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107TH CONGRESS
1ST SESSION

H. R. 1097

To amend the Federal Food, Drug, and Cosmetic Act with respect to tobacco products, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 20, 2001

Mr. GANSKE (for himself, Mr. DINGELL, Mr. BALDACCI, Mr. BARTLETT of Maryland, Mr. BEREUTER, Mr. BLUMENAUER, Mrs. BONO, Mrs. CAPPS, Mr. DEFAZIO, Ms. DEGETTE, Mr. DOGGETT, Ms. ESHOO, Mr. EVANS, Mr. FRANK, Mr. GALLEGLY, Mr. GILMAN, Mr. GREEN of Texas, Mr. HANSEN, Mr. HINCHEY, Mr. HORN, Ms. KAPTUR, Mr. KIND, Mr. KUCINICH, Mr. LAFALCE, Mr. LEACH, Mr. LIPINSKI, Mr. LUTHER, Mrs. MALONEY of New York, Mr. MCDERMOTT, Mr. MCGOVERN, Mr. MEEHAN, Mr. MORAN of Virginia, Mrs. MORELLA, Mr. NADLER, Mr. NETHERCUTT, Mr. OLVER, Mr. PALLONE, Mr. PAYNE, Ms. ROYBAL-ALLARD, Ms. SCHAKOWSKY, Mr. SNYDER, Mr. STARK, Mr. STUPAK, Mrs. TAUSCHER, Mr. THOMPSON of California, Mr. UDALL of New Mexico, Mr. UNDERWOOD, Mr. WAXMAN, Mr. WEINER, and Mr. WELLER) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to 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.

This Act may be cited as the ''FDA Tobacco Authority Amendments Act''.

SEC. 2. FINDINGS.

The Congress finds as follows:

(1) Tobacco products are addictive.

(2) Such products cause over 400,000 deaths each year in the United States.

(3) The Supreme Court has held that there is no congressional intent to provide the Food and Drug Administration with the authority to regulate tobacco products.

(4) The Congress should amend the Federal Food, Drug, and Cosmetic Act to provide the Food and Drug Administration with the authority to regulate tobacco products.

SEC. 3. DEFINITIONS.

(a) DRUG.—Section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)) is amended by inserting after the first sentence the following: ''Such term includes nicotine in a tobacco product.''.

(b) DEVICES.—Section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)) is amended by adding at the end the following: ''Such term includes a tobacco product.''.

(c) OTHER DEFINITIONS.—Section 201 of the Federal Food, Drug, and Cosmetic Act (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.''.

SEC. 4. AMENDMENTS TO CHAPTER V.

(a) MISBRANDING.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) is amended by adding at the end the following:

''(u) In the case of a tobacco product, if it does not comply with a requirement under subchapter F.''.

(b) CLARIFICATION OF AUTHORITY REGARDING ADVERTISING AND PROMOTION; EQUAL TREATMENT OF RETAIL OUTLETS.—Section 520(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(e)) is amended by adding at the end the following:

''(3) In the case of tobacco products:

''(A) The restrictions on sale and distribution authorized by paragraph (1) shall include restrictions on advertising and promotion of tobacco products.

''(B) The Secretary shall ensure that such restrictions are applied uniformly to all entities that make retail sales of tobacco products. For purposes

of the preceding sentence, such restrictions may not exempt or apply differently to retail establishments that predominantly or exclusively sell tobacco products.''.

(c) PREEMPTION.—Section 521 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360k) is amended—

(1) in subsection (a), by striking ''Except as provided in subsection (b)'' and inserting ''Except in the case of tobacco products and as provided in subsection (b)''; and

(2) by adding at the end the following:

Tobacco Products

''(c) If the package or advertisement of a tobacco product is required to bear a warning under this Act, no statement relating to the use of the tobacco product and health, other than a statement required under this Act, may be required by any State or local statute or regulation to be included on any package or in any advertisement of such tobacco product.''.

SEC. 5. SPECIAL PROVISIONS FOR TOBACCO PRODUCTS.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

"Subchapter F—Special Provisions for Tobacco Products

"SEC. 565. SPECIAL STANDARD FOR TOBACCO PRODUCTS.

''In the case of tobacco products, an action that is appropriate for the protection of public health shall be deemed to provide a reasonable assurance of safety and effectiveness.

"SEC. 566. WARNINGS REGARDING CIGARETTES AND SMOKELESS TOBACCO; REGULATIONS.

''(a) IN GENERAL.—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.

''(b) REDUCED-RISK PRODUCTS.—No manufacturer of a tobacco product may state or imply in the labeling or advertisements of the tobacco product that the tobacco product presents a reduced risk to health unless the Secretary has determined that the tobacco product does present a significantly reduced risk to public health.

''(c) SAVINGS PROVISION.—Subsection (a) or (b) may not be construed as limiting the authority provided under

other provisions of this Act with respect to tobacco products.

"SEC. 567. RULE OF CONSTRUCTION REGARDING FARMERS AND RELATED ENTITIES.

"The provisions of this Act relating to tobacco products shall not apply to tobacco leaf that is not in the possession of the manufacturer, or to the producers of tobacco leaf, including tobacco growers, tobacco warehouses, and tobacco grower cooperatives, nor shall any employee of the Food and Drug Administration have any authority whatsoever to enter onto a farm owned by a producer of tobacco leaf without the written consent of such producer. Notwithstanding any other provision of this subparagraph, if a producer of tobacco leaf is also a tobacco product manufacturer or controlled by a tobacco product manufacturer, the producer shall be subject to this chapter in the producer's capacity as a manufacturer. Nothing in this chapter shall be construed to grant the Secretary authority to promulgate regulations on any matter that involves the production of tobacco leaf or a producer thereof, other than activities by a manufacturer affecting production. For purposes of the preceding sentence, the term 'controlled by' means a member of the same controlled group of corporations as that term is used in section 52(a) of the Internal Revenue Code of 1986, or under common con-

trol within the meaning of the regulations promulgated under section 52(b) of such Code.''.

SEC. 6. VALIDATION OF FDA RULE.

Effective one year after the date of the enactment of this Act, all provisions of the regulations related to tobacco products promulgated by the Secretary of Health and Human Services on August 28, 1996 (61 Fed. Reg. 44615–44618) shall take effect under authority of the Federal Food, Drug, and Cosmetic Act as amended by this Act. The Secretary shall amend the designations of authorities in such regulations accordingly.

SEC. 7. GENERAL PROVISIONS.

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

''(bb) The violation of any requirement under this Act relating to tobacco products.''.

(b) ACCESS TO INFORMATION.—Section 701 (21 U.S.C 371) is amended by adding at the end the following:

''(i) To acquire information related to tobacco products, the Secretary may administer oaths and require the testimony of witnesses and the production of documents and other materials. The Secretary may disclose to the public information acquired under this subsection if the Secretary determines that disclosure is appropriate to protect public health.''.

SEC. 8. REPEALS.

Effective on the date the regulations described in section 566(a) of the Federal Food, Drug, and Cosmetic Act take effect—

(1) the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1331 et seq.), other than sections 6, 8, 10, and 11, is repealed; and

(2) the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4401 et seq.), other than sections 3(f), 5, and 6, is repealed.

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