Tobacco - FDA

CAMPAIGN for TOBACCO-FREE Kids

NATIONAL CENTER FOR TOBACCO-FREE KIDS

Facsimile Transmission

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TO: Tom F.

FROM:

DATE: Sath Bal

SUBJECT:

This is something I did for the ALA but I know the public health community has concerns about a separate chapter for FDA.

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WHY A SEPARATE "CHAPTER" FOR TOBACCO PRODUCTS IS *NOT* THE PREFERED METHOD OF FDA REGULATION OF TOBACCO PRODUCTS

1. Tobacco products are medically, scientifically , and legally "drugs" and or "devices" under the Food Drug and Cosmetic Act. This view is supported by the public health community, the Food and Drug Administration as well as the tobacco industry's own internal documents and statements. The Food and Drug Administration has already claimed jurisdiction and is already using its existing authorities to regulate the sales and marketing of tobacco products to children. Treating such products as anything less than a "drug" would not be in the interests of the public health community, and would continue the special treatment and exceptions that have been provided to the tobacco industry for more than three decades.
2. The purpose of the "drug" and "device" provisions of the Act and the purpose and mission of the FDA itself is to not only ensure that safe and effective drug and device products are brought to the market place but to ensure that adulterated, misbranded and unsafe products are either kept off the market or appropriately controlled and regulated.
3. The definition of a drug and a device under the Food Drug and Cosmetic Act was intended by Congress to encompass and deal with products which were not listed in drug registries but which were intended by the manufacturer to "affect function and structure of the body" as well as intended " to mitigate or prevent disease". (i.e. low tar and nicotine). The legislative history of the Act as well as case law dating back to the 1950's clearly establishes the coverage of the FD&C Act over tobacco products.
4. FDA has a long standing history of regulating a myriad of products under its drug and device authorities; including the manufacturing sales and distribution, labeling and advertising and marketing of such products.
5. Tobacco products and the nicotine contained in them should be viewed as a "class" of drugs related to the use, abuse, and cessation of tobacco products. It makes sense to ensure that such products are regulated in a consistent and comprehensive manner – with the higher risk products being regulated more stringently and with the lower risk cessation products being subjected to less regulation.
6. There is well established regulatory and judicial case law for FDA regulation of "drugs" and "devices" Retaining FDA authorities over tobacco as "drugs" and or "devices" allows the agency to draw on years of regulatory experience as well as well established case law governing the regulation of "drugs" and "devices" . Establishing a new chapter could subject the FDA to endless lawsuits from the tobacco companies, who if their past actions are any indication would challenge every rule and regulation issued under a new regulatory scheme. Relying on well established authorities and procedures will limit such actions by the companies and more effectively ensure protection of the public health.

White House Press Release

REMARKS BY THE PRESIDENT ON TOBACCO SETTLEMENT REVIEW

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release September 17, 1997

REMARKS BY THE PRESIDENT
ON **TOBACCO** SETTLEMENT REVIEW

The Oval Office

10:55 A.M. EDT

THE PRESIDENT: Thank you very much. Mr. Vice President, Secretary Shalala, Secretary Glickman, thank you for your work. Thank you, Bruce Reed. I'd like to say a special word of thanks to David Kessler for the work he did -- historic work he did at the FDA when he was here. Thank you, Dr. Koop, and members of the public community who are here. To members of Congress, the Attorneys General, the representatives of plaintiffs in the private litigation -- and we have one of the injured parties here representing all of the them. We thank all of them for coming today.

This is a time of prosperity and hope and optimism for America, with our economy improving, making progress on our social problems, our efforts to lead the world to a more prosperous and peaceful future making headway. But I think we all know that this country still has some significant challenges, especially in the health field. And if we think about what we want America to be like in the 21st century, the health of our people and especially the health of our children must be paramount in our thinking, in our vision, and in our efforts.

That's why, a year ago, I worked with the FDA and we launched this nationwide effort to protect our children from the dangers of **tobacco** by reducing youth access to **tobacco** products, by preventing companies from advertising to our children.

The purpose of the FDA rule was to reduce youth smoking

would be willing to work with us. But we cannot have the FDA crippled here, and we have to have real and meaningful penalties if the targets for youth smoking are not met. And so I feel very good about that.

I think the Congress -- I think it's highly likely that they will take action. When they take action depends, I think, upon when they can work through the issues for themselves and how they decide how to divide up the work among the committees. But it's not too soon to start. We could have hearings on this fairly soon, and I would hope to work with the Congress to develop a bill that would embody these principles.

Q Mr. President, you haven't said what you're willing to agree to for the **tobacco** industry. Are you will to agree to immunity from future **liability**?

THE PRESIDENT: Well, I don't think they've asked for future **liability**, I think they've asked for immunity from **liability** for past suits. And the question there would be, what are they willing to agree to. They need to come and meet with us. We need to discuss it, and we need to see whether we can embody these five principles. These are the things I'm interested in.

To me, I'll say again, this is not primarily about money. This is about changing the behavior of the United States, both the behavior of the **tobacco** companies, the behavior of the American people, the future behavior of our children. I'm trying to create an environment here with these five principles that I believe would achieve that. And if they want to be our partners in it, I think we can get there. And I hope they will be.

Q Are you willing to put your prestige on the line to ensure that this becomes law?

THE PRESIDENT: Well, I think my personal prestige on this has been on the line for more than a year now. (Laughter.) There for a while, I thought more than my prestige was on the line. (Laughter.) You know, for a person involved in public life in Washington today, personal prestige may be an oxymoron. (Laughter.) But at least you still have your neck most days.

Q What do you say to the people -

Q -- protect the well-being of **tobacco** farmers - sounds like you're going to take away their livelihood.

THE PRESIDENT: Well, there are a number of things which can be done, and I don't want to get into the details. Secretary Glickman can talk about it. But we have had farmers in various sectors in our agriculture society facing constricted incomes before, and we have done things which helped them. There was a -- for example, I remember a few years ago something that affected dairy farmers in my state. There was a massive buy-out program for dairy farmers, and in a lot of states like Arkansas, there were any number of small farmers that were having a very difficult time who had a chance to start their life on a different basis.

I don't want to minimize this. **Tobacco** has a very high return per acre. So it's not a simple thing. You can't just say to a **tobacco** farmer to go plant soybeans, even if the soil will hold them. This is, from an agricultural point of view, economically complex. But, nonetheless, we have a responsibility to these people. They haven't done anything wrong. They haven't done anything illegal. They're good, hard-working, tax-paying citizens, and they

105TH CONGRESS
1ST SESSION

S. _____

IN THE SENATE OF THE UNITED STATES

Mr. JEFFORDS introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

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.

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "_____ Act".

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

SEC. 2. 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) 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.

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

(4) 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.

(5) The Office on Smoking and Health 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.

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

(7) 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 research, including policy-oriented, programmatic, be-

havioral, and biomedical research should be a substantial component of a national program to reduce the use of tobacco products.

(8) 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.

SEC. 3. GOALS AND PURPOSES.

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

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

(2) decrease 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 Food and Drug Administration 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 education, counter-advertising.

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

(1) provide for the funding by the tobacco industry of an aggressive [Federal 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;

(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 daily 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 cigarette products 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 cigarette products 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 cigarette products shall be at least 60 percent.

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

(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 products 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 products 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 products 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 B of title III.

→ Sec. 5 Definitions

TITLE I—REGULATION OF TOBACCO PRODUCTS AND TOBACCO PRODUCT DEVELOPMENT

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

(a) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

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

"(y) 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.".

(b) 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".

(c) REGULATION OF TOBACCO PRODUCTS.—The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is amended—

(1) by redesignating chapter IX as chapter X;

(2) by redesignating sections 901, 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. DEFINITIONS.

"In this chapter:

"(1) CIGARETTE.—The term 'cigarette' means any product which contains nicotine, is intended to be burned 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 re-

sult, 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.—The term 'tobacco product' means cigarettes and smokeless tobacco products for which no therapeutic claim is made.

"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 _____ 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 emphasis on discouraging the use of such products by young Americans, the Secretary shall—

"(1) develop and implement health risk management standards for tobacco products under section 902;

"(2) develop and implement good manufacturing practice standards for tobacco products under section 903;

"(3) develop and implement tobacco product labeling, warning, and packaging standards under section 904;

"(4) develop and implement standards that encourage the development and use of reduced risk tobacco products under section 906;

"(5) develop and implement tobacco product marketing standards under section 907;

"(6) establish and oversee a tobacco products scientific advisory committee under section 908 to provide advice on the establishment of tobacco product marketing standards under section 902, 903, 904, and 906; and

"(7) submit reports to Congress evaluating the effectiveness of this chapter and the _____ Act as described in section 909.

"SEC. 902. TOBACCO PRODUCT HEALTH RISK MANAGEMENT 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 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 proposed rulemaking for the establishment, amendment, or revocation of any health risk management standard for a tobacco product under this section. The Secretary shall publish an advance notice of proposed rulemaking in order to solicit broad input at an earlier stage in the rulemaking process.

"(B) CONTENTS OF NOTICE.—A notice of proposed rulemaking for the establishment or amendment of a health risk management stand-

ard 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 30 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 management standard for the tobacco product, including a draft or proposed health risk management standard, for consideration by the Secretary.

"(C) NOTICE OF REVOCATION.—A notice of proposed rulemaking for the revocation of a health risk management standard shall set forth a finding with supporting justification that the health risk management standard is no longer necessary with respect to the tobacco product.

"(D) COMMENTS.—The Secretary shall provide for a comment period of not less than 60 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 management 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 management 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 management standard and publish in the Federal Register findings on the matters referred to in subsection (b); 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 management 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 unless the Secretary determines that an earlier effective date is necessary for the protection of the public health. Such date or dates shall be established so as to minimize economic loss to, and disruption or dislocation of, domestic and international trade.

"(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 management standard for a tobacco product.

"(B) EFFECTIVENESS OF AMENDMENT.—The Secretary may declare a proposed amend-

ment of a health risk management 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 management 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 management standard under this section that requires—

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

"(i) the gradual reduction of nicotine yields of the product; or

"(ii) the reduction or elimination of other harmful constituents, ingredients (in-

cluding 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;

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

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

"(A) include provisions, subject to notice and comment, that are designed to reduce the overall health risks to the public, including the reduction in risk to the consumers of such products, individuals who reduce or cease the use of

such products, and individuals who do not initiate the use of such products, and based upon—

"(i) the best available technology; and

"(ii) the consideration of whether such provisions will result in the creation of a significant demand for, and supply of, contraband products or other tobacco products that do not meet the requirements of this chapter;

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

"(i) if technologically and commercially feasible, 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;

"(ii) specifying the procedures for the testing of such products, including devising procedures to be used by tobacco product manufacturers, the Secretary, or other ap-

propriate 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 management standards; and

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

"(C) as required under section 904, 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 tobacco products and determinations concerning such products under subsection (d).

"(3) 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 a class of tobacco products or elimination of nicotine.

"(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 management standard, except that with respect to a standard that results in a general prohibition of a class of tobacco products or the elimination of nicotine, such standard shall only take effect upon 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 CONSTITUENTS.—The health risk management standards promulgated under subsection (c)(4) 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.—

"(A) IN GENERAL.—The health risk management regulations under subsection (c)(4) 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 or such other ingredients for which testing has been required; 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.—Not 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 subsection (e)(1)(A) with respect to each brand of tobacco product manufactured by each such manufacturer.

"(B) AVAILABILITY OF NEW INFORMATION.—The Secretary may include in the regulations promulgated under this section, provisions that permit manufacturers to, in subsequent years, 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 simple 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 qualified third party organizations on behalf of more than 1 manufacturer for 1 or more product or 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 in the minds of competent scientists that the ingredient, sub-

stance, 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) 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 no-

tice of such 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.

"(ii) 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.

"(iii) 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 in-

volved until such time as the succeeding annual risk assessment is submitted by the manufacturer and the ingredient, substance, or compound is subsequently disapproved or conditioned.

"(e) ANNUAL SUBMISSION.—

"(1) IN GENERAL.—Each manufacturer of a tobacco product shall annually provide the Secretary with—

"(A) a list of all ingredients, substances, and compounds (other than tobacco, water or reconstituted tobacco sheet made wholly from tobacco) that are added in the manufacture of the tobacco product, for each brand of tobacco product so manufactured;

"(B) a description of the quantity of the ingredients, substances, and compounds that are listed under subparagraph (A) with respect to each brand of tobacco product;

"(C) a description of the nicotine content of the product, measured in milligrams of nicotine; and

"(D) any other information determined appropriate by the Secretary and included as a re-

quirement in a regulation promulgated under this section.

"(2) GENERAL DISCLOSURE AND CONFIDENTIALITY.—

"(A) REQUIREMENT.—Regulations under subsection (c)(4) shall require that each person who manufacturers, packages, or imports cigarettes or smokeless tobacco products shall annually provide the Secretary with the information required under this section, including information as to all ingredients, substances and compounds in a tobacco product.

"(B) CONFIDENTIALITY.—

"(i) PETITION BY MANUFACTURER.—Upon the submission of the information required under subsection (d)(1), or the submission of any other information under any other provisions of this chapter, a manufacturer may petition the Secretary to exempt certain ingredients, substances, or compounds or other information submitted from public disclosure under this subsection on the basis that such information should be considered confidential as a trade secret. Such petition may be accom-

panied by such data as the manufacturer elects to submit.

"(ii) DETERMINATION.—Not later than 90 days after receiving a petition under clause (i), the Secretary, in consultation with the Attorney General, shall make a determination with respect to whether the information described in the petition should be exempt from disclosure under clause (i) as a trade secret. The Secretary shall provide the manufacturer involved with notice of such determination, but the decision of the Secretary shall be final.

"(iii) PROCEDURES FOR CONFIDENTIAL INFORMATION.—The Secretary shall develop procedures to maintain the confidentiality of information that is treated as a trade secret under a determination under clause (ii). Such procedures shall include—

"(I) a requirement that such information be maintained in a secure facility; and

"(II) a requirement that only the Secretary, or the authorized agents of

the Secretary, will have access to the information and shall be instructed to maintain the confidentiality of such information.

"(iv) HEALTH DISCLOSURE.—Notwithstanding a determination under clause (ii), the Secretary may require that any ingredient, substance, or compound contained in a tobacco product that is determined to be exempt from disclosure be disclosed if the Secretary determines that it is in the interest of public health to disclose such ingredient, substance, or compound.

"(v) OTHER DISCLOSURE.—The Secretary (or any employee of the Department of Health and Human Services) shall not disclose any information described in subclause (I) if such disclosure is prohibited under any provision of law. Any information that is not required to be disclosed to the public under this subsection, shall be 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, and shall be considered

confidential and shall not be disclosed, except that such information may be disclosed to other officers or employees as provided for in clause (iii)(II) or when relevant in any proceeding under this chapter.

"(3) GENERAL DISCLOSURE OF SAFETY.—With respect to each annual submission under paragraph (1) during the 5-year period beginning on the date of enactment of this chapter, the manufacturer shall, for each ingredient, substance, or compound contained on the list of the manufacturer for the year involved, disclose whether the manufacturer has determined that the ingredient, substance, or compound would be exempt from public disclosure under this chapter.

"(f) COMPLIANCE.—

"(1) IN GENERAL.—Health risk management 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 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.

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

"SEC. 903. GOOD MANUFACTURING PRACTICE STANDARDS.

"(a) AUTHORITY.—

"(1) IN GENERAL.—The Secretary shall, in accordance with subsections (a) and (b) of section 902, 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 peti-

tion 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 902;

"(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 Schedule 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 absolute compliance with such requirement is not required to assure that the product will comply with this section 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 meth-

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

"(d) RECORDKEEPING AND REPORTING.—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).

"(e) INSPECTION AUTHORITY.—As provided in section 704, the officers and employees of the Secretary shall have the authority to conduct unannounced inspections of any factory, warehouse, or other establishment of any tobacco product manufacturer and shall have access to the

records, files, papers, processes, controls, and facilities relating to tobacco product manufacturing.

"(f) AGRICULTURAL PRODUCERS.—The Secretary may not promulgate any regulation under this section that has the effect of placing regulatory burdens on tobacco producers (as such term is used for purposes of the Agricultural Adjustment Act of 1938 (7 U.S.C. 1281 et seq.) and the Agricultural Act of 1949 (7 U.S.C. 1441 et seq.)) in excess of the regulatory burdens generally placed on other agricultural commodity producers.

"(g) 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. 904. 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: If You Think Smoking Is Dead, You Are Cool.

"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: If You Think Smoking Is Dead, You Are Cool.

"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 manu-

facturer 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 PRODUCTS.—

"(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 product 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 products to advertise or cause to be advertised within the United States any smokeless tobacco product 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 products 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 products 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 pre-

scribe 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 product 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 rule 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 _____ Act un-

less the Secretary can demonstrate extraordinary circumstances.

"(3) COMMON OR USUAL NAMES.—The Secretary, in accordance with the procedures set forth in section 902, 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 descending order of predominance by weight, except that such regulations—

"(A) may provide for the disclosure of spices, flavorings, and colorings without naming 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) PREEMPTION.—No statement relating to the use of cigarettes or smokeless tobacco products and health, other than the statements required by subsections (a), (b), or (c), shall be required on any package or in any advertisement of cigarettes or a smokeless tobacco product.

"(f) EXPORTS.—Packages of cigarettes or smokeless tobacco products 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 products 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. 905. RESTRICTION ON MARKETING AND ADVERTISING.

"(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, or placards.

"(B) STADIA AND ARENAS.—Except as otherwise provided in this chapter, a manufacturer, distributor, or retailer shall not advertise tobacco products in any arena or stadium where

athletic, musical, artistic, or other social or cultural events or activities occur.

"(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 inaccessible in or from the United States.

"(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) ADULT-ONLY STORES AND TOBACCO OUTLETS.—Subparagraph (A) shall not apply to point of sale advertising at adult-only stores and tobacco outlets.

"(C) 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) MARKET SHARE MANUFACTURERS.—A manufacturer with at least 25 percent of the market share of the tobacco product involved may display an additional point-of-sale advertisement in or at each location at which tobacco products are offered for sale.

"(iii) 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. No manufacturer or distributor may enter into any arrangement with a retailer to limit the ability of the retailer to display any form of permissible point-of-sale advertisement or promotional material originating with another manufacturer or distributor.

"(D) LIMITATIONS.—

"(i) IN GENERAL.—A point of sale advertisement permitted under this paragraph shall be comprised of a display area than 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.

"(E) 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 product, 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 FDA SPECIFIED MEDIA.—

"(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 indi-

cia of tobacco product identification only in newspapers, in magazines, in periodicals or other publications (whether periodic or limited distribution), on billboards, posters and placards in accordance with subsection (a)(1), 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.

"(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 payment shall be made by any manufacturer, distributor, or re-

tailer for the placement of any tobacco product or tobacco product package or advertisement—

"(i) as a prop in any television program or motion picture produced for viewing by the general public; 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.

"(4) RESTRICTIONS ON GLAMORIZATION OF TOBACCO PRODUCTS.—No direct or indirect payment shall be made by any manufacturer, distributor, or retailer to any entity for the purpose of promoting the image or use of a tobacco product through print or film media that appeals to individuals under 18 years of age or through a live performance by an entertainment artist that appeals to such individuals.

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

"(1) IN GENERAL.—Except as provided in paragraphs (2) and (3), each manufacturer, 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 and self-service displays are permitted under this chapter if the advertising involved—

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

"(II) 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 publi-

cation' 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; and

"(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) USE OF PRODUCT DESCRIPTORS.—

"(1) IN GENERAL.—With respect to a tobacco product, the label of which bears a product description (such as 'light' or 'low tar'), such label shall also contain, and any advertisement concerning such product shall contain, a mandatory disclaimer, to be established by the Secretary, that states that such product has not been shown to be less hazardous than another product of that type.

"(2) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to limit the authority of the Food and Drug Administration with respect to words used as product descriptors.

"SEC. 906. REDUCED RISK TOBACCO PRODUCTS.

"(a) GENERAL RULE.—Except as provided in subsection (b), the regulations promulgated in accordance with section 902 shall require that a tobacco product be deemed to be in violation with this chapter if the labeling of the package of the product, or the claims of the manufacturer in connection with the product, can reasonably be interpreted as stating or implying that the product presents a reduced health risk as compared to other similar products. No tobacco product that is subject to regulation

under this chapter may contain in its labeling any claim for the diagnosis, cure, mitigation, treatment, or prevention of a disease.

"(b) EXCEPTION.—

"(1) IN GENERAL.—Subsection (a) shall not apply to the labeling of a tobacco product, or the claims of the manufacturer in connection with the product, if—

"(A) the manufacturer, based on scientific evidence, demonstrates to the Secretary that the product reduces the risk to the health of the user as compared to other similar tobacco products; and

"(B) the Secretary approves the specific claim that will be made a part of the labeling of the product, or the specific claims of the manufacturer in connection with the product.

"(2) REDUCTION IN HEALTH RISK.—The Secretary shall promulgate regulations to permit the inclusion of scientifically-based specific health claims on the labeling of a tobacco product package, or the making of such claims by the manufacturer in connection with the product, where the Secretary determines that the inclusion or making of such claims

would reduce the health risk to consumers and otherwise promote public health.

"(c) 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. Such notification shall not be required until adequate intellectual property protections have been secured by the manufacturer, such as the issuance of a patent or the execution of a licensing agreement.

"(2) CONFIDENTIALITY.—The Secretary shall promulgate regulations to provide a manufacturer with appropriate confidentiality protections with respect to technology that is the subject of a notification under paragraph (1) that contains evidence that the technology involved is in the early developmental stages.

"(3) LICENSING.—

"(A) IN GENERAL.—With respect to any technology for which a notification has been provided under paragraph (1), the manufac-

turer shall permit the use of such technology by other manufacturers of tobacco products to which this chapter applies.

"(B) FEES.—The Secretary of Commerce shall promulgate regulations 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.

"(d) 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 Sec-

retary may, in accordance with this subsection and through the issuance or amendment of a health risk standard under section 902—

"(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.

"SEC. 907. TOBACCO PRODUCT MARKETING RESTRICTIONS.

"(a) IN GENERAL.—The Secretary, acting through the Office of Smoking and Health of the Centers for Disease Control and Prevention, shall by regulation implement the prohibitions described in this section concerning the marketing of tobacco products to minors.

"(b) SALES TO MINORS PROHIBITED.—No retailer may distribute a tobacco product to any individual who is under 18 years of age.

"(c) PHOTO IDENTIFICATION.—

"(1) REQUIREMENT.—Except as provided in paragraph (2), each retailer shall verify, by means of a driver's license or other form of identification issued by a government authority containing the date

of birth of the bearer, that no individual purchasing a tobacco product is under 18 years of age.

"(2) EXCEPTION.—No verification under paragraph (1) is required for any individual who is at least 21 years of age.

"(3) LOCATION OF PRODUCTS.—Except as provided in subsection (j), a retailer shall ensure that all tobacco products are located in areas where customers do not have access to the products.

"(d) FACE-TO-FACE TRANSACTIONS.—Except as provided in subsection (i)(1), a retailer may sell tobacco products only in a direct, face-to-face exchange without the assistance of any electronic or mechanical device.

"(e) OUT-OF-PACKAGE DISTRIBUTION.—No retailer may break or otherwise open a tobacco product to sell or distribute to individuals portions of such product (including individual cigarettes or a number of cigarettes that is smaller than the quantity in the minimum package size, or any quantity of cigarette tobacco or smokeless tobacco that is smaller than the smallest package distributed by the retailer for individual consumer use).

"(f) RETAILER COMPLIANCE WITH RESPECT TO SELF-SERVICE.—Each retailer shall ensure that all tobacco-related self-service displays, advertising, labeling, and other items that are located in the establishment of

the retailer and that do not comply with the requirements of this section are removed or are brought into compliance with the requirements of this section.

"(g) MINIMUM CIGARETTE PACKAGE SIZE.—Except as otherwise provided in this section, no manufacturer, distributor, or retailer may sell or cause to be sold, or distribute or cause to be distributed, any cigarette package that contains fewer than 20 cigarettes.

"(h) PROHIBITION ON SAMPLING.—No manufacturer, distributor, or retailer may distribute or cause to be distributed any free samples of any tobacco product.

"(i) PROHIBITION ON DISTRIBUTION THROUGH SELF-SERVICE MODES OF SALE.—

"(1) VENDING MACHINES.—Except as provided in subsection (j)(1)(B), no manufacturer, distributor, or retailer may distribute or cause to be distributed any tobacco product through a vending machine.

"(2) OTHER DISPLAYS.—Except as provided in subsection (j)(1)(C), no manufacturer, distributor, or retailer may distribute or cause to be distributed any tobacco product through a self-service display.

"(j) PERMITTED SELF-SERVICE MODES OF SALE.—

"(1) IN GENERAL.—Notwithstanding any other provision of this section, the following methods of distributing tobacco products are permitted:

"(A) Mail-order sales as provided for in paragraph (2), except that mail-order redemption of coupons and the distribution of free samples through the mail shall be prohibited.

"(B) Distribution through vending machines that are located in facilities where the retailer ensures that no individuals under 18 years of age are present or permitted to enter at any time.

"(C) Distribution through self-service displays that are located in facilities where the retailer ensures that no individuals under 18 years of age are present or permitted to enter at any time.

"(2) MAIL-ORDER SALES.—

"(A) IN GENERAL.—A manufacturer, distributor, or retailer may distribute or cause to be distributed a tobacco product through mail-order sales only if such sales are subject to a procedure for verifying that no individual purchasing such products is under 18 years of age.

"(B) REVIEW BY SECRETARY.—Not later than 2 years after the date of enactment of this section, the Secretary shall review the verification procedures implemented under subparagraph (A) to determine whether individuals under 18 years of age are obtaining tobacco products through the mail. If the Secretary determines that a significant number of underage individuals are obtaining such products through the mail, the Secretary may promulgate regulations in accordance with section 902 to prohibit the distribution of tobacco products through the mail.

"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 902, 903, 904, or 906.

"(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 anti-tobacco organizations; and

"(E) a representative of the general public selected from pro-tobacco organizations.

"(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—

"(1) assist the Secretary in establishing, amending, or revoking regulations under section 902, 903, 904, or 906;

"(2) examine and make recommendations concerning the effects of the alteration of the nicotine yield levels in tobacco products;

"(3) examine and make recommendations concerning 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) 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 management 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 addi-

tional 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 unsupported by substantial evidence on the record taken as a whole.

"(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 ~~may~~ shall within 60 days of the enactment of this Act assess and collect fees 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 Act.

"(b) TOBACCO PRODUCT FEE.—

"(1) IN GENERAL.—With respect to tobacco products sold in the United States, each manufacturer of such products shall be subject to a fee for the sale of such products.

"(2) AMOUNT OF FEE.—With respect to a manufacturer, the amount of the fee under paragraph (1) for a fiscal year shall be equal to an amount that bears the same ratio to $100,000,000 as the number of tobacco products sold by such manufacturer for the year involved bears to the total number of to-

bacco products sold by all manufacturers in such year.

"(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.

"SEC. 912. PREEMPTION.

"(a) LIMITATION.—No requirement with respect to a tobacco product shall be applied by any State or local statute or regulation if such requirement conflicts with the requirements of section 902, 903, 904, 905, or 906.

"(b) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as prohibiting a State or political subdivision of a State from enacting statutes or regulations concerning tobacco products so long as such statutes or regulations do not conflict with the requirements of section 902, 903, 904, or 906.".

SEC. 102. TECHNICAL PROVISIONS.

(a) APPLICATION OF FEDERAL CIGARETTE LABELING AND ADVERTISING ACT.—The provisions of the Fed-

eral 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.

SEC. 103. 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 subtitle.

(c) INDIAN TRIBES AND TRIBAL LANDS.—For purposes of applying and enforcing the provisions of this subtitle 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. 201. AMENDMENT TO PUBLIC HEALTH SERVICE ACT

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.

"[To be supplied]

"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 number of underage consumers of tobacco products through the imposition of substantial financial surcharges on participating manufacturers if certain underage tobacco-use reduction targets are not met.

"SEC. 2812. DETERMINATION OF UNDERAGE USE BASE PERCENTAGES.

"(a) CIGARETTES.—For purposes of this section, the underage use base percentage for cigarettes shall be a percentage determined by the Secretary, weighted by the relative population of the age groups involved as determined using data compiled in 1995 by the Bureau of the Census, based on—

"(1) the average of the percentages of 12th graders (individuals who are 16 or 17 years of age) who used cigarette products on a daily basis for each of the calendar years 1986 through 1996;

"(2) the average of the percentages of 10th graders (individuals who are 14 or 15 years of age)

who used cigarette products on a daily basis for each of the calendar years 1991 through 1996; and

"(3) the average of the percentages of 8th graders (individuals who are 13 years of age) who used cigarette products on a daily basis for each of the calendar years 1991 through 1996.

"(b) SMOKELESS TOBACCO.—For purposes of this section, the underage use base percentage for smokeless tobacco products shall be a percentage determined by the Secretary, weighted by the relative population of the age groups involved as determined using data compiled in 1995 by the Bureau of the Census, based on—

"(1) the average of the percentages of 12th graders (individuals who are 16 or 17 years of age) who used smokeless tobacco products on a daily basis in 1996;

"(2) the average of the percentages of 10th graders (individuals who are 14 or 15 years of age) who used smokeless tobacco products on a daily basis in 1996; and

"(3) the average of the percentages of 8th graders (individuals who are 13 years of age) who used smokeless tobacco products on a daily basis in 1996.

"(c) USE OF CERTAIN DATA OR METHODOLOGY.—For purposes of determining the percentages under para-

graphs (1) through (3) of subsections (a) and (b), the Secretary shall use the data contained in the National High School Drug Use Survey entitled Monitoring the Future by the University of Michigan or such other comparable index, as determined appropriate by the Secretary after notice and an opportunity for a hearing, that utilizes methodology identical to that used by the University of Michigan in such survey.

"SEC. 2813. ANNUAL DAILY INCIDENCE OF UNDERAGE USE OF TOBACCO PRODUCTS.

"(a) ANNUAL DETERMINATION.—Not later than the expiration of the 5-year period beginning on the date of enactment of this Act, and annually thereafter, the Secretary shall determine the average annual incidence of the daily use of tobacco products by individuals who are under 18 years of age.

"(b) CIGARETTES.—With respect to cigarette products, a determination under subsection (a) for a year shall be based on the percentage, as weighted by the relative population of the age groups involved as determined using data compiled in 1995 by the Bureau of the Census, of—

"(1) 12th graders (individuals who are 16 or 17 years of age) who used cigarette products on a daily basis during the year involved;

"(2) 10th graders (individuals who are 14 or 15 years of age) who used cigarette products on a daily basis during the year involved; and

"(3) 8th graders (individuals who are 13 years of age) who used cigarette products on a daily basis during the year involved.

"(c) SMOKELESS TOBACCO.—With respect to smokeless tobacco products, a determination under subsection (a) for a year shall be based on the percentage, as weighted by the relative population of the age groups involved as determined using data compiled in 1995 by the Bureau of the Census, of—

"(1) 12th graders (individuals who are 16 or 17 years of age) who used smokeless tobacco products on a daily basis during the year involved;

"(2) 10th graders (individuals who are 14 or 15 years of age) who used smokeless tobacco products on a daily basis during the year involved; and

"(3) 8th graders (individuals who are 13 years of age) who used cigarette smokeless tobacco on a daily basis during the year involved.

"(d) USE OF CERTAIN DATA OR METHODOLOGY.—

"(1) IN GENERAL.—For purposes of determining the percentages under paragraphs (1) through (3) of subsections (b) and (c), the Secretary shall

use the data contained in the National High School Drug Use Survey entitled Monitoring the Future by the University of Michigan (if such survey is still being undertaken) or such other comparable index, as determined appropriate by the Secretary after notice and an opportunity for a hearing, that utilizes methodology identical to that used by the University of Michigan in such survey.

"(2) ALTERATION OF METHODOLOGY.—If the Secretary determines that the methodology used by the University of Michigan in the survey referred to in paragraph (1) has been altered in a material manner from the methodology used during the period from 1986 to 1996 (including by altering States or regions on which the survey is based), the Secretary, after notice and an opportunity for a hearing, shall use percentages based on an index developed by the Secretary that utilizes methodology identical to that used by the University of Michigan in such survey.

"SEC. 2814. REQUIRED REDUCTION IN UNDERAGE TOBACCO USE.

"(a) IN GENERAL.—For purposes of assessing surcharges under section 405, the Secretary shall determine whether the required percentage reduction in the underage

use of tobacco products for a year (based on the national goals described in section 4 of the _____ Act) has been achieved for the year involved. Such determination shall be based on—

"(1) with respect to cigarette products, the average annual incidence of the daily use of tobacco products by individuals who are under 18 years of age for the year involved (as determined under section 403(b)) as compared to the underage use base percentage for cigarette products (as determined under section 402(a)); and

"(2) with respect to smokeless tobacco products, the average annual incidence of the daily use of smokeless tobacco products by individuals who are under 18 years of age for the year involved (as determined under section 403(c)) as compared to the underage use base percentage for smokeless tobacco products (as determined under section 402(b)).

"(b) PERCENTAGE REDUCTION IN UNDERAGE USE OF TOBACCO PRODUCTS.—For purposes of subsection (a), the required percentage reduction in the underage use of tobacco products with respect to each tobacco product shall be determined based on the national goals for the reduction in underage tobacco use under section 4.

"SEC. 2815. APPLICATION OF SURCHARGES.

"(a) IN GENERAL.—If the Secretary determines that the percentage reduction in the underage use of tobacco products for a year has not been achieved as required under section 2814, the Secretary shall impose a surcharge on the participating manufacturers of the tobacco products involved.

"(b) AMOUNT OF SURCHARGE.—

"(1) IN GENERAL.—

"(A) CIGARETTES.—With respect to cigarettes, the amount of any surcharge to be imposed under this section for a calendar year shall be equal to the product of—

"(i) $80,000,000, and the number of applicable surcharge percentage points as determined under subsection (c) up to 5 percentage points;

"(ii) $400,000,000, and the number of applicable surcharge percentage points as determined under subsection (c), if such percentage points are greater than 5 but less than 11 percentage points; and

"(iii) $500,000,000, and the number of applicable surcharge percentage points as determined under subsection (c), if such

percentage points are 11 or more percentage points; and

"(B) SMOKELESS TOBACCO.—With respect to smokeless tobacco, the amount of any surcharge to be imposed under this section for a calendar year shall be equal to the product of—

"(i) $15,000,000, and the number of applicable surcharge percentage points as determined under subsection (c) up to 5 percentage points;

"(ii) $30,000,000, and the number of applicable surcharge percentage points as determined under subsection (c), if such percentage points are greater than 5 but less than 11 percentage points; and

"(iii) $45,000,000, and the number of applicable surcharge percentage points as determined under subsection (c), if such percentage points are 11 or more percentage points.

"(2) ADJUSTMENTS.—The amount applicable under paragraph (1) shall be annually adjusted by the Secretary based on with respect to subparagraph (A) of such paragraph—

"(A) the proportional percentage increase or decrease, as compared to calendar year 1995, in the population of individuals residing in the United States who are at least 13 years of age but less than 18 years of age;

"(B) the proportional percentage increase or decrease, as compared to calendar year 1996, in the average profit per unit (measured in cents and weighted by annual sales) earned by participating manufacturers for the tobacco product involved (as determined by the Secretary through a contract with a nationally recognized accounting firm having no connection to such manufacturers).

"(c) DETERMINATION OF APPLICABLE SURCHARGE PERCENTAGE POINTS.—

"(1) IN GENERAL.—With respect to a calendar year, the applicable surcharge percentage points shall be equal to the percentage point difference between—

"(A) the required incidence goal in the underage use of the tobacco product involved for the year (based on the national goals described in section 4 of the _____ Act); and

"(B) the number of percentage points by which the average annual incidence of the daily use of the tobacco products involved by individuals who are under 18 years of age for the year (as determined under section 2813) is less than the underage use base percentage for such products (as determined under section 2812).

"(2) ADJUSTMENT.—If for any calendar year the Secretary determines that the average annual incidence of the daily use of the tobacco products involved by individuals who are under 18 years of age (as determined under section 2813) is greater than the underage use base percentage for such products (as determined under section 2812), the applicable surcharge percentage point shall be equal to—

"(A) the percentage point amount determined under paragraph (1)(A); and

"(B) the number of percentage points by which the average annual incidence of the daily use of the tobacco products involved by individuals who are under 18 years of age (as determined under section 2813) is greater than the underage use base percentage for such products (as determined under section 2812).

"(3) TYPE OF PRODUCT.—Separate determinations shall be made under this section for cigarette products and smokeless tobacco products.

"(d) JOINT AND SEVERAL OBLIGATION.—Any surcharge imposed under this section with respect to a tobacco product (cigarette products or smokeless tobacco products) shall be the joint and several obligation of all participating manufacturers of such product as allocated by the market share of each such manufacturer with respect to such product. The market share of each manufacturer for each such product shall be based on the market share of such product for the year preceding the year for which the determination is being made.

"(e) ASSESSMENT.—Not later than May 1 of each year in which a surcharge will be imposed under this section, the Secretary shall assess, pursuant to subsection (d), to each participating manufacturer the amount for which such manufacturer is obligated. Not later than July 1 of any year in which a manufacturer receives an assessment under this section, the manufacturer shall pay such assessment in full or be subject to such interest on such amount as the Secretary may by regulation prescribe.

"(f) USE OF AMOUNTS.—Amounts received under this section shall be used to further the purposes of this title.

"(g) PROHIBITION.—No stay or other injunctive relief may be granted by the Secretary or any court that has the effect of enjoining the imposition and collection of the surcharges to be applied under this section.

"SEC. 2816. ABATEMENT PROCEDURES.

"(a) PETITIONS.—Upon payment by a participating manufacturer of the amount assessed to the manufacturer under section 2815(f), the manufacturer may submit a petition to the Secretary for an abatement of the assessment. A notice of such abatement petition shall be submitted to the attorney general of each State.

"(b) HEARING.—The Secretary shall provide for the conduct of a hearing on an abatement petition received under subsection (a) pursuant to the procedures described in sections 554, 556, and 557 of title 5, United States Code. The attorney general of any State shall be permitted to be heard at any hearing conducted under this subsection.

"(c) BURDEN.—The burden at any hearing under subsection (b) shall be on the participating manufacturer to prove, by a preponderance of the evidence, that the manufacturer should be granted the abatement.

"(d) BASIS OF DECISION.—Any decision regarding a petition for an abatement under this section shall be based on a determination as to whether—

"(1) the participating manufacturer has acted in good faith and in full compliance with this title and any regulations or State or local laws promulgated in furtherance of this title;

"(2) the participating manufacturer has pursued all reasonably available measures to attain the reductions;

"(3) there is any evidence of any direct or indirect action by the participating manufacturer to undermine the achievement of the reductions required under section 2814 or to undermine any other provision of this title; and

"(4) the participating manufacturer has taken (or failed to take) any other action as determined appropriate by the Secretary.

"(e) AMOUNT.—Upon a determination granting an abatement under this section, the Secretary shall order the abatement of not more than 75 percent of the amount paid by the participating manufacturer (as determined by the Secretary), together with interest that may have accrued on such amount during the period between the date on which payment by the manufacturer was made and the date on which the abatement order was granted. Such interest shall be equal to that provided for the average 52-week Treasury Bill during the period involved.

"(f) AGGRIEVED PARTIES.—Any participating manufacturer or attorney general of any State that is aggrieved by an abatement that is granted under this section may seek judicial review of the abatement decision within 30 days of the date of such decision in the Court of Appeals for the District of Columbia Circuit. Review in such cases shall be subject to the procedures described in sections 701 through 706 of title 5, United States Code.

"(g) PROHIBITION.—A participating manufacturer may not file a petition under subsection (a) until such time as the manufacturer has fully paid the Secretary the amount assessed to the manufacturer under section 405(f).

"SEC. 2817. INCENTIVE FOR EXCEEDING REDUCTION GOALS.

"If the Secretary determines that the percentage reduction in the underage use of tobacco products for a year exceeds 60 percent for cigarettes and 45 percent for smokeless tobacco products for a year as required under section 2814, the Secretary shall adjust the amount of the fee that a participating manufacturer shall be required to pay for such year under [_____].

"Subtitle B—Restriction on Access to Tobacco Products

"SEC. 2821. [TO BE SUPPLIED]

"Subtitle C—State and Community Action Program

"SEC. 2831. FUNDING FROM TOBACCO SETTLEMENT TRUST FUND.

"(a) IN GENERAL.—There shall be made available from the Tobacco Settlement Trust Fund to carry out this subtitle—

"(1) $145,000,000 for each of the fiscal years 1999 and 2000;

"(2) $170,000,000 for fiscal year 2001;

"(3) $240,000,000 for each of the fiscal years 2002 and 2003;

"(4) $340,000,000 for each of the fiscal years 2004 and 2005;

"(5) $385,000,000 for each of the fiscal years 2006 and 2007; and

"(6) $440,000,000 for fiscal year 2008.

"(b) SUNSET PROVISION.—This subtitle shall terminate on September 30, 2009.

"SEC. 2832. ALLOTMENTS.

"(a) IN GENERAL.—From the amount made available under section 2831 for any fiscal year, the Secretary,

acting through the Director of the Office on Smoking and Health of the Centers for Disease Control and Prevention (referred to in this subtitle as the 'Director'), shall allot to each State the applicable percentage of such amount in accordance with the following table:

State	Applicable Percentage
Alabama	1.238619
Alaska	0.500000
Arizona	1.134776
Arkansas	0.732229
California	8.585426
Colorado	1.027658
Connecticut	1.557000
Delaware	0.500000
District of Columbia	0.521120
Florida	3.500870
Georgia	1.956917
Hawaii	0.626458
Idaho	0.500000
Illinois	4.166040
Indiana	1.671714
Iowa	0.739712
Kansas	0.743167
Kentucky	1.828537
Louisiana	1.868947
Maine	0.848964
Maryland	2.000535
Massachusetts	3.607905
Michigan	4.320991
Minnesota	2.412484
Mississippi	0.830156
Missouri	1.617624
Montana	0.500000
Nebraska	0.500000
Nevada	0.500000
New Hampshire	0.538242
New Jersey	3.406803
New Mexico	0.500000
New York	14.166024
North Carolina	2.045166
North Dakota	0.500000
Ohio	4.572863
Oklahoma	0.820915
Oregon	1.065587
Pennsylvania	5.102394
Rhode Island	0.801176
South Carolina	0.861529
South Dakota	0.500000
Tennessee	2.417855
Texas	4.340060

Utah	0.500000
Vermont	0.500000
Virginia	1.339502
Washington	1.749731
West Virginia	0.978560
Wisconsin	2.046211
Wyoming	0.500000
American Samoa	0.008463
N. Mariana Islands	0.001481
Guam	0.006343
U.S. Virgin Islands	0.004683
Puerto Rico	0.188344

"(b) REALLOTMENT.—To the extent that amounts made available under section 2831 for a fiscal year are not otherwise allotted to States because—

"(1) 1 or more States have not submitted an application or description of activities in accordance with section 2835 for the fiscal year;

"(2) 1 or more States have notified the Secretary that they do not intend to use the full amount of their allotment; or

"(3) the Secretary has determined that the State is not in compliance with this title, and therefore is subject to penalties under section 2837;

such excess amount shall be reallotted among each of the remaining States in proportion to the amount otherwise allotted to such States for the fiscal year involved without regard to this subsection.

"(c) REGULATIONS.—Not later than 18 months after the date of enactment of this title, the Secretary shall promulgate regulations to implement this subtitle. This sub-

title shall take effect regardless of the date on which such regulations are promulgated.

"SEC. 2833. PAYMENTS UNDER ALLOTMENTS TO STATES.

"(a) IN GENERAL.—

"(1) METHOD OF PAYMENT.—The Secretary shall make payments to States under allotments under this subtitle as provided for under section 203 of the Intergovernmental Cooperation Act of 1968.

"(2) AVAILABILITY OF FUNDS.—Any amount paid to a State for a fiscal year under this subtitle and remaining unobligated at the end of such year shall remain available to such State for the next fiscal year for the purposes for which such payment was made.

"(b) REDUCTIONS.—The Secretary, at the request of a State, may reduce the amount of payments to the State under subsection (a) by—

"(1) the fair market value of any supplies or equipment furnished by the Secretary to the State; and

"(2) the amount of the pay, allowances, and travel expenses of any officer or employee of the Federal Government when detailed to the State and the amount of any other costs incurred in connection with the detail of such officer or employee;

when the furnishing of such supplies or equipment or the detail of such an officer or employee is for the convenience of and at the request of the State and for the purpose of conducting activities described in section 2834. The amount by which any payment is so reduced shall be available for payment by the Secretary of the costs incurred in furnishing the supplies or equipment or in detailing the personnel, on which reduction of the payment is based, and the amount shall be deemed to be part of the payment and shall be deemed to have been paid to the State.

"SEC. 2834. USE OF ALLOTMENTS.

"(a) STATE AND COMMUNITY ACTION ACTIVITIES.—

"(1) IN GENERAL.—Except as provided in subsections (b) and (c), amounts paid to a State under section 2833 may be used for the following:

"(A) Activities described in the plan of the State, submitted in accordance with section 2835, including—

"(i) evidence-based State and community initiatives for tobacco use prevention and control;

"(ii) infrastructure development modeled after the National Cancer Society's ASSIST program, or another evidence-based models approved by the Director;

"(iii) [redacted] to develop effective counter advertising;

"(iv) the development and implementation of anti-tobacco education programs and public policy initiatives; and

"(v) school-based efforts to prevent tobacco use and addiction, developed scientifically and approved by the Director.

"(B) Planning, administration, and educational activities related to the activities described in subparagraph (A).

"(C) The monitoring and evaluation of activities carried out under subparagraphs (A) and (B).

"(2) COORDINATION.—State and community action activities permitted under paragraph (1) may be conducted in coordination with the following programs:

"(A) The special supplemental food program under section 17 of the Child Nutrition Act of 1966 (42 U.S.C. 1786)

"(B) The Maternal and Child Health Services Block Grant program under title V of the Social Security Act (42 U.S.C. 701 et seq.).

"(K) The medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.).

"(L) Programs administered by the Department of Veterans Affairs.

"(3) TECHNICAL ASSISTANCE.—The Secretary may provide technical assistance to States in planning and operating activities to be carried out under this subtitle.

"(b) LIMITATION.—A State may not use amounts paid to the State under section 2833 to—

"(1) purchase or improve land, purchase, construct, or permanently improve (other than minor remodeling) any building or other facility, or purchase major medical equipment;

"(2) satisfy any requirement for the expenditure of non-Federal funds as a condition of the receipt of Federal funds;

"(3) provide financial assistance to any entity other than a public or nonprofit private entity; or

"(4) fund educational, recreational, or health activities not scientifically proven to prevent youth smoking or lead to success of cessation efforts among youths.

"(c) ADMINISTRATION.—Not more than 10 percent of the allotment of a State for a the fiscal year under this subtitle may be used by the State to administer the funds paid to the State under section 2833. The State shall pay from non-Federal sources the remaining costs of administering such funds.

"SEC. 2835. APPLICATION FOR PAYMENTS; STATE PLAN.

"(a) IN GENERAL.—The Secretary may make payments under section 2833 to a State for a fiscal year only if—

"(1) the State submits to the Secretary an application for such payments;

"(2) the application contains a State plan in accordance with subsection (b);

"(3) the application contains the certification described in subsection (c);

"(4) the application contains such assurances as the Secretary may require regarding the compliance of the State with the requirements of this subtitle (including assurances regarding compliance with the agreements described in subsection (c)); and

"(5) the application is in such form and is submitted by such date as the Secretary may require.

"(b) STATE PLAN.—A State plan required under subsection (a)(2) for a fiscal year is in accordance with this subsection if the plan meets the following conditions:

"(1) The plan is developed by the State agency with principal responsibility for public health programs, in consultation with the advisory committee established pursuant to subsection (c)(2).

"(2) The plan specifies the activities authorized under section 2834 that are to be carried out with payments made to the State under section 2833.

"(3) The plan specifies the amount of such payments to be expended for each of such activities and includes a description of the programs and projects to be carried out.

"(4) The plan describes the measurable objectives, developed in consultation with the Secretary, that will be used to evaluate program outcomes.

"(c) STATE CERTIFICATION.—The certification referred to in subsection (a)(3) for a fiscal year is a certification to the Secretary by the chief executive officer of the State involved as follows:

"(1)(A) In the development of the State plan required in subsection (a)(2)—

"(i) the chief health officer of the State held public hearings on the plan; and

"(ii) proposals for the plan were made public in a manner that facilitated comments from public and private entities (including Federal and other public agencies).

"(B) The State agrees that, if any revisions are made in such plan during the fiscal year, the State will, with respect to the revisions, hold hearings and make proposals public in accordance with subparagraph (A), and will submit to the Secretary a description of the revisions.

"(2) The State has established an advisory committee in accordance with subsection (d).

"(3) The State agrees to expend payments under section 2833 only for the activities authorized in section 2834.

"(4) The State agrees to expend such payments in accordance with the State plan submitted under subsection (a)(2) (with any revisions submitted to the Secretary under paragraph (1)(B)), including making expenditures to carry out the strategy contained in the plan pursuant to subsection (b)(5).

"(5)(A) The State agrees that, in the case of each population for which such strategy is carried out, the State will measure the extent of progress

being made toward improving the health status of the population.

"(B) The State agrees that—

"(i) the State will collect and report data in accordance with section 2836(a);

"(ii) for purposes of subparagraph (A), progress will be measured through the use of the applicable uniform data items developed by the Secretary under section 2836(a)(2), or if no such items are applicable, through use of the uniform criteria developed by the Secretary under section 2836(a)(3).

"(6) With respect to the activities authorized in section 2834, the State agrees to maintain State expenditures for such activities at a level that is not less than the average level of such expenditures maintained by the State for the 2-year period preceding the fiscal year for which the State is applying to receive payments under section 2833.

"(7) The State agrees to establish reasonable criteria to evaluate the effective performance of entities that receive funds from such payments and procedures for procedural and substantive independent State review of the failure by the State to provide funds for any such entity.

"(8) The State agrees to permit and cooperate with Federal investigations undertaken in accordance with section 2837.

"(d) STATE ADVISORY COMMITTEE.—

"(1) IN GENERAL.—For purposes of subsection (c)(2), an advisory committee is in accordance with this subsection if such committee meets the conditions described in this subsection.

"(2) DUTIES.—A condition under paragraph (1) for a State is that the duties of the committee are—

"(A) to hold public hearings on the State plan required under subsection (a)(2); and

"(B) to make recommendations pursuant to subsection (b)(1) regarding the development and implementation of such plan, including recommendations on—

"(i) the conduct of assessments of [to be supplied];

"(ii) which of the activities authorized in section 2834 should be carried out in the State;

"(iii) the allocation of payments made to the State under section 2833;

"(iv) the coordination of activities carried out under such plan with relevant programs of other entities; and

"(v) the collection and reporting of data in accordance with section 2836(a).

"(3) COMPOSITION.—

"(A) IN GENERAL.—A condition under paragraph (1) for a State is that the advisory committee be composed of such members of the general public, and such officials of the health departments of political subdivisions of the State, as may be necessary to provide adequate representation of the general public and of such health departments.

"(B) REPRESENTATIVES.—With respect to compliance with subparagraph (A), the membership of the advisory committee established pursuant to subsection (c)(2) may include representatives of community-based organizations (including minority community-based organizations), schools of public health, and entities to which the State involved awards grants or contracts to carry out activities authorized under section 2834.

"(4) CHAIRPERSON; MEETINGS.—A condition under paragraph (1) for a State is that the State public health officer shall serve as the chairperson of the advisory committee, and that the committee meet not less than twice each fiscal year.

"SEC. 2836. REPORTS, DATA, AND AUDITS.

"(a) DATA.—

"(1) COLLECTION AND REPORTING.—For purposes of section 2835(c)(5)(B)(i), a State is collecting and reporting data for a fiscal year in accordance with this subsection if the State submits to the Secretary, not later than February 1 of the succeeding fiscal year year, a report that—

"(A) describes the purposes for which the State expended payments made to the State under section 2833;

"(B) pursuant to section 2835(c)(5)(A), describes the extent of progress made by the State for purposes of such section;

"(C) meets the conditions described paragraph (2); and

"(D) contains such additional information regarding activities authorized under section 2834, and is submitted in such form, as the Secretary may require.

"(2) UNIFORM DATA SETS.—

"(A) IN GENERAL.—The Secretary, in consultation with the States, shall develop sets of data for uniformly defining levels of youth and adult use of tobacco products (referred to as 'uniform tobacco product use data items'). The Secretary shall develop formats for the uniform collecting and reporting of information on such items.

"(B) LATER FISCAL YEARS.—In the case of fiscal year 2000 and each subsequent fiscal year, a condition under paragraph (1) for a State is that the State will, in accordance with the applicable format under subparagraph (A), collect during such year, and include in the report under paragraph (1), the necessary information for each of the tobacco product use data items.

"(3) UNIFORM CRITERIA.—The Secretary, in consultation with the States, shall establish criteria for the uniform collection and reporting of data on activities authorized in section 2844 with respect to which no uniform tobacco product use data items under paragraph (2) exist.

"(4) PUBLIC INSPECTION OF REPORTS.—A condition under paragraph (1) for a fiscal year is that

the State involved will make copies of the report submitted under such paragraph for the fiscal year available for public inspection, and will upon request provide a copy of the report to any individual for a charge not exceeding the cost of providing the copy.

"(b) AUDITS.—

"(1) FISCAL CONTROL AND ACCOUNTING PROCEDURES.—Each State shall establish fiscal control and fund accounting procedures as may be necessary to ensure the proper disbursal of and accounting for Federal funds paid to the State under section 2833, ~~and funds transferred under section [4(e)] for use under this subtitle~~.

"(2) ANNUAL SUBMISSION.—Each State shall annually audit its expenditures from payments received under section 2833. Such State audits shall be conducted by an entity independent of any agency administering a program funded under this subtitle, and, in so far as practical, in accordance with the Comptroller General's standards for auditing governmental organizations, programs, activities, and functions. Within 30 days following the date on which each audit is completed, the chief executive officer of the State shall transmit a copy of that audit to the Secretary.

"(3) REPAYMENTS.—Each State shall, after being provided by the Secretary with adequate notice and an opportunity for a hearing within the State, repay to the United States amounts found not to have been expended in accordance with the requirements of this subtitle or the certification provided by the State under section 2835. If such repayment is not made, the Secretary shall, after providing the State with adequate notice and opportunity for a hearing within the State, offset such amounts against the amount of any allotment to which the State is or may become entitled under this subtitle.

"(4) AVAILABILITY.—The State shall make copies of the reports and audits required by this subsection available for public inspection within the State.

"(5) EVALUATION.—The Comptroller General of the United States shall, from time to time, evaluate the expenditures by the States of payments under this subtitle in order to ensure that expenditures are consistent with the provisions of this subtitle and the certification provide by the State under section 2835.

"(6) REPORT BY SECRETARY.—Not later than October 1, 2000, the Secretary shall prepare and

submit to the appropriate committees of Congress a report concerning the activities of the States that have received funds under this subtitle and may include in the report any recommendations for appropriate changes in legislation.

"(c) NONAPPLICATION OF CERTAIN PROVISIONS.—Title XVII of the Omnibus budget Reconciliation Act of 1981 shall not apply with respect to audits of funds allotted under this subtitle.

"SEC. 2837. WITHHOLDING.

"(a) WITHHOLDING FOR MISUSE.—

"(1) IN GENERAL.—The Secretary shall, after adequate notice and opportunity for a hearing conducted within the affected State, withhold funds from any State which does not use its allotment in accordance with the requirements of this subtitle or the certifications otherwise provided by States under this subtitle. The Secretary shall withhold such funds until the Secretary finds that the reason for the withholding has been removed and there is reasonable assurance that it will not recur.

"(2) INVESTIGATION.—The Secretary may not institute proceedings to withhold funds under paragraph (1) unless the Secretary has conducted an investigation concerning whether the State has used

its allotment in accordance with the requirements of this subtitle or the certifications otherwise provided under this subtitle. Investigations required by this paragraph shall be conducted within the affected State by qualified investigators.

"(3) RESPONSE TO COMPLAINTS.—The Secretary shall respond in an expeditious manner to complaints of a substantial or serious nature that a State has failed to use funds in accordance with the requirements of this subtitle or the certifications otherwise provided under this subtitle.

"(4) MINOR FAILURES.—The Secretary may not withhold funds under paragraph (1) from a State for a minor failure to comply with the requirements of this subtitle or certifications otherwise provided under this subtitle.

"(b) INVESTIGATIONS.—

"(1) BY SECRETARY.—The Secretary shall conduct in several States in each fiscal year investigations of the use of funds received by the States under this subtitle in order to evaluate compliance with the requirements of this subtitle and certifications otherwise provided under this subtitle.

"(2) BY COMPTROLLER GENERAL.—The Comptroller General of the United States may conduct in-

vestigations of the use of funds received under this subtitle by a State in order to insure compliance with the requirements of this subtitle and certifications otherwise provided under this subtitle.

"(c) AVAILABILITY OF RECORDS.—Each State, and each entity which has received funds from an allotment made to a State under this subtitle, shall make appropriate books, documents, papers, and records available to the Secretary or the Comptroller General of the United States, or any of their duly authorized representatives, for examination, copying, or mechanical reproduction on or off the premises of the appropriate entity upon a reasonable request therefor.

"(d) LIMITATION.—

"(1) IN GENERAL.—In conducting any investigation in a State, the Secretary or the Comptroller General of the United States may not make a request for any information not readily available to such State or an entity which has received funds from an allotment made to the State under this subtitle or make an unreasonable request for information to be compiled, collected, or transmitted in any form not readily available.

"(2) NONAPPLICATION TO JUDICIAL PROCEEDINGS.—Paragraph (1) does not apply to the collec-

tion, compilation, or transmittal of data in the course of a judicial proceeding.

"SEC. 2838. NONDISCRIMINATION.

"(a) PROGRAMS AND ACTIVITIES.—

"(1) IN GENERAL.—For the purpose of applying the prohibitions against discrimination on the basis of age under the Age Discrimination Act of 1975, on the basis of handicap under section 504 of the Rehabilitation Act of 1973, on the basis of sex under title IX of the Education Amendments of 1972, or on the basis of race, color, or national origin under title VI of the Civil Rights Act of 1964, programs and activities funded in whole or in part with funds made available under this subtitle are considered to be programs and activities receiving Federal financial assistance.

"(2) GENDER OR RELIGION.—No person shall on the ground of gender or religion be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any program or activity funded in whole or in part with funds made available under this subtitle.

"(b) FAILURE TO COMPLY.—Whenever the Secretary finds that a State, or an entity that has received a payment from an allotment to a State under this subtitle, has

failed to comply with a provision of law referred to in subsection (a)(1), with subsection (a)(2), or with an applicable regulation (including one prescribed to carry out subsection (a)(2)), the Secretary shall notify the chief executive officer of the State and shall request such officer to secure compliance. If within a reasonable period of time, not to exceed 60 days, the chief executive officer fails or refuses to secure compliance, the Secretary may—

"(1) refer the matter to the Attorney General with a recommendation that an appropriate civil action be instituted;

"(2) exercise the powers and functions provided by title VI of the Civil Rights Act of 1964, the Age Discrimination Act of 1975, or section 504 of the Rehabilitation Act of 1973, as may be applicable; or

"(3) take such other action as may be provided by law.

"(c) ACTION BY ATTORNEY GENERAL.—When a matter is referred to the Attorney General pursuant to subsection (b)(1), or whenever he has reason to believe that a State or an entity is engaged in a pattern or practice in violation of a provision of law referred to in subsection (a)(1) or in violation of subsection (a)(2), the Attorney General may bring a civil action in any appropriate

district court of the United States for such relief as may be appropriate, including injunctive relief.

"SEC. 2839. CRIMINAL PENALTY FOR FALSE STATEMENTS.

"Whoever—

"(1) knowingly and willfully makes or causes to be made any false statement or representation of a material fact in connection with the furnishing of items or services for which payment may be made by a State from funds allotted to the State under this subtitle; or

"(2) having knowledge of the occurrence of any event affecting his or her initial or continued right to any such payment conceals or fails to disclose such event with an intent fraudulently to secure such payment either in a greater amount than is due or when no such payment is authorized;

shall be fined not more than $25,000 or imprisoned for not more than 5 years, or both.

"Subtitle D—Smoking Cessation Programs

"SEC. 2841. FUNDING FROM TOBACCO SETTLEMENT TRUST FUND.

"(a) FUNDING.—There shall be made available from the Tobacco Settlement Trust Fund to carry out this section—

"(1) $1,000,000,000 for each of the fiscal years 1999 through 2002; and

"(2) $1,500,000,000 for each of the fiscal years 2003 through 2008.

"(b) LIMITATION.—Not more than 2 percent of the amount available for any fiscal year under subsection (a) shall be made available to the Secretary to carry out the activity described in section 2842(c).

"(c) SUNSET PROVISION.—This subtitle shall terminate on September 30, 2009.

"SEC. 2842. ALLOTMENTS.

"(a) IN GENERAL.—From the amount made available under section 2841 for any fiscal year, the Secretary shall allot to each State the applicable percentage of such amount in accordance with the following table:

State	Applicable Percentage
Alabama	1.238619
Alaska	0.500000
Arizona	1.134776
Arkansas	0.732229
California	8.585426
Colorado	1.027658
Connecticut	1.557000
Delaware	0.500000
District of Columbia	0.521120
Florida	3.500870
Georgia	1.956917
Hawaii	0.626458
Idaho	0.500000
Illinois	4.166040
Indiana	1.671714
Iowa	0.739712
Kansas	0.743167
Kentucky	1.828537
Louisiana	1.868947
Maine	0.848964
Maryland	2.000535
Massachusetts	3.607905

Michigan	4.320991
Minnesota	2.412484
Mississippi	0.830156
Missouri	1.617624
Montana	0.500000
Nebraska	0.500000
Nevada	0.500000
New Hampshire	0.538242
New Jersey	3.406803
New Mexico	0.500000
New York	14.166024
North Carolina	2.045166
North Dakota	0.500000
Ohio	4.572863
Oklahoma	0.820915
Oregon	1.065587
Pennsylvania	5.102394
Rhode Island	0.801176
South Carolina	0.861529
South Dakota	0.500000
Tennessee	2.417855
Texas	4.340060
Utah	0.500000
Vermont	0.500000
Virginia	1.339502
Washington	1.749731
West Virginia	0.978560
Wisconsin	2.046211
Wyoming	0.500000
American Samoa	0.008463
N. Mariana Islands	0.001481
Guam	0.006343
U.S. Virgin Islands	0.004683
Puerto Rico	0.188344

"(b) REALLOTMENT.—To the extent that amounts made available under section 2831 for a fiscal year are not otherwise allotted to States because—

"(1) 1 or more States have not submitted an application or description of activities in accordance with section 2845 for the fiscal year;

"(2) 1 or more States have notified the Secretary that they do not intend to use the full amount of their allotment; or

"(3) the Secretary has determined that the State is not in compliance with this title, and therefore is subject to penalties under section 2847;

such excess amount shall be reallotted among each of the remaining States in proportion to the amount otherwise allotted to such States for the fiscal year involved without regard to this subsection.

"(c) ANALYSES.—The Secretary, acting through the Administrator of the Agency Health Care Policy and Research, shall conduct periodic analyses of the best available scientific information in the area of smoking and tobacco product use cessation.

"(d) REGULATIONS.—Not later than 9 months after the date of enactment of this title, the Secretary shall promulgate regulations to implement this subtitle. This subtitle shall take effect regardless of the date on which such regulations are promulgated.

"SEC. 2843. PAYMENTS UNDER ALLOTMENTS TO STATES.

"(a) IN GENERAL.—

"(1) METHOD OF PAYMENT.—The Secretary shall make payments to States under allotments under this subtitle as provided for under section 203 of the Intergovernmental Cooperation Act of 1968.

"(2) AVAILABILITY OF FUNDS.—Any amount paid to a State for a fiscal year under this subtitle

and remaining unobligated at the end of such year shall remain available to such State for the next fiscal year for the purposes for which such payment was made.

"(b) REDUCTIONS.—The Secretary, at the request of a State, may reduce the amount of payments to the State under subsection (a) by—

"(1) the fair market value of any supplies or equipment furnished by the Secretary to the State; and

"(2) the amount of the pay, allowances, and travel expenses of any officer or employee of the Federal Government when detailed to the State and the amount of any other costs incurred in connection with the detail of such officer or employee;

when the furnishing of such supplies or equipment or the detail of such an officer or employee is for the convenience of and at the request of the State and for the purpose of conducting activities described in section 2844. The amount by which any payment is so reduced shall be available for payment by the Secretary of the costs incurred in furnishing the supplies or equipment or in detailing the personnel, on which reduction of the payment is based, and the amount shall be deemed to be part of the payment and shall be deemed to have been paid to the State.

"SEC. 2844. USE OF ALLOTMENTS.

"(a) STATE AND COMMUNITY ACTION ACTIVITIES.—

"(1) IN GENERAL.—Except as provided in subsections (b) and (c), amounts paid to a State under section 2843 may be used for the following:

"(A) Activities described in the plan of the State, submitted in accordance with section 2845, including—

"(i) science-based programs designed to assist individuals who to quit their use of tobacco products;

"(ii) training in cessation intervention methods for health plans and health professionals, including physicians, nurses, dentists, and other health care providers; and

"(iii) programs to encourage health insurers and health plans to provide coverage for science-based tobacco use cessation treatment.

"(B) Planning, administration, and educational activities related to the activities described in subparagraph (A).

"(C) The monitoring and evaluation of activities carried out under subparagraphs (A) and (B).

"(2) COORDINATION.—Tobacco use cessation activities permitted under paragraph (1) may be conducted in coordination with the following programs:

"(A) The special supplemental food program under section 17 of the Child Nutrition Act of 1966 (42 U.S.C. 1786)

"(B) The Maternal and Child Health Services Block Grant program under title V of the Social Security Act (42 U.S.C. 701 et seq.).

"(C) The State Children's Health Insurance Program of the State under title XXXI of the Social Security Act (42 U.S.C. 13397aa et seq.).

"(D) A Head Start program under the Head Start Act (42 U.S.C. 9801 et seq.).

"(E) The school lunch program uknder the National School Lunch Act (42 U.S.C. 1751 et seq.).

"(F) An Indian Health Service Program.

"(G) The community health center program under section 330 of the Public Health Service Act (42 U.S.C. 254b).

"(H) Programs under title X of the Public Health Service Act (42 U.S.C. 300 et seq.).

"(I) State-initiated smoking cessation programs that include provisions for reimbursing individuals for medications or other therapeutic techniques.

"(J) The substance abuse an mental health services block grant program, and the preventive health services block grant program, under title XIX of the Public Health Service Act (42 U.S.C. 300w et seq.).

"(K) The medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.).

"(L) Programs administered by the Department of Veterans Affairs.

"(3) TECHNICAL ASSISTANCE.—The Secretary may provide technical assistance to States in planning and operating activities to be carried out under this subtitle.

"(b) LIMITATION.—A State may not use amounts paid to the State under section 2843 to—

"(1) make cash payments to intended recipients of tobacco use cessation services;

"(2) purchase or improve land, purchase, construct, or permanently improve (other than minor

remodeling) any building or other facility, or purchase major medical equipment;

"(3) satisfy any requirement for the expenditure of non-Federal funds as a condition of the receipt of Federal funds; or

"(4) provide financial assistance to any entity other than a public or nonprofit private entity.

"(c) ADMINISTRATION.—Not more than 8 percent of the allotment of a State for a the fiscal year under this subtitle may be used by the State to administer the funds paid to the State under section 2843. The State shall pay from non-Federal sources the remaining costs of administering such funds.

"SEC. 2845. APPLICATION FOR PAYMENTS; STATE PLAN.

"(a) IN GENERAL.—The Secretary may make payments under section 2843 to a State for a fiscal year only if—

"(1) the State submits to the Secretary an application for such payments;

"(2) the application contains a State plan in accordance with subsection (b);

"(3) the application contains the certification described in subsection (c);

"(4) the application contains such assurances as the Secretary may require regarding the compli-

ance of the State with the requirements of this subtitle (including assurances regarding compliance with the agreements described in subsection (c)); and

"(5) the application is in such form and is submitted by such date as the Secretary may require.

"(b) STATE PLAN.—A State plan required in subsection (a)(2) for a fiscal year is in accordance with this subsection if the plan meets the following conditions:

"(1) The plan is developed by the State agency with principal responsibility for public health programs, in consultation with the advisory committee established pursuant to subsection (c)(2).

"(2) The plan provides for tobacco use cessation treatment consistent with the smoking cessation guidelines issued by the Agency for Health Care Policy and Research, or another evidence-based guidelines approved by the Secretary.

"(3) The plan specifies the populations in the State for which such activities are to be carried out, and specifies the populations in the State that have a disparate need for such activities.

"(4) With respect to each population specified under paragraph (3), the plan contains a strategy

for expending such payments to carry out such activities. Such strategy shall include—

"(A) a description of the programs and projects to be carried out;

"(B) an estimate of the number of individuals to be served by the programs and projects; and

"(C) an estimate of the number of public health personnel needed to carry out the strategy.

"(5) The plan specifies the amount of such payments to be expended for each of such activities and, with respect to the activity involved, the amount to be expended for each population specified under paragraph (3).

"(6) The plan provides for training in tobacco use cessation intervention methods for health plans and health professionals, including physicians, nurses, dentists, and other health care providers.

"(7) The plan ensures access to smoking cessation programs for rural and underserved populations.

"(8) The plan describes the measurable objectives, developed in consultation with the Secretary, that will be used to evaluate program outcomes.

"(c) STATE CERTIFICATION.—The certification referred to in subsection (a)(3) for a fiscal year is a certification to the Secretary by the chief executive officer of the State involved as follows:

"(1)(A) In the development of the State plan required in subsection (a)(2)—

"(i) the chief health officer of the State held public hearings on the plan; and

"(ii) proposals for the plan were made public in a manner that facilitated comments from public and private entities (including Federal and other public agencies).

"(B) The State agrees that, if any revisions are made in such plan during the fiscal year, the State will, with respect to the revisions, hold hearings and make proposals public in accordance with subparagraph (A), and will submit to the Secretary a description of the revisions.

"(2) The State has established an advisory committee in accordance with subsection (d).

"(3) The State agrees to expend payments under section 2843 only for the activities authorized in section 2844.

"(4) The State agrees to expend such payments in accordance with the State plan submitted under

subsection (a)(2) (with any revisions submitted to the Secretary under paragraph (1)(B)), including making expenditures to carry out the strategy contained in the plan pursuant to subsection (b)(5).

"(5)(A) The State agrees that, in the case of each population for which such strategy is carried out, the State will measure the extent of progress being made toward improving the health status of the population.

"(B) The State agrees that—

"(i) the State will collect and report data in accordance with section 2846(a)

"(ii) for purposes of subparagraph (A), progress will be measured through the use of the applicable uniform data items developed by the Secretary under section 2846(a)(2), or if no such items are applicable, through use of the uniform criteria developed by the Secretary under section 2846(a)(3).

"(6) With respect to the activities authorized in section 2844, the State agrees to maintain State expenditures for such activities at a level that is not less than the average level of such expenditures maintained by the State for the 2-year period pre-

ceding the fiscal year for which the State is applying to receive payments under section 2843.

"(7) The State agrees to establish reasonable criteria to evaluate the effective performance of entities that receive funds from such payments and procedures for procedural and substantive independent State review of the failure by the State to provide funds for any such entity.

"(8) The State agrees to permit and cooperate with Federal investigations undertaken in accordance with section 2847.

"(d) STATE ADVISORY COMMITTEE.—

"(1) IN GENERAL.—For purposes of subsection (c)(2), an Advisory Committee is in accordance with this subsection if such committee meets the conditions described in this subsection.

"(2) DUTIES.—A condition under paragraph (1) for a State is that the duties of the committee are—

"(A) to hold public hearings on the State plan required under subsection (a)(2); and

"(B) to make recommendations pursuant to subsection (b)(1) regarding the development and implementation of such plan, including recommendations on—

"(i) the conduct of assessments of the public health;

"(ii) which of the activities authorized in section 2844 should be carried out in the State;

"(iii) the allocation of payments made to the State under section 2843;

"(iv) the coordination of activities carried out under such plan with relevant programs of other entities; and

"(v) the collection and reporting of data in accordance with section 2846(a).

"(3) COMPOSITION.—

"(A) IN GENERAL.—A condition under paragraph (1) for a State is that the Advisory Committee be composed of such members of the general public, and such officials of the health departments of political subdivisions of the State, as may be necessary to provide adequate representation of the general public and of such health departments.

"(B) REPRESENTATIVES.—With respect to compliance with subparagraph (A), the membership of the advisory committee established pursuant to subsection (c)(2) may include rep-

resentatives of community-based organizations (including minority community-based organizations), schools of public health, and entities to which the State involved awards grants or contracts to carry out activities authorized under section 2844.

"(4) CHAIRPERSON; MEETINGS.—A condition under paragraph (1) for a State is that the State public health officer serves as the chairperson of the committee, and that the committee meets not less than twice each fiscal year.

"SEC. 2846. REPORTS, DATA, AND AUDITS.

"(a) DATA.—

"(1) COLLECTION AND REPORTING.—For purposes of section 2845(c)(5)(B)(i), a State is collecting and reporting data for a fiscal year in accordance with this subsection if the State submits to the Secretary, not later than February 1 of the succeeding fiscal year year, a report that—

"(A) describes the purposes for which the State expended payments made to the State under section 2843;

"(B) pursuant to section 2845(c)(5)(A), describes the extent of progress made by the State for purposes of such section;

"(C) meets the conditions described paragraph (2); and

"(D) contains such additional information regarding activities authorized under section 2844, and is submitted in such form, as the Secretary may require.

"(2) UNIFORM DATA SETS.—

"(A) IN GENERAL.—The Secretary, in consultation with the States, shall develop sets of data for uniformly defining levels of youth and adult use of tobacco products (referred to as 'uniform tobacco product use data items'). The Secretary shall develop formats for the uniform collecting and reporting of information on such items.

"(B) LATER FISCAL YEARS.—In the case of fiscal year 2000 and each subsequent fiscal year, a condition under paragraph (1) for a State is that the State will, in accordance with the applicable format under subparagraph (A), collect during such year, and include in the report under paragraph (1), the necessary information for each of the tobacco product use data items.

"(3) UNIFORM CRITERIA.—The Secretary, in consultation with the States, shall establish criteria

for the uniform collection and reporting of data on activities authorized in section 2844 with respect to which no uniform tobacco product use data items under paragraph (2) exist.

"(4) PUBLIC INSPECTION OF REPORTS.—A condition under paragraph (1) for a fiscal year is that the State involved will make copies of the report submitted under such paragraph for the fiscal year available for public inspection, and will upon request provide a copy of the report to any individual for a charge not exceeding the cost of providing the copy.

"(b) AUDITS.—

"(1) FISCAL CONTROL AND ACCOUNTING PROCEDURES.—Each State shall establish fiscal control and fund accounting procedures as may be necessary to ensure the proper disbursal of and accounting for Federal funds paid to the State under section 2843 and funds transferred under section [4(c)] for use under this subtitle.

"(2) ANNUAL SUBMISSION.—Each State shall annually audit its expenditures from payments received under section 2843. Such State audits shall be conducted by an entity independent of any agency administering a program funded under this subtitle, and, in so far as practical, in accordance with the

Comptroller General's standards for auditing governmental organizations, programs, activities, and functions. Within 30 days following the date on which each audit is completed, the chief executive officer of the State shall transmit a copy of that audit to the Secretary.

"(3) REPAYMENTS.—Each State shall, after being provided by the Secretary with adequate notice and an opportunity for a hearing within the State, repay to the United States amounts found not to have been expended in accordance with the requirements of this subtitle or the certification provided by the State under section 2845. If such repayment is not made, the Secretary shall, after providing the State with adequate notice and opportunity for a hearing within the State, offset such amounts against the amount of any allotment to which the State is or may become entitled under this subtitle.

"(4) AVAILABILITY.—The State shall make copies of the reports and audits required by this subsection available for public inspection within the State.

"(5) EVALUATION.—The Comptroller General of the United States shall, from time to time, evaluate the expenditures by the States of payments

under this subtitle in order to ensure that expenditures are consistent with the provisions of this subtitle and the certification provide by the State under section 2845.

"(6) REPORT BY SECRETARY.—Not later than October 1, 2000, the Secretary shall prepare and submit to the appropriate committees of Congress a report concerning the activities of the States that have received funds under this subtitle and may include in the report any recommendations for appropriate changes in legislation.

"(c) NONAPPLICATION OF CERTAIN PROVISIONS.—Title XVII of the Omnibus budget Reconciliation Act of 1981 shall not apply with respect to audits of funds allotted under this subtitle.

"SEC. 2847. WITHHOLDING.

"(a) WITHHOLDING FOR MISUSE.—

"(1) IN GENERAL.—The Secretary shall, after adequate notice and opportunity for a hearing conducted within the affected State, withhold funds from any State which does not use its allotment in accordance with the requirements of this subtitle or the certifications otherwise provided by States under this subtitle. The Secretary shall withhold such funds until the Secretary finds that the reason for

the withholding has been removed and there is reasonable assurance that it will not recur.

"(2) INVESTIGATION.—The Secretary may not institute proceedings to withhold funds under paragraph (1) unless the Secretary has conducted an investigation concerning whether the State has used its allotment in accordance with the requirements of this subtitle or the certifications otherwise provided under this subtitle. Investigations required by this paragraph shall be conducted within the affected State by qualified investigators.

"(3) RESPONSE TO COMPLAINTS.—The Secretary shall respond in an expeditious manner to complaints of a substantial or serious nature that a State has failed to use funds in accordance with the requirements of this subtitle or the certifications otherwise provided under this subtitle.

"(4) MINOR FAILURES.—The Secretary may not withhold funds under paragraph (1) from a State for a minor failure to comply with the requirements of this subtitle or certifications otherwise provided under this subtitle.

"(b) INVESTIGATIONS.—

"(1) BY SECRETARY.—The Secretary shall conduct in several States in each fiscal year investiga-

tions of the use of funds received by the States under this subtitle in order to evaluate compliance with the requirements of this subtitle and certifications otherwise provided under this subtitle.

"(2) BY COMPTROLLER GENERAL.—The Comptroller General of the United States may conduct investigations of the use of funds received under this subtitle by a State in order to insure compliance with the requirements of this subtitle and certifications otherwise provided under this subtitle.

"(c) AVAILABILITY OF RECORDS.—Each State, and each entity which has received funds from an allotment made to a State under this subtitle, shall make appropriate books, documents, papers, and records available to the Secretary or the Comptroller General of the United States, or any of their duly authorized representatives, for examination, copying, or mechanical reproduction on or off the premises of the appropriate entity upon a reasonable request therefor.

"(d) LIMITATION.—

"(1) IN GENERAL.—In conducting any investigation in a State, the Secretary or the Comptroller General of the United States may not make a request for any information not readily available to such State or an entity which has received funds

from an allotment made to the State under this subtitle or make an unreasonable request for information to be compiled, collected, or transmitted in any form not readily available.

"(2) NONAPPLICATION TO JUDICIAL PROCEEDINGS.—Paragraph (1) does not apply to the collection, compilation, or transmittal of data in the course of a judicial proceeding.

"SEC. 2848. NONDISCRIMINATION.

"(a) PROGRAMS AND ACTIVITIES.—

"(1) IN GENERAL.—For the purpose of applying the prohibitions against discrimination on the basis of age under the Age Discrimination Act of 1975, on the basis of handicap under section 504 of the Rehabilitation Act of 1973, on the basis of sex under title IX of the Education Amendments of 1972, or on the basis of race, color, or national origin under title VI of the Civil Rights Act of 1964, programs and activities funded in whole or in part with funds made available under this subtitle are considered to be programs and activities receiving Federal financial assistance.

"(2) GENDER OR RELIGION.—No person shall on the ground of gender or religion be excluded from participation in, be denied the benefits of, or be sub-

jected to discrimination under, any program or activity funded in whole or in part with funds made available under this subtitle.

"(b) FAILURE TO COMPLY.—Whenever the Secretary finds that a State, or an entity that has received a payment from an allotment to a State under this subtitle, has failed to comply with a provision of law referred to in subsection (a)(1), with subsection (a)(2), or with an applicable regulation (including one prescribed to carry out subsection (a)(2)), the Secretary shall notify the chief executive officer of the State and shall request such officer to secure compliance. If within a reasonable period of time, not to exceed 60 days, the chief executive officer fails or refuses to secure compliance, the Secretary may—

"(1) refer the matter to the Attorney General with a recommendation that an appropriate civil action be instituted;

"(2) exercise the powers and functions provided by title VI of the Civil Rights Act of 1964, the Age Discrimination Act of 1975, or section 504 of the Rehabilitation Act of 1973, as may be applicable; or

"(3) take such other action as may be provided by law.

"(c) ACTION BY ATTORNEY GENERAL.—When a matter is referred to the Attorney General pursuant to

subsection (b)(1), or whenever he has reason to believe that a State or an entity is engaged in a pattern or practice in violation of a provision of law referred to in subsection (a)(1) or in violation of subsection (a)(2), the Attorney General may bring a civil action in any appropriate district court of the United States for such relief as may be appropriate, including injunctive relief.

"SEC. 2849. CRIMINAL PENALTY FOR FALSE STATEMENTS.

"Whoever—

"(1) knowingly and willfully makes or causes to be made any false statement or representation of a material fact in connection with the furnishing of items or services for which payment may be made by a State from funds allotted to the State under this subtitle; or

"(2) having knowledge of the occurrence of any event affecting his or her initial or continued right to any such payment conceals or fails to disclose such event with an intent fraudulently to secure such payment either in a greater amount than is due or when no such payment is authorized;

shall be fined not more than $25,000 or imprisoned for not more than 5 years, or both.

"Subtitle E—Tobacco-Related Research Initiatives

"SEC. 2851. INTERAGENCY COUNCIL FOR REDUCING SMOKING AND USE OF TOBACCO PRODUCTS FOR THE LONG TERM. [TO BE SUPPLIED]

"SEC. 2852. STUDY BY THE INSTITUTE OF MEDICINE. [TO BE SUPPLIED]

"SEC. 2853. DEMONSTRATION GRANTS FOR REDUCING SMOKING AND USE OF TOBACCO PRODUCTS FOR THE LONG TERM. [TO BE SUPPLIED]

"Subtitle F—National Public Education Campaign

"SEC. 2861. [TO BE SUPPLIED]

TITLE III—STANDARDS TO REDUCE INVOLUNTARY EXPOSURE TO TOBACCO SMOKE

SEC. 301. [TO BE SUPPLIED]

Title II, Subtitle B
Restrictions on Access to Tobacco Products

- $65 million annually from Tobacco Settlement Trust Fund -- distributed to states along same formula as other public health provisions
- oversight from CDC Office on Smoking and Health
- states required to enact law on youth access; bill will outline a model law
- states penalized for noncompliance, including failure to reach 80% retailer compliance; incentive for states to reach 95% retailer compliance
  - penalty for noncompliance is loss of enforcement dollars; after 3d year of noncompliance state loses funding entirely, can negotiate with Secretary to reinstate. Nondisbursed funds distributed to other states.
- state law must include:
  - licensing of tobacco retailers
  - prohibition on sale of tobacco products to persons under 18
  - penalties for clerks/employees
  - penalties for retailers/licensees (phased in over 10 years, emphasis on license suspension)
  - penalties against minors for purchase, possession, use
  - requirement that retailer to post signs
  - defense against penalties if minor used a fake ID and retailer has complied with other provisions
  - random unannounced inspections to assess level of compliance
  - designation of a state agency with law enforcement authority to enforce the law
- states must report annually to the Secretary on methods, success, etc.

Title II, Subtitle E
Tobacco-Related Research Initiatives

- Secretary must contract with Institute of Medicine to do independent study and recommendations outlining a strategy for tobacco-related research to include:
  - prevention (public education, media, community strategies)
  - science of addiction
  - cessation treatment methodologies
  - surveillance and epidemiology
  - prevention and treatment of tobacco-related diseases
- allocates research dollars to NIH, CDC, and AHCPR to carry out research strategy, and includes a trigger to ensure that tobacco research dollars do not supplant current baselines
- provides for an interagency council to ensure adherence to research strategy, and to ensure that science-based developments are disseminated to states and communities for incorporation into local efforts

tobacco / FDA

FDA's authority to regulate tobacco products as contemplated in S. 1648

The President has stated that the Administration will support proposed tobacco legislation only if it affirms the FDA's full authority to regulate tobacco products. That means the authority must be as effective as FDA's authority over other drugs and devices, and must be sufficiently flexible to meet changing circumstances. S. 1648, if enacted, does not meet that standard. The bill has two problems. First, the bill deprives the FDA of needed elements of regulatory authority. Second, by creating a separate Chapter for tobacco products, the bill unnecessarily impinges on FDA's ability to exercise, in the most effective and efficient manner, its authority over tobacco products..

I. The separate Chapter created by S. 1648 to regulate tobacco product suffers from the following specific deficiencies:

A. Access. The bill deprives FDA or any other HHS agency of the ability to modify access requirements if the current access restrictions in the FDA rule are inadequate or require redirection (such as limiting the types of stores where tobacco products can be sold). The bill also bifurcates access and advertising regulatory authority, the former going to the Centers for Disease Control; the latter to FDA. That division of responsibility weakens both authorities.

B. Advertising. The bill deprives FDA of the authority to modify advertising restrictions if the ones in the current rule require amendment or supplementation.

C. Flexibility. The bill requires that both Houses of Congress act affirmatively -- by enacting a law --to eliminate nicotine or to eliminate tobacco products (even if, in the distant future, a safer alternative to nicotine or the product is developed).

D. Product Safety. The bill limits FDA's authority to set standards pertaining to nicotine and other ingredients in tobacco products, and deprives FDA of the authority to require safer products through regulation of, for example, the filter, paper or tobacco leaf. In addition, the bill eliminates FDA's ability to require premarket approval and rigorous testing for new tobacco products.

E. Enforcement. The bill does not contain the following enforcement authorities that are in current law: civil money penalties; recall authority; authority to detain illegal products without a court order; and authority to seize products pursuant to a court order. Additionally, the bill eliminates FDA's current adulteration and misbranding authority for tobacco products – which is the authority to bring individual enforcement actions without issuing a regulation.

II. Even if all of the above elements of FDA authority were added to S. 1648, the creation of a separate Chapter for regulation of tobacco products creates unnecessary obstacles to the effective exercise of FDA authority. Three points illustrate this.

A. The inference that would be drawn from enactment of a new Chapter is that Congress intended to create a tobacco jurisdiction in FDA not only separate from but different than that

exercised over all other FDA-regulated products. The current statutory scheme that FDA has used to regulate tobacco has been interpreted in more than 20 years of regulations, guidances and judicial cases. Enactment of a new Chapter would replace all of that with a stand-alone, uninterpreted and unexplicated new jurisdiction, the full scope and extent of which would have to be re-built through agency action and judicial rulings.

By contrast, clarification in the Food Drug and Cosmetic Act of the definitions of "drug" and "device" to explicitly include tobacco products -- and clarification of FDA's statutory authority to place restrictions on medical device products to explicitly include tobacco advertising -- leaves in place this entire regulatory context. Should Congress so choose, the standard for safety and efficacy of new products could be amended to one that achieves an enhanced public health outcome.

B. New statutes require years to implement. A new Chapter will almost certainly require new rules, which will take years to implement, especially given the virtual certainty of legal challenges.

C. Finally, a new Chapter will almost certainly generate litigation over whether the FDA must scrap entirely its current regulation and re-start the regulatory process after new legislation is adopted.

3/5
1 p.m.