106TH CONGRESS
2D SESSION

S. 2379

To provide for the protection of children from tobacco.

IN THE SENATE OF THE UNITED STATES

APRIL 6, 2000

Mr. HARKIN (for himself, Mr. L. CHAFEE, and Mr. GRAHAM) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To provide for the protection of children from tobacco.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Kids Deserve Freedom from Tobacco Act of 2000'' or the ''KIDS Act''.

TITLE I—PROTECTION OF CHILDREN FROM TOBACCO

Subtitle A—Food and Drug Administration Jurisdiction and General Authority

SEC. 101. REFERENCE.

Whenever in this title an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

SEC. 102. STATEMENT OF GENERAL AUTHORITY.

The regulations promulgated by the Secretary in the rule dated August 28, 1996 (Vol. 61, No. 168 C.F.R.), adding part 897 to title 21, Code of Federal Regulations, shall be deemed to have been lawfully promulgated under the Food, Drug, and Cosmetic Act as amended by this title. Such regulations shall apply to all tobacco products.

SEC. 103. NONAPPLICABILITY TO OTHER DRUGS OR DEVICES.

Nothing in this title, or an amendment made by this title, shall be construed to affect the regulation of drugs and devices that are not tobacco products by the Secretary under the Federal Food, Drug, and Cosmetic Act.

SEC. 104. CONFORMING AMENDMENTS TO CONFIRM JURISDICTION.

(a) DEFINITIONS.—

(1) DRUG.—Section 201(g)(1) (21 U.S.C. 321(g)(1)) is amended by striking ''; and (D)'' and inserting ''; (D) nicotine in tobacco products; and (E)''.

(2) DEVICES.—Section 201(h) (21 U.S.C. 321(h)) is amended by adding at the end the following: ''Such term includes a tobacco product.''.

(3) OTHER DEFINITIONS.—Section 201 (21 U.S.C. 321) is amended by adding at the end the following:

''(kk) The term 'tobacco product' means any product made or derived from tobacco that is intended for human consumption.''.

(b) PROHIBITED ACTS.—Section 301 (21 U.S.C. 331) is amended by adding at the end the following:

''(aa) The manufacture, labeling, distribution, advertising and sale of any adulterated or misbranded tobacco product in violation of—

''(1) regulations issued under this Act; or

''(2) the KIDS Act, or regulations issued under such Act.''.

(c) ADULTERATED DRUGS AND DEVICES.—

(1) IN GENERAL.—Section 501 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351) is amended by adding at the end the following:

''(j) If it is a tobacco product and it does not comply with the provisions of subchapter D of this chapter or the KIDS Act.''.

(2) MISBRANDING.—Section 502(q) (21 U.S.C. 352(q)) is amended—

(A) by striking ''or (2)'' and inserting in lieu thereof ''(2)''; and

(B) by inserting before the period the following: '', or (3) in the case of a tobacco product, it is sold, distributed, advertised, labeled, or used in violation of this Act or the KIDS Act, or regulations prescribed under such Acts''.

(d) RESTRICTED DEVICE.—Section 520(e) (21 U.S.C. 360j(e)) is amended—

(1) in paragraph (1), by striking ''or use—'' and inserting ''or use, including restrictions on the access to, and the advertising and promotion of, tobacco products—''; and

(2) by adding at the end the following:

''(3) Tobacco products are a restricted device under this paragraph.''.

(e) REGULATORY AUTHORITY.—Section 503(g) (21 U.S.C. 353(g)) is amended by adding at the end the following:

''(5) The Secretary may regulate any tobacco product as a drug, device, or both, and may designate the office of the Administration that shall be responsible for regulating such products.''.

SEC. 105. GENERAL RULE.

Section 513(a)(1)(B) (21 U.S.C. 360c(a)(1)(B)) is amended by adding at the end the following: ''The sale of tobacco products to adults that comply with performance standards established for these products under section 514 and other provisions of this Act and any regulations prescribed under this Act shall not be prohibited by the Secretary, notwithstanding sections 502(j), 516, and 518.''.

SEC. 106. SAFETY AND EFFICACY STANDARD AND RECALL AUTHORITY.

(a) SAFETY AND EFFICACY STANDARD.—Section 513(a) (21 U.S.C. 360c(a)) is amended—

(1) in paragraph (1)(B), by inserting after the first sentence the following: ''For a device which is a tobacco product, the assurance in the previous sentence need not be found if the Secretary finds that

special controls achieve the best public health result.''; and

(2) in paragraph (2)—

(A) by redesignating subparagraphs (A), (B) and (C) as clauses (i), (ii) and (iii), respectively;

(B) by striking ''(2) For'' and inserting ''(2)(A) For''; and

(C) by adding at the end the following:

''(B) For purposes of paragraph (1)(B), subsections (c)(2)(C), (d)(2)(B), (e)(2)(A), (f)(3)(B)(i), and (f)(3)(C)(i), and sections 514, 519(a), 520(e), and 520(f), the safety and effectiveness of a device that is a tobacco product need not be found if the Secretary finds that the action to be taken under any such provision would achieve the best public health result. The finding as to whether the best public health result has been achieved shall be determined with respect to the risks and benefits to the population as a whole, including users and non-users of the tobacco product, and taking into account—

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

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

(b) RECALL AUTHORITY.—Section 518(e)(1) (21 U.S.C. 360h(e)(1)) is amended by inserting after ''adverse health consequences or death,'' the following: ''and for tobacco products that the best public health result would be achieved,''.

Subtitle B—Regulation of Tobacco Products

SEC. 111. PERFORMANCE STANDARDS.

Section 514(a) (21 U.S.C. 60d(a)) is amended—

(1) in paragraph (2), by striking ''device'' and inserting ''nontobacco product device'';

(2) by redesignating paragraphs (3) and (4) as paragraphs (6) and (7), respectively; and

(3) by inserting after paragraph (2) the following:

''(3) The Secretary may adopt a performance standard under section 514(a)(2) for a tobacco product regardless of whether the product has been classified under section 513. Such standard may—

''(A) include provisions to achieve the best public health result;

''(B) where necessary to achieve the best public health result, include—

''(i) provisions respecting the construction, components, constituents, ingredients, and properties of the tobacco product device, including the reduction or elimination (or both) of nicotine and the other components, ingredients, and constituents of the tobacco product, its components and its by-products, based upon the best available technology;

''(ii) provisions for the testing (on a sample basis or, if necessary, on an individual basis) of the tobacco product device or, if it is determined that no other more practicable means are available to the Secretary to assure the conformity of the tobacco product device to such standard, provisions for the testing (on a sample basis or, if necessary, on an individual basis) by the Secretary or by another person at the direction of the Secretary;

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

''(iv) provisions requiring that the results of each test or of certain tests of the tobacco

product device required to be made under clause (ii) demonstrate that the tobacco product device is in conformity with the portions of the standard for which the test or tests were required; and

''(v) a provision that the sale and distribution of the tobacco product device be restricted but only to the extent that the sale and distribution of a tobacco product device may otherwise be restricted under this Act; and

''(C) where appropriate, require the use and prescribe the form and content of labeling for the use of the tobacco product device.

''(4) Not later than 1 year after the date of enactment of the KIDS Act, the Secretary (acting through the Commissioner of Food and Drugs) shall establish a Scientific Advisory Committee to evaluate whether a level or range of levels exists at which nicotine yields do not produce drug-dependence. The Advisory Committee shall also review any other safety, dependence or health issue assigned to it by the Secretary. The Secretary need not promulgate regulations to establish the Committee.''.

SEC. 112. APPLICATION OF FEDERAL FOOD, DRUG, AND COSMETIC ACT TO TOBACCO PRODUCTS.

(a) TOBACCO PRODUCTS REGULATION.—Chapter V (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

''SUBCHAPTER F—TOBACCO PRODUCT DEVELOPMENT, MANUFACTURING, AND ACCESS RESTRICTIONS

''SEC. 570. PROMULGATION OF REGULATIONS.

''Any regulations necessary to implement this subchapter shall be promulgated not later than 12 months after the date of enactment of this subchapter using notice and comment rulemaking (in accordance with chapter 5 of title 5, United States Code). Such regulations may be revised thereafter as determined necessary by the Secretary.

''SEC. 571. MAIL-ORDER SALES.

''(a) IN GENERAL.—Not later than 2 years after the date of enactment of this subchapter, the Secretary shall review and determine whether persons under the age of 18 years are obtaining tobacco products by means of the mail.

''(b) RESTRICTIONS.—Based solely upon the review conducted under subsection (a), the Secretary may take regulatory and administrative action to restrict or eliminate mail order sales of tobacco products.

"SEC. 572. IMPLEMENTATION OF THE PROPOSED RESOLUTION.

"(a) ADDITIONAL RESTRICTIONS ON MARKETING, ADVERTISING, AND ACCESS.—Not later than 18 months after the date of the enactment of this subchapter, the Secretary shall revise the regulations related to tobacco products promulgated by the Secretary on August 28, 1996 (61 Fed. Reg. 44396) to include the additional restrictions on marketing, advertising, and access described in Title IA and Title IC of the Proposed Resolution entered into by the tobacco manufacturers and the State attorneys general on June 20, 1997, except that the Secretary shall not include an additional restriction on marketing or advertising in such regulations if its inclusion would violate the First Amendment to the Constitution.

"(b) WARNINGS.—Not later than 18 months after the date of the enactment of this subchapter, the Secretary shall promulgate regulations to require warnings on cigarette and smokeless tobacco labeling and advertisements. The content, format, and rotation of warnings shall conform to the specifications described in Title IB of the Proposed Resolution entered into by the tobacco manufacturers and the State attorneys general on June 20, 1997.

"(c) RULES OF CONSTRUCTION.—

"(1) IN GENERAL.—Nothing in this section shall be construed to limit the ability of the Sec-

retary to change the text or layout of any of the warning statements, or any of the labeling provisions, under the regulations promulgated under subsection (b) and other provisions of this Act, if determined necessary by the Secretary in order to make such statements or labels larger, more prominent, more conspicuous, or more effective.

''(2) UNFAIR ACTS.—Nothing in this section (other than the requirements of subsections (a) and (b)) shall be construed to limit or restrict the authority of the Federal Trade Commission with respect to unfair or deceptive acts or practices in the advertising of tobacco products.

''(d) LIMITED PREEMPTION.—

''(1) STATE AND LOCAL ACTION.—No warning label with respect to tobacco products, or any other tobacco product for which warning labels have been required under this section, other than the warning labels required under this Act, shall be required by any State or local statute or regulation to be included on any package of a tobacco product.

''(2) EFFECT ON LIABILITY LAW.—Nothing in this section shall relieve any person from liability at common law or under State statutory law to any other person.

''(e) VIOLATION OF SECTION.—Any tobacco product that is in violation of this section shall be deemed to be misbranded.

"SEC. 573. GENERAL RESPONSIBILITIES OF MANUFACTURERS, DISTRIBUTORS AND RETAILERS.

''Each manufacturer, distributor, and retailer shall ensure that the tobacco products it manufactures, labels, advertises, packages, distributes, sells, or otherwise holds for sale comply with all applicable requirements of this Act.

"SEC. 574. DISCLOSURE AND REPORTING OF TOBACCO AND NONTOBACCO INGREDIENTS AND CONSTITUENTS.

''(a) DISCLOSURE OF ALL INGREDIENTS.—

''(1) IMMEDIATE AND ANNUAL DISCLOSURE.—Not later than 30 days after the date of enactment of this subchapter, and annually thereafter, each manufacturer of a tobacco product shall submit to the Secretary an ingredient list for each brand of tobacco product it manufactures that contains the information described in paragraph (2).

''(2) REQUIREMENTS.—The list described in paragraph (1) shall, with respect to each brand or variety of tobacco product of a manufacturer, include—

''(A) a list of all ingredients, constituents, substances, and compounds that are found in or added to the tobacco or tobacco product (including the paper, filter, or packaging of the product if applicable) in the manufacture of the tobacco product, for each brand or variety of tobacco product so manufactured, including, if determined necessary by the Secretary, any material added to the tobacco used in the product prior to harvesting;

''(B) the quantity of the ingredients, constituents, substances, and compounds that are listed under subparagraph (A) in each brand or variety of tobacco product;

''(C) the nicotine content of the product, measured in milligrams of nicotine;

''(D) for each brand or variety of cigarettes—

''(i) the filter ventilation percentage (the level of air dilution in the cigarette as provided by the ventilation holes in the filter, described as a percentage);

''(ii) the pH level of the smoke of the cigarette; and

"(iii) the tar, unionized (free) nicotine, and carbon monoxide delivery level and any other smoking conditions established by the Secretary, reported in milligrams of tar, nicotine, and carbon monoxide per cigarette;

"(E) for each brand or variety of smokeless tobacco products—

"(i) the pH level of the tobacco;

"(ii) the moisture content of the tobacco expressed as a percentage of the weight of the tobacco; and

"(iii) the nicotine content—

"(I) for each gram of the product, measured in milligrams of nicotine;

"(II) expressed as a percentage of the dry weight of the tobacco; and

"(III) with respect to unionized (free) nicotine, expressed as a percentage per gram of the tobacco and expressed in milligrams per gram of the tobacco; and

"(F) any other information determined appropriate by the Secretary.

''(3) METHODS.—The Secretary shall have the authority to promulgate regulations to establish the methods to be used by manufacturers in making the determinations required under paragraph (2).

''(4) OTHER TOBACCO PRODUCTS.—The Secretary shall prescribe such regulations as may be necessary to establish information disclosure procedures for other tobacco products.

''(b) SAFETY ASSESSMENTS.—

''(1) APPLICATION TO NEW INGREDIENTS.—

''(A) IN GENERAL.—Not later than 1 year after the date of enactment of this subchapter, and annually thereafter, each manufacturer shall submit to the Secretary a safety assessment for each new ingredient, constituent, substance, or compound that such manufacturer desires to make a part of a tobacco product. Such new ingredient, constituent, substance, or compound shall not be included in a tobacco product prior to approval by the Secretary of such a safety assessment.

''(B) METHOD OF FILING.—A safety assessment submitted under subparagraph (A) shall be signed by an officer of the manufacturer who is acting on behalf of the manufac-

turer and who has the authority to bind the manufacturer, and contain a statement that ensures that the information contained in the assessment is true, complete and accurate.

''(C) DEFINITION OF NEW INGREDIENT.—For purposes of subparagraph (A), the term 'new ingredient, constituent, substance, or compound' means an ingredient, constituent, substance, or compound listed under subsection (a)(1) that was not used in the brand or variety of tobacco product involved prior to January 1, 1998.

''(2) APPLICATION TO OTHER INGREDIENTS.—With respect to the application of this section to ingredients, constituents substances, or compounds listed under subsection (a) to which paragraph (1) does not apply, all such ingredients, constituents, substances, or compounds shall be reviewed through the safety assessment process within the 5-year period beginning on the date of enactment of this subchapter. The Secretary shall develop a procedure for the submission of safety assessments of such ingredients, constituents, substances, or compounds that staggers such safety assessments within the 5-year period.

''(3) BASIS OF ASSESSMENT.—The safety assessment of an ingredient, constituent, substance, or compound described in paragraphs (1) and (2) shall—

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

''(B) demonstrate that there is a reasonable certainty among experts qualified by scientific training and experience who are consulted, that the ingredient, constituent, substance, or compound will not present any risk to consumers or the public in the quantities used under the intended conditions of use.

''(c) PROHIBITION.—

''(1) REGULATIONS.—Not later than 12 months after the date of enactment of this subchapter, the Secretary shall promulgate regulations to prohibit the use of any ingredient, constituent, substance, or compound in the tobacco product of a manufacturer—

''(A) if no safety assessment has been submitted by the manufacturer for the ingredient, constituent, substance, or compound as otherwise required under this section; or

''(B) if the Secretary finds that the manufacturer has failed to demonstrate the safety of the ingredient, constituent, substance, or compound that was the subject of the assessment under paragraph (2).

''(2) REVIEW OF ASSESSMENTS.—

''(A) GENERAL REVIEW.—Not later than 180 days after the receipt of a safety assessment under subsection (b), the Secretary shall review the findings contained in such assessment and approve or disapprove of the safety of the ingredient, constituent, substance, or compound that was the subject of the assessment. The Secretary may, for good cause, extend the period for such review. The Secretary shall provide notice to the manufacturer of an action under this subparagraph.

''(B) INACTION BY SECRETARY.—If the Secretary fails to act with respect to an assessment of an existing ingredient, constituent, substance, or additive during the period referred to in subparagraph (A), the manufacturer of the tobacco product involved may continue to use the ingredient, constituent, substance, or compound involved until such time as the Secretary

makes a determination with respect to the assessment.

''(d) RIGHT TO KNOW; FULL DISCLOSURE OF INGREDIENTS TO THE PUBLIC.—

''(1) IN GENERAL.—Except as provided in paragraph (3), a package of a tobacco product shall disclose all ingredients, constituents, substances, or compounds contained in the product in accordance with regulations promulgated under section 701(a) by the Secretary.

''(2) DISCLOSURE OF PERCENTAGE OF DOMESTIC AND FOREIGN TOBACCO.—The regulations referred to in paragraph (1) shall require that the package of a tobacco product disclose, with respect to the tobacco contained in the product—

''(A) the percentage that is domestic tobacco; and

''(B) the percentage that is foreign tobacco.

''(3) HEALTH DISCLOSURE.—Notwithstanding section 301(j), the Secretary may require the public disclosure of any ingredient, constituent, substance, or compound contained in a tobacco product that relates to a trade secret or other matter referred to in section 1905 of title 18, United States Code, if the

Secretary determines that such disclosure will promote the public health.

"SEC. 575. REDUCED RISK PRODUCTS.

"(a) PROHIBITION.—

"(1) IN GENERAL.—No manufacturer, distributor or retailer of tobacco products may make any direct or implied statement in advertising or on a product package that could reasonably be interpreted to state or imply a reduced health risk associated with a tobacco product unless the manufacturer demonstrates to the Secretary, in such form as the Secretary may require, that based on the best available scientific evidence the product significantly reduces the overall health risk to the public when compared to other tobacco products.

"(2) SUBMISSION TO SECRETARY.—Prior to making any statement described in paragraph (1), a manufacturer, distributor or retailer shall submit such statement to the Secretary, who shall review such statement to ensure its accuracy and, in the case of advertising, to prevent such statement from increasing, or preventing the contraction of, the size of the overall market for tobacco products.

"(b) DETERMINATION BY SECRETARY.—If the Secretary determines that a statement described in subsection

(a)(2) is permissible because the tobacco product does present a significantly reduced overall health risk to the public, the Secretary may permit such statement to be made.

''(c) DEVELOPMENT OR ACQUISITION OF REDUCED RISK TECHNOLOGY.—

''(1) IN GENERAL.—Any manufacturer that develops or acquires any technology that the manufacturer reasonably believes will reduce the risk from tobacco products shall notify the Secretary of the development or acquisition of the technology. Such notice shall be in such form and within such time as the Secretary shall require.

''(2) CONFIDENTIALITY.—With respect to any technology described in paragraph (1) that is in the early stages of development (as determined by the Secretary), the Secretary shall establish protections to ensure the confidentiality of any proprietary information submitted to the Secretary under this subsection during such development.

''SEC. 576. ACCESS TO COMPANY INFORMATION.

''(a) COMPLIANCE PROCEDURES.—Each manufacturer of tobacco products shall establish procedures to ensure compliance with this Act.

''(b) REQUIREMENT.—In addition to any other disclosure obligations under this Act, the KIDS Act, or any other law, each manufacturer of tobacco products shall, not later than 90 days after the date of the enactment of the KIDS Act and thereafter as required by the Secretary, disclose to the Secretary all nonpublic information and research in its possession or control relating to the addiction or dependency, or the health or safety of tobacco products, including (without limitation) all research relating to processes to make tobacco products less hazardous to consumers and the research and documents described in subsection (c).

''(c) RESEARCH AND DOCUMENTS.—The documents described in this section include any documents concerning tobacco product research relating to—

''(1) nicotine, including—

''(A) the interaction between nicotine and other components in tobacco products including ingredients in the tobacco and smoke components;

''(B) the role of nicotine in product design and manufacture, including product charters, and parameters in product development, the tobacco blend, filter technology, and paper;

''(C) the role of nicotine in tobacco leaf purchasing;

''(D) reverse engineering activities involving nicotine (such as analyzing the products of other companies);

''(E) an analysis of nicotine delivery; and

''(F) the biology, psychopharmacology and any other health effects of nicotine;

''(2) other ingredients, including—

''(A) the identification of ingredients in tobacco products and constituents in smoke, including additives used in product components such as paper, filter, and wrapper;

''(B) any research on the health effects of ingredients; and

''(C) any research or other information explaining what happens to ingredients when they are heated and burned;

''(3) less hazardous or safer products, including any research or product development information on activities involving reduced risk, less hazardous, low-tar or reduced-tar, low-nicotine or reduced-nicotine or nicotine-free products; and

''(4) tobacco product advertising, marketing and promotion, including—

''(A) documents related to the design of advertising campaigns, including the desired demographics for individual products on the market or being tested;

''(B) documents concerning the age of initiation of tobacco use, general tobacco use behavior, beginning smokers, pre-smokers, and new smokers;

''(C) documents concerning the effects of advertising; and

''(D) documents concerning future marketing options or plans in light of the requirements and regulations to be imposed under this subchapter or the KIDS Act.

''(d) AUTHORITY OF SECRETARY.—With respect to tobacco product manufacturers, the Secretary shall have the same access to records and information and inspection authority as is available with respect to manufacturers of other medical devices.

''SEC. 577. OVERSIGHT OF TOBACCO PRODUCT MANUFACTURING.

''The Secretary shall by regulation prescribe good manufacturing practice standards for tobacco products. Such regulations shall be modeled after good manufacturing practice regulations for medical devices, food, and

other items under section 520(f). Such standards shall be directed specifically toward tobacco products, and shall include—

''(1) a quality control system, to ensure that tobacco products comply with such standards;

''(2) a system for inspecting tobacco product materials to ensure their compliance with such standards;

''(3) requirements for the proper handling of finished tobacco products;

''(4) strict tolerances for pesticide chemical residues in or on tobacco or tobacco product commodities in the possession of the manufacturer, except that nothing in this paragraph shall be construed to affect any authority of the Environmental Protection Agency;

''(5) authority for officers or employees of the Secretary to inspect any factory, warehouse, or other establishment of any tobacco product manufacturer, and to have access to records, files, papers, processes, controls and facilities related to tobacco product manufacturing, in accordance with appropriate authority and rules promulgated under this Act; and

''(6) a requirement that the tobacco product manufacturer maintain such files and records as the

Secretary may specify, as well as that the manufacturer report to the Secretary such information as the Secretary shall require, in accordance with section 519.

''SEC. 578. PRESERVATION OF STATE AND LOCAL AUTHORITY.

''Notwithstanding section 521 and except as otherwise provided for in section 572(e), nothing in this subchapter shall be construed as prohibiting a State or locality from imposing requirements, prohibitions, penalties or other measures to further the purposes of this subchapter that are in addition to the requirements, prohibitions, or penalties required under this subchapter. State and local governments may impose additional tobacco product control measures to further restrict or limit the use of such products.''.

SEC. 113. FUNDING.

(a) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this subtitle (and the amendments made by this subtitle).

(b) TRIGGER.—No expenditures shall be made under this subtitle (or the amendments made by this subtitle) during any fiscal year in which the annual amount appro-

priated for the Food and Drug Administration is less than the amount so appropriated for the prior fiscal year.

SEC. 114. REPEALS.

The following provisions of law are repealed:

(1) The Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1331 et seq.), except for sections 5(d)(1) and (2) and 6.

(2) The Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4401 et seq.), except for sections 3(f) and 8(a) and (b).

(3) The Comprehensive Smoking Education Act of 1964 (Public law 98-474).

TITLE II—MISCELLANEOUS PROVISIONS

SEC. 201. NONAPPLICATION TO TOBACCO PRODUCERS.

(a) IN GENERAL.—This Act and the amendments made by this Act shall not apply to the producers of tobacco leaf, including tobacco growers, tobacco warehouses, and tobacco grower cooperatives.

(b) RULE OF CONSTRUCTION.—Nothing in this Act, or an amendment made by this Act, shall be construed to provide the Secretary of Health and Human Services with the authority to—

(1) enter onto a farm owned by a producer of tobacco leaf without the written consent of such producer; or

(2) promulgate regulations on any matter that involves the production of tobacco leaf or a producer thereof, other than activities by a manufacturer that affect production.

(c) MANUFACTURER ACTING AS PRODUCER.—Notwithstanding any other provision of this section, if a producer of tobacco leaf is also a tobacco product manufacturer or is owned or controlled by a tobacco product manufacturer, the producer shall be subject to the provisions of this Act, and the amendments made by this Act, in the producer's capacity as a manufacturer.

(d) DEFINITION.—In this section, the term ''controlled by'' means a producer that is a member of the same controlled group of corporations, as that term is used for purposes of section 52(a) of the Internal Revenue Code of 1986, or under common control within the meaning of the regulations promulgated under section 52(b) of such Code.

SEC. 202. EQUAL TREATMENT OF RETAIL OUTLETS.

The Secretary of Health and Human Services shall promulgate regulations to require that retail establishments that are accessible to individuals under the age of

18, for which the predominant business is the sale of tobacco products, comply with any advertising restrictions applicable to such establishments.

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