NLWJC - Kagan
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Tobacco-Settlement: New Legislation-Jeffords Bill

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Tobacco - settlement - New Legislation - Tether to bill

AMENDMENT NO. ____ Calendar No. ____

Purpose: To provide the Secretary with general authority to enforce the Act.

IN THE SENATE OF THE UNITED STATES—105th Cong., 1st Sess.

S. 1648

To amend the Public Health Service Act and the Food, Drug and Cosmetic Act to provide for reductions in youth smoking, for advancements in tobacco-related research, and the development of safer tobacco products, and for other purposes.

Referred to the Committee on _____
and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. JEFFORDS to the amendment (No. ____) proposed by _____

Viz:

On page 85 of the amendment, between lines 12 and 13, insert the following and redesignate the remaining section accordingly:

"SEC. 914. ENFORCEMENT. Interstate Commerce

"(a) CIVIL ENFORCEMENT.—

"(1) IN GENERAL.—Except as provided in paragraph (2), any person who violates a requirement of this chapter shall be liable to the United States for

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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.

"(2) ADULTERATION.—

"(A) IN GENERAL.—Any person who introduces into interstate commerce or delivers for introduction into interstate commerce a tobacco product that is adulterated shall be subject to a civil money penalty of not more than $50,000 in the case of an individual and $250,000 in the case of any other person for such introduction or delivery, not to exceed $500,000 for all such violations adjudicated in a single proceeding.

"(B) GROWERS.—Subparagraph (A) shall not apply to any person who grew the tobacco used in the tobacco product that is adulterated. ~~If the Secretary assesses a civil penalty against~~ any person under this paragraph, ~~the~~ Secretary may not use the seizure authorities of subsection (b) or the injunction authorities of subsection (c) with respect to the tobacco product ~~that is adulterated~~.

"(3) OTHER VIOLATIONS.—Any person that the Secretary finds—

"(A) knowingly made or caused to be made, to any officer, employee, or agent of the Department of Health and Human Services, a false statement or misrepresentation of a material fact in connection with a tobacco product;

"(B) bribed or attempted to bribe or paid or attempted to pay an illegal gratuity to any officer, employee, or agent of the Department of Health and Human Services in connection with a tobacco product;

"(C) destroyed, altered, removed, or secreted, or procured the destruction, alteration, removal, or secretion of, any material document or other material evidence which was the property of or in the possession of the Department of Health and Human Services for the purpose of interfering with that Department's discharge of its responsibilities in connection with a tobacco product;

"(D) knowingly failed to disclose, to an officer or employee of the Department of Health and Human Services, a material fact which

such person had an obligation to disclose relating to any tobacco product; or

"(E) knowingly obstructed an investigation of the Department of Health and Human Services into any tobacco product;

shall be liable to the United States for a civil penalty for each such violation in an amount not to exceed $250,000 in the case of an individual and $1,000,000 in the case of any other person.

"(4) LIMITATION.—Paragraphs (1), (2) and (3) shall not apply to any person who commits minor violations of this chapter if such person otherwise demonstrates substantial compliance with this chapter.

"(5) PROCEDURE.—

"(A) ASSESSMENT.—A civil penalty under paragraph (1), (2) or (3) shall be assessed by the Secretary by an order made on the record after opportunity for a hearing provided in accordance with this subparagraph and section 554 of title 5, United States Code. Before issuing such an order, the Secretary shall give written notice to the person to be assessed a civil penalty under such order of the Secretary's proposal to issue such order and provide such per-

son an opportunity for a hearing on the order. In the course of any investigation, the Secretary may issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation.

"(B) AMOUNT.—In determining the amount of a civil penalty under this subsection, the Secretary shall take into account the nature, circumstances, extent, and gravity of the violation or violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require.

"(C) MODIFICATION.—The Secretary may compromise, modify, or remit, with or without conditions, any civil penalty which may be assessed under paragraph (1), (2) or (3). The amount of such penalty, when finally determined, or the amount agreed upon in compromise, may be deducted from any sums owing by the United States to the person charged.

"(6) HEARINGS.—Any person who requested, in accordance with paragraph (5)(A), a hearing re-

specting the assessment of a civil penalty and who is aggrieved by an order assessing a civil penalty may file a petition for judicial review of such order with the United States Court of Appeals for the District of Columbia Circuit or for any other circuit in which such person resides or transacts business. Such a petition may only be filed within the 60-day period beginning on the date the order making such assessment was issued.

"(7) JURISDICTION.—Actions under paragraph (1) may be brought in the district court of the United States for the district wherein any act or omission or transaction constituting the violation occurred, or in such court for the district where the defendant is found or transacts business, and process in such cases may be served in any other district of which the defendant is an inhabitant or wherever the defendant may be found.

"(8) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed as requiring the Secretary to report for the institution of proceedings minor violations of this chapter whenever the Secretary believes that the public interest will be adequately served by a suitable written notice or warning.

"(9) COMPLIANCE.—If any person fails to pay an assessment of a civil penalty under this subsection—

"(A) after the order making the assessment becomes final, and if such person does not file a petition for judicial review of the order in accordance with paragraph (6); or

"(B) after a court in an action brought under paragraph (6) has entered a final judgment in favor of the Secretary;

the Attorney General shall recover the amount assessed (plus interest at currently prevailing rates from the date of the expiration of the 60-day period referred to in paragraph (6) or the date of such final judgment, as the case may be) in an action brought in any appropriate district court of the United States. In such an action, the validity, amount, and appropriateness of such penalty shall not be subject to review.

"(10) ADDITIONAL REMEDIES.—The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law.

"(b) SEIZURE.—

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

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

"(B) when the Secretary has probable cause to believe from facts found, without hear-

ing, by the Secretary or any officer or employee of the Department that the misbranded tobacco product is dangerous to health, or that the labeling of the misbranded product is fraudulent. In any case where the number of libel for condemnation proceedings is limited as provided in this paragraph, the proceeding pending or instituted shall, on application of the claimant, seasonably made, be removed for trial to any district agreed upon by stipulation between the parties, or, in case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business to which the case shall be removed for trial.

"(2) SCOPE.—Any adulterated or misbranded tobacco product shall be liable to be proceeded against at any time on libel of information and condemned in any district court of the United States or United States court of a Territory within the jurisdiction of which they are found.

"(3) PROCESS.—

"(A) IN GENERAL.—The tobacco product proceeded against under this subsection shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this subsection shall conform, as nearly as may be, to the procedure in admiralty, except that on demand of either party any issue of fact joined in any such case shall be tried by jury.

"(B) SAME CLAIMANTS.—When libel for condemnation proceedings under this subsection, involving the same claimant and the same issues of adulteration or misbranding, are pending in 2 or more jurisdictions, such pending proceedings, upon application of the claimant seasonably made to the court of one such jurisdiction, shall be consolidated for trial by order of such court, and tried in—

"(i) any district selected by the claimant where one of such proceedings is pending; or

"(ii) a district agreed upon by stipulation between the parties.

If no order for consolidation is made under this subparagraph within a reasonable time, the

claimant may apply to the court of one such jurisdiction, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, in which all such pending proceedings shall be consolidated for trial and tried.Such order of consolidation shall not apply so as to require the removal of any case the date for trial of which has been fixed. The court granting such order shall give prompt notification thereof to the other courts having jurisdiction of the cases covered thereby.

"(4) SAMPLE.—The court at any time after seizure up to a reasonable time before trial shall by order allow any party to a condemnation proceeding, the attorney or agent of such party, to obtain a representative sample of the tobacco product seized and a true copy of the analysis, if any, on which the proceeding is based and the identifying marks or numbers, if any, of the packages from which the samples analyzed were obtained.

"(5) DISPOSAL.—

"(A) IN GENERAL.—Any tobacco product condemned under this subsection shall, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, direct and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States, but such article shall not be sold under such decree contrary to the provisions of this Act or the laws of the jurisdiction in which sold.

"(B) DELIVERY FOR DESTRUCTION.—After entry of a decree under subparagraph (A) and upon the payment of the costs of such proceedings and the execution of a good and sufficient bond conditioned that such tobacco product shall not be sold or disposed of contrary to the provisions of this Act or the laws of any State or Territory in which sold, the court may by order direct that such product be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this Act under the supervision of an officer or employee duly designated by the Secretary, and the expenses of such supervision shall be paid by the

person obtaining release of the article under bond.

"(C) IMPORTER PRODUCTS.—If a tobacco product to which this paragraph applies was imported into the United States and the person seeking its release establishes—

"(i) that the adulteration, misbranding, or violation did not occur after the tobacco product was imported; and

"(ii) that the person had no cause for believing that it was adulterated, misbranded, or in violation before it was released from customs custody;

the court may permit the product to be delivered to the owner for exportation in lieu of destruction upon a showing by the owner that all of the conditions of section 801(e) can and will be met.

"(D) EQUIPMENT.—

"(i) IN GENERAL.—The provisions of subparagraph (A) shall, to the extent deemed appropriate by the court, apply to any equipment or other thing which is not otherwise within the scope of such para-

graph and which is referred to in this subsection.

"(ii) REQUIREMENTS.—Whenever in any proceeding under this subsection, involving the condemnation of any equipment or thing (other than a tobacco product) is decreed, the court shall allow the claim of any claimant, to the extent of such claimant's interest, for remission or mitigation of such forfeiture if such claimant proves to the satisfaction of the court—

"(I) that the owner has not committed or caused to be committed any prohibited act referred to in this subsection and has no interest in any tobacco product referred to herein;

"(II) that the owner has an interest in such equipment or other thing as owner or lienor or otherwise, acquired by the owner in good faith; and

"(III) that the owner at no time had any knowledge or reason to believe that such equipment or other thing was being or would be used in,

or to facilitate, the violation of laws of the United States relating to tobacco products in violation of this chapter.

"(6) EXPENSES.—When a decree of condemnation is entered against a tobacco product, court costs and fees, and storage and other proper expenses, shall be awarded against the person, if any, intervening as claimant of the tobacco product.

"(7) REMOVAL FOR ~~TRIAL~~ TRIAL.—In the case of removal for trial of any case as provided by paragraph (1)—

"(A) the clerk of the court from which removal is made shall promptly transmit to the court in which the case is to be tried all records in the case necessary in order that such court may exercise jurisdiction; and

"(B) the court to which such case was removed shall have the powers and be subject to the duties for purposes of such case, which the court from which removal was made would have had, or to which such court would have been subject, if such case had not been removed.

"(8) INSPECTIONS.—

"(A) IN GENERAL.—If during an inspection conducted under this chapter of a facility

or a vehicle, a tobacco product which the officer or employee making the inspection has reason to believe is adulterated or misbranded is found in such facility or vehicle, such officer or employee may order the tobacco product detained (in accordance with regulations prescribed by the Secretary) for a reasonable period which may not exceed 20 days unless the Secretary determines that a period of detention greater than 20 days is required to institute an action under paragraph (1) or subsection (c), in which case he may authorize a detention period of not to exceed 30 days. Regulations of the Secretary prescribed under this subparagraph shall require that before a tobacco product may be ordered detained under this paragraph the Secretary or an officer or employee designated by the Secretary approve such order. A detention order under this paragraph may require the labeling or marking of a tobacco product during the period of its detention for the purpose of identifying the product as detained. Any person who would be entitled to claim a tobacco product if it were seized under paragraph (1) may appeal to the Secretary a detention of such de-

product or tobacco product? not device

vice under this paragraph. Within 5 days of the date an appeal of a detention is filed with the Secretary, the Secretary shall after affording opportunity for an informal hearing by order confirm the detention or revoke it.

"(B) LIMITATIONS.—

"(i) IN GENERAL.—Except as authorized by clause (ii), a tobacco product subject to a detention order issued under subparagraph (A) shall not be moved by any person from the place at which it is ordered detained until—

"(I) released by the Secretary; or

"(II) the expiration of the detention period applicable to such order,

whichever occurs first.

"(ii) PERMISSIVE REMOVAL.—A tobacco product subject to a detention order under subparagraph (A) may be moved—

"(I) in accordance with regulations prescribed by the Secretary; and

"(II) if not in final form for shipment, at the discretion of the manufacturer of the tobacco product for the

purpose of completing the work required to put it in such form.

"(c) RECALL AUTHORITY.—

"(1) IN GENERAL.—If the Secretary finds that there is a reasonable probability that a tobacco product has been distributed in violation of this chapter in a manner that would pose a greater thereat to public health than the threat normally posed to public health by similar tobacco products, the Secretary shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the product) to immediately cease distribution of such 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 device. 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 TO ORDER.—

"(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 subparagraphs (B) and (C), amend the order to require a recall. The Secretary shall specify a timetable in which the device recall will occur and shall require periodic reports to the Secretary describing the progress of the recall.

"(B) LIMITATIONS.—An amended order under subparagraph (A)—

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

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

"(d) INJUNCTION PROCEEDINGS.—

"(1) IN GENERAL.—The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown, to restrain violations of this chapter.

"(2) TRIAL.—In case of violations of an injunction or restraining order under paragraph (1), which also constitutes a violation of this chapter, trial shall be by the court, or, upon demand of the accused, by a jury.

Jeffords - Hatch Discussion Draft 3/25/98

Tob-act-new legislation

S.L.C. Jeffords/Hatch on FDA

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Preventing Addiction to Smoking among Teens Act" or the "PAST Act".

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

SEC. 2. FINDINGS.

(a) GENERAL FINDINGS.—Congress makes the following findings:

(1) Tobacco is an addictive substance the use of which constitutes the Nation's number 1 preventable cause of death.

(2) Nicotine is a highly addictive drug. Substantial evidence exists that the tobacco industry has altered the amounts of nicotine in tobacco products, and added chemicals to make the nicotine in such products stronger, in order to make such products more additive than they would naturally be. As such, it is appropriate for Congress to regulate tobacco products and nicotine.

(3) The use of tobacco products by the nation's children is a serious and growing public health problem that results in new generations of tobacco-dependent children and adults.

(4) There is a consensus within the scientific, public health, and medical communities that currently marketed tobacco products are inherently unsafe and cause cancer, heart disease, and other serious adverse health effects.

(5) Virtually all new users of tobacco products are under the age of 18. Tobacco industry advertising and marketing is directed at adolescents and as such, sweeping new restrictions on the sale, promotion, and distribution of such products are needed.

(6) The Office on Smoking and Health of the Centers for Disease Control and Prevention has found that more than 70 percent of the nation's 50,000,000 current smokers have tried unsuccessfully to quit, and about 20,000,000 try to quit each year, with little success.

(7) Current research shows that new and cost-effective treatments are available that could dramatically improve the success rate of smoking cessation attempts.

(8) While State laboratory models, such as those developed in California and Massachusetts, demonstrate that comprehensive programs to reduce tobacco use can be effective, tobacco-related re-

search, including policy-oriented, programmatic, behavioral, public health, and biomedical research should be a substantial component of a national program to prevent and reduce the use of tobacco products.

(9) Enhancing the available prevention, research, and treatment resources with respect to tobacco will allow our Nation to address more effectively the problems associated with the use of tobacco products.

(10) States have been instrumental in reducing smoking rates, and States should continue to play a leading role in tobacco control efforts.

(11) While the Synar amendment has established the importance of restricting access to tobacco products as a way to reduce smoking among teens, most teens who smoke buy cigarettes themselves. Thus, greater emphasis must be placed on the enforcement of effective restrictions on access and the elimination of marketing and advertising to children and teens.

(b) FINDINGS RELATING TO ADVERTISING.—Congress makes the following findings:

(1) In 1995, the tobacco industry spent close to $4,900,000,000 to attract new users, retain current

users, increase current consumption, and generate favorable long-term attitudes toward smoking and tobacco use.

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

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

(4) 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.

(5) 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.

(6) Tobacco advertising helps increase the size of the tobacco market by increasing consumption of tobacco products including increasing tobacco sales to young people.

(7) Children are more influenced by tobacco advertising than adults, they smoke the most advertised brands, and children as young as 3 through 6 years of age can recognize a character associated with smoking.

(8) Tobacco company documents indicate that young people are an important and often crucial segment of the tobacco market.

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

(10) Constitutionally permissible restrictions on advertising are necessary to reduce youth smoking.

SEC. 3. GOALS AND PURPOSES.

(a) GOALS.—It is a goal of this Act to—

(1) decrease and prevent youth smoking and tobacco product use and reduce the marketing of tobacco products to young Americans;

(2) decrease and prevent tobacco use by all Americans by encouraging public education and smoking cessation programs and to decrease the exposure of individuals to environmental (second-hand) smoke;

(3) develop effective strategies to prevent the underage use of tobacco products;

(4) advance our knowledge of the health effects of nicotine and tobacco products on the human body, the factors that influence behavior related to the use and nonuse of tobacco products, and the factors that influence successful cessation efforts;

(5) establish the authority of the Secretary with respect to the types of tobacco products that may be lawfully sold; and

(6) invest tobacco revenues in important public health priorities, such as smoking cessation, public health education and health promotion, counter-advertising.

(b) PURPOSES.—It is the purpose of this Act to—

(1) provide for the funding by the tobacco industry of an aggressive enforcement program relating to tobacco advertising and distribution, including a State-administered retail licensing system to prevent minors from obtaining tobacco products;

(2) subject the tobacco industry to severe financial penalties in the event that underage tobacco usage does not decline radically over the next 10 years;

(3) provide annual payments to the States to fund comprehensive tobacco education and use prevention programs at the State and community levels;

(4) provide annual payments to States to fund effective smoking cessation treatment efforts at the State and community levels;

(5) provide for the establishment of national standards to control the manufacturing of tobacco products and the ingredients used in such products;

(6) provide certain regulatory powers to the Secretary of Health and Human Services to encourage the development and marketing by the tobacco industry of "less hazardous tobacco products", including the power to regulate the level of nicotine in such products;

(7) provide for the establishment of a national education-oriented counter advertising and tobacco use prevention campaign to be funded through the National Tobacco Settlement Trust Fund; and

(8) establish a minimum Federal standard to limit smoking in public places, including the halls of Congress.

SEC. 4. NATIONAL GOALS FOR THE REDUCTION IN UNDERAGE TOBACCO USE.

(a) IN GENERAL.—With respect to the average annual incidence of the monthly use of tobacco products by individuals who are under 18 years of age, it shall be the

national goals of the United States that such use be reduced as follows:

(1) CIGARETTES.—With respect to cigarettes—

(A) in the fifth and sixth calendar years after the date of enactment of this Act the percentage decrease in the use of cigarettes shall be at least 30 percent;

(B) in the seventh, eighth and ninth calendar years after the date of enactment of this Act the percentage decrease in the use of cigarettes shall be at least 50 percent; and

(C) in the tenth and subsequent calendar years after the date of enactment of this Act the percentage decrease in the use of cigarettes shall be at least 60 percent.

(2) SMOKELESS TOBACCO.—With respect to smokeless tobacco—

(A) in the fifth and sixth calendar years after the date of enactment of this Act the percentage decrease in the use of smokeless tobacco shall be at least 25 percent;

(B) in the seventh, eighth and ninth calendar years after the date of enactment of this Act the percentage decrease in the use of

smokeless tobacco shall be at least 35 percent; and

(C) in the tenth and subsequent calendar years after the date of enactment of this Act the percentage decrease in the use of smokeless tobacco shall be at least 45 percent.

(b) DETERMINATIONS.—Determinations as to whether the national goals described in subsection (a) have been met shall be made in accordance with the provisions of subtitle A of title XXVIII of the Public Health Service Act (as added by section 202).

TITLE I—REGULATION OF TOBACCO PRODUCTS AND TOBACCO PRODUCT DEVELOPMENT

SEC. 101. REGULATION OF TOBACCO PRODUCTS AND TOBACCO PRODUCT DEVELOPMENT.

(a) REGULATION AS A DRUG.—Section 201(g)(1) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(g)(1)) is amended—

(1) by striking "; and (D)" and inserting "; (D) nicotine in tobacco products; and (E)"; and

(2) by adding at the end the following: "A tobacco product that contains the drug nicotine that is in conformity with the provisions of chapter IX

shall not be subject to the provisions of chapter V. A tobacco product that is not in conformity with the provisions of chapter IX shall be subject to the provisions of chapter V.".

(b) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended—

(1) in subsection (j), by striking "or 721" and inserting "721, 902, 903, or 907"; and

(2) by adding at the end the following:

"(aa) The introduction or delivery for introduction into interstate commerce of any tobacco product that does not comply with the provisions of chapter IX.

"(bb) The failure by the manufacturer of a tobacco product to comply with a tobacco product health risk management standard, a good manufacturing practice standard, a tobacco product labeling, warning or packaging standard, or any other requirement of chapter IX.".

(c) SEIZURE.—Section 304(a)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 334(a)(2)) is amended—

(1) by striking "and (D)" and inserting "(D)"; and

(2) by inserting before the period the following: ", and (E) Any adulterated or misbranded tobacco product".

(d) RECORDS OF INTERSTATE SHIPMENT.—Section 703 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 373 et seq.) is amended—

(1) by striking "or cosmetics" each place that such appears and inserting "cosmetics, or tobacco products"; and

(2) by striking "or cosmetic" each place that such appears and inserting "cosmetics, or tobacco product".

(e) INSPECTIONS.—Section 704(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)(1)) is amended—

(1) in subparagraph (A), by striking "or cosmetics" each place that such appears and inserting ", cosmetics, or tobacco products"; and

(2) in the second sentence, by striking "drugs or" each place that such appears and inserting "drugs, tobacco products or".

(f) PUBLICITY.—Section 705(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 375(b)) is amended by striking "or cosmetics" and inserting "cosmetics, or tobacco products".

(g) PRESUMPTION.—Section 709 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379a) is amended by striking "or cosmetic" and inserting "cosmetic, or tobacco product".

(h) IMPORTS AND EXPORTS.—Section 801 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 381 et seq.) is amended—

(1) by redesignating subsection (f) as subsection (g); and

(2) by inserting after subsection (e), the following:

"(f)(1) A tobacco product intended for export shall not be deemed to be adulterated or misbranded under this Act if it—

"(A) accords to the specifications of the foreign purchaser;

"(B) is not in conflict with the laws of the country to which it is intended for export;

"(C) is labeled on the outside of the shipping package that it is intended for export; and

"(D) is not sold or offered for sale in domestic commerce.

"(2) Paragraph (1) does not apply to any tobacco product which is intended to be manufactured, exported

or packaged for sale or distribution to members or units of the Armed Forces of the United States.".

SEC. 102. CODIFICATION OF REGULATIONS CONCERNING CIGARETTES AND SMOKELESS TOBACCO.

The provisions of the final regulations promulgated by the Secretary in the rule dated August 28, 1996 (61 Fed. Reg. 44615-18) shall be construed as follows:

(1)(A) The regulations codified in sections 897.16(a), 897.30(a) through (c), 897.32(a) and (b), and 897.34(a) through (c) of title 21, Code of Federal Regulations, shall be deemed to have been promulgated by the Secretary pursuant to chapter IX of the Federal Food, Drug and Cosmetic Act (as added by section 103 of this Act).

(B) In applying the provisions referred to in subparagraph (A), references—

(i) to "this part" in section 897.32(a)(1) shall be deemed to be a reference to section [2825(k) of the Public Health Service Act]; and

(ii) to "this subpart D" in section 897.30(c) shall be deemed to be a reference to section 906 of the Food, Drug and Cosmetic Act and the regulations described in this paragraph.

(C) The Secretary shall promulgate a regulation under section 553(b)(3)(B) of title 5, United States Code, to—

(i) transfer the regulations referred to in subparagraph (A) to the appropriate part of the Code of Federal Regulations;

(ii) amend the cross references in sections 897.30(c) and 897.32(a)(1) as provided for in subparagraph (B); and

(iii) make such other amendments to such regulations if the Secretary determines that such amendments are necessary to conform such regulations to the provisions of the _____ Act.

(2)(A) The regulations codified in sections 897.10, 897.12, 897.14(a) through (c), and 897.16(b) through (d) shall be deemed to have been

promulgated by the Secretary pursuant to [subtitle B of title XXVIII of the Public Health Service Act].

(B) The Secretary shall promulgate a regulation under section 553(b)(3)(B) of title 5, United States Code, to—

(i) transfer the regulations referred to in subparagraph (A) to the appropriate part of the Code of Federal Regulations; and

(ii) make such other amendments to such regulations if the Secretary determines that such amendments are necessary to conform such regulations to the provisions of the _____ Act.

(3) Any portion or provision of the final regulations not specifically referred to in paragraph (1) or (2) shall be considered null and void.

SEC. 103. NO EFFECT ON NON-TOBACCO PRODUCTS; INTERPRETATION.

(a) IN GENERAL.—Nothing in this Act, the amendments made to the Federal Food, Drug and Cosmetic Act, or any policy or regulation promulgated pursuant to this Act or amendments, shall be construed to affect the regulation, interpretation, or enforcement of any regulation of, or any policy on, any product that is not a tobacco product under the Federal Food, Drug and Cosmetic Act.

(b) RULE OF CONSTRUCTION.—In administering chapter IX of the Federal Food, Drug and Cosmetic Act (as added by section 104), the Secretary shall ensure that any term in such chapter relating to tobacco products that is the same as or substantially similar to a term in such Act relating to drugs or devices, is interpreted in a manner similar to the interpretation (including judicial interpretation) of such term as it relates to drugs or devices.

SEC. 103. HEALTH AND SAFETY REGULATORY REQUIREMENTS.

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, 902, 903, 904, and 905 as sections 1001, 1002, 1003, 1004, and 1005, respectively; and

(3) by adding after chapter VIII the following new chapter:

"CHAPTER IX—HEALTH AND SAFETY REGULATORY REQUIREMENTS RELATING TO TOBACCO PRODUCTS

"SEC. 900. ADULTERATION AND MISBRANDING; DEFINITIONS.

"(a) ADULTERATION.—A tobacco product shall be deemed to be adulterated—

"(1) if it consists in whole or in part of any filthy, putrid, or decomposed substance;

"(2) if it has been prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health in a manner beyond the normal risks associated with such products;

"(3) if the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or holding are not in conformity with applicable current good manufacturing practice requirements under this section;

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

"(5) if it is a tobacco product which is subject to a standard established under section 903, unless such product is in all respects in conformity with such standard; or

"(6) if it is not in compliance with the requirements under subsection (g), (h), or (i) of section 2825 of the Public Health Service Act.

"(b) MISBRANDING.—A tobacco product shall be deemed to be misbranded—

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

"(2) if any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not placed thereon in conformance with such requirement;

"(3) if its labeling is not in conformance with the requirements of this section or any other applicable requirement of this chapter;

"(4) if the labeling of the package of the product, or any claim of the manufacturer in connection with the product, states or implies (as determined by the Secretary) that the product presents a reduced health risk except to the extent such labeling or claim is authorized under section 907;

"(5) if it is subject to a standard under section 903, unless it bears such labeling as may be prescribed in such standard;

"(6) if it was manufactured in an establishment not duly registered under section 904(a)(2);

"(7) if there was a failure or refusal to comply with any requirement under section 902(a), 902(b), 902(c), 903(d)(3), or 906(b)(1) with respect to such tobacco product; or

"(8) if it is a Reduced Risk Tobacco Product under section 907, and it is not in compliance with a requirement under section 907(a)(3).

[Note: Definitions to be revised]

"(c) DEFINITIONS.—In this chapter:

"(1) CIGARETTE.—The term 'cigarette' means any product which contains nicotine, is intended to be burned or heated under ordinary conditions of use, and consists of—

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

"(B) any roll of tobacco wrapped in any substance containing tobacco 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 described in subparagraph (A).

"(2) CIGARETTE TOBACCO.—The term 'cigarette tobacco' means any product that consists of loose tobacco that contains or delivers nicotine and is intended for use by persons in a cigarette. Unless otherwise stated, the requirements of this title pertaining to cigarettes shall also apply to cigarette tobacco.

"(3) 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.

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

"(5) TAR.—The term 'tar' means mainstream total particulate matter minus nicotine and water.

"(6) TOBACCO ADDITIVE.—The term 'tobacco additive' means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in the substance becoming a component of, or otherwise affecting the characteristics of, any tobacco product, including any substance that may have been removed from the tobacco product and then readded in the substance's original or modified form.

"(7) TOBACCO PRODUCT.—

"(A) IN GENERAL.—The term 'tobacco product' means cigarettes and smokeless tobacco.

"(B) LIMITATION.—Tobacco leaf that is not in the possession of a tobacco product manufacturer shall not be considered to be a tobacco product within the meaning of subparagraph (A). The provisions of this chapter shall not apply to tobacco leaf that is not in the possession of the manufacturer, or to the producers of tobacco leaf, including tobacco growers and tobacco grower cooperatives. Notwithstanding any other provision of this subparagraph, if a producer of tobacco leaf is also a tobacco plant manufacturer, such producer shall be subject to this chapter in the producers' capacity as a manufacturer. The Secretary shall consult with the Secretary of Agriculture or the Administrator of the Environmental Protection Agency with respect to any matter that involves tobacco leaf or a producer thereof.

"Subchapter A—Tobacco Product Regulation

"SEC. 901. STATEMENT OF GENERAL DUTIES.

"As part of the comprehensive health promotion and disease prevention program established under this chapter and the PAST Act (and the amendments made by such Act) relating to diseases and conditions associated with the use of tobacco products, and that places a special em-

phasis on discouraging the use of such products by young Americans, the Secretary shall—

"(1) receive, assess, and provide appropriate confidentiality regarding information submitted to the Secretary under section 902;

"(2) develop and implement health risk reduction standards for tobacco products under section 903;

"(3) develop and enforce good manufacturing practice standards for tobacco products under section 904;

"(4) enforce, and as appropriate, revise tobacco product labeling, warning, and packaging standards under section 905;

"(5) enforce tobacco product restriction on marketing and advertising under section 906;

"(6) develop and implement standards that encourage the development and use of reduced risk tobacco products under section 907 and designate as 'Reduced Risk Tobacco Products' those products that meet the standards under such section;

"(7) establish and oversee a tobacco products scientific advisory committee under section 908 to provide advice on the establishment of health risk reduction standards, good manufacturing practice reg-

ulations, tobacco product labeling, warning and packaging standards, and standards for the review of reduced risk tobacco products under sections 903, 904, 905, and 907;

"(8) submit reports to Congress evaluating the effectiveness of this chapter and the PAST Act as described in section 909; and

"(9) assess and collect fees under section 911.

"SEC. 902. SUBMISSION OF HEALTH INFORMATION TO THE SECRETARY.

"(a) REQUIREMENT.—Not later than 6 months after the date of enactment of this chapter, each manufacturer or importer of tobacco products, or agents thereof, shall submit to the Secretary the following information:

"(1) A listing of all tobacco ingredients, substances and compounds (other than tobacco, water or reconstituted tobacco sheet made wholly from tobacco) that are, on such date, added by the manufacturer to the tobacco, paper, filter or other component of each tobacco product by brand and by quantity in each brand and subbrand.

"(2) A description of the nicotine content of each tobacco product measured in milligrams of nicotine.

"(3) All documents (including underlying scientific information) relating to research activities, and research findings, conducted, supported, or processed by the manufacturer (or agents thereof) on the health or physiologic effects of tobacco products, their constituents, ingredients, and components, and tobacco additives, described in paragraph (1).

"(4) All documents (including underlying scientific information), whether or not subject to notification under section 907(e), relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer 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.

"(5) All documents (including underlying scientific information) relating to marketing research involving the use of tobacco products.

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

"(b) ANNUAL SUBMISSION.—A manufacturer or importer that is required to submit information under sub-

section (a) shall update such information on an annual basis pursuant to a schedule determined by the Secretary.

"(c) TIME FOR SUBMISSION.—

"(1) NEW PRODUCTS.—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 this chapter, the manufacturer of such product shall provide the information required under subsection (a) and such product shall be subject to the annual submission under subsection (b).

"(2) MODIFICATION OF EXISTING PRODUCTS.—If at any time a manufacturer adds to its tobacco products a new tobacco additive, increases or decreases the quantity of an existing tobacco additive or the nicotine level, or eliminates a tobacco additive from any tobacco product, the manufacturer shall within 60 days of such action so advise the Secretary in writing and reference such modification in submissions made under subsection (b).

"(d) CONFIDENTIALITY.—Any information obtained by the Secretary under this section that is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of

such section shall be considered confidential and shall not be disclosed.

"SEC. 903. TOBACCO PRODUCT HEALTH RISK REDUCTION STANDARDS.

"(a) AUTHORITY.—

"(1) IN GENERAL.—The Secretary shall by regulation (promulgated under the authority of section 701(a) and consistent with the procedures described in section 553 of title 5, United States Code) establish tobacco product health risk reduction standards.

"(2) CONSULTATION.—In developing and promulgating regulations under this chapter, the Secretary shall consult (as the Secretary determines appropriate) with—

"(A) Federal public health and safety officials; and

"(B) other public health and safety experts, including State and local public health and safety officials, and other interested members of the public and affected parties.

"(b) PROCEDURES FOR THE ESTABLISHMENT OF STANDARDS.—

"(1) PUBLICATION OF NOTICE.—

"(A) IN GENERAL.—The Secretary shall publish in the Federal Register a notice of pro-

posed rulemaking for the establishment, amendment, or revocation of any health risk reduction standard for a tobacco product under this section.

"(B) CONTENTS OF NOTICE.—A notice of proposed rulemaking for the establishment or amendment of a health risk reduction standard for a tobacco product shall be accompanied by a justification of the proposed action and shall—

"(i) invite interested persons to submit to the Secretary, within 120 days of the publication of the notice, requests for changes in the standard based on new information relevant to the standard; and

"(ii) invite interested persons to submit an existing health risk reduction standard for the tobacco product, including a draft or proposed health risk reduction standard, for consideration by the Secretary.

"(C) NOTICE OF REVOCATION.—A notice of proposed rulemaking for the revocation of a health risk reduction standard shall set forth a finding with supporting justification that the

health risk reduction standard is no longer necessary with respect to the tobacco product.

"(D) COMMENTS.—The Secretary shall provide for a comment period, other than for requests made under subparagraph (B)(i), of not less than 120 days after the date on which a notice has been published under this paragraph.

"(2) REQUEST FOR CHANGE.—If, after the publication of a notice in accordance with paragraph (1), the Secretary receives a request for a change in the health risk reduction standard for a tobacco product, the Secretary shall, within 60 days of the publication of the notice, either deny the request and provide a written response explaining the reasons for the denial, or give notice of an intent to initiate such a change.

"(3) REGULATION FOR ESTABLISHMENT.—

"(A) IN GENERAL.—After the expiration of the period for comment on a notice of proposed rulemaking published under paragraph (1) with respect to a health risk reduction standard, and after consideration of such comments and any report from the tobacco products advisory committee under section 908, the Secretary shall—

"(i) promulgate a regulation establishing a health risk reduction standard and publish in the Federal Register findings and considerations on the matters referred to in subsection (c); or

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

"(B) CONTENTS.—A regulation establishing a health risk reduction standard under subparagraph (A) shall set forth the date or dates upon which the standard shall take effect, but no such regulation may take effect before the expiration of the 1-year period beginning on the date of its publication and such date or dates shall be established so as to minimize economic loss to, and disruption or dislocation of, domestic and international trade, unless the Secretary determines that an earlier effective date is necessary for the protection of the public health.

"(4) AMENDING OR REVOKING OF STANDARDS.—

"(A) IN GENERAL.—The Secretary, upon the initiative of the Secretary or upon petition

of an interested person, may by regulation, promulgated in accordance with the requirements of paragraphs (1), (2), and (3), amend or revoke a health risk reduction standard for a tobacco product.

"(B) EFFECTIVENESS OF AMENDMENT.—The Secretary may declare a proposed amendment of a health risk reduction standard under this section 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. A proposed amendment of a health risk reduction standard made so effective under the preceding sentence may not prohibit, during the period in which it is so effective, the introduction or delivery for introduction into interstate commerce of a tobacco product which conforms to such standard without the change or changes provided by such proposed amendment.

"(c) REGULATION OF THE COMPOSITION OF TOBACCO PRODUCTS.—

"(1) IN GENERAL.—The Secretary may adopt a health risk reduction standard under this section that requires—

"(A) the modification of a tobacco product in a manner that involves—

"(i) the gradual modification of nicotine yields of the product;

"(ii) the reduction or elimination of other harmful constituents, ingredients (including tobacco additives), substances, compounds and properties of the product in accordance with subsection (d)(4)(B), including the establishment of levels of nicotine and other components, ingredients (including tobacco additives), and constituents of the product, or smoke emitted by such products; or

"(iii) other changes to reduce the likelihood of cigarette induced fires;

"(B) effective not earlier than the expiration of the 10-year period beginning on the date of enactment of this chapter, the reduction of nicotine yields of a tobacco product to zero; or

"(C) effective not earlier than the expiration of the 10-year period beginning on the date

of enactment of this chapter, the prohibition of cigarettes or smokeless tobacco.

"(2) OBJECTIVE.—Tobacco product health risk reduction standards established under this section shall—

"(A) have as their objective reducing the overall health risks to the public, including the reduction in risk to the consumers of such products, to individuals who reduce or cease the use of such products, and to individuals who do not initiate the use of such products;

"(B) where necessary to meet the objectives in subparagraph (A), include requirements—

"(i) with respect to the construction, components, constituents, ingredients (including tobacco additives), and properties of the product, including the establishment of levels of nicotine and other components, ingredients (including tobacco additives), and constituents of the product, or smoke emitted by such products taking into account the technological feasibility of such requirements;

"(ii) specifying the procedures for the testing of such products, including devising procedures to be used by tobacco product manufacturers, the Secretary, or other appropriate entities, to measure relevant health-related characteristics of such products;

"(iii) for the testing of such products, including devising procedures to be used by manufacturers, the Secretary, or other appropriate entities to measure the relevant health related characteristics of such products to assess the conformity of such products with the applicable health risk reduction standards; and

"(iv) to limit the sale and distribution of tobacco products to the extent authorized by this chapter;

"(C) as required under section 905, prescribe certain conditions pertaining to the labeling and advertising of tobacco products; and

"(D) comply with regulations promulgated by the Secretary that specify the health risk assessment procedures for the testing of tobacco and nontobacco constituents contained in to-

bacco products and determinations concerning such products under subsection (d).

"(3) CONSIDERATIONS.—In determining whether to require a modification or prohibition described in paragraph (1), the Secretary shall identify, make available for public comment, and consider relevant factors including whether the modification or prohibition—

"(A) will result in a significant reduction in the health risks associated with the use of the tobacco product, constituent, or component involved;

"(B) will result in a significant increase in the number of individuals seeking tobacco product cessation or withdrawal treatments, including an assessment of the effectiveness and accessibility of such treatments;

"(C) will result in any possible countervailing effects on the health of adolescent tobacco users, adult tobacco users, or non-tobacco users, such as the creation of a significant demand for, and supply of, contraband products specifically including other tobacco products that do not meet the requirements of this chapter;

"(D) is technologically feasible for commercial manufacturing; and

"(E) is likely to be accepted by and affordable to adult consumers of tobacco products.

"(4) PROCEDURE FOR GENERAL PROHIBITION OF TOBACCO PRODUCTS AND ELIMINATION OF NICOTINE.—

"(A) NONDELEGATION.—The Secretary may not delegate the authority provided under this section to promulgate a regulation that results in a general prohibition of cigarettes or smokeless tobacco or the reduction of nicotine yields of a tobacco product to zero.

"(B) CONGRESSIONAL REVIEW.—In accordance with section 801 of title 5, United States Code, Congress shall review, and may disapprove, any rule of the Secretary establishing, amending, or revoking a tobacco product health risk reduction standard, except that with respect to a standard that results in a general prohibition of cigarettes or smokeless tobacco or the reduction of nicotine yields of a tobacco product to zero, such standard shall only take effect following the date of enactment of a joint resolution of approval of such standard. The

provisions of section 802 of title 5, United States Code, relating to certain disapproval resolutions shall apply to the consideration of any joint resolution of approval under this subsection.

"(d) TOBACCO PRODUCTS RISK ASSESSMENT STANDARDS.—

"(1) TOBACCO INGREDIENTS, COMPOUNDS, ADDITIVES, AND CONSTITUENTS.—The health risk reduction standards promulgated under subsection (c)(2)(D) with respect to the testing of tobacco products shall include provisions relating to the assessment of the health risks posed by the components of tobacco, including but not limited to nicotine and tar, and by tobacco use including carbon-monoxide.

"(2) NONTOBACCO INGREDIENTS, COMPOUNDS, ADDITIVES, AND CONSTITUENTS.—

"(A) IN GENERAL.—The health risk reduction regulations under subsection (c)(2)(D) with respect to the testing of nontobacco ingredients used in tobacco products—

"(i) during the 5-year period beginning on the date of enactment of this chapter, shall apply to new ingredients (those ingredients that were not previously used

in such products on such date of enactment) used in such products and to ingredients in use prior to such date of enactment as the Secretary may require; and

"(ii) after the expiration of the 5-year period described in clause (i), shall apply to all ingredients used in such products.

"(B) IMPLEMENTATION.—In carrying out this section, all requirements with respect to nontobacco ingredients, substances, and compounds shall be implemented in accordance with subparagraph (A).

"(3) HEALTH RISK ASSESSMENTS.—

"(A) REQUIREMENT.—In compliance with paragraphs (1) and (2), and in no case later than 5 years after the date of enactment of this chapter, and annually thereafter, each manufacturer shall submit to the Secretary a health risk assessment for each ingredient, substance, or compound that is listed under section 902(a)(1) with respect to each brand and subbrand of tobacco product manufactured by each such manufacturer.

"(B) AVAILABILITY OF NEW INFORMATION.—The Secretary may include in the regu-

lations promulgated under this section, provisions that permit or, as appropriate, require manufacturers to, in subsequent years, promptly revise information that was submitted under subparagraph (A) in previous years if new data becomes available to that manufacturer. Such regulations may require that a manufacturer submit a notification to the Secretary where the manufacturer determines that no new data has become available during the previous year.

"(C) JOINT SUBMISSION.—At the discretion of the Secretary, the health risk assessments under this paragraph may be conducted by a qualified third party organization on behalf of more than 1 manufacturer for 1 or more product, ingredient, substance or compound if a joint submission is consistent with the public health. Such joint submissions shall be subject to the brand specific requirements of subparagraph (A).

"(D) BASIS OF ASSESSMENT.—The health risk assessment of an ingredient, substance, or compound described in subparagraph (A) shall—

"(i) be based on the best scientific evidence available at the time of the submission of the assessment; and

"(ii) ascertain whether there is a reasonable certainty among experts qualified by scientific training and experience that the ingredient, substance, or compound is not harmful in the quantities used under the intended conditions of use.

"(4) REGULATORY ACTION.—

"(A) ABSENCE OF A RISK ASSESSMENT.—Not later than 12 months after the date of enactment of this chapter and subject to the requirements of paragraphs (1), (2) and (3)(A), the Secretary shall promulgate regulations to prohibit the use of any ingredient, substance, or compound in the tobacco product of a manufacturer if no health risk assessment has been submitted as required under this subsection by the manufacturer for the ingredient, substance, or compound.

"(B) REVIEW OF HEALTH RISK ASSESSMENTS.—

"(i) APPROVAL, CONDITIONAL APPROVAL, OR DISAPPROVAL.—The Secretary

shall approve or disapprove of, or condition, the use of the ingredient, substance, or compound that was the subject of the assessment under this subsection within 180 days of the date on which the health risk assessment is received and provide notice of such approval, conditional approval, or disapproval to the manufacturer. The manufacturer may continue to use ingredients, substances, or compounds that are the subject of such an assessment until the Secretary disapproves or conditions such ingredient, substance, or compound. The Secretary shall establish a procedure to allow manufacturers adequate time to comply with any such condition or disapproval.

"(ii) NEW INGREDIENTS, SUBSTANCES, COMPOUNDS, AND ADDITIVES.—Notwithstanding clause (i), a new ingredient, substance, compound, or additive shall not be introduced into commerce during the 30-day period beginning on the date on which a health risk assessment has been submitted to the Secretary for such new ingredient, substance, compound, or addi-

tive. The Secretary may by order prohibit the use of such new ingredient, substance, compound, or additive until the Secretary completes a review of the assessment involved.

"(iii) GENERAL APPLICABILITY.—At the discretion of the Secretary, the approval, conditional approval, or disapproval of a particular ingredient, substance, or compound under clause (i) may by regulation be made generally applicable to tobacco product manufacturers or a subgroup of such manufacturers. In the case of a conditional approval, the Secretary shall develop a procedure to enable manufacturers to certify that the condition will be complied with.

"(iv) INACTION BY SECRETARY.—If the Secretary fails to act with respect to an assessment during the period referred to in clause (i), the manufacturer submitting the assessment may continue to use the ingredient, substance, or compound involved until such time as the Secretary makes a final decision, or the succeeding

annual risk assessment is submitted by the manufacturer and the ingredient, substance, or compound is subsequently disapproved or conditioned. The Secretary shall establish a procedure to allow manufacturers adequate time to comply with any such condition or disapproval.

"(e) COMPLIANCE.—

"(1) IN GENERAL.—Health risk reduction standards under this section shall apply to all tobacco products to which such standards are relevant.

"(2) LIMITATION.—During the period in which a regulation promulgated under this section establishing a health risk reduction standard is in effect, a tobacco product shall not be considered to be in violation of section 301 if such product is in compliance with such regulation, and the requirements of sections 904 and 905.

"(f) EVALUATION.—The Secretary shall periodically evaluate tobacco product health risk reduction standards to determine whether such standards should be amended to reflect new medical, scientific, or technological information.

"SEC. 904. GOOD MANUFACTURING PRACTICE STANDARDS.

"(a) AUTHORITY.—

"(1) IN GENERAL.—The Secretary shall, in accordance with subsections (a) and (b) of section 903, prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, packing, and storage of a tobacco product conform to current good manufacturing practice, as prescribed in such regulations, to ensure that such products will be in compliance with this chapter.

"(2) REGISTRATION.—The regulations promulgated under paragraph (1) shall require that all tobacco product manufacturers register with the Secretary.

"(3) SPECIAL CONSULTATION PROCEDURES.—In developing and promulgating any regulation under paragraph (1) the Secretary shall afford the Tobacco Products Scientific Advisory Committee established under section 908 an opportunity (with a reasonable time period) to submit recommendations in response to the notice of proposed rulemaking.

"(4) LIMITATION.—Good manufacturing practice regulations described in paragraph (1) shall be appropriate for the manufacture of a product derived from a raw agricultural commodity for which no therapeutic claim is made.

"(b) PESTICIDE RESIDUES.—The regulations promulgated under subsection (a) shall at a minimum require, after consultation with the Administrator of the Environmental Protection Agency, the development and adherence to applicable tolerances with respect to pesticide chemical residues in finished tobacco products, except that such tolerances shall only apply if the Administrator determines that such tolerances are necessary to prevent such residues from being injurious to health when used in tobacco products.

"(c) PETITIONS FOR EXEMPTIONS AND VARIANCES.—

"(1) IN GENERAL.—Any person subject to any requirement prescribed by regulations under subsection (a) may petition the Secretary for an exemption or variance from such requirement. Such a petition shall be submitted to the Secretary in such form and manner as the Secretary shall by regulation prescribe and shall—

"(A) 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 ensure that the tobacco product is in compliance with section 903;

"(B) 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 product in lieu of the methods, facilities, and controls prescribed by the requirement; and

"(C) contain such other information as the Secretary shall prescribe.

"(2) TOBACCO PRODUCT REQUIREMENTS WAIVER BOARD.—

"(A) AUTHORITY.—The Secretary shall establish a Tobacco Product Requirements Waiver Board (referred to in this paragraph as the 'Waiver Board') to provide advice and make recommendations to the Secretary with respect to the approval or disapproval of petitions submitted under paragraph (1).

"(B) MEMBERSHIP.—The Waiver Board shall be composed of 9 members to be appointed by the Secretary, of which—

"(i) 3 members shall be appointed from among individuals who are officers or employees of the Federal Government or a State or local government;

"(ii) 2 members shall be appointed from among individuals who are representatives of the interests of the cigarette and smokeless tobacco industries;

"(iii) 2 members shall be appointed from among individuals who are representatives of the interests of physicians and other health professionals; and

"(iv) 2 members shall be appointed from among individuals who are representatives of the interests of the general public.

"(C) CHAIRPERSON.—The Secretary shall designate 1 of the members of the Waiver Board to serve as the Chairperson.

"(D) COMPENSATION AND EXPENSES.—

"(i) COMPENSATION.—Members of the Waiver Board who are not officers or employees of the United States, while attending conferences or meetings of the Waiver Board or otherwise serving at the request of the Secretary, shall be entitled to receive compensation at rates to be fixed by the Secretary, which rates may not exceed the daily equivalent of the rate of pay for level 4 of the Senior Executive Sched-

ule under section 5382 of title 5, United States Code, for each day (including traveltime) they are so engaged.

"(ii) EXPENSES.—While conducting the business of the Waiver Board 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 of the United States Code for persons in the Government service employed intermittently.

"(3) ACTION ON PETITION.—

"(A) IN GENERAL.—Not later than 120 days of the date on which the Secretary receives the recommendations of the Waiver Board, the Secretary shall issue an order approving or denying a petition submitted under paragraph (1). 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 product will comply with this sec-

tion and is otherwise consistent with the public health; 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 product in lieu of the methods, controls, and facilities prescribed by the requirement are sufficient to ensure that the product will comply with this section and is otherwise in compliance with the public health.

"(B) 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 ensure that the product will comply with this section.

"(4) INFORMAL HEARING.—After the issuance of an order under paragraph (3) respecting a peti-

tion, the petitioner shall have an opportunity for an informal hearing on such order.

"(d) RECORDKEEPING AND REPORTING.—

"(1) IN GENERAL.—The regulations promulgated under subsection (a) shall require that manufacturers maintain such files and records as the Secretary may reasonably require relating to tobacco product safety. Such regulations may require manufacturers to report serious adverse events that are not well-known or well-documented by the scientific community (including events related to contamination or a change in any ingredient or any major change in manufacturing processes).

"(2) REPORTING.—A report shall be submitted under paragraph (1) concerning a tobacco product for serious adverse events that are not well-known or well-documented by the scientific community, including events related to contamination, or a change in any ingredient or any manufacturing process.

"(e) EFFECTIVE DATE OF CERTAIN REGULATIONS.—Regulations promulgated under this section shall be implemented over a 2-year period in consultation with manufacturers of tobacco products and tobacco producers.

"SEC. 905. TOBACCO PRODUCT LABELING, WARNING, AND PACKAGING STANDARDS.

"(a) CIGARETTES.—

"(1) IN GENERAL.—

"(A) PACKAGING.—It shall be unlawful for any person to manufacture, package, 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 subsection, one of the following statements:

"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.

"(B) ADVERTISING.—It shall be unlawful for any manufacturer or importer of cigarettes to advertise or cause to be advertised within the United States any cigarette unless the advertising bears, in accordance with the requirements of this subsection, one of the following statements:

"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) REQUIREMENTS FOR LABEL STATEMENTS.—

"(A) LOCATION.—Each label statement required by subparagraph (A) of paragraph (1) shall be located on the upper portion of the front panel of the cigarette package (or carton) and occupy not less than 25 percent of such front panel.

"(B) TYPE AND COLOR.—With respect to each label statement required by subparagraph (A) of paragraph (1), the phrase 'WARNING' shall appear in capital letters and the label statement shall be printed in 17 point type with adjustments as determined appropriate by the Secretary to reflect the length of the required statement. All the letters in the label statement shall appear in conspicuous and legible type, in contrast by typography, layout, or color with all other printed material on the package, and be printed in an alternating black-on-white and white-on-black format as determined appropriate by the Secretary.

"(C) EXCEPTION.—The provisions of subparagraph (A) shall not apply in the case of a flip-top cigarette package (offered for sale on April 1, 1997) where the front portion of the flip-top does not comprise at least 25 percent of

the front panel. In the case of such a package, the label statement required by subparagraph (A) of paragraph (1) shall occupy the entire front portion of the flip top.

"(3) REQUIREMENTS FOR ADVERTISING.—

"(A) LOCATION.—Each label statement required by subparagraph (B) of paragraph (1) shall occupy not less than 20 percent of the area of the advertisement involved.

"(B) TYPE AND COLOR.—

"(i) TYPE.—With respect to each label statement required by subparagraph (B) of paragraph (1), the phrase 'WARNING' shall appear in capital letters and the label statement shall be printed in the following types:

"(I) With respect to whole page advertisements on broadsheet newspaper—45 point type.

"(II) With respect to half page advertisements on broadsheet newspaper—39 point type.

"(III) With respect to whole page advertisements on tabloid newspaper—39 point type.

"(IV) With respect to half page advertisements on tabloid newspaper—27 point type.

"(V) With respect to DPS magazine advertisements—31.5 point type.

"(VI) With respect to whole page magazine advertisements—31.5 point type.

"(VII) With respect to 28cm x 3 column advertisements—22.5 point type.

"(VIII) With respect to 20cm x 2 column advertisements—15 point type.

The Secretary may revise the required type sizes as the Secretary determines appropriate within the 20 percent requirement.

"(ii) COLOR.—All the letters in the label statement under this subparagraph shall appear in conspicuous and legible type, in contrast by typography, layout, or color with all other printed material in the advertisement, and be printed in an alternating black-on-white and white-on-black

format as determined appropriate by the Secretary.

"(4) ROTATION OF LABEL STATEMENTS.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), the label statements specified in subparagraphs (A) and (B) of paragraph (1) shall be rotated by each manufacturer or importer of cigarettes quarterly in alternating sequence on packages of each brand of cigarettes manufactured by the manufacturer or importer and in the advertisements for each such brand of cigarettes in accordance with a plan submitted by the manufacturer or importer and approved by the Secretary. The Secretary shall approve a plan submitted by a manufacturer or importer of cigarettes which will provide the rotation required by this paragraph and which assures that all of the label statements required by subparagraphs (A) and (B) will be displayed by the manufacturer or importer at the same time.

"(B) APPLICATION OF OTHER ROTATION REQUIREMENTS.—

"(i) IN GENERAL.—A manufacturer or importer of cigarettes may apply to the

Secretary to have the rotation schedule described in clause (iii) apply with respect to a brand style of cigarettes manufactured or imported by such manufacturer or importer if—

"(I) the number of cigarettes of such brand style sold in the fiscal year of the manufacturer or importer preceding the submission of the application is less than ¼ of 1 percent of all the cigarettes sold in the United States in such year; and

"(II) more than ½ of the cigarettes manufactured or imported by such manufacturer or importer for sale in the United States are packaged into brand styles which meet the requirements of subclause (I).

If an application is approved by the Secretary, the rotation schedule described in clause (iii) shall apply with respect to the applicant during the 1-year period beginning on the date of the application approval.

"(ii) PLAN.—An applicant under clause (i) shall include in its application a plan under which the label statements specified in subparagraph (A) of paragraph (1) will be rotated by the applicant manufacturer or importer in accordance with the label rotation described in clause (iii).

"(iii) OTHER ROTATION REQUIREMENTS.—Under the rotation schedule which the manufacturer or importer with an approved application may put into effect, each of the label statements specified in subparagraph (A) of paragraph (1) shall appear on the packages of each brand style of cigarettes with respect to which the application was approved an equal number of times within the 12-month period beginning on the date of the approval by the Secretary of the application.

"(5) APPLICATION OF REQUIREMENT.—Paragraph (1) does not apply to a distributor or retailer of cigarettes who does not manufacture, package, or import cigarettes for sale or distribution within the United States.

"(6) TELEVISION AND RADIO ADVERTISING.—It shall be unlawful to advertise cigarettes and little cigars on any medium of electronic communications subject to the jurisdiction of the Federal Communications Commission.

"(b) SMOKELESS TOBACCO.—

"(1) IN GENERAL.—

"(A) PACKAGING.—It shall be unlawful for any person to manufacture, package, or import for sale or distribution within the United States any smokeless tobacco the package of which fails to bear, in accordance with the requirements of this subsection, one of the following statements:

WARNING: This Product May Cause Mouth Cancer.

WARNING: This Product May Cause Gum Disease And Tooth Loss.

WARNING: This Product Is Not A Safe Alternative To Cigarettes.

WARNING: Smokeless Tobacco Is Addictive.

"(B) ADVERTISING.—It shall be unlawful for any manufacturer or importer of smokeless tobacco to advertise or cause to be advertised

within the United States any smokeless tobacco unless the advertising bears, in accordance with the requirements of this subsection, one of the following statements:

WARNING: This Product May Cause Mouth Cancer.

WARNING: This Product May Cause Gum Disease And Tooth Loss.

WARNING: This Product Is Not A Safe Alternative To Cigarettes.

WARNING: Smokeless Tobacco Is Addictive.

"(2) REQUIREMENTS FOR LABEL STATEMENTS.—

"(A) LOCATION.—Each label statement required by subparagraph (A) of paragraph (1) shall be located on the principal display panel of the product and occupy not less than 25 percent of such panel.

"(B) TYPE AND COLOR.—With respect to each label statement required by subparagraph (A) of paragraph (1), the phrase 'WARNING' shall appear in capital letters and the label statement shall be printed in 17 point type with adjustments as determined appropriate by the

Secretary to reflect the length of the required statement. All the letters in the label statement shall appear in conspicuous and legible type in contrast by typography, layout, or color with all other printed material on the package and be printed in an alternating black on white and white on black format as determined appropriate by the Secretary.

"(3) ADVERTISING AND ROTATION.—The provisions of paragraphs (3) and (4)(A) of subsection (a) shall apply to advertisements for smokeless tobacco and the rotation of the statements required under paragraph (1)(A) on such products.

"(4) APPLICATION OF REQUIREMENT.—Paragraph (1) does not apply to a distributor or retailer of smokeless tobacco who does not manufacture, package, or import such products for sale or distribution within the United States.

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

"(c) ADDITIONAL TOBACCO PRODUCT STATEMENTS.—

"(1) REQUIREMENT.—Each manufacturer, distributor, and retailer advertising or causing to be advertised, disseminating or causing to be disseminated advertising concerning, tobacco products otherwise permitted under this chapter shall include, in a type size and format as the Secretary may prescribe in a regulation promulgated under subsection (d), the product name and a statement of the general use of the product as provided for in paragraph (2).

"(2) GENERAL USE STATEMENTS.—

"(A) CIGARETTES.—A statement of general use for cigarettes or cigarette tobacco is as follows (whichever is appropriate):

'Cigarettes—A Dangerous Tobacco Product Intended For Use Only By Persons 18 or Older.

'Cigarette Tobacco—A Dangerous Tobacco Product Intended For Use Only By Persons 18 or Older.

"(B) SMOKELESS TOBACCO.—A statement of general use for a smokeless tobacco is as follows (whichever is appropriate):

'Loose Leaf Chewing Tobacco—A Dangerous Tobacco Product Intended For Use Only By Persons 18 or Older.

'Plug Chewing Tobacco—A Dangerous Tobacco Product Intended For Use Only By Persons 18 or Older.

'Twist Chewing Tobacco—A Dangerous Tobacco Product Intended For Use Only By Persons 18 or Older.

'Moist Snuff—A Dangerous Tobacco Product Intended For Use Only By Persons 18 or Older.

'Dry Snuff—A Dangerous Tobacco Product Intended For Use Only By Persons 18 or Older.

"(d) REGULATIONS.—

"(1) IN GENERAL.—Not later than 180 days after the date of the enactment of this title, the Secretary shall promulgate such regulations as may be necessary to implement subsections (a), (b), and (c).

"(2) AUTHORITY TO REVISE TOBACCO PRODUCT LABELING STATEMENTS.—

"(A) IN GENERAL.—The Secretary may by informal notice and comment rulemaking change the text of any of the statements required under subsections (a) and (b). A rule promulgated under this subparagraph shall not become effective prior to the expiration of the 1-year period beginning on the date on which

the final rule is published in the Federal Register.

"(B) LIMITATION.—The Secretary may not promulgate any rule under subparagraph (A) during the 5-year period beginning on the effective date of the PAST Act unless the Secretary can demonstrate extraordinary circumstances.

"(C) ASSESSMENTS.—The Secretary, in consultation with the Tobacco Products Scientific Advisory Committee and other relevant experts, shall, as scientific data regarding the effectiveness of warning labels in deterring youth smoking becomes available, periodically (but not more frequently that once every 3 years) assess the efficacy of current labels and the public health benefits of revising such labels.

"(3) COMMON OR USUAL NAMES.—The Secretary, in accordance with the procedures set forth in section 903, shall promulgate regulations requiring the disclosure to the public of the common or usual name of each ingredient (other than tobacco, water, or reconstituted tobacco sheet made wholly from tobacco) contained in a tobacco product in de-

scending order of predominance by weight, except that such regulations—

"(A) may provide for the disclosure of spices, flavorings, and colorings but shall not name each spice, flavoring, or coloring; and

"(B) may exempt from disclosure incidental additives, including processing aids and chemical preservatives, that are present in a tobacco product at insignificant levels that the Secretary determines do not have any functional effect or health risk.

"(e) EXPORTS.—Packages of cigarettes or smokeless tobacco manufactured, imported, or packaged—

"(1) for export from the United States; or

"(2) for delivery to a vessel or aircraft, as supplies, for consumption beyond the jurisdiction of the internal revenue laws of the United States;

shall be exempt from the requirements of this chapter, but such exemptions shall not apply to cigarettes or smokeless tobacco manufactured, imported, or packaged for sale or distribution to members or units of the Armed Forces of the United States located outside of the United States.

"SEC. 906. RESTRICTION ON MARKETING AND ADVERTISING.

[Bolded language to be discussed based on 1st amendment concerns]

"(a) PROHIBITIONS ON ADVERTISING.—

"(1) PROHIBITION ON OUTDOOR ADVERTISING.—

"(A) IN GENERAL.—No manufacturer, distributor, or retailer may use any form of outdoor tobacco product advertising, including billboards, posters, placards, or other fixed or movable outdoor product advertising within 1,000 feet of the perimeter of any elementary or secondary school, or with 1,000 feet of the perimeter of a public playground, pool, or playground area in a public park.

"(B) STADIA AND ARENAS.—A manufacturer, distributor, or retailer shall not advertise, by signage or other means that is fixed and permanent, tobacco products in any arena or stadium where athletic, musical, artistic, or other social or cultural events or activities occur unless such advertis-

ing takes place during an athletic, musical, artistic or other social or cultural event or activity that does not include a significant number of individuals who are under 18 years of age in the audience.

"(2) PROHIBITION ON USE OF HUMAN IMAGES AND CARTOONS.—No manufacturer, distributor, or retailer may use a human image or a cartoon character or cartoon-type character in its advertising, labeling, or promotional material with respect to a tobacco product.

"(3) PROHIBITION ON ADVERTISING ON THE INTERNET.—No manufacturer, distributor, or retailer may use the Internet to advertise tobacco products unless such an advertisement is—

"(A) inaccessible in or from the United States; or

"(B) located at an Internet site that is not likely to be viewed by a significant number of individual who are under 18 years of age.

"(4) PROHIBITION ON POINT-OF-SALE ADVERTISING.—

"(A) IN GENERAL.—Except as otherwise provided in this paragraph, no manufacturer, distributor, or retailer may use point-of-sale advertising of tobacco products.

"(B) PERMISSIBLE ADVERTISING.—

"(i) IN GENERAL.—Each manufacturer of tobacco products may display not more than 2 separate point-of-sale advertisements in or at each location at which tobacco products are offered for sale.

"(ii) RETAILERS.—A retailer may have not more than 1 point-of-sale advertisement relating to the retailer's own or its wholesaler's contracted retailer or private label brand of tobacco product.

"(C) LIMITATIONS.—

"(i) IN GENERAL.—A point of sale advertisement permitted under this paragraph shall be comprised of a display area that is not larger than 576 square inches (either individually or in the aggregate)

and shall consist only of black letters on a white background or other recognized typographical marks. Such advertisement shall not be attached to nor located within 2 feet of any fixture on which candy is displayed for sale.

"(ii) AUDIO AND VIDEO FORMATS.—Audio and video advertisements permitted under subsection (c)(3) may be distributed to individuals who are 18 years of age or older at point of sale but may not be played or viewed at such point of sale.

"(iii) DISPLAY FIXTURES.—Display fixtures in the form of signs consisting of brand name and price and not larger than 2 inches in height are permitted.

"(D) DEFINITION.—For purposes of this paragraph, the term 'point-of-sale advertising' means all printed or graphical materials bearing the brand name (alone or in conjunction with any other word), logo, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification similar or identical to those used for tobacco products which, when used for its intended purpose, can

reasonably be anticipated to be seen by customers at a location at which tobacco products are offered for sale.

"(b) GENERAL RESTRICTIONS.—

"(1) RESTRICTION ON PRODUCT NAMES.—**A manufacturer shall not use a trade or brand name of a nontobacco product as the trade or brand name for a cigarette or smokeless tobacco, except for a tobacco product whose trade or brand name was on both a tobacco product and a nontobacco product that were sold in the United States on or before January 1, 1995.**

"(2) ADVERTISING LIMITED TO MEDIA SPECIFIED BY THE SECRETARY.—

"(A) IN GENERAL.—**A manufacturer, distributor, or retailer may, in accordance with this chapter, disseminate or cause to be disseminated advertising or labeling which bears a tobacco product brand name (alone or in conjunction with any other word) or any other indicia of tobacco product identification only in news-**

papers, in magazines, in periodicals or other publications (whether periodic or limited distribution), in nonpoint-of-sale promotional material (including direct mail), in point-of-sale promotional material, and in audio or video formats delivered at a point-of-sale without notice to the Secretary.

"(B) LIMITATION.—A manufacturer, distributor, or retailer that intends to disseminate, or to cause to be disseminated, advertising or labeling for a tobacco product in a medium that is not described in subparagraph (A) shall notify the Commissioner not less than 30 days prior to the date on which such medium is to be used. Such notice shall describe the medium and discuss the extent to which the advertising or labeling may be seen by individuals who are under 18 years of age.

"(3) RESTRICTION ON PLACEMENT IN ENTERTAINMENT MEDIA.—

"(A) IN GENERAL.—No direct or indirect payment shall be made by any manufacturer, distributor, or retailer for the placement or use of any tobacco product or tobacco product package or advertisement—

"(i) as a prop in any television program or motion picture likely to be viewed by a significant number of individuals who are under 18 years of age; or

"(ii) in a video or on a video game machine.

"(B) VIDEO GAME.—The term 'video game' means any electronic amusement device that utilizes a computer, microprocessor, or similar electronic circuitry and its own cathode ray tube, or is designed to be used with a television set or a monitor, that interacts with the user of the device.

"(c) FORMAT AND CONTENT REQUIREMENTS FOR LABELING AND ADVERTISING.—

"(1) IN GENERAL.—Except as provided in paragraphs (2) and (3), each manufac-

turer, distributor, and retailer advertising or causing to be advertised, disseminating or causing to be disseminated, any labeling or advertising for a tobacco product shall use only black text on a white background.

"(2) CERTAIN ADVERTISING EXCEPTED.—

"(A) IN GENERAL.—Paragraph (1) shall not apply to advertising—

"(i) in any facility where vending machines are permitted under this chapter if the advertising involved—

"(I) occurs in a facility that has not been prohibited by the applicable laws of the State or political subdivision involved from selling tobacco products;

"(II) is not visible from outside of the facility; and

"(III) is affixed to a wall or fixture in the facility; and

"(ii) that appears in any publication (whether periodic, limited,

or controlled distribution) that the manufacturer, distributor, or retailer demonstrates is an adult publication.

"(B) ADULT PUBLICATION.—For purposes of subparagraph (A)(ii), the term 'adult publication' means a newspaper, magazine, periodical, or other publication—

"(i) whose readers under 18 years of age constitute 15 percent or less of the total readership as measured by competent and reliable survey evidence; or

"(ii) that is read by fewer than 2,000,000 individuals who are under 18 years of age as measured by competent and reliable survey evidence.

"(3) AUDIO OR VIDEO FORMATS.—Each manufacturer, distributor, and retailer advertising or causing to be advertised any advertising for a tobacco product in an audio or video format shall comply with the following:

"(A) With respect to an audio format, the advertising shall be limited to words only with no music or sound effects.

"(B) With respect to a video format, the advertising shall be limited to static black text only on a white background. Any audio with the video advertising shall be limited to words only with no music or sound effects.

"(d) BAN ON NONTOBACCO ITEMS AND SERVICES, CONTESTS AND GAMES OF CHANCE, AND SPONSORSHIP OF EVENTS.—

"(1) BAN ON ALL NONTOBACCO MERCHANDISE.—No manufacturer, importer, distributor, or retailer shall market, license, distribute, sell, or cause to be marketed, licensed, distributed or sold any item (other than tobacco products) or service which bears the brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification

similar or identifiable to those used for any brand of tobacco products.

"(2) GIFTS, CONTESTS, AND LOTTERIES.—No manufacturer, distributor, or retailer shall offer or cause to be offered to any person purchasing tobacco products any gift or item (other than a tobacco product) in consideration of the purchase of such products, or to any person in consideration of furnishing evidence, such as credits, proofs-of-purchase, or coupons, of such a purchase.

"(3) SPONSORSHIP.—

"(A) IN GENERAL.—No manufacturer, distributor, or retailer shall sponsor or cause to be sponsored any athletic, musical, artistic, or other social or cultural event, or any entry or team in any event, in which the brand name (alone or in conjunction with any other word), logo, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification similar or

identical to those used for tobacco products is used.

"(B) USE OF CORPORATE NAME.—A manufacturer, distributor, or retailer may sponsor or cause to be sponsored any athletic, musical, artistic, or other social or cultural event in the name of the corporation which manufactures the tobacco product if—

"(i) both the corporate name and the corporation were registered and in use in the United States prior to January 1, 1995; and

"(ii) the corporate name does not include any brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia or product identification identical or similar to, or identifiable with, those used for any brand of tobacco products.

"(e) ADDITIONAL RESTRICTIONS.—The Secretary may by informal notice and comment rulemaking, and only in conjunction with the Federal Trade Commission, impose additional restrictions on the marketing and advertising of tobacco products if the Secretary determines that such marketing and advertising is significantly contributing to the use of tobacco products by individuals who are under 18 years of age. The Federal Trade Commission and the Secretary shall set forth their respective duties in a memorandum of understanding to be submitted to the Committee on Commerce of the House of Representatives, the Committee on Commerce of the Senate and the Committee on Labor and Human Resources of the Senate.

"SEC. 907. REDUCED RISK TOBACCO PRODUCTS.

"(a) REQUIREMENTS.—

"(1) IN GENERAL.—For purposes of this chapter, the term 'Reduced Risk Tobacco Product' means a tobacco product that delivers nicotine to the human body while simultaneously delivering 1 or more other toxic substances to the human body, and which the Secretary designates as a Reduced Risk Tobacco product under paragraph (2).

"(2) DESIGNATION.—A product shall be designated by the Secretary as a Reduced Risk Tobacco Product if—

"(A) the Secretary finds that the product has the potential to reduce harm to individuals and overall public health caused by a tobacco product, based on an application submitted by the manufacturer of the product (or other responsible person) that—

"(i) demonstrates, on the basis of chemical analysis, that use of such product results in ingestion or inhalation of a substantially lower yield of toxic substances than use of conventional tobacco products in the same category as the proposed reduced risk product; and

"(ii) demonstrates, through appropriate testing on animals and humans, that use of the product presents substantially less risk to human health than use of conventional tobacco products; and

"(B) the manufacturer (or other person) agrees to conduct studies of the long-term health effects of such product (in accordance with 1 or more protocols agreed upon between the manufacturer of the product and the Secretary) and submit the results of such study, together with underlying data, to the Secretary.

"(3) MARKETING REQUIREMENTS.—A tobacco product may be marketed as a Reduced Risk Tobacco Product only if such product—

"(A) bears a label, prescribed by the Secretary, stating that the product contains toxic substances other than nicotine, that such product should only be used by persons who use tobacco products, and other relevant information;

"(B) bears a label, as prescribed by the Secretary, concerning the product's contribution to reducing harm to health; and

"(C) complies with requirements prescribed by the Secretary relating to marketing and advertising of the product, and other provisions of this chapter as prescribed by the Secretary.

"(b) REVOCATION OF DESIGNATION.—At any time after the date on which a tobacco product is designated as a Reduced Risk Tobacco Product under this section the Secretary may, after providing an opportunity for an informal hearing, revoke such designation if the Secretary determines, based on information not available at the time of the designation, that—

"(1) the finding made under subsection (a)(2)(A) is no longer valid; or

"(2) the studies required under subsection (a)(2)(B) are not conducted on a timely basis.

"(c) STUDIES.—The Secretary, in consultation with the Tobacco Products Scientific Advisory Committee, shall conduct and support, through grants and contracts, studies of the role of smoking cessation products and reduced risk tobacco products in reducing the burden of illness and death in the United States resulting from the use of tobacco products.

"(d) REGULATION AS A NEW DRUG.—Any tobacco product accompanied by a claim to diagnose, cure, mitigate, treat, or prevent a disease, not including statements that the Secretary may permit for reduced risk tobacco products under this section, will be subject to regulation as a new drug under section 505.

"(e) DEVELOPMENT OF REDUCED RISK TOBACCO PRODUCT TECHNOLOGY.—

"(1) NOTIFICATION OF SECRETARY.—The manufacturer of a tobacco product shall provide written notice to the Secretary upon the development or acquisition by the manufacturer of any technology that would reduce the risk of such products to the health of the user for which the manufacturer is not seeking designation as a 'Reduced Risk Tobacco Product' under subsections (a) and (b).

"(2) DETERMINATION.—Within 6 months of the date on which a notice is received by the Secretary under paragraph (1), the Secretary shall determine whether the technology described in such notice is likely to result in tobacco products that are less hazardous to the health of users.

"(3) CONFIDENTIALITY.—The Secretary shall, not later than 180 days after the date of enactment of this chapter, promulgate regulations to provide a manufacturer with appropriate confidentiality protections with respect to technology that is the subject of a determination under paragraph (2), but in no case will require the disclosure to the public of any trade secret or confidential commercial information.

"(4) LICENSING.—

"(A) IN GENERAL.—With respect to any technology for which a notification has been provided under paragraph (1), the manufacturer shall permit the licensure and use of such technology by other manufacturers of tobacco products to which this chapter applies.

"(B) FEES.—The Secretary of Commerce shall, not later than 180 days after the date of enactment of this chapter, promulgate regula-

tions to provide for the payment of a commercially reasonable fee by each manufacturer that uses the technology described under subparagraph (A) to the manufacturer that submits the notice under paragraph (1) for such technology. Such regulations shall contain procedures for the resolution of fee disputes between manufacturers under this subparagraph through the use of expert arbitrators.

"(f) REQUIREMENT OF MANUFACTURE AND MARKETING.—

"(1) PURPOSE.—It is the purpose of this subsection to provide for a mechanism to create incentives that help ensure that tobacco products that are designed to be less hazardous to the health of users are developed, tested, and made available to consumers.

"(2) DETERMINATION.—Upon a determination by the Secretary that the manufacture of a tobacco product that is less hazardous to the health of users is technologically and commercially feasible, the Secretary may, in accordance with this subsection and through the issuance or amendment of a health risk reduction standard under section 903—

"(A) require the disclosure of the existence of such technology;

"(B) prohibit the use of technology that is superseded by such new technology; and

"(C) require that manufacturers cease manufacturing and marketing tobacco products that do not incorporate such technology.

"(g) BASIS FOR DETERMINATION.—For purposes of subsections (e)(2) and (f)(2), the determination as to whether a tobacco product may be less hazardous to the health of users shall take into account the reduced risk to the health of the user, its contribution to reducing addiction to tobacco products, and the overall public health.

"SEC. 908. TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE.

"(a) ESTABLISHMENT.—Not later than 1 year after the date of enactment of this chapter, the Secretary shall establish an advisory committee, to be known as the 'Tobacco Products Scientific Advisory Committee', to assist the Secretary in establishing, amending, or revoking a regulation promulgated under section 903, 904, 905, or 907.

"(b) MEMBERSHIP.—

"(1) IN GENERAL.—The Secretary shall appoint as members of the Tobacco Products Scientific Advisory Committee—

"(A) individuals with expertise in the medicine, science, or technology involving the manufacture and use of tobacco products, who are of appropriately diversified professional backgrounds;

"(B) individuals with expertise in law or ethics;

"(C) a representative of tobacco product manufacturers;

"(D) a representative of the general public selected from public health organizations; and

"(E) a representative of the general public selected from organizations representing users of 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 Federal Government. The Secretary may appoint Federal officials as ex-officio members.

"(3) CHAIRPERSON.—The Secretary shall designate 1 of the members of advisory committee to serve as chairperson of the Advisory Committee.

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

"(1) in establishing, amending, or revoking regulations under section 903, 904, 905, or 907;

"(2) on the effects of the alteration of the nicotine yield levels in tobacco products;

"(3) on whether there is a threshold level below which nicotine yields do not produce dependence on the tobacco product involved, and, if so, determine what that level is; and

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

"SEC. 909. REPORTS.

"Not later than 18 months after the date of enactment of this chapter, and biennially thereafter, the Secretary shall prepare and submit to Congress a report containing—

"(1) a description of the current sales, advertising, and marketing practices associated with tobacco products;

"(2) a description of the use patterns of tobacco products, including a report on use by individuals under 18 years of age;

"(3) a description of the effects of health promotion and disease prevention efforts related to the use of tobacco products;

"(4) an evaluation of the health promotion and disease prevention efforts relating to tobacco products and the identification of areas appropriate for further research; and

"(5) such recommendations for legislation and administrative action relating to tobacco products as the Secretary considers appropriate.

"SEC. 910. JUDICIAL REVIEW.

"(a) APPLICATION OF SECTION.—

"(1) IN GENERAL.—Not later than 60 days after the effective date of any regulation under this chapter establishing, amending, or revoking a health risk reduction standard for a tobacco product, any person adversely affected by such regulation may file a petition with the United States Court of Appeals for the District of Columbia or for the circuit wherein such person resides or has its principal place of business for judicial review of such regulation. A copy of the petition shall be transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose.

"(2) RECORD OF PROCEEDING.—The Secretary shall file in the court under paragraph (1) the record of the proceedings on which the Secretary

based the regulation involved as provided for in section 2112 of title 28, United States Code.

"(3) DEFINITION.—For purposes of this section, the term 'record' means all notices and other matter published in the Federal Register with respect to the regulation reviewed, all information submitted to the Secretary with respect to such regulation, proceedings of any panel or advisory committee with respect to such regulation, any hearing held with respect to such regulation, and any other information identified by the Secretary, in the administrative proceeding held with respect to such regulation, as being relevant to such regulation.

"(b) ADDITIONAL DATA, VIEWS, AND ARGUMENTS.—If the petitioner applies to the court under this section for leave to adduce additional data, views, or arguments respecting the regulation being reviewed and shows to the satisfaction of the court that such additional data, views, or arguments are material and that there were reasonable grounds for the petitioner's failure to adduce such data, views, or arguments in the proceedings before the Secretary, the court may order the Secretary to provide additional opportunity for the oral presentation of data, views, or arguments and for written submissions. The Secretary may modify such findings, or make new findings by reason

of the additional data, views, or arguments so taken and shall file with the court such modified or new findings, and the recommendations of the Secretary, if any, for the modification or setting aside of the regulation or order being reviewed, with the return of such additional data, views, or arguments.

"(c) STANDARD FOR REVIEW.—Upon the filing of the petition under subsection (a) judicial review of a regulation, the court shall have jurisdiction to review the regulation 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 promulgated under this chapter shall not be affirmed if it is found to be arbitrary and capricious.

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

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

"(f) STATEMENT OF REASONS.—To facilitate judicial review under this section or under any other provision of

law of a regulation issued under this chapter, each such regulation shall contain a statement of the reasons for its issuance and the basis, in the record of the proceedings held in connection with its issuance, for its issuance.

"SEC. 911. AUTHORITY TO ASSESS AND USE FEES.

"(a) IN GENERAL.—The Secretary shall, not later than 60 days after the date of enactment of this chapter, annually assess and collect fees for submissions made under sections 902, 903, and 907 in accordance with this section to be used as the sole source of funding with respect to the regulation and control of tobacco products under this chapter.

"(b) TOBACCO PRODUCT FEE.—The Secretary shall set the amount of the fees under subsection (a) for a fiscal year to equal $100,000,000.

"(c) PAYMENT SCHEDULE.—The Secretary shall promulgate regulations to implement procedures for the assessment and collection of fees under this section.

"(d) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (b) 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) APPORTIONMENT OF FEES.—The Secretary shall, not later than 60 days after the enactment of this chapter, issue regulations apportioning fees under subsection (a) among submissions required under sections 902, 903, and 907.

"SEC. 912. PRESERVATION OF STATE AND LOCAL AUTHORITY.

"(a) ADDITIONAL REQUIREMENTS.—

"(1) IN GENERAL.—Except as provided in paragraph (3), nothing in this Act shall be construed as prohibiting a State or political subdivision thereof from adopting or enforcing a requirement applicable to a tobacco product that is in addition to, or more stringent than, requirements established under this chapter.

"(2) APPLICATION OF STATE LAW.—In the case of a requirement of a State or political subdivision thereof that is more stringent than a requirement established under this chapter, the requirement of the State or political subdivision shall apply.

"(3) PREEMPTION OF STATE AND LOCAL REQUIREMENTS.—No State or political subdivision of a State may establish or continue in effect with respect to a tobacco product or manufacturer thereof any requirement that relates to, and is different

from or in addition to, any requirement applicable under sections 902, 903, 904, 905, and 907.

[“(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.] [To be revised]

“(c) WAIVERS.—Upon the application of a State or political subdivision thereof, the Secretary may, by regulation promulgated after notice and an opportunity for an oral hearing, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a tobacco product if—

“(1) the requirement is more stringent than a requirement applicable under the provisions described in subsection (a)(3) which would be applicable to the tobacco product if an exemption were not in effect under this subsection; or

“(2) the requirement—

“(A) is required by compelling local conditions; and

“(B) compliance with the requirement would not cause the tobacco product to be in

violation of any applicable requirement of this chapter.

"SEC. 913. RECALL AUTHORITY.

"(a) IN GENERAL.—If the Secretary finds that there is a reasonable probability that a tobacco product has been distributed in violation of this chapter in a manner that would pose a greater thereat to public health than the threat normally posed to public health by similar tobacco products, the Secretary shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the product) to immediately cease distribution of such 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 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.

"(b) AMENDMENT TO ORDER.—

"(1) IN GENERAL.—If, after providing an opportunity for an informal hearing under subsection (a), 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 paragraphs (2) and (3), 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.

"(2) LIMITATIONS.—An amended order under paragraph (1)—

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

"(B) shall provide for notice to individuals subject to the risks associated with the use of such product.

"SEC. 914. SEVERABILITY AND STATEMENT OF AUTHORITY.

"(a) SEVERABILITY.—If any provision of this chapter or the application thereof to any person or circumstance is held invalid, the invalidity shall not affect the other provisions of this chapter and the application of such provision to other persons or circumstances shall not be affected thereby.

"(b) TECHNICAL STATEMENT OF AUTHORITY.—The regulations describing the general provisions and the restrictions on labels, labeling and advertising of tobacco

products promulgated by the Secretary in the rule dated August 28, 1996, adding subparts A and B of part 897 to title 21, Code of Federal Regulations, shall be deemed to have been promulgated under the this chapter.".

SEC. 104. TECHNICAL PROVISIONS.

(a) APPLICATION OF FEDERAL CIGARETTE LABELING AND ADVERTISING ACT.—The provisions of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1331 et seq.) that apply to cigarettes shall be superseded by the provisions of this title (and the amendments made by this title).

(b) REPEAL.—The Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4401 et seq.) is repealed.

(c) PRESERVATION OF FEDERAL TRADE COMMISSION AUTHORITY.—Nothing in this title, or an amendment made by this title, shall be construed to limit the authority of the Federal Trade Commission to regulate the advertising and marketing of tobacco products pursuant to its authority under sections 5 and 12 of the Federal Trade Commission Act.

SEC. 105. FEDERAL LICENSING OF MILITARY AND OTHER ENTITIES.

(a) IN GENERAL.—The Secretary, in consultation with the Secretary of Defense, Secretary of State, and

other appropriate Federal officials, shall establish and implement a Federal tobacco licensing program to be applied to entities that sell or distribute tobacco products—

(1) on any military installation (as defined in section 2801(c)(2) of title X, United States Code);

(2) in any United States embassy;

(3) in any facility owned and operated by the Federal Government either in the United States or in a foreign country;

(4) in any duty-free shop located within the United States; or

(5) through any other Federal entity or on any other Federal property as determined appropriate by the Secretary.

(b) REQUIREMENTS OF PROGRAM.—The program established under subsection (a) shall apply requirements (including those for penalties, suspensions, and revocations) similar to those required to be implemented by States under this title (and the amendments made by this title).

(c) INDIAN TRIBES AND TRIBAL LANDS.—For purposes of applying and enforcing the provisions of this title (and the amendments made by this title) to entities that sell or otherwise distribute tobacco products on Indian reservations (as defined in section 403(9) of the Indian Child

Protection and Family Violence Prevention Act (25 U.S.C. 3202(9))), an Indian tribe or tribal organization shall be treated as a State.

TITLE II—NATIONAL EFFORTS TO REDUCE YOUTH SMOKING

SEC. 201. SHORT TITLE.

This title may be cited as the "Tobacco Use by Minors Prevention Act".

SEC. 202. AMENDMENT TO PUBLIC HEALTH SERVICE ACT

(a) IN GENERAL.—The Public Health Service Act (42 U.S.C. 201 et seq.) is amended by adding at the end the following:

"TITLE XXVIII—NATIONAL EFFORTS TO REDUCE YOUTH SMOKING

"SEC. 2801. DEFINITIONS.

"For purposes of this title, the definitions contained in section 900 of the Food, Drug and Cosmetic Act shall apply.

"Subtitle A—Required Reduction in Underage Use of Tobacco Products

"SEC. 2811. PURPOSE.

"It is the purpose of this title to encourage the achievement of dramatic and immediate reductions in the

J. PHIL CARLTON, ESQUIRE

Tob - set - new legislation - Jeffords bill

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March 10, 1998

The Honorable James M. Jeffords
Chairman
Committee on Labor and Human Resources
428 Dirksen Senate Office Building
Washington, D.C. 20510-6300

Dear Senator Jeffords:

I write on behalf of Philip Morris Companies Inc., RJR Nabisco, Inc., Lorillard Tobacco Company, Brown & Williamson Tobacco Corporation, and United States Tobacco Company.

We have had an opportunity to review your mark of S. 1648, the Preventing Addiction to Smoking Among Teens Act. Unfortunately, the proposed substitute has not addressed any of the concerns the industry expressed about the bill as introduced. If anything, the substitute has enhanced our concerns, and represents a significant step backward in efforts to achieve comprehensive tobacco legislation. The industry cannot support any legislation that is so fundamentally flawed and involves such drastic infringements of its constitutional rights.

Many aspects of the proposed substitute are problematic. Industry representatives have raised these issues with your staff, and I will not attempt to list them here. The most troublesome, however, include (but are not limited to) the following areas:

- **Advertising.** The substitute would impose advertising restrictions by legislation, which would violate the First Amendment. As virtually all constitutional scholars who have addressed the issue have recognized, the extensive advertising restrictions to which the tobacco industry has agreed must be implemented through enforceable agreements with the federal government and the states. They cannot be imposed by statute or rule.

- **Look-back.** As part of the tobacco settlement, the industry agreed to a look-back provision that would require it to pay annually, up-front, the total value of the anticipated lifetime "profits" that would be earned from sales to any underage tobacco users in excess of the look-back targets. Even though the industry would comply fully with the many measures mandated to reduce underage tobacco use, the newly proposed

look-back mechanism could still confiscate tens of billions of dollars from the industry annually if the massive reductions in underage tobacco use were not fully achieved.

The amounts and allocation method of the proposed substitute could automatically operate to put the entire industry out of business and confiscate all of its assets, despite the industry's scrupulous adherence to the new regime. Such a confiscatory taking — without fault — cannot constitutionally be effected without the industry's consent. The industry cannot possibly consent to legislation containing the look-back provisions included in the substitute.

- **Trade secrets.** The substitute would permit FDA to disseminate the precise brand-by-brand recipes for each company's products -- highly valuable and competitively sensitive trade secrets that the companies would be compelled to submit to FDA. Such destruction of the companies' intellectual property, without just compensation, would violate the Taking Clause of the Fifth Amendment.

- **Back-door Prohibition.** The substitute would allow FDA to establish a back-door ban on tobacco products by establishing performance standards or ordering the manufacturers to produce "reduced risk" products that are not technologically feasible or will not be accepted by consumers. No one in this debate has advocated prohibition and it should not be provided for indirectly.

- **Preemption.** The substitute would largely abandon the 30-year policy of national uniformity in the regulation of cigarette advertising and labeling. It would overturn the *Cipollone* decision, and it would allow states to require health warnings in advertisements in addition to those required by the bill, and even to ban what little advertising the bill would continue to permit.

- **Documents.** The substitute appears to seek the public release of internal company documents containing trade secrets and communications protected by the attorney-client privilege. In addition to the Taking Clause violation, this automatic abrogation of the attorney-client privilege would abridge the companies' constitutional right to assistance of counsel.

The national tobacco settlement negotiated by the Attorneys General, representatives of the public health community, attorneys for class-action plaintiffs, and the tobacco industry marked a monumental step toward resolving the many issues relating to tobacco that have plagued our nation for decades, and achieving many of the public health community's most important goals, including steps intended to accomplish sharp reductions in underage tobacco use. While Congress and the President ultimately must determine the precise terms of any

national tobacco legislation, the fact is that the basic elements of the settlement agreement represent a carefully balanced compromise among parties with divergent and even antagonistic interests, which would significantly advance public health objectives while allowing the tobacco industry to move into the future on a new footing.

Any measure as extreme and unbalanced as the proposed substitute places any resolution of these issues in jeopardy. We are certain that this is not your intention. We hope you will reconsider the elements in the substitute that we have identified above, and the others that we have raised with your staff, before you proceed to markup.

As always, we would be happy to discuss this or any other issue with you.

Sincerely,

J. Phil Carlton

cc: The Honorable Dan Coats
The Honorable Judd Gregg
The Honorable Bill Frist
The Honorable Mike DeWine
The Honorable Michael B. Enzi
The Honorable Tim Hutchinson
The Honorable Susan M. Collins
The Honorable John W. Warner
The Honorable Mitch McConnell
The Honorable Edward M. Kennedy
The Honorable Christopher J. Dodd
The Honorable Tom Harkin
The Honorable Barbara A. Mikulski
The Honorable Jeff Bingaman
The Honorable Paul D. Wellstone
The Honorable Patty Murray
The Honorable Jack Reed

Tobacco - settlement - new legislation - Jeffords bill

Thomas L. Freedman
02/13/98 10:48:50 AM

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Subject: Jeffords Bill FYI

Friday February 13 6:37 AM EST

Senator Unveils Public Health Tobacco Bill

By Joanne Kenen

WASHINGTON (Reuters) - A key senator has introduced a tobacco bill that expands the authority of the Food and Drug Administration but does not address such touchy issues as how much cigarettes should cost or whether the industry should get any protection from lawsuits.

Sen. James Jeffords, a Vermont Republican and chairman of the Senate Labor and Human Relations Committee, drafted a bill that goes further in some respects than the proposed settlement negotiated by the tobacco companies and the states suing them last June.

It does not address financial and legal questions outside his committee's jurisdiction.

The Jeffords bill gives the FDA greater authority over nicotine than contemplated in the industry-backed proposal, and it significantly increases the penalties the companies would have to pay if they fail to meet targets for reducing youth smoking.

Instead of $80 million for each percentage point off the goal, penalties would be as high as $500 million a point.

Under current law, the FDA regulates products that must be "safe and effective." Since Jeffords said Thursday it is "ludicrous" to try to have cigarettes fit such criteria, his bill sets up a new category of FDA authority to cover tobacco and nicotine.

The FDA could reduce nicotine levels if the scientific evidence warranted it, but could not ban tobacco products. Such a decision, should it ever occur, would require Congressional approval, he said.

"The bill gives the FDA strong, effective and unambiguous authority to regulate cigarettes and nicotine," Jeffords told a news conference, also attended by Republican co-sponsors Sens. Susan Collins of Maine and Mike Enzi of Wyoming.

Enzi is also pushing a separate bill that would create a fund to pay smokers' medical bills and take the burden off Medicare and Medicaid.

However, in testimony before Jeffords' committee earlier this week, FDA deputy commissioner for policy William Schultz criticized some of the mechanisms Jeffords used. Shultz said it would "place

unacceptable limits on FDA's authority and future flexibility to regulate tobacco products."

By putting certain provisions into federal law, rather than agency-issued regulations, the FDA would be limited in its "authority to make future adjustments in regulating tobacco products" or to react to new scientific developments.

The bill bans cigarette vending machines and requires states to pass, and enforce, strict laws prohibiting the sale and distribution of tobacco products to minors. Underage smokers would also face civil penalties themselves.

Some public health experts also objected to Jeffords move to put the CDC in charge of state enforcement efforts, not the FDA which has traditionally had more regulatory authority.

Under the Jeffords bill, the industry would make payments, which Jeffords did not characterize as a tax, that would fund a Tobacco Settlement Trust Fund. It would pay for anti-smoking programs and programs to help people quit smoking and related public health initiatives. Some money would also go to smoking-related research at the National Institutes of Health and the Centers for Disease Control.

It would require the Occupational Safety and Health Administration to set rules within a year about indoor air quality in the workplace.

^REUTERS@

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