point, but it has taken us far too long. It has been more than 45 years since the landmark Surgeon General report that found that cigarette smoking was responsible for a 70 percent increase in the mortality rate of smokers over nonsmokers and a 10 to 20 times greater risk of developing lung cancer. Forty-five years. That delay is a tragic testament to the power and influence of Big Tobacco in our country and on Congress. But that power is fading. Times have changed. Public opinion has changed. And the tobacco industry's ability to block essential public health legislation has come to an end.

Today is a day when strong and effective regulation finally is established as the crucial counterweight to the efforts and even deceptive practices of this industry. This is the day when Americans can begin to truly kick the habit with the full force of our laws marshaled to protect consumers, and especially our young people.

Many of us remember vividly the milestones that have led us to this moment. In 1994, tobacco executives stood up before my subcommittee and swore under oath that nicotine was not addictive. In 1996, the FDA tried to regulate tobacco products, but the Supreme Court told them they needed Congress to give them that specific legal authority. And now, 13 years later, here we are finally giving FDA that authority to regulate the leading preventable cause of death in America.

Regulating tobacco is the single most important thing that 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.

I am pleased that the Senate acted quickly and sent us back legislation nearly identical to what we passed 2 months ago with overwhelming support in this House. This legislation will direct FDA to end marketing and sales of tobacco to kids, to stop manufacturers from calling cigarettes ''light'' or ''less dangerous'' when they're not, and to require changes to what is in a cigarette, like toxic ingredients such as formaldehyde, benzene, radioactive elements, and other deadly chemicals.

Some have objected that this bill is too big a challenge for an already overburdened FDA. I disagree. It's clear to me that FDA's recent struggles are primarily a result of years of chronic underfunding and a failure of leadership in the last administration.

This history does not mean that FDA, with the strong and committed leadership it now has, cannot take on this critical role of protecting the country against the harm from cigarettes and other tobacco products. It simply means that when we give the agency this new responsibility, we must also 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 new user fees 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 setting up this system, we have ensured that the new tobacco program will have no impact on other vital programs at FDA. In fact, the agency's new commissioner, Dr. Margaret Hamburg, has expressed her enthusiastic support for the bill as a ''major advance in protecting the public health.''

In a recent letter to Senator KENNEDY about this legislation, Commissioner Hamburg made clear that FDA is eager to begin carrying out its new responsibilities under this law. President Obama has also praised this legislation as both historic and common sense, describing it as an integral part of his plan to protect America's children and reform our health care system. It's clear that this administration and FDA itself are more than ready to take this on, and we just need to give them the law that will allow them to begin.

In the bill, we have provided everything necessary to take this historic step: a comprehensive and flexible set of new authorities and full, certain funding. The final ingredient is the political will to do the right thing. For the first time in many years, we have finally got that, too.

The breadth of support for this bill is remarkable; it includes over 1,000 medical, public health, faith and community groups from AARP to the American Academy of Pediatrics, from the Southern Baptist Convention to the Islamic Society of North America. It is supported by the American Lung Association, the American Heart Association, the American Cancer Society, the groups that are best situated to understand the damage caused by tobacco and to recognize that a renewed FDA can and must take on this new authority.

The diversity of support for this bill shows just how critical it is to all Americans. Tobacco does not discriminate when it robs people of their health, their productivity, and their lives. That is why we must come together to rob tobacco of its influence over Americans.

Finally, I want to note that this bill reflects a number of changes made throughout the process to respond to specific concerns that we've heard. In committee consideration of this bill over the past 2 years, we made changes to ensure fairness and flexibility for convenience stores, tobacco growers, and small manufacturers. We worked with Republican colleagues to incorporate their suggestions. We worked with members of the Congressional Black Caucus to ensure that menthol cigarettes will be an early focus of attention by the agency, and that the agency has the authority to deal with these and other products.

I know that the Senate also has made changes to further strengthen the bill in response to input from both sides of the aisle. I want to thank my colleague, Representative TODD PLATTS, for his strong leadership on this legislation, as well as Representatives JOHN DINGELL and FRANK PALLONE for their diligent work in moving this bill forward over the years.

I also want to thank Representatives ED TOWNS, STEPHEN LYNCH and IKE SKELTON, all of whom were critical in getting us to this point. Each of these individuals made this possible and produced a great victory for public health.

Today is a tremendous day. I am proud to be part of this historic moment when Congress finally stands up to Big Tobacco and stands up for the health of all Americans. That is the task before us as we send this bill on to the President of the United States.

Madam Speaker, I wish to reserve the balance of my time.

Mr. BUYER. Madam Speaker, I yield myself such time as I may consume.

I would like to congratulate HENRY WAXMAN and Senator KENNEDY and others with regard to their tenacity and persistence over the years. What is unfortunate is that we were not able to incorporate harm reduction strategies. It is also unfortunate that we are continuing to place more burdens and responsibilities upon FDA.

What I had sought to do is to regulate tobacco. I do not smoke, I do not encourage anyone to smoke. The health risks associated with smoking, I believe people recognize them and are cognizant.

Tobacco is an adult product. It's legal. And we are faced with this question of moralism versus pragmatism. And you have to be careful when you go down this path in weighing the balance of moralism versus pragmatism. So what I had sought to do was choose the pragmatic side of the equation and to incorporate a harm reduction strategy with the abstinence approach in the Kennedy-Waxman legislation.

While the authors of the bill, Madam Speaker, would say, Well, STEVE, we have harm reduction in the bill. Well, it is mentioned in the bill, but there is a 2-tier standard in the bill that has been cleverly written in a manner to be an entry barrier to new innovative tobacco products. And that 2-tier standard is one that first must be achieved at the individual level, and then you must achieve this standard at the public at large. And the purpose is truly an entry barrier.

Now, if we wanted to work together and truly have a new scientific, pragmatic approach to improve the public health of our country, we would be doing both; we would be doing abstinence along with harm reduction. You see, that's exactly what HENRY WAXMAN and others in this body do when it comes to teenage sex. They say, okay, by this body, Democrats and Republicans enjoin, we have both; we promote abstinence while also we have policies that promote harm reduction in our efforts to lower sexually transmitted diseases.

With regard to HIV, there are needle-exchange programs while we also try to promote abstinence. But all of a sudden now, when it comes to tobacco, approaches that we take in other forms of public health, whether it's in sanitary issues or whether it's in teenage sex issues or in HIV issues, all of a sudden we don't want to apply it to tobacco. It is a curious thing for me that we don't want to apply harm reduction strategies to tobacco.

So I would say to my good friend, Mr. WAXMAN, I think where we are is that you can have your day in the light, you have earned it, but we are going to have to come back to the table because what we have done is we have locked down the marketplace. You have given a big checkmark to Phillip Morris and said that your market share is okay. And when you lock down the marketplace, and we then stifle innovation and we do not have competition in that marketplace, we truly don't have the ability, then, for these companies to track at-risk capital to make investments in a harm reduction strategy whereby we can migrate people down the continuum of risk.

□ 1030

So if this bill becomes law, we've got some real challenges in front of us. One of them is how do we stand up this new mission within FDA, an agency that is already very stressed and underresourced, and we're already going to be addressing issues in the committee regarding food safety and drug safety while we pile on more missions.

So I would say to my good friend that as soon as this bill is signed into law, a couple of things are going to happen. Number one, the lawyers will make a run to the Federal courts, and the Supreme Court will be back sitting in judgment over the provisions on advertising restrictions, not only potential unconstitutional provisions on the First Amendment with regard to the regulation of commercial speech, but also in the Fifth Amendment with regard to whether it's a constitutional taking or not.

So while that is going on, I will introduce legislation, I'll work with Ms. HARMAN, I'll work with others, I'll work with the chairman, on how we can best incorporate these harm-reduction strategies to truly improve public health.

Madam Speaker, I embrace the sincerity of Mr. WAXMAN and Mr. KENNEDY that they truly want to improve public health in the country, but this legislation, when we lock ourselves down to only what is presently available and that these nicotine replacement therapies only have a 7 percent success rate, I don't believe anyone here would endorse a 7 percent success rate as a good thing. It's failure. So we are going to have to go back to the drawing board here and figure out how we do a harm-reduction strategy to improve public health.

Madam Speaker, I reserve the balance of my time.

Mr. WAXMAN. Madam Speaker, I want to inform my colleagues that there is a section in this bill that gives the FDA authority to develop harm-reduction strategies, and I think that's where it ought to be, in the hands of people who will follow the science in order to protect the public health.

Madam Speaker, I yield, at this time, 2 minutes to the chairman of our Health Subcommittee of the Energy and Commerce Committee, who has been a staunch supporter of this legislation and has looked after all the health matters that come before the Congress, the gentleman from New Jersey (Mr. PALLONE).

Mr. PALLONE. I want to thank Chairman WAXMAN for his tireless work on this tobacco legislation. Madam Speaker, today is long overdue, and he should be so proud of the fact that this is finally passing today and going to the President's desk.

As we pursue serious and historical health care reform, this legislation comes at the right time. Smoking kills. Smoking also is a major cause of cardiovascular disease, cancer, and a host of other illnesses. Almost half a million Americans die from their own cigarette smoking a year. And even more alarming, studies have estimated that more than 6 million children alive today will ultimately die from smoking.

In President Obama's call for health care reform, he cited the need to use our resources wisely and efficiently. Tobacco is a health care issue that taxes and burdens our health care system. The costs to private and public payers are over $96 billion annually. Regulating tobacco products is a win-win for our Nation's health and our need to be fiscally responsible in a time of economic hardship.

This bill will finally give the FDA the authority to regulate tobacco products, restrict tobacco marketing, especially the marketing techniques designed to entice and addict our children. They are vulnerable and impressionable, and the tobacco industry exploits that.

I was proud to be an original cosponsor of this bill in the House, and I'm even prouder to vote for this bill today because I know that it is long overdue.

Mr. BUYER. Madam Speaker, I yield myself 30 seconds to respond to my good friend Mr. WAXMAN.

To say that harm-reduction strategies are best left to the FDA gives me great concern. If you truly believe that, then you should have never set a 2-tiered standard and built a paradigm in which they are to make judgments, if you truly believe that they're the ones who should have designed the strategies to improve public health. So I would be more than happy to work with the gentleman to repeal the 2-tiered standard if we're going to let them set the standard based on sound science to improve public health.

Madam Speaker, I now yield 2 minutes to the gentleman from Pennsylvania (Mr. PLATTS).

Mr. PLATTS. I appreciate the gentleman's yielding time to me, especially given that we have different views on this piece of legislation.

Madam Speaker, I rise in strong support of H.R. 1256, the Family Smoking Prevention and Tobacco Control Act. I appreciate the Senate's swift consideration of this bill. After many years of consideration, I'm pleased that this important public health legislation will finally be signed into law.

As one of the deadliest products on the market, tobacco must be subject to the same serious regulation and oversight that most other products consumed by Americans are subject to. This bill will help to ensure that Americans are fully aware of the harmful effects posed by tobacco products.

Most importantly, this legislation will ensure that tobacco products are not advertised to or sold to children. Addiction to tobacco begins almost universally in childhood and adolescence. 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 sponsorship of sporting 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 will go a long way in preventing young people in America from starting to smoke and will save billions of dollars and, most importantly, countless lives in the years to come.

It is important to emphasize that this bill does not ban tobacco products. Rather, H.R. 1256 allows the FDA to scientifically evaluate the health benefits and risks posed by ingredients in cigarettes and takes steps to reduce the harm caused by tobacco products. This legislation preserves an adult's choice to smoke and makes sure that tobacco products marketed as safe alternatives to cigarettes are, in fact, scientifically safer.

I am pleased to have worked with my colleague, the distinguished chairman of the House Energy and Commerce Committee, HENRY WAXMAN, the gentleman from California, on this legislation. I commend him for his leadership on this issue as well as former Congressman Tom Davis.

I encourage a ''yes'' vote.

Mr. BUYER. Madam Speaker, I yield myself such time as I may consume.

It is nicotine that causes the consumption of tobacco. So I understand how truly, in my words, outraged then Chairman WAXMAN was and still is with regard to testimony that occurred years ago when he was the chairman of the Subcommittee on Health.

Now, if it is the nicotine from which adult users receive their satisfaction, the real issue is how do they gain access to nicotine in a manner that reduces their health risk? That's the issue. That's my passion.

I am not a smoker. I don't advocate for people to smoke. My charge and challenge is how do we improve public health in our country? And I don't want this abstinence-only approach. So if it's nicotine for which people want to gain access to and it's an adult product, then shouldn't we be trying to figure out methods or products where people can gain access to nicotine that is less harmful?

During the debate on the rule, Madam Speaker, I would share to my colleague, Chairman WAXMAN, an individual brought up a head of lettuce and said that there is more regulation on a head of lettuce than tobacco. And I guess it was an effort to be cute, but the real point here is what I shared, Madam Speaker, and to my friend Mr. WAXMAN, you could have smoked that lettuce and you would still end up with the same problems. You could cut the grass in your yard, dry it and roll it up in a cigarette and smoke it, and you're still going to have a lot of problems. It is the smoke that kills, not the nicotine. It's the smoke.

So when you look and you say, well, if the smoke is the killer because of the inhalation of the tobacco smoke, that's responsible for the pandemic of cancers, heart disease, respiratory disease, and these deadly results.

So I'm going back to this harm reduction. So despite decades of intense efforts to eradicate smoking, more than 40 million adults continue to smoke cigarettes, and they're likely to continue because we don't have this ability to migrate them to other products. It's extremely important, when we talk about a harm-reduction strategy, that not only is it the access to a particular product, it is the education of the people at large as to what type of products that they can avail themselves to that have less harmful health results. That should be our goal and that has been embraced.

The American Association of Public Health Physicians noted last year, Enhancement of current policies based on the premise that all tobacco products are equally risky will yield only small and barely measurable reductions in tobacco-related illness and death.

So in the public debate, there is sort of this presumption that all tobacco products are harmful. Well, all tobacco products have a degree of health hazards, but some are more harmful than others. So cigar and pipe are not subject to this legislation; yet they are the most harmful to the human body of all of the carcinogens that can be inhaled.

So how do we migrate people? And I think that's what is extremely important. And let's stop this premise that all tobacco products are equally risky; that Swedish snus, even though it's 98 percent less harmful than an unfiltered cigarette, should not be treated as though they're both just as harmful. They're not. If you're able to pasteurize and take away the nitrosamines, yet people can gain access to their nicotine, you know what? That ought to be something we should talk about. That ought to be something we should promote.

And the reason, Madam Speaker, that if we just turn this over to the FDA, like Chairman WAXMAN has just suggested, and let them come up with these strategies, it's not going to be able to get into the hands of the American people because of the 2-tiered standard that has been set in this legislation.

Madam Speaker, I reserve the balance of my time.

Mr. WAXMAN. Madam Speaker, I yield 3 minutes to my esteemed colleague from the State of Minnesota (Mr. OBERSTAR).

Mr. OBERSTAR. I thank the gentleman for yielding, my good friend and colleague of 34 years ago. We entered Congress together.

I do not propose to read this entire document, but it is the report of the hearings, the committee report conducted by my predecessor in Congress, John Blatnik, in 1957 on false and misleading advertising among a number of products and the failure of the Federal Trade Commission to intervene on behalf of the public.

The leading testimony on false and misleading advertising on filter-tipped cigarettes was a statement of Dr. Kyler Hammond, Director of Statistical Research for the American Cancer Society: We found lung cancer death rates to be extremely low among nonsmokers and high among heavy cigarette smokers; 2,665 excess deaths, and this was 1957, among smokers. The conclusion of Dr. Hammond: The sum total of scientific evidence establishes beyond reasonable doubt that cigarette smoking is a causative factor in the rapidly increasing incidence of human epidermoid carcinoma of the lung.

Fifty-two years ago and we still have people in this Chamber and in the other body saying it's not a problem.

□ 1045

The report of the committee goes on to say, Benzpyrene is one of the substances containing carcinogenic agents. A known cancer-producing agent has been found in the smoke from cigarette paper and an amount from the tobacco itself. This component is known as 3,4-benzpyrene.

The report of the committee concludes:

The cigarette manufacturers have deceived the American public through their advertising of filter-tip cigarettes. Ironically, while denying the alleged health hazards of cigarette smoking, the industry has, in its advertising, made these charges appear true. Filter gives you more of what a filter is for, clean smoking; snowy white; pure; miracle tip; 20,000 filter traps, gives you more of what you changed to a filter for.

The committee concludes:

The Federal Trade Commission has failed to approach the problem of false and misleading advertising.

They failed then, 52 years ago. They failed us today. It is way long past time, many millions of deaths later, for this Congress to act decisively in the public interest. And also as a tribute to my predecessor, John Blatnik, who led this charge 52 years ago and who was rewarded with dissolution of his subcommittee for having rung the bell on false and misleading advertising by the cigarette companies.

Mr. WAXMAN. Madam Speaker, I am pleased at this time to yield to one of the people without whom this bill would not even be possible, and that is the Speaker of the House, NANCY PELOSI, who has been such a strong leader for advancing the public health.

The SPEAKER pro tempore. The gentlewoman from California is recognized for 1 minute.

Ms. PELOSI. Madam Speaker, I thank the gentleman for his generous recognition and rise to say, as a mother and a grandmother, what an important day this is for America's children and to say thank you to Mr. DINGELL. Some of the giants of the Congress have worked to help the children of America. Mr. DINGELL, Mr. WAXMAN, and Mr. PALLONE on the committee. On the Senate side, this legislation passing also is a real tribute to the leadership of Senator TED KENNEDY. It's really a great day. It's momentous. It's historic. We can't say that all the time about the legislation that we pass here. It would be impossible to exaggerate the importance of what is happening here today.

Today we have an opportunity to protect public health and prevent disease; and today we have an opportunity to honor our responsibility to our children, to protect them from the harm that can come to them from the use of tobacco.

Madam Speaker, tobacco is the number one cause of preventable deaths in the United States. According to the Centers for Disease Control, it is responsible for about one in five, or 443,000, deaths annually. Again, I want to acknowledge the great work of Chairman WAXMAN, Chairman DINGELL and Chairman PALLONE. We passed this bill before Easter. Happily last night, yesterday, it passed the Senate so that we can now pass the bill and send it to the President's desk for his signature.

Mr. OBERSTAR, in his role on Transportation and understanding how we

had to get smoking out of Transportation, spelled out for us what the study told us and how it has been 52 years since we should have taken action. There is so much support on the outside of the Congress as well. A thousand organizations, everyone from the American Cancer Society, which we would suspect, the Campaign For Tobacco-Free Kids, the AARP, and the Presbyterian Church, just to name a few. They believe that passing this bill will save lives.

Every day Americans benefit from the oversight of the FDA on foods that we eat and medicines we take. That's their jurisdiction. Yet despite the fact that tobacco is one of the deadliest products in America, the FDA has had no authority to regulate it. This is just not right, and today we can correct that wrong. Right now tobacco is exempt from standards that apply to a can of soda or a box of pasta. Tobacco makers are exempt from critical and basic consumer protections, such as ingredient disclosure, product testing and restrictions on marketing to children.

This legislation grants the FDA the authority to regulate tobacco products. It also requires detailed disclosure of tobacco product ingredients and restricts tobacco marketing and sales to young people, among other things. And this legislation does all of this in a fiscally responsible way, funding the FDA tobacco activity through a user fee on tobacco manufacturers.

Because of lost productivity and health care expenditures, cigarette smoking costs our Nation more than $193 billion a year, almost $200 billion a year. By reducing the number of smokers, not only will this legislation save lives and reduce chronic disease, it will also reduce health care costs.

Today, approximately 3,500 young people will try a cigarette for the first time and another 1,000 will become addicted and become new regular, daily smokers. One-third of those children will eventually die prematurely because of smoking. We must do all that we can to prevent premature death from smoking, and today we have that opportunity.

Madam Speaker, I urge all of my colleagues to support the aptly named Family Smoking Prevention and Tobacco Control Act. I hope that the children of America will see a strong bipartisan vote. This legislation deserves it, and then we can send it on to the President to be signed into law hopefully no later than next week.

Again, Mr. DINGELL, as a mother and a grandmother, I'm deeply in your debt for what you're doing for America's children. Mr. WAXMAN, thank you so much for bringing this bill to the floor. We went into session in January. Before Easter this bill had passed the House. Thank you for your leadership. Mr. PALLONE was very much a part of it. Again, Mr. OBERSTAR, thank you for your leadership.

But let's just say about Senator KENNEDY, this has been part of his life's work. He's worked on this for a very long time, of itself, discretely, the tobacco and smoking issue and then, of course, just as with Mr. DINGELL, the larger health issue for America. Today in passing this legislation, enabling the FDA to regulate tobacco, we are taking a giant step forward in making America healthier. Thank you all for your leadership.

Mr. BUYER. Madam Speaker, I yield myself as much time as I may consume.

It is with great disappointment that I hear the words of the Speaker because she is truly endorsing a 7 percent success rate as an acceptable level of success for those who are trying to quit smoking. Also, if we really wanted to try to help children, then she should have endorsed what I sought to do; that is, put tobacco on an equal plain as alcohol to make it illegal to possess. But we're not doing that today.

I also said that the States, with regard to the MSA, the Master Settlement Agreement, the States are not spending the money like they should. In the last 10 years, States have spent just 3.2 percent of their tobacco-generated revenue on prevention and cessation programs. In the current fiscal year, no State is funding tobacco prevention programs at levels recommended by the CDC. So I had offered an opportunity here to the body to strengthen and truly protect children, yet it was not adopted by this body. So be very careful about coming to the floor and saying we're doing it for the children when, in fact, the opportunity was there and you did not.

I now yield 3 minutes to the gentleman from Texas (Mr. PAUL).

(Mr. PAUL asked and was given permission to revise and extend his remarks.)

Mr. PAUL. I thank the gentleman for yielding.

Madam Speaker, I don't think anybody can argue at all with the intentions of the proposal of this bill. There is no question that cigarettes are very harmful. The question for me here is the process, and I find the process here atrocious because it assumes that authoritarianism is right, proper and that it works and that volunteerism, education, self-reliance and depending on oneself to take care of oneself is a proper approach. We totally reject our free society and assume that if we just have tobacco police roaming the country, that all of a sudden bad habits are going to be cleared up. We're dealing with bad habits, and these are bad for health. But let me tell you, I can bring you a list here of dozens and dozens of bad habits that lead to death. As a matter of fact, one of the things that we ought to consider is, how many people die from our drug war? We have a drug war, and about 3,000 people die from the use of illegal drugs. So we have a drug war going on, and tens of thousands of people die.

It's so exasperating at times because we always have two proposals here, or we have two ways of solving problems or dealing with tobacco. For decades, what did we do? We subsidized tobacco, and now we want to prohibit tobacco. Why don't we just let the people decide. This whole idea of either having to subsidize something or prohibit something shows a shallowness that I think we ought to challenge.

One part of this bill that I find particularly bad, but it is pervasive in so much of what we do, about 100 years ago we took the First Amendment and freedom of speech and chopped it into two pieces. We have political speech. Of course we like that. We're in the business of politics. But we take commercial speech, and we put it over here, and we regulate the living daylights out of commercial speech. That's not a First Amendment. That's chopping freedom in half, and that just leads to more problems. But this will lead to prohibition, and it won't work. This will just give us a lot more trouble.

You say, Well, how will these problems be handled if we just permit people to advertise? Well, you are not allowed to commit fraud; you are not allowed to commit slander; you are not allowed to commit any libel or slander or fraud. So there are prohibitions. But this approach can't work. It is assumed that people are total idiots, that they won't respond to education, that we have to be the nanny state. We want to expand the war on drugs, which is a total failure.

And look at what happened to the prohibition of alcohol. You say, Well, no, this is not going to be a prohibition. It is going to be prohibition. This is a form of prohibition. When you have prohibition or even approach prohibition, what do you create? You create the black market. We will see the black market come. Already the taxes are opening up the doors of the black market.

All I ask for is people to reconsider, believe that freedom, self-reliance and individualism can solve these problems a lot better than a bunch of politicians, bureaucrats and tobacco police here from Washington, D.C.

Mr. BUYER. I yield myself 30 seconds.

I would say that the gentleman and I are not always in total agreement. The substitute that I brought to the floor actually sought to regulate tobacco, and I know you did not agree with my substitute. I believe in the regulation of tobacco. I sought to do that. I just don't believe it should be done in FDA. We tried to create a harm reduction center to do that. But I respect the gentleman's views.

I reserve the balance of my time.

Mr. WAXMAN. Madam Speaker, I am pleased at this time to yield 3 minutes to the very distinguished chairman emeritus of the Energy and Commerce Committee, the gentleman from Michigan (Mr. DINGELL), who has played an essential role in fighting against tobacco and getting us to this day today.

(Mr. DINGELL asked and was given permission to revise and extend his remarks.)

Mr. DINGELL. I thank my good friend and colleague, the chairman of the committee, Mr. WAXMAN; and I commend him for his leadership on this matter. I am also delighted that we have this bill on the floor today. I urge my colleagues to support the Family Smoking Prevention and Tobacco Control Act. I would point out that we will be shortly following it up with legislation to protect Americans from dangerous foods and to give the Food and Drug Administration the authority and the money which it needs. That will be followed by additional legislation to address the question of pharmaceuticals.

I urge my colleagues to recognize that this not only does what needs doing, but it also gives to the Food and Drug Administration the authority and the money which it needs and the personnel which it needs to carry forward its mission as it goes about its business. I would point out, for too long we have starved them for authority, resources and personnel. It is time something be done about this. I am not going to give you an argument about this situation—that will be in my written extended remarks—but I want to tell my colleagues that the graveyards are full of people who occupy those places because they smoked and because we tried volunteerism.

□ 1100

Well, volunteerism filled the graveyards, and the constant attacks that have been made on the Food and Drug Administration and the deprival of proper authority to carry forward its responsibilities and the personnel it needs have brought us to the situation where we have to do the kind of thing that we are saying.

So don't talk to me about volunteerism. Understand that it has failed calamitously and people are dying every day because they have smoked.

Having said that, I want to tell you a little story about when we passed the first legislation to begin to warn people about the dangers of tobacco that were found by the Surgeon General in his report to the United States and to the Congress.

A little guy came before the committee, and he testified before my dear friend John Moss and I, who were the major proponents of that particular legislation at that time. He said, Now, you don't know me, but I am a pathologist and an internal medicine man. That means that I can tell you why you are going to die, or I can tell you why you did die.

He said, I don't have a prepared statement here today, but I do have a number of exhibits I would like to present to the committee.

So he reached in his briefcase and he pulled out a human lung. He said, Now, this is a normal person's human lung. It had a certain life to it.

The next exhibit he pulled out was one of a fellow who had died of squamous cancer. He said, These are squamous cells. It looked like a bowl of caviar, a painful way to go.

He then showed us the lung of somebody who had died of emphysema. It was white. It lacked life. He said, This man literally strangled because he did not have the ability to derive the oxygen from the air.

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

Mr. WAXMAN. I yield an additional 1 minute.

Mr. DINGELL. I thank the gentleman.

He pulled out another lung. He said, Now, this is the lung of a smoker. It was black, dirty and nasty, and you would not want to have it inside of you.

He said, Now, my message to the committee is very simple. If you smoke long enough, you are going to die of cancer of the lung or you are going to die of some other kind of ailment which is induced by your smoking, whether it is of the lung or whether it is of some other organ, including the mouth, the throat, or another part of the body as far away as the fingertips.

I just want my colleagues to understand, finally we are doing something. If a person wants to be silly enough to smoke, he can still do so; but he is going to get a warning, and the tobacco companies are going to have to provide proper, decent, honorable behavior, and they are going to have to do the things that warn the American people of this.

We have a responsible agency which this legislation will properly fund and finance. We will give them the authority and the personnel and the capabilities of doing what they need to do. We are going to follow it with other legislation.

I urge my colleagues to support this and support the other legislation when it comes.

I rise today in strong support of the Senate Amendment to H.R. 1256, "Family Smoking Prevention and Tobacco Control Act".

The decision to vote in favor of today's bill is a very easy one. It was an easy one, because I am convinced that the "Family Smoking Prevention and Tobacco Control Act" will go a long way in regulating the most unregulated consumer product on the market today. A product which:

Is the leading preventable cause of death in the United States;

Kills more than 400,000 Americans annually; and

Accounts for more than $96 billion in health care costs every year.

Every day, approximately 3,500 kids will try a cigarette for the first time, and another 1,000 we become new, regular habituate smokers.

The legislation will restrict marketing and sales to youth; grant FDA authority to restrict tobacco marketing; require detailed disclosure of ingredients; and allow FDA to require changes to tobacco products to protect the public health.

I commend Chairman WAXMAN and my dear friend, Senator KENNEDY, for their persistent leadership on this legislation in the Congress. I am honored to have my name associated with the legislation and for the opportunity I had to work with them on this issue.

Madam Speaker, I know firsthand that the "Family Smoking Prevention and Tobacco Control Act" is good piece of legislation. I had the distinct pleasure of shepherding it through the Energy and Commerce Committee last year. Today's legislation largely reflects the work we did then.

Madam Speaker, this legislation has been in the works for a long time. Nothing stands in our way to send it to the President's desk. I urge my colleagues to vote in favor of the "Family Smoking Prevention and Tobacco Control Act"—the American people need it and they deserve it.

Mr. BUYER. Madam Speaker, I now yield 2 minutes to the gentleman from California (Mr. MCCLINTOCK).

Mr. MCCLINTOCK. I thank the gentleman for yielding.

Madam Speaker, many years ago, author and commentator Bruce Herschensohn made the point that for every pleasure in life, there is a corresponding risk. I think that is a universal truth: for every pleasure in life, there is a corresponding risk.

And he pointed out it is true that with enough taxes and laws and restrictions and regulations and penalties and lectures, government can produce a virtually risk-free society, but it will also be one of the most colorless, pleasureless, tedious, and miserable societies ever conceived by the mind of man.

I think that is the case. The health dangers of smoking are real and they are well-documented. We all agree on that. It is a very bad thing to do.

Our schools rightly make a concerted effort to inform every child of the health risks associated with tobacco products, and they do a good job of it.

Our government warns every adult of the risks associated with tobacco products, and they do a good job of it, too.

As a result, I don't believe there is a single individual in the United States today who doesn't well and fully comprehend the health dangers of tobacco. But once those warnings are issued, how much further should government go to make individual decisions for rational adults as they weigh the risks of smoking for themselves? Personally, I think they are making a very bad decision, but they probably think others are making bad decisions when they decide to go skiing or bungee jumping or sky diving or thousands of other pleasures that incur corresponding and calculated risks.

I would ask today, whatever happened to the notion of individual responsibility? And whatever happened to the notion, as Jefferson put it, of a wise and frugal government, which shall restrain men from injuring one another, but shall leave them otherwise free to regulate their own pursuits of industry and improvement?

Mr. WAXMAN. Madam Speaker, I yield 2 minutes to the gentlewoman from Illinois (Ms. SCHAKOWSKY), a member of the Health Subcommittee.

Ms. SCHAKOWSKY. Madam Speaker, I rise today in strong support of H.R. 1256, the Family Smoking Prevention and Tobacco Control Act. I do it with enormous gratitude to Chairman WAXMAN for working for years to get legislation of this sort that would improve public health by strengthening the regulation of tobacco products.

There are a lot of diseases that we don't have the cure for today. There are lots of resources put into medical research that hopefully will find a cure to cancer and to AIDS and other terrible diseases. But we do know how we can prevent over 435,000 tobacco-related deaths that occur each year, and that is by preventing smoking.

There are over 44 million smokers in the United States of America. In Illinois alone, 24.3 percent of adults and 29.2 percent of youth smoke tobacco. In Illinois, 16,000 people die from smoking-related illnesses and 29,000 adults and children die of secondhand smoke in Illinois. In addition, $3.2 billion is spent in direct medical expenditures related to smoking in Illinois. And every day 4,000 kids try their cigarette, and about half of them become addicted.

Finally, we have legislation giving the FDA the power and resources to regulate the tobacco industry and safeguard the public health and our children. It would lessen the cost of smoking-related medical illnesses and prevent adolescents and teens from smoking at a young age.

In Illinois, I want to congratulate Alexandra Slane, an elementary school student from Peoria, Illinois, who won the Tar Wars anti-smoking annual poster contest with her drawing of a light bulb shaped as a human head. She wrote the caption in the human-shaped light bulb warning America, ''Be Bright, Don't Light.''

Let's start by passing H.R. 1256.

Mr. WAXMAN. May I inquire how much time each side has.

The SPEAKER pro tempore. The gentleman from California has 9½ minutes remaining. The gentleman from Indiana has 10 minutes remaining.

Mr. WAXMAN. We have no other requests for speakers and I would like to close the debate. We continue to reserve our time.

Mr. BUYER. Madam Speaker, there are a couple of issues that I would like to address that I mentioned in my opening. The last two issues that I will address are, one, on the constitutionality, and, secondly, is the FDA the right agency.

While we all agree that steps need to be taken to help lessen the use of tobacco products by underage youth, we must not do so in ways that clearly violate the First Amendment. Unfortunately, the bill in front of us I believe fails to meet that test.

The speech restrictions in this bill are clearly the most sweeping in the history of the United States for any legal product. Numerous top legal experts from every point of the political spectrum have looked at these provisions and declared that they will not meet First Amendment scrutiny.

During the debate on the rule, I questioned the responsibility of this body. I believe it is irresponsible for us to pass legislation that is prima facie unconstitutional.

What we are doing in this body is two things: we are taking the regs from the 1996 rule that the Supreme Court found unconstitutional and we are making them statutory, which means, attention to lawyers in America: you have an access and avenue right back to Federal Court immediately upon the President's signature of this legislation.

Also under the Constitution, private speech, private speech and the regulation of private speech among individuals, that is, companies, if individuals seek to restrict their speech between themselves or how they seek to communicate, they can do that in the private marketplace between themselves. Where the First Amendment comes in is when governments, States, municipalities or the Federal Government then step in and begin to regulate speech.

In this case, it is commercial speech, and that is what we are doing. When we take the MSA, the master settlement agreement, and also place these restrictions and then make them statutory, bang, we are right back to the Supreme Court. And I just find that very bothersome.

Larry Tribe, the noted constitutional expert and Harvard University law professor, commenting on the types of provisions in this legislation, stated, ''Given the extensive regulation of tobacco manufacturing (for example, the creation of manufacturing standards, the regulation of cigarette ingredients, and so on) elsewhere in the proposed legislation, and the mandates for new and improved warnings, it would be difficult to defend the sweeping restrictions on advertising as being narrowly tailored to an important governmental interest. The paternalistic view that tobacco advertising must be restricted because consumers might find it pervasive is antithetical to the assumption on which the First Amendment is based.''

Wow. Now you are going to find me quoting the American Civil Liberties Union. You may want to listen to this, because it is probably the first time I have ever cited the ACLU.

They also said in their testimony on identical language contained in this legislation, they stated if this type of legislation were to be passed, it would be ''wholly unprecedented'' and ''will most likely fail to withstand constitutional challenge.''

On the other side of the spectrum, the Washington Legal Foundation and Judge Bork also have called these proposals ''patently unconstitutional.'' Numerous other legal scholars have taken similar positions.

Now, in our zeal here to restrict tobacco products, there have been these comments by some, Madam Speaker, to say we are doing it for the children. It is wonderful. We can say we are doing it for the children. What does the Court say about that?

The Supreme Court has already examined one of the provisions in the FDA proposal, and that is the 1,000 foot ban on outdoor adds, and has suggested it violates the First Amendment because it is not narrowly tailored.

The Supreme Court rejected the efforts of the Massachusetts Attorney General to ''childproof'' the flow of information in our society. Children deserve to be protected from inappropriate or harmful material, but the government may not use the guise of protecting children to impose sweeping restrictions on information intended for adults.

So we come to the floor and we say we are doing it for the children. Yet we are taking provisions which the Supreme Court has already found to be unconstitutional, i.e., commercial speech that is not merely tailored to a legitimate government interest.

In Bolger v. Youngs Drug Products Corporation, the court stated that efforts to restrict advertising cannot lower disclosure in society ''to the level of the sandbox,'' and cited in the case Butler v. Michigan that ''government may not reduce the adult population to reading only that which is fit for children.''

So the type of drastic speech censorship that is contained in this legislation is almost certain to lead to challenges in the Federal courts, and I find that troubling and counterproductive.

□ 1115

Let me move to the FDA. This bill establishes a general standard that actions by FDA are in the best interest of public health, that they're the ones, that they can reasonably be likely to have measured scientific results.

What do we mean by results?

Substantial reductions in morbidity and mortality rates among smokers. That's what we seek to achieve.

So the great challenge that I have here is that, in the committee, we are now looking at legislation with regard to food safety and drug safety. The FDA is charged with approving medical products based on scientific evidence that benefits of the products outweigh the risks. Tobacco products are inherently risk products that cause disease when used as directed.

Now, we're going to turn to the FDA and say, we want you to regulate the tobacco product. So we take the gold standard of the FDA now, and apply it to tobacco, and now there is this inference that somehow the FDA has said that tobacco's a safe product. That is something we should not be doing. It's why I sought to create a separate agency, rather than the FDA, creating a mission that is counter to their present mission.

You see, if you use a cigarette and follow the instructions, and you do

that every day, it will kill you. Now, think about that. It will kill you. We don't want the FDA to create some type of inference into society that somehow it's okay.

President Obama stated on March 14 of this year that 95 percent of America's 150,000 food processing plants and warehouses go uninspected each year. Wow. Each year, 74 million people in the United States are sickened by tainted food, and about 5,000 die, according to the CDC. That's on food alone.

Then, with regard to drugs, I look forward to working with Chairman WAXMAN, Madam Speaker, and with Mr. DINGELL, with regard to drug safety because right now we have 11 international mail facilities by the United States Government. You count the three private carriers that also have international mail facilities, and they are taking up to around 30,000 drug packages that are coming into our country by people who are going on to the Internet. Every time we do an inspection of those mail packages, we find that 80 percent of them are either counterfeit knockoffs or adulterated drugs. When, in fact, you do the math and you say, okay, wow, take that 14 times 30,000 times 365, then times 80 percent, we are looking at 96 million. Think about that. 96 million drug packages coming in. So what we're doing now is we're lumping this onto FDA, and FDA is a challenged, a very challenged agency.

I urge individuals to vote ''no'' on this legislation. There is a better way to regulate tobacco.

Mr. WAXMAN. So, Madam Speaker, it's come down to this, a musing that perhaps FDA is not the right agency; we ought to create a brand new one, but don't give them any power to do anything.

Or what we need is harm reduction, even though this legislation gives the FDA the ability to look for ways to reduce the harm from cigarette smoking.

But the best way, the best way is not to smoke. And the best way is to make sure that people don't start smoking. And if they do smoke, to give it up.

And then the next argument, it's not constitutional. And my colleague has cited the fact that he believes the Supreme Court, when they ruled on the issue of the regulations being proposed by the FDA, that they said that those were unconstitutional.

Well, the truth of the matter is the Supreme Court said FDA did not have the legal authority and that Congress had to vote to give them the legal authority to adopt those regulations. That is what we are about to do today.

I've been working on the issue of tobacco for over three decades, and in fact, I thought about this issue as I prepared a book that's going to be coming out on a lot of different issues in the next couple of weeks.

And I remember the hearings we had where the tobacco industry had so-called scientists argue there really wasn't any harm from cigarette smoking. It was just coincidental.

I remember well when the CEOs came before our committee, and that was a real turning point. And they took an oath to tell the truth, and they said, no harm from cigarette smoking; it's not connected to cancer; it's not connected to heart disease; it's not connected to all these other problems; it's only a coincidence. They said cigarette smoking was not addictive because nicotine is not addictive. They swore that under oath. They said they didn't manipulate the nicotine to make it even stronger and more addictive a product. And they said, with righteous indignation, they certainly wouldn't target kids to smoke.

Well, after that appearance in 1994, we pierced the veil that hung over the industry and started to find out what they were saying in their own corporate boardrooms and what their own scientists understood the case to be.

We later had a hearing where a scientist that worked for the tobacco industry told us he understood the harm. The industry wanted to know what harm it did, and they knew that, in fact, it caused a tremendous amount of death and disease in this country. They were looking at ways to patent new ways to raise the nicotine levels so they can keep people smoking, because they were very well aware of the fact that nicotine was addictive and they could, in fact, make sure that nicotine grabbed on to those smokers and kept them captive to that habit.

And the Joe Camel advertising campaign was marketed in France to see if it really got kids to be loyal to that brand. And in their boardroom they discussed how important it was to get kids to start smoking at 14 or 15 years of age because then they would be loyal to that brand, let alone addicted to the product.

We later found out how the tobacco industry spent millions and millions of dollars on a phony operation to say that they were studying whether the harm was there from cigarette smoking, and what they did was manipulated the media, deceived the American people, to argue the science wasn't really there to claim cigarettes was a problem. The science is still out.

By the way, we hear this about global warming today. Even though the overwhelming consensus was there from reputable scientists, they tried to make people believe, don't worry about it, you can continue to smoke; it's not going to do you harm.

And they tried so hard and successfully, for decades, to keep secret the fact that nonsmokers were harmed by simply being in the presence of smokers.

I remember the power of the tobacco industry that kept the Congress from acting, and it was by one vote that the House of Representatives decided to try and experiment to see if we could have airplane flights, commercial airplane flights of an hour or less, without any smoking permitted. And Members stood up on the floor of the House and said smokers would never tolerate such a thing.

Well, it was so widely popular that it's hard to find any airline in the world that allows smoking on airplane flights of whatever length it may be.

The public has come to understand this industry, and they know the dishonesty of this industry, and they know that the clout of this industry kept the government from acting for decades.

But people now don't realize how it was 30 years ago. Thirty years ago people who smoked felt they had the right to light up a cigarette, no matter where they were.

We've heard the argument that the Court may look at the constitutionality of any free speech matter that might relate to advisories about cigarette smoking.

Well, it's hard for me to believe that a Supreme Court that once said the Constitution does not mean that the freedom of speech allows people to yell ''fire'' in a crowded room would now come to the point where they'd say it would be unconstitutional to prohibit an industry from trying to get children to smoke a product that's illegal for them to buy in any State of the Union.

I think we are, today, at the last gasp of the tobacco industry's efforts to protect their profits at the expense of the health and lives of the American people and to get children to take up this habit. We're moving away from it fast in this country. The FDA will help us succeed in ending this tobacco epidemic.

My heart goes out to people around the world as American tobacco companies are telling people in other countries, be like Americans. If you're a woman, you can smoke—don't let your culture keep you from taking up this habit. As they tell children around the world, start smoking. You can be more like Americans who you so admire. You can be cool, and all the stuff that was blabbered out in the decades in the United States to get so many millions of people to smoke.

Madam Speaker, this bill, authored by Senator KENNEDY in the Senate and by myself in the House, has come a long way. It took us a long time to get here. But we're here now, and I urge my colleagues to vote for passage of this legislation.

Mr. VAN HOLLEN. Madam Speaker, this is a very important and historic day for the American people. I rise in strong support of the bipartisan Family Smoking Prevention and Tobacco Control Act, of which I am a proud original cosponsor. I want to thank and acknowledge the leadership of Chairman WAXMAN, Senator KENNEDY, and so many others who have fought the battles for so many years to see this day happen.

Granting the Food and Drug Administration the authority to regulate tobacco products is long overdue. The legislation is a critical step in protecting the health and well being of millions of Americans from the deadly effects of

tobacco use. It is a shame that tobacco products were not regulated in this country. Though the FDA has the authority to regulate products that are not addictive, we always had this gap in their regulatory authority when it came to the very addictive products of nicotine and tobacco products.

For far too long, the tobacco companies have taken advantage of this loophole and have exploited it by marketing their deadly products to young people. Generation after generation, the tobacco companies knowingly targeted our kids through flavored cigarettes, manipulating the ingredients in their products, false advertising and other deceiving methods—all to ensure that their profit margins remained high. In fact, they had to do that. In order for these companies to continue to make their profits, they had to find ways to hook people on tobacco products.

I am very proud of the efforts Maryland has taken to curb the effects of tobacco use. It has increased the tobacco tax and youth smoking has declined. Maryland also passed a comprehensive smokefree indoor air law in 2007. I am also proud that the Congress took steps earlier this year to decrease tobacco use by increasing federal excise taxes on cigarettes as part of the reauthorization of the State Children's Health Insurance Program.

Let's make sure that future generations of young people do not get addicted to tobacco products. Addiction to tobacco products has had a huge cost to our society in terms of lives and money by killing over 400,000 Americans each year. This legislation will save lives and money. I strongly urge my colleagues to join me in putting an end to this deadly cycle and vote yes on this very important bill.

Ms. FOXX. Madam Speaker, this bill includes more than $5 billion in new tax increases on tobacco companies and gives sweeping control of the tobacco market to the FDA. Chairman DINGELL, discussing the salmonella outbreak last summer, was quoted in The Wall Street Journal as saying that ''there's a total inability of the FDA to carry out its mission.'' This isn't the first Democrat to raise questions about the effectiveness of the FDA. It is therefore highly hypocritical of them to extend the agency's regulatory authority to a multi-billion dollar industry of which the FDA has no expertise.

This bill undermines the established purpose of the FDA. As FDA Commissioner Andrew von Eschenbach testified before the House Energy and Commerce Committee in October 2007, the FDA is an agency intended to promote and protect the public health. In the Commissioner's opinion, requiring the FDA to ''approve'' tobacco products as a result of this bill would dramatically change the agency's focus. Mr. von Eschenbach stated that ''Associating any agency whose mission is to promote public health with the approval of inherently dangerous products would undermine its mission and likely have perverse incentive effects.''

While establishing FDA authority to regulate tobacco products, this bill would also retain the FTC's federal authority to regulate tobacco advertising and circulation. It would provide only limited pre-emption of state laws, allowing more rigid state restrictions on tobacco advertising.

This bill imposes undue bureaucratic and logistical hardships on tobacco manufacturers by burying them under multiple layers of regulation. It is important to remember that the sale of tobacco is legal in the United States and is credited with hundreds of thousands of jobs across the country. We cannot afford to lose more American jobs especially when we are facing such economic challenges.

FDA regulation will have a devastating economic impact on small tobacco companies, their employees, associated businesses, and the largely rural communities which they support. Under this legislation they will not be able to comply with and afford what is sure to be a costly and complex regulatory regime.

There are some 350 small tobacco manufacturing companies throughout the United States. Together with their suppliers, vendors, distributors and tobacco growers, these companies employ thousands of people. Tobacco growing in particular has long been an important part of rural communities. As most of these companies are located in rural, economically depressed areas, the jobs, employee health and pension benefits and revenue they provide is critical to our local economies. While large tobacco companies can absorb the cost of FDA regulation, many of these smaller companies cannot. This legislation will force them to close their doors, leaving their employees jobless.

Ms. LEE of California. Madam Speaker; I rise in strong support of the Senate Amendments to H.R. 1256, the Family Smoking Prevention and Tobacco Control Act.

I want to thank Chairman WAXMAN and his staff, and Senator KENNEDY for their tireless work over the years to ensure that we could get to this moment.

The federal regulation of tobacco has been a long time coming. I'm pleased that today's action will complete consideration of this bill and send it on to the President to finally get it enacted into law.

According to the Centers for Disease Control and Prevention, smoking is the leading cause of premature death in the United States. More than one in five Americans smoke, and according to the CDC's most recent report, in 2004 this included about 21 percent of adults and more than 22 percent of high school students.

Each year about 1 in 5 deaths, about 443,000 people, are a result of smoking or exposure to secondhand smoke. And for each person who dies from a smoking related disease about 20 more are living with a smoking attributable chronic illness—or about 8.6 million people.

In addition to the significant effects of smoking on the health of our constituents, the estimated costs of smoking-related medical expenses and loss of productivity exceed $167 billion annually.

Thankfully, in my state of California we have known the dangers of smoking for a long time, and we were one of the first states to move forward in banning indoor smoking in public places, including bars and restaurants. As a result our State has the second lowest prevalence level of smoking among both adults and youth, at 14.8 percent and 13.2 percent respectively.

It is long past time that we try to take a national approach to address the dangers of smoking.

I'm pleased that this bipartisan legislation will grant the Food and Drug Administration authority to regulate the advertising, marketing, and manufacturing of tobacco products. And I'm also pleased that it takes steps to ban flavor additives, including menthol, as well as further restricting marketing directed to our children.

But passage of this bill really is just the first step. We've also got to make sure that we follow through on the regulatory authority provided in this bill to help encourage smokers to quit, and to provide help to those who choose to do so.

However I'm pleased that we are finally taking this action today, and I'm convinced that it will help to improve public health and reduce costs to our health care system in the long run.

I urge my colleagues to support this bill.

Mr. MCINTYRE. Madam Speaker, I rise today to express grave concerns about H.R. 1256, the Family Smoking Prevention and Tobacco Control Act.

This bill will grant the Food and Drug Administration (FDA) 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. The last thing we want is government bureaucrats coming on the farm!

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 over $23.9 billion.

The manufacturing provisions and ''FDA on the farm'' provisions of this bill will put many companies and growers out of business. In this time of economic uncertainty, we can't afford to lose more jobs!

In addition, the FDA is already overburdened with its food safety and drug approval mission. Placing another large regulatory burden on an already overwhelmed agency will further divert attention away from the FDA's primary role of protecting our food supply and regulating prescription drugs.

Mr. TOWNS. Madam Speaker, today, I rise in support of H.R. 1256 because of the public health benefits this legislation will provide to the country.

I am deeply troubled, however, that the legislation we are voting on today does not include many provisions of great importance to Federal employees. These provisions were adopted unanimously by this chamber and were included in the tobacco legislation that was sent to the Senate.

The Oversight and Government Reform Committee worked closely with the sponsors of H.R. 1256 in crafting this legislation. The bill modernizes the Federal Employee Thrift Savings Plan, and these changes to the TSP provide the revenue that covers the cost of new tobacco prevention programs. As a matter of simple fairness, a portion of this revenue generated by Federal employees was devoted to simple fixes to the Federal retirement system that will make it more fair and efficient for Federal employees and management.

The House-passed legislation included provisions to eliminate inconsistency in how part-time service, breaks in service, and unused sick leave are considered in calculating retirement benefits. These provisions would help encourage highly-talented individuals to return to government service at a time when we need to be attracting such individuals to prepare for a wave of upcoming retirements, and

would help that wave of retirements be more predictable and orderly.

Unfortunately, the Senate amendments to this bill left out these critical provisions. It is very disappointing, and unfair to Federal employees, that they are used to generate the revenue for these important changes, but that a portion of that revenue will not fund important reforms that will make the Federal personnel system more efficient. I will continue to work with my colleagues to ensure that these inequities and inefficiencies in the Federal retirement system are addressed.

Mr. WU. Madam Speaker, I rise today in support of H.R. 1256, the Family Smoking Prevention and Tobacco Control Act, and ask my colleagues to agree to the Senate amendments.

The statistics being heard on this floor are handed out on this floor like candy. Because numbers are often passed off as nothing more than empty words, we fail to recognize what they mean—in this Speaker, I rise today in support case we are talking about people's lives. It was Irving Selikoff, a medical researcher who co-discovered a cure for tuberculosis who said, ''Statistics are real people with the tears wiped away.''

For instance, smoking-related diseases cause an estimated 440,000 American deaths each year. And a 2004 study by the CDC's National Center for Chronic Disease Prevention and Health Promotion found that cigarette smoke contains over 4,800 chemicals, 69 of which are known to cause cancer.

Ninety percent of adult smokers are addicted to tobacco before they reach the age of 18; 50 percent before the age of 14. Currently the average age of initiation to tobacco is 11.

Forty-eight million adults smoke in the U.S., which is 22.9 percent of the population overall, and 33 percent of youth currently smoke.

Those real people are our parents and children, our family and friends, who suffer the consequences of addiction to tobacco. I want my children to grow up healthy and to make healthy decisions. To help that happen, H.R. 1256 will put in place the proper authority for the Food and Drug Administration to establish regulations over tobacco products. We need the FDA to protect our population from the harmful effects of cigarettes and tobacco products by being able to provide sound, scientific regulations governing these products.

Even with all the warnings, and the money spent on education campaigns, kids are still picking up smoking at the alarming rate of 3,000 a day in the United States.

The health concerns that will face these children are costly, painful, and deadly.

But they are also ultimately preventable.

I am acutely concerned that tobacco companies have used Portland, Oregon, as a test market for new smokeless tobacco products. Products like snus, or other tobacco-based nicotine delivery products have been repeatedly tested in markets like Portland.

Many of these products look like candy and taste sweet. They are an addictive tobacco trap for children and should be either banned or heavily regulated away from kids.

I ask my colleagues to agree to the Senate amendments to H.R. 1256, the Family Smoking Prevention and Tobacco Control Act, and send this bill to the President's desk for him to sign.

Mr. WAXMAN. I yield back the balance of my time.

The SPEAKER pro tempore. Pursuant to House Resolution 532, the previous question is ordered.

The question is on the motion offered by the gentleman from California (Mr. WAXMAN).

The question was taken; and the Speaker pro tempore announced that the ayes appeared to have it.

Mr. BUYER. Madam Speaker, on that I demand the yeas and nays.

The yeas and nays were ordered.

The vote was taken by electronic device, and there were—yeas 307, nays 97, not voting 30, as follows:

[Roll No. 335]

YEAS—307

Abercrombie
Altmire
Andrews
Arcuri
Austria
Bachus
Baird
Baldwin
Barrow
Bartlett
Bean
Becerra
Berkley
Berman
Berry
Biggert
Bilbray
Bilirakis
Bishop (GA)
Bishop (NY)
Blumenauer
Boccieri
Bono Mack
Boren
Boswell
Boucher
Boyd
Brady (PA)
Brady (TX)
Braley (IA)
Brown (SC)
Brown-Waite, Ginny
Burton (IN)
Butterfield
Camp
Cantor
Cao
Capito
Capps
Capuano
Cardoza
Carnahan
Carney
Carson (IN)
Cassidy
Castle
Castor (FL)
Chandler
Clarke
Clay
Cleaver
Clyburn
Cohen
Connolly (VA)
Conyers
Cooper
Costa
Costello
Courtney
Crenshaw
Crowley
Cuellar
Cummings
Dahlkemper
Davis (AL)
Davis (CA)
Davis (IL)
DeFazio
DeGette
Delahunt
DeLauro
Dent
Dicks
Dingell
Doggett
Donnelly (IN)
Doyle
Dreier
Driehaus
Duncan
Edwards (MD)
Edwards (TX)
Ellison
Ellsworth
Emerson
Engel
Etheridge
Fallin
Farr
Fattah
Filner
Fleming
Fortenberry
Foster
Frank (MA)
Frelinghuysen
Fudge
Gerlach
Giffords
Gonzalez
Gordon (TN)
Granger
Grayson
Green, Al
Green, Gene
Griffith
Grijalva
Gutierrez
Hall (NY)
Hall (TX)
Halvorson
Hare
Harman
Harper
Hastings (FL)
Heinrich
Herseth Sandlin
Higgins
Hill
Himes
Hinchey
Hinojosa
Hirono
Hodes
Holden
Honda
Hoyer
Inslee
Israel
Jackson (IL)
Jackson-Lee (TX)
Johnson (GA)
Johnson (IL)
Johnson, E. B.
Kagen
Kanjorski
Kaptur
Kildee
Kilpatrick (MI)
Kilroy
Kind
King (NY)
Kirk
Klein (FL)
Kosmas
Kratovil
Kucinich
Lance
Langevin
Larsen (WA)
Larson (CT)
LaTourette
Lee (CA)
Lee (NY)
Levin
Lipinski
LoBiondo
Loebsack
Lofgren, Zoe
Lowey
Luján
Lungren, Daniel E.
Lynch
Maffei
Maloney
Manzullo
Markey (CO)
Markey (MA)
Marshall
Massa
Matheson
Matsui
McCarthy (CA)
McCarthy (NY)
McCaul
McCollum
McDermott
McGovern
McKeon
McMahon
McMorris Rodgers
McNerney
Meek (FL)
Meeks (NY)
Melancon
Michaud
Miller (MI)
Miller (NC)
Miller, George
Minnick
Mitchell
Mollohan
Moore (KS)
Moore (WI)
Moran (VA)
Murphy (CT)
Murphy (NY)
Murphy, Patrick
Murphy, Tim
Murtha
Nadler (NY)
Napolitano
Neal (MA)
Nye
Oberstar
Obey
Olver
Ortiz
Pallone
Pascrell
Pastor (AZ)
Paulsen
Payne
Pelosi
Perlmutter
Peters
Peterson
Pingree (ME)
Platts
Poe (TX)
Polis (CO)
Pomeroy
Price (NC)
Putnam
Quigley
Rahall
Rangel
Rehberg
Reichert
Reyes
Richardson
Rodriguez
Rogers (AL)
Ros-Lehtinen
Roskam
Ross
Rothman (NJ)
Roybal-Allard
Rush
Ryan (OH)
Salazar
Sánchez, Linda T.
Sarbanes
Schakowsky
Schauer
Schiff
Schock
Schrader
Schwartz
Scott (GA)
Scott (VA)
Serrano
Sestak
Shea-Porter
Sherman
Shimkus
Simpson
Sires
Skelton
Slaughter
Smith (NJ)
Smith (TX)
Smith (WA)
Snyder
Space
Speier
Spratt
Stark
Stearns
Stupak
Sutton
Tanner
Tauscher
Taylor
Teague
Terry
Thompson (CA)
Thompson (MS)
Tiberi
Tierney
Titus
Tonko
Towns
Tsongas
Turner
Upton
Van Hollen
Velázquez
Visclosky
Walden
Walz
Wamp
Wasserman Schultz
Waters
Watson
Watt
Waxman
Weiner
Welch
Wexler
Wittman
Wolf
Woolsey
Wu
Yarmuth
Young (AK)
Young (FL)

NAYS—97

Aderholt
Akin
Alexander
Bachmann
Barton (TX)
Bishop (UT)
Boehner
Bonner
Boozman
Boustany
Bright
Broun (GA)
Burgess
Buyer
Calvert
Campbell
Carter
Chaffetz
Coble
Coffman (CO)
Cole
Conaway
Culberson
Davis (KY)
Davis (TN)
Diaz-Balart, L.
Diaz-Balart, M.
Flake
Forbes
Foxx
Franks (AZ)
Garrett (NJ)
Goodlatte
Graves
Guthrie
Heller
Hensarling
Herger
Hoekstra
Hunter
Inglis
Issa
Jenkins
Johnson, Sam
Jordan (OH)
King (IA)
Kingston
Kirkpatrick (AZ)
Kissell
Lamborn
Latham
Latta
Lewis (CA)
Linder
Lucas
Lummis
Mack
McClintock
McCotter
McHenry
McHugh
McIntyre
Mica
Miller (FL)
Moran (KS)
Myrick
Neugebauer
Olson
Paul
Pence
Perriello
Petri
Pitts
Posey
Price (GA)
Radanovich
Roe (TN)
Rogers (KY)
Rohrabacher
Rooney
Royce
Ryan (WI)
Scalise
Schmidt
Sensenbrenner
Sessions
Shadegg
Shuler
Shuster
Smith (NE)
Souder
Thompson (PA)
Thornberry
Tiahrt
Westmoreland
Whitfield
Wilson (SC)

NOT VOTING—30

Ackerman
Adler (NJ)
Baca
Barrett (SC)
Blackburn
Blunt
Brown, Corrine
Buchanan
Childers
Deal (GA)
Ehlers
Eshoo
Gallegly
Gingrey (GA)
Gohmert
Hastings (WA)
Holt
Jones
Kennedy
Kline (MN)
Lewis (GA)
Luetkemeyer
Marchant
Miller, Gary
Nunes
Rogers (MI)
Ruppersberger
Sanchez, Loretta
Sullivan
Wilson (OH)

□ 1154

So the motion to concur was agreed to.

The result of the vote was announced as above recorded.

A motion to reconsider was laid on the table.

Stated for:

Ms. ESHOO. Madam Speaker, I was not present during Senate Amendment to H.R. 1256, the Family Smoking Prevention and Tobacco Control Act, on June 12, 2009. Had I been present I would have voted ''yea.''

GENERAL LEAVE

Mr. WAXMAN. I ask unanimous consent that Members have 5 legislative