

103D CONGRESS  
1ST SESSION

# H. R. 2147

To amend the Federal Food, Drug, and Cosmetic Act to regulate the manufacture, labeling, sale, distribution, and advertising and promotion of tobacco and other products containing nicotine, tar, additives and other potentially harmful constituents, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

MAY 18, 1993

Mr. SYNAR (for himself, Mr. DURBIN, Mr. ANDREWS of Texas, Mr. WYDEN, Mrs. COLLINS of Illinois, Ms. SCHENK, Mr. BLACKWELL, Mr. WHEAT, Mr. HUFFINGTON, and Mr. EVANS) 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 to regulate the manufacture, labeling, sale, distribution, and advertising and promotion of tobacco and other products containing nicotine, tar, additives and other potentially harmful constituents, and for other purposes.

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; REFERENCE.**

4 (a) SHORT TITLE.—This Act may be cited as the  
5 “Fairness in Tobacco and Nicotine Regulation Act of  
6 1993”.

51002 0928

1 (b) REFERENCE.—Whenever in this Act (other than  
2 sections 5(b)(1) and 5(b)(2)) an amendment or repeal is  
3 expressed in terms of an amendment to, or repeal of, a  
4 section or other provision, the reference shall be consid-  
5 ered to be made to a section or other provision of the  
6 Federal Food, Drug, and Cosmetic Act.

7 **SEC. 2. FINDINGS.**

8 The Congress finds that—

9 (1) Cigarette smoking and tobacco use account  
10 for approximately 450,000 deaths each year in the  
11 United States.

12 (2) Cigarette smoking accounts for approxi-  
13 mately \$65 billion in lost productivity and health  
14 care costs.

15 (3) Environmental tobacco smoke is a cause of  
16 disease in nonsmokers.

17 (4) In spite of well established dangers of ciga-  
18 rette smoking and tobacco use, no Federal regu-  
19 latory agency has the authority to regulate the man-  
20 ufacture, sale, distribution, labeling, and advertising  
21 of such products.

22 (5) Tobacco is as addictive as cocaine and  
23 heroin.

24 (6) The tobacco industry spends approximately  
25 \$4 billion each year to promote its products.

1           (7) The tobacco industry's voluntary advertising  
2 code which was enacted to prohibit the use of images  
3 of sexual attraction, sophistication, and athletic  
4 abilities and the making of implied health claims has  
5 for the last 30 years not been followed or enforced.

6           (8) Each day 3,000 children try cigarettes for  
7 the first time and many become life-long addicted  
8 smokers.

9           (9) There is no Federal minimum age of sale of  
10 cigarettes and tobacco products.

11           (10) The labeling of tobacco products is inad-  
12 equate as to provide smokers and nonsmokers alike  
13 with full and complete information about tobacco  
14 products.

15           (11) The tobacco industry adds chemical addi-  
16 tives to their products that are neither disclosed to  
17 the public or tested for health and safety in a com-  
18 parable manner to food.

19           (12) There is no listing of chemical constituents  
20 found in mainstream and sidestream smoke (includ-  
21 ing benzene, arsenic, cyanide, etc.).

22           (13) The Food and Drug Administration is the  
23 most qualified Federal agency to comprehensively  
24 regulate tobacco products.

51002 0930

1           (14) It is inconsistent for the Food and Drug  
2       Administration to regulate the manufacture, sale,  
3       distribution, labeling, advertising, and promotion of  
4       other nicotine containing products used as sub-  
5       stitutes for cigarette smoking and tobacco use and  
6       not be able to regulate tobacco products in a com-  
7       parable manner.

8   **SEC. 3. DEFINITIONS.**

9       Section 201 (21 U.S.C. 321) is amended by adding  
10   at the end thereof the following new paragraphs:

11       “(gg) The term ‘tobacco product’ means cigarettes,  
12   cigars, little cigars, pipe tobacco, smokeless tobacco, snuff,  
13   and chewing tobacco.

14       “(hh) The term ‘tobacco additive’ means any sub-  
15   stance the intended use of which results or may reasonably  
16   be expected to result, directly or indirectly, in its becoming  
17   a component or otherwise affecting the characteristics of  
18   any tobacco product.

19       “(ii) The term ‘constituent’ means any element of  
20   cigarette mainstream or sidestream smoke which is  
21   present in quantities which represent a potential health  
22   hazard or where the health effect is unknown.

23       “(jj) The term ‘tar’ means mainstream total articu-  
24   late matter minus nicotine and water.

1 **SEC. 4. ENFORCEMENT.**

2 Section 301 (21 U.S.C. 331) is amended by adding  
3 at the end thereof the following new subsection:

4 “(u) The manufacture, labeling, sale, distribution,  
5 advertising, and promotion of tobacco products in violation  
6 of regulations of the Secretary pursuant to section 701.”

7 **SEC. 5. REGULATION OF TOBACCO PRODUCTS.**

8 (a) REGULATION.—The Federal Food, Drug, and  
9 Cosmetic Act is amended by redesignating chapters VII,  
10 VIII, and IX as chapters VIII, IX, and X, respectively,  
11 and by adding after chapter VI the following:

12 “CHAPTER VII—TOBACCO PRODUCTS

13 “REGULATIONS

14 “SEC. 701. (a) PROMULGATION.—The Secretary  
15 shall promulgate regulations governing the manufacture,  
16 distribution, sale, labeling, and advertising and promotion  
17 of tobacco products which are consistent with the manner  
18 in which other products which are ingested into the body  
19 are regulated, except that the Secretary may not promul-  
20 gate a regulation which prohibits the sale and distribution  
21 of a tobacco product solely on the basis of the fact that  
22 tobacco causes disease. Such regulations shall be promul-  
23 gated not later than 12 months after the date the Sec-  
24 retary receives the recommendations of the Tobacco and  
25 Nicotine Products Advisory Committee under section  
26 702(e).

1       “(b) MINIMUM REQUIREMENTS.—

2               “(1) SALE OR DISTRIBUTION.—Regulations  
3       under subsection (a) shall with respect to the sale or  
4       distribution of tobacco products make unlawful—

5               “(A) the sale of a tobacco product intended  
6       for use by man to any person under the age of  
7       18 years or under such other age greater than  
8       18 years as the State in which the sale occurs  
9       may establish by law,

10              “(B) the distribution of a tobacco product  
11       as a free sample or the distribution of a tobacco  
12       product as a result of coupons or other mate-  
13       rials which allow for the obtaining of free or  
14       discounted tobacco products, or

15              “(C) the sale or distribution of a tobacco  
16       product if the label fails to carry the following  
17       statement: “Federal Law Prohibits Sale To  
18       Minors”.

19       The Secretary shall enforce this paragraph in a  
20       manner that can reasonably be expected to ensure  
21       that tobacco products are not made available to indi-  
22       viduals under the age of 18 years.

23              “(2) LABELING.—

24              “(A) IN GENERAL.—Regulations under  
25       subsection (a) with respect to the labeling of to-

1           bacco products shall require that a tobacco  
2           product shall be deemed misbranded if—

3                   “(i) it is not in compliance with the  
4                   labeling requirements of the Federal Ciga-  
5                   rette Labeling and Advertising Act and the  
6                   Comprehensive Smokeless Tobacco Health  
7                   Education Act of 1986,

8                   “(ii) it does not include a warning and  
9                   information about the dangers associated  
10                  with environmental tobacco smoke,

11                  “(iii) it does not provide a list of  
12                  chemical additives and constituents found  
13                  in tobacco products and tobacco smoke, or

14                  “(iv) it contains any implied or direct  
15                  health claim, including the use of such  
16                  terms as light, lower tar, medium, lowest,  
17                  or nicotine free, unless such terms have  
18                  been approved by the Secretary on the  
19                  basis of sound scientific data and the Sec-  
20                  retary determines that such terms will  
21                  have a significant impact on the health  
22                  consequences associated with cigarette  
23                  smoking and other tobacco use.

24                  “(B) SPECIFIC INFORMATION.—The Sec-  
25                  retary may include in regulations under sub-

51002 0934

1 section (a) relating to labeling of tobacco prod-  
2 ucts labeling requirements requiring manufac-  
3 turers of tobacco products to provide to con-  
4 sumers by way of labeling of packages, package  
5 inserts, or other means—

6 “(i) information about the adverse ef-  
7 fects of tobacco products,

8 “(ii) adequate warnings and directions  
9 for use,

10 “(iii) contraindications,

11 “(iv) adequate warnings against use  
12 in pathological conditions, and

13 “(v) any other information deemed  
14 necessary by the Secretary.”

15 “(3) ADVERTISING AND PROMOTION.—

16 “(A) CONSISTENCY.—Regulations under  
17 subsection (a) with respect to the advertising  
18 and promotion of tobacco products shall be con-  
19 sistent with regulations governing the advertis-  
20 ing and promotion of prescription drugs, espe-  
21 cially such drugs which contain nicotine.

22 “(B) SPONSORSHIP.—In such regulations,  
23 the Secretary shall make it unlawful for any  
24 sporting event, cultural event, or any other  
25 event or function open to the public to be spon-



1           sored by a tobacco manufacturer who at such  
2           event or function displays the name or logo of  
3           any brand of cigarettes or tobacco product of  
4           such manufacturer.

5           “(C) CONSTRUCTION.—Such regulations  
6           and the authority provided the Secretary does  
7           not repeal or modify the authority of the Fed-  
8           eral Trade Commission in carrying out its  
9           responsibilities.

10          “(4) MANUFACTURING.—Regulations under  
11          subsection (a) governing the manufacture of tobacco  
12          products shall—

13               “(A) require that all additives used in the  
14               manufacture of tobacco products are safe,

15               “(B) classify as a drug any nicotine con-  
16               taining product which does not meet the defini-  
17               tion of a tobacco product, and

18               “(C) have the authority to subpoena any  
19               document which relates to the manner in which  
20               tobacco products are manufactured.

21               “ADVISORY COMMITTEE

22          “SEC. 702. (a) ESTABLISHMENT.—To assist in the  
23          development of regulations required by section 701, there  
24          is established in the Food and Drug Administration a To-  
25          bacco and Nicotine Products Advisory Committee (herein-

1 after in this section referred to as the "advisory commit-  
2 tee").

3       “(b) MEMBERSHIP.—

4               “(1) SECRETARIAL APPOINTMENTS.—The Sec-  
5       retary shall appoint to the advisory committee 10 in-  
6       dividuals who are qualified by training and experi-  
7       ence to evaluate and make recommendations for the  
8       issuance of regulations governing the manufacture,  
9       distribution, sale, labeling, and advertising and pro-  
10      motion of tobacco products which, to the greatest ex-  
11      tent practical, promote and protect the public's  
12      health without banning the product. The 10 mem-  
13      bers shall consist of—

14               “(A) one expert in the field of nicotine  
15      addiction,

16               “(B) one expert in the field of pharmacol-  
17      ogy,

18               “(C) one expert in the field of food and  
19      drug law,

20               “(D) one expert in the field of marketing  
21      and promotion of products,

22               “(E) one expert in the field of public  
23      education,

24               “(F) one expert in the field of toxicology,

1           “(G) two representing the interests of fam-  
2           ily medicine, internal medicine, or pediatrics,  
3           and

4           “(H) two consumer representatives from  
5           the public health community.

6           “(2) EX OFFICIO.—The Directors of the Na-  
7           tional Cancer Institute, the National Heart, Lung,  
8           and Blood Institute, the National Institute of Drug  
9           Abuse, the Centers for Disease Control and Preven-  
10          tion, and the Surgeon General of the United States  
11          shall serve as ex officio members of the advisory  
12          committee.

13          “(3) CHAIRMAN.—The chairman of the advisory  
14          committee shall be appointed by the Secretary with  
15          the advice and consent of the Commissioner of Food  
16          and Drugs.

17          “(4) APPOINTMENT DATE.—The Secretary shall  
18          make appointments to the advisory committee within  
19          60 days of the date of the enactment of this section.

20          “(c) FUNCTION.—The advisory committee shall give  
21          specific consideration to—

22               “(1) reviewing the available scientific evidence  
23               on the effects of tobacco products on human health,  
24               including the effects of environmental tobacco smoke  
25               on nonsmokers,



1 is in business on the date of the enactment of this Act  
2 shall register with the Secretary not later than 120 days  
3 after the date of the enactment of this section.

4 "TOBACCO PRODUCT MANUFACTURER FEE

5 "SEC. 704.(a) FEE PURPOSE.—For the purpose of  
6 paying the costs of implementing this chapter, each to-  
7 bacco product manufacturer shall pay an annual fee estab-  
8 lished pursuant to paragraph (2). Such fee shall be pay-  
9 able on or before January 31 of each year.

10 "(b) ESTABLISHMENT BY THE SECRETARY.—Subject  
11 to the amount established in appropriation Acts, the an-  
12 nual tobacco product manufacturer fee shall be deter-  
13 mined by the Secretary based upon the total market share  
14 for each brand of tobacco product.

15 "(c) CREDITING AND AVAILABILITY OF FEES.—

16 "(1) IN GENERAL.—Fees collected for a fiscal  
17 year pursuant to subsection (a) shall be credited to  
18 the appropriation account for salaries and expenses  
19 of the Food and Drug Administration and shall be  
20 available in accordance with appropriation Acts until  
21 expended without fiscal year limitation.

22 "(2) COLLECTIONS AND APPROPRIATION  
23 ACTS.—The fees authorized by subsection (a)—

24 "(A) shall be collected in each fiscal year  
25 in an amount equal to the amount specified in  
26 appropriation Acts for such fiscal year, and

1           “(B) shall only be collected and available  
2           to defray the costs of implementing this chap-  
3           ter.”.

4           (b) CONFORMING AMENDMENTS.—

5           (1) TOBACCO LABELING AND ADVERTISING.—

6           The Federal Cigarette Labeling and Advertising Act  
7           (15 U.S.C. 1331 et seq.) is amended—

8                   (A) in section 4 (15 U.S.C. 1333) by strik-  
9                   ing out “SURGEON GENERAL’S WARN-  
10                   ING: Cigarette Smoke Contains Carbon Mon-  
11                   oxide” each place it appears and inserting in  
12                   lieu thereof “SURGEON GENERAL’S WARN-  
13                   ING: Smoking is Addictive. Once You Start  
14                   You May Not Be Able to Stop”, and

15                   (B) by repealing sections 5(b) and 7 (15  
16                   U.S.C. 1334(b), 1335a).

17           (2) SMOKELESS TOBACCO.—The Comprehensive  
18           Smokeless Tobacco Health Education Act of 1986 is  
19           amended—

20                   (A) in section 3(a)(1) (15 U.S.C.  
21                   4402(a)(1)), by striking out the close quotation  
22                   marks and the period following at the end and  
23                   inserting the following:

51002 0941

1           “WARNING: THIS PRODUCT IS AD-  
2           DICTIVE. ONCE YOU START YOU MAY  
3           NOT BE ABLE TO QUIT’.”,

4           (B) in section 3(b)(1) (15 U.S.C.  
5           4402(b)(1), by inserting in the matter in sub-  
6           paragraph (B) the following:



7           (3) RECORDS OF INTERSTATE SHIPMENT.—Sec-  
8           tion 703 (21 U.S.C. 373) is amended—

9           (A) by striking out “or cosmetics” and in-  
10          serting in lieu thereof “cosmetics, or tobacco  
11          products”, and

12          (B) by striking out “or cosmetic” and in-  
13          serting in lieu thereof “cosmetic, or tobacco  
14          product”.

15          (4) FACTORY INSPECTION.—Section 704 (21  
16          U.S.C. 374) is amended—

51002 0942

1 (A) in subsection (a)(1), by striking out  
2 "or cosmetics" and inserting in lieu thereof  
3 "cosmetics, or tobacco products",

4 (B) in subsection (a)(1), by striking out  
5 "or restricted devices" each place it appears  
6 and inserting in lieu thereof ", restricted de-  
7 vices, or tobacco products", and

8 (C) in subsection (b), by striking out "or  
9 cosmetic" and inserting in lieu thereof "cos-  
10 metic, or tobacco product".

11 (5) REDESIGNATIONS.—Sections 701 through  
12 711 are redesignated as sections 801 through 811,  
13 respectively, section 721 is redesignated as section  
14 821, sections 731 through 736 are redesignated as  
15 sections 831 through 836, respectively, sections 801  
16 through 803 are redesignated as sections 901  
17 through 903, respectively, sections 901 through 903  
18 are redesignated as sections 1001 through 1003, re-  
19 spectively, and the references to the redesignated  
20 sections are changed to refer to the sections as  
21 redesignated.

22 (c) SECRETARIAL AUTHORITY.—The Secretary of  
23 Health and Human Services may, by regulation—

24 (1) modify the warning labels required by the  
25 Federal Cigarette Labeling and Advertising Act and



1 the Comprehensive Smokeless Tobacco Health Edu-  
2 cation Act of 1986 if the modification in the content  
3 of the label does not weaken the health message con-  
4 tained in the label and is in the best interests of the  
5 public health, and

6 (2) increase the size and placement of such re-  
7 quired labels.

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