

107TH CONGRESS
1ST SESSION

S. 247

To provide for the protection of children from tobacco.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 6, 2001

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

A BILL

To provide for the protection of children from tobacco.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Kids Deserve Freedom
5 from Tobacco Act of 2001” or the “KIDS Act”.

1 **TITLE I—PROTECTION OF**
2 **CHILDREN FROM TOBACCO**
3 **Subtitle A—Food and Drug Admin-**
4 **istration Jurisdiction and Gen-**
5 **eral Authority**

6 **SEC. 101. REFERENCE.**

7 Whenever in this title an amendment or repeal is ex-
8 pressed in terms of an amendment to, or repeal of, a sec-
9 tion or other provision, the reference shall be considered
10 to be made to a section or other provision of the Federal
11 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

12 **SEC. 102. STATEMENT OF GENERAL AUTHORITY.**

13 The regulations promulgated by the Secretary of
14 Health and Human Services in the rule dated August 28,
15 1996 (Vol. 61, No. 168 C.F.R.), adding part 897 to title
16 21, Code of Federal Regulations, shall be deemed to have
17 been lawfully promulgated under the Food, Drug, and
18 Cosmetic Act as amended by this title. Such regulations
19 shall apply to all tobacco products.

20 **SEC. 103. NONAPPLICABILITY TO OTHER DRUGS OR DE-**
21 **VICES.**

22 Nothing in this title, or an amendment made by this
23 title, shall be construed to affect the regulation of drugs
24 and devices that are not tobacco products by the Secretary

1 of Health and Human Services under the Federal Food,
 2 Drug, and Cosmetic Act.

3 **SEC. 104. CONFORMING AMENDMENTS TO CONFIRM JURIS-**
 4 **DICTION.**

5 (a) DEFINITIONS.—

6 (1) DRUG.—Section 201(g)(1) (21 U.S.C.
 7 321(g)(1)) is amended by striking “; and (D)” and
 8 inserting “; (D) nicotine in tobacco products; and
 9 (E)”.

10 (2) DEVICES.—Section 201(h) (21 U.S.C.
 11 321(h)) is amended by adding at the end the fol-
 12 lowing: “Such term includes a tobacco product.”.

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

16 “(kk) The term ‘tobacco product’ means any
 17 product made or derived from tobacco that is in-
 18 tended for human consumption.”.

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

21 “(aa) The manufacture, labeling, distribution, adver-
 22 tising and sale of any adulterated or misbranded tobacco
 23 product in violation of—

24 “(1) regulations issued under this Act; or

1 “(2) the KIDS Act, or regulations issued under
2 such Act.”.

3 (c) ADULTERATED DRUGS AND DEVICES.—

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

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

10 (2) MISBRANDING.—Section 502(q) (21 U.S.C.
11 352(q)) is amended—

12 (A) by striking “or (2)” and inserting
13 “(2)”; and

14 (B) by inserting before the period the fol-
15 lowing: “, or (3) in the case of a tobacco prod-
16 uct, it is sold, distributed, advertised, labeled,
17 or used in violation of this Act or the KIDS
18 Act, or regulations prescribed under such
19 Acts”.

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

22 (1) in paragraph (1), by striking “or use—”
23 and inserting “or use, including restrictions on the
24 access to, and the advertising and promotion of, to-
25 bacco products—”; and

1 (2) by adding at the end the following:

2 “(3) Tobacco products are a restricted device under
3 this paragraph.”.

4 (e) REGULATORY AUTHORITY.—Section 503(g) (21
5 U.S.C. 353(g)) is amended by adding at the end the fol-
6 lowing:

7 “(5) The Secretary may regulate any tobacco product
8 as a drug, device, or both, and may designate the office
9 of the Administration that shall be responsible for regu-
10 lating such products.”.

11 **SEC. 105. GENERAL RULE.**

12 Section 513(a)(1)(B) (21 U.S.C. 360c(a)(1)(B)) is
13 amended by adding at the end the following: “The sale
14 of tobacco products to adults that comply with perform-
15 ance standards established for these products under sec-
16 tion 514 and other provisions of this Act and any regula-
17 tions prescribed under this Act shall not be prohibited by
18 the Secretary, notwithstanding sections 502(j), 516, and
19 518.”.

20 **SEC. 106. SAFETY AND EFFICACY STANDARD AND RECALL**
21 **AUTHORITY.**

22 (a) SAFETY AND EFFICACY STANDARD.—Section
23 513(a) (21 U.S.C. 360c(a)) is amended—

24 (1) in paragraph (1)(B), by inserting after the
25 first sentence the following: “For a device which is

1 a tobacco product, the assurance in the previous sen-
 2 tence need not be found if the Secretary finds that
 3 special controls achieve the best public health re-
 4 sult.”; and

5 (2) in paragraph (2)—

6 (A) by redesignating subparagraphs (A),
 7 (B) and (C) as clauses (i), (ii) and (iii), respec-
 8 tively;

9 (B) by striking “(2) For” and inserting
 10 “(2)(A) For”; and

11 (C) by adding at the end the following:

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

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

(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,”.

11 SEC. 111. PERFORMANCE STANDARDS.

13 (1) in paragraph (2), by striking “device” and
14 inserting “nontobacco product device”;

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

23 “(A) include provisions to achieve the best pub-
24 lic health result;

1 “(B) where necessary to achieve the best public
2 health result, include—

3 “(i) provisions respecting the construction,
4 components, constituents, ingredients, and
5 properties of the tobacco product device, includ-
6 ing the reduction or elimination (or both) of
7 nicotine and the other components, ingredients,
8 and constituents of the tobacco product, its
9 components and its by-products, based upon the
10 best available technology;

11 “(ii) provisions for the testing (on a sam-
12 ple basis or, if necessary, on an individual
13 basis) of the tobacco product device or, if it is
14 determined that no other more practicable
15 means are available to the Secretary to assure
16 the conformity of the tobacco product device to
17 such standard, provisions for the testing (on a
18 sample basis or, if necessary, on an individual
19 basis) by the Secretary or by another person at
20 the direction of the Secretary;

21 “(iii) provisions for the measurement of
22 the performance characteristics of the tobacco
23 product device;

24 “(iv) provisions requiring that the results
25 of each test or of certain tests of the tobacco

1 product device required to be made under
2 clause (ii) demonstrate that the tobacco product
3 device is in conformity with the portions of the
4 standard for which the test or tests were re-
5 quired; and

6 “(v) a provision that the sale and distribu-
7 tion of the tobacco product device be restricted
8 but only to the extent that the sale and dis-
9 tribution of a tobacco product device may other-
10 wise be restricted under this Act; and

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

14 “(4) Not later than 1 year after the date of enact-
15 ment of the KIDS Act, the Secretary (acting through the
16 Commissioner of Food and Drugs) shall establish a Sci-
17 entific Advisory Committee to evaluate whether a level or
18 range of levels exists at which nicotine yields do not
19 produce drug-dependence. The Advisory Committee shall
20 also review any other safety, dependence or health issue
21 assigned to it by the Secretary. The Secretary need not
22 promulgate regulations to establish the Committee.”.

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

3 (a) TOBACCO PRODUCTS REGULATION.—Chapter V
4 (21 U.S.C. 351 et seq.) is amended by adding at the end
5 the following:

6 “SUBCHAPTER F—TOBACCO PRODUCT DEVEL-
7 OPMENT, MANUFACTURING, AND ACCESS
8 RESTRICTIONS

9 **“SEC. 570. PROMULGATION OF REGULATIONS.**

10 “Any regulations necessary to implement this sub-
11 chapter shall be promulgated not later than 12 months
12 after the date of enactment of this subchapter using notice
13 and comment rulemaking (in accordance with chapter 5
14 of title 5, United States Code). Such regulations may be
15 revised thereafter as determined necessary by the Sec-
16 retary.

17 **“SEC. 571. MAIL-ORDER SALES.**

18 “(a) IN GENERAL.—Not later than 2 years after the
19 date of enactment of this subchapter, the Secretary shall
20 review and determine whether persons under the age of
21 18 years are obtaining tobacco products by means of the
22 mail.

23 “(b) RESTRICTIONS.—Based solely upon the review
24 conducted under subsection (a), the Secretary may take
25 regulatory and administrative action to restrict or elimi-
26 nate mail order sales of tobacco products.

1 **“SEC. 572. IMPLEMENTATION OF THE PROPOSED RESOLU-**
2 **TION.**

3 “(a) ADDITIONAL RESTRICTIONS ON MARKETING,
4 ADVERTISING, AND ACCESS.—Not later than 18 months
5 after the date of the enactment of this subchapter, the
6 Secretary shall revise the regulations related to tobacco
7 products promulgated by the Secretary on August 28,
8 1996 (61 Fed. Reg. 44396) to include the additional re-
9 strictions on marketing, advertising, and access described
10 in Title IA and Title IC of the Proposed Resolution en-
11 tered into by the tobacco manufacturers and the State at-
12 torneys general on June 20, 1997, except that the Sec-
13 retary shall not include an additional restriction on mar-
14 keting or advertising in such regulations if its inclusion
15 would violate the First Amendment to the Constitution.

16 “(b) WARNINGS.—Not later than 18 months after the
17 date of the enactment of this subchapter, the Secretary
18 shall promulgate regulations to require warnings on ciga-
19 rette and smokeless tobacco labeling and advertisements.
20 The content, format, and rotation of warnings shall con-
21 form to the specifications described in Title IB of the Pro-
22 posed Resolution entered into by the tobacco manufactur-
23 ers and the State attorneys general on June 20, 1997.

24 “(c) RULES OF CONSTRUCTION.—

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

1 retary to change the text or layout of any of the
2 warning statements, or any of the labeling provi-
3 sions, under the regulations promulgated under sub-
4 section (b) and other provisions of this Act, if deter-
5 mined necessary by the Secretary in order to make
6 such statements or labels larger, more prominent,
7 more conspicuous, or more effective.

8 “(2) UNFAIR ACTS.—Nothing in this section
9 (other than the requirements of subsections (a) and
10 (b)) shall be construed to limit or restrict the au-
11 thority of the Federal Trade Commission with re-
12 spect to unfair or deceptive acts or practices in the
13 advertising of tobacco products.

14 “(d) LIMITED PREEMPTION.—

15 “(1) STATE AND LOCAL ACTION.—No warning
16 label with respect to tobacco products, or any other
17 tobacco product for which warning labels have been
18 required under this section, other than the warning
19 labels required under this Act, shall be required by
20 any State or local statute or regulation to be in-
21 cluded on any package of a tobacco product.

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

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

4 **“SEC. 573. GENERAL RESPONSIBILITIES OF MANUFACTUR-**
 5 **ERS, DISTRIBUTORS AND RETAILERS.**

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

11 **“SEC. 574. DISCLOSURE AND REPORTING OF TOBACCO AND**
 12 **NONTOBACCO INGREDIENTS AND CONSTITU-**
 13 **ENTS.**

14 “(a) DISCLOSURE OF ALL INGREDIENTS.—

15 “(1) IMMEDIATE AND ANNUAL DISCLOSURE.—
 16 Not later than 30 days after the date of enactment
 17 of this subchapter, and annually thereafter, each
 18 manufacturer of a tobacco product shall submit to
 19 the Secretary an ingredient list for each brand of to-
 20 bacco product it manufactures that contains the in-
 21 formation described in paragraph (2).

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

1 “(A) a list of all ingredients, constituents,
2 substances, and compounds that are found in or
3 added to the tobacco or tobacco product (in-
4 cluding the paper, filter, or packaging of the
5 product if applicable) in the manufacture of the
6 tobacco product, for each brand or variety of to-
7 bacco product so manufactured, including, if
8 determined necessary by the Secretary, any ma-
9 terial added to the tobacco used in the product
10 prior to harvesting;

11 “(B) the quantity of the ingredients, con-
12 stituents, substances, and compounds that are
13 listed under subparagraph (A) in each brand or
14 variety of tobacco product;

15 “(C) the nicotine content of the product,
16 measured in milligrams of nicotine;

17 “(D) for each brand or variety of
18 cigarettes—

19 “(i) the filter ventilation percentage
20 (the level of air dilution in the cigarette as
21 provided by the ventilation holes in the fil-
22 ter, described as a percentage);

23 “(ii) the pH level of the smoke of the
24 cigarette; and

1 “(iii) the tar, unionized (free) nico-
2 tine, and carbon monoxide delivery level
3 and any other smoking conditions estab-
4 lished by the Secretary, reported in milli-
5 grams of tar, nicotine, and carbon mon-
6 oxide per cigarette;

7 “(E) for each brand or variety of smoke-
8 less tobacco products—

9 “(i) the pH level of the tobacco;

10 “(ii) the moisture content of the to-
11 bacco expressed as a percentage of the
12 weight of the tobacco; and

13 “(iii) the nicotine content—

14 “(I) for each gram of the prod-
15 uct, measured in milligrams of nico-
16 tine;

17 “(II) expressed as a percentage
18 of the dry weight of the tobacco; and

19 “(III) with respect to unionized
20 (free) nicotine, expressed as a percent-
21 age per gram of the tobacco and ex-
22 pressed in milligrams per gram of the
23 tobacco; and

24 “(F) any other information determined ap-
25 propriate by the Secretary.

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

5 “(4) OTHER TOBACCO PRODUCTS.—The Sec-
6 retary shall prescribe such regulations as may be
7 necessary to establish information disclosure proce-
8 dures for other tobacco products.

9 “(b) SAFETY ASSESSMENTS.—

10 “(1) APPLICATION TO NEW INGREDIENTS.—

11 “(A) IN GENERAL.—Not later than 1 year
12 after the date of enactment of this subchapter,
13 and annually thereafter, each manufacturer
14 shall submit to the Secretary a safety assess-
15 ment for each new ingredient, constituent, sub-
16 stance, or compound that such manufacturer
17 desires to make a part of a tobacco product.
18 Such new ingredient, constituent, substance, or
19 compound shall not be included in a tobacco
20 product prior to approval by the Secretary of
21 such a safety assessment.

22 “(B) METHOD OF FILING.—A safety as-
23 sessment submitted under subparagraph (A)
24 shall be signed by an officer of the manufac-
25 turer who is acting on behalf of the manufac-

1 turer and who has the authority to bind the
2 manufacturer, and contain a statement that en-
3 sures that the information contained in the as-
4 sessment is true, complete and accurate.

5 “(C) DEFINITION OF NEW INGREDIENT.—

6 For purposes of subparagraph (A), the term
7 ‘new ingredient, constituent, substance, or com-
8 pound’ means an ingredient, constituent, sub-
9 stance, or compound listed under subsection
10 (a)(1) that was not used in the brand or variety
11 of tobacco product involved prior to January 1,
12 1998.

13 “(2) APPLICATION TO OTHER INGREDIENTS.—

14 With respect to the application of this section to in-
15 gredients, constituents, substances, or compounds
16 listed under subsection (a) to which paragraph (1)
17 does not apply, all such ingredients, constituents,
18 substances, or compounds shall be reviewed through
19 the safety assessment process within the 5-year pe-
20 riod beginning on the date of enactment of this sub-
21 chapter. The Secretary shall develop a procedure for
22 the submission of safety assessments of such ingre-
23 dients, constituents, substances, or compounds that
24 stagger such safety assessments within the 5-year
25 period.

1 “(3) BASIS OF ASSESSMENT.—The safety as-
 2 sessment of an ingredient, constituent, substance, or
 3 compound described in paragraphs (1) and (2)
 4 shall—

5 “(A) be based on the best scientific evi-
 6 dence available at the time of the submission of
 7 the assessment; and

8 “(B) demonstrate that there is a reason-
 9 able certainty among experts qualified by sci-
 10 entific training and experience who are con-
 11 sulted, that the ingredient, constituent, sub-
 12 stance, or compound will not present any risk
 13 to consumers or the public in the quantities
 14 used under the intended conditions of use.

15 “(c) PROHIBITION.—

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

22 “(A) if no safety assessment has been sub-
 23 mitted by the manufacturer for the ingredient,
 24 constituent, substance, or compound as other-
 25 wise required under this section; or

1 “(B) if the Secretary finds that the manu-
2 facturer has failed to demonstrate the safety of
3 the ingredient, constituent, substance, or com-
4 pound that was the subject of the assessment
5 under paragraph (2).

6 “(2) REVIEW OF ASSESSMENTS.—

7 “(A) GENERAL REVIEW.—Not later than
8 180 days after the receipt of a safety assess-
9 ment under subsection (b), the Secretary shall
10 review the findings contained in such assess-
11 ment and approve or disapprove of the safety of
12 the ingredient, constituent, substance, or com-
13 pound that was the subject of the assessment.
14 The Secretary may, for good cause, extend the
15 period for such review. The Secretary shall pro-
16 vide notice to the manufacturer of an action
17 under this subparagraph.

18 “(B) INACTION BY SECRETARY.—If the
19 Secretary fails to act with respect to an assess-
20 ment of an existing ingredient, constituent, sub-
21 stance, or additive during the period referred to
22 in subparagraph (A), the manufacturer of the
23 tobacco product involved may continue to use
24 the ingredient, constituent, substance, or com-
25 pound involved until such time as the Secretary

1 makes a determination with respect to the as-
 2 sessment.

3 “(d) RIGHT TO KNOW; FULL DISCLOSURE OF IN-
 4 GREDIENTS TO THE PUBLIC.—

5 “(1) IN GENERAL.—Except as provided in para-
 6 graph (3), a package of a tobacco product shall dis-
 7 close all ingredients, constituents, substances, or
 8 compounds contained in the product in accordance
 9 with regulations promulgated under section 701(a)
 10 by the Secretary.

11 “(2) DISCLOSURE OF PERCENTAGE OF DOMES-
 12 TIC AND FOREIGN TOBACCO.—The regulations re-
 13 ferred to in paragraph (1) shall require that the
 14 package of a tobacco product disclose, with respect
 15 to the tobacco contained in the product—

16 “(A) the percentage that is domestic to-
 17 bacco; and

18 “(B) the percentage that is foreign to-
 19 bacco.

20 “(3) HEALTH DISCLOSURE.—Notwithstanding
 21 section 301(j), the Secretary may require the public
 22 disclosure of any ingredient, constituent, substance,
 23 or compound contained in a tobacco product that re-
 24 lates to a trade secret or other matter referred to in
 25 section 1905 of title 18, United States Code, if the

1 Secretary determines that such disclosure will pro-
2 mote the public health.

3 **“SEC. 575. REDUCED RISK PRODUCTS.**

4 “(a) PROHIBITION.—

5 “(1) IN GENERAL.—No manufacturer, dis-
6 tributor or retailer of tobacco products may make
7 any direct or implied statement in advertising or on
8 a product package that could reasonably be inter-
9 preted to state or imply a reduced health risk associ-
10 ated with a tobacco product unless the manufacturer
11 demonstrates to the Secretary, in such form as the
12 Secretary may require, that based on the best avail-
13 able scientific evidence the product significantly re-
14 duces the overall health risk to the public when com-
15 pared to other tobacco products.

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

24 “(b) DETERMINATION BY SECRETARY.—If the Sec-
25 retary determines that a statement described in subsection

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

5 “(c) DEVELOPMENT OR ACQUISITION OF REDUCED
 6 RISK TECHNOLOGY.—

7 “(1) IN GENERAL.—Any manufacturer that de-
 8 velops or acquires any technology that the manufac-
 9 turer reasonably believes will reduce the risk from
 10 tobacco products shall notify the Secretary of the de-
 11 velopment or acquisition of the technology. Such no-
 12 tice shall be in such form and within such time as
 13 the Secretary shall require.

14 “(2) CONFIDENTIALITY.—With respect to any
 15 technology described in paragraph (1) that is in the
 16 early stages of development (as determined by the
 17 Secretary), the Secretary shall establish protections
 18 to ensure the confidentiality of any proprietary in-
 19 formation submitted to the Secretary under this sub-
 20 section during such development.

21 **“SEC. 576. ACCESS TO COMPANY INFORMATION.**

22 “(a) COMPLIANCE PROCEDURES.—Each manufac-
 23 turer of tobacco products shall establish procedures to en-
 24 sure compliance with this Act.

1 “(b) REQUIREMENT.—In addition to any other dis-
 2 closure obligations under this Act, the KIDS Act, or any
 3 other law, each manufacturer of tobacco products shall,
 4 not later than 90 days after the date of the enactment
 5 of the KIDS Act and thereafter as required by the Sec-
 6 retary, disclose to the Secretary all nonpublic information
 7 and research in its possession or control relating to the
 8 addiction or dependency, or the health or safety of tobacco
 9 products, including (without limitation) all research relat-
 10 ing to processes to make tobacco products less hazardous
 11 to consumers and the research and documents described
 12 in subsection (c).

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

16 “(1) nicotine, including—

17 “(A) the interaction between nicotine and
 18 other components in tobacco products including
 19 ingredients in the tobacco and smoke compo-
 20 nents;

21 “(B) the role of nicotine in product design
 22 and manufacture, including product charters,
 23 and parameters in product development, the to-
 24 bacco blend, filter technology, and paper;

1 “(C) the role of nicotine in tobacco leaf
2 purchasing;

3 “(D) reverse engineering activities involv-
4 ing nicotine (such as analyzing the products of
5 other companies);

6 “(E) an analysis of nicotine delivery; and

7 “(F) the biology, psychopharmacology and
8 any other health effects of nicotine;

9 “(2) other ingredients, including—

10 “(A) the identification of ingredients in to-
11 bacco products and constituents in smoke, in-
12 cluding additives used in product components
13 such as paper, filter, and wrapper;

14 “(B) any research on the health effects of
15 ingredients; and

16 “(C) any research or other information ex-
17 plaining what happens to ingredients when they
18 are heated and burned;

19 “(3) less hazardous or safer products, including
20 any research or product development information on
21 activities involving reduced risk, less hazardous, low-
22 tar or reduced-tar, low-nicotine or reduced-nicotine
23 or nicotine-free products; and

24 “(4) tobacco product advertising, marketing
25 and promotion, including—

9 “(C) documents concerning the effects of
10 advertising; and

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

22 “The Secretary shall by regulation prescribe good
23 manufacturing practice standards for tobacco products.
24 Such regulations shall be modeled after good manufac-
25 turing practice regulations for medical devices, food, and

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

4 “(1) a quality control system, to ensure that to-
5 bacco products comply with such standards;

6 “(2) a system for inspecting tobacco product
7 materials to ensure their compliance with such
8 standards;

9 “(3) requirements for the proper handling of
10 finished tobacco products;

11 “(4) strict tolerances for pesticide chemical resi-
12 dues in or on tobacco or tobacco product commod-
13 ities in the possession of the manufacturer, except
14 that nothing in this paragraph shall be construed to
15 affect any authority of the Environmental Protection
16 Agency;

17 “(5) authority for officers or employees of the
18 Secretary to inspect any factory, warehouse, or other
19 establishment of any tobacco product manufacturer,
20 and to have access to records, files, papers, proc-
21 esses, controls and facilities related to tobacco prod-
22 uct manufacturing, in accordance with appropriate
23 authority and rules promulgated under this Act; and

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

1 Secretary may specify, as well as that the manufac-
2 turer report to the Secretary such information as
3 the Secretary shall require, in accordance with sec-
4 tion 519.

5 **“SEC. 578. PRESERVATION OF STATE AND LOCAL AUTHOR-**
6 **ITY.**

7 “Notwithstanding section 521 and except as other-
8 wise provided for in section 572(e), nothing in this sub-
9 chapter shall be construed as prohibiting a State or local-
10 ity from imposing requirements, prohibitions, penalties or
11 other measures to further the purposes of this subchapter
12 that are in addition to the requirements, prohibitions, or
13 penalties required under this subchapter. State and local
14 governments may impose additional tobacco product con-
15 trol measures to further restrict or limit the use of such
16 products.”.

17 **SEC. 113. FUNDING.**

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

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

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

3 **SEC. 114. REPEALS.**

4 The following provisions of law are repealed:

5 (1) The Federal Cigarette Labeling and Adver-
 6 tising Act (15 U.S.C. 1331 et seq.), except for the
 7 first section and sections 5(d)(1) and (2) and 6.

8 (2) The Comprehensive Smokeless Tobacco
 9 Health Education Act of 1986 (15 U.S.C. 4401 et
 10 seq.), except for sections 1, 3(f) and 8(a) and (b).

11 (3) The Comprehensive Smoking Education Act
 12 of 1964 (Public Law 98–474).

13 **TITLE II—MISCELLANEOUS**
 14 **PROVISIONS**

15 **SEC. 201. NONAPPLICATION TO TOBACCO PRODUCERS.**

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

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

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

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

8 (c) MANUFACTURER ACTING AS PRODUCER.—Not-
 9 withstanding any other provision of this section, if a pro-
 10 ducer of tobacco leaf is also a tobacco product manufac-
 11 turer or is owned or controlled by a tobacco product manu-
 12 facturer, the producer shall be subject to the provisions
 13 of this Act, and the amendments made by this Act, in the
 14 producer’s capacity as a manufacturer.

15 (d) DEFINITION.—In this section, the term “con-
 16 trolled by” means a producer that is a member of the same
 17 controlled group of corporations, as that term is used for
 18 purposes of section 52(a) of the Internal Revenue Code
 19 of 1986, or under common control within the meaning of
 20 the regulations promulgated under section 52(b) of such
 21 Code.

22 **SEC. 202. EQUAL TREATMENT OF RETAIL OUTLETS.**

23 The Secretary of Health and Human Services shall
 24 promulgate regulations to require that retail establish-
 25 ments that are accessible to individuals under the age of

- 1 18, for which the predominant business is the sale of to-
- 2 bacco products, comply with any advertising restrictions
- 3 applicable to such establishments.

