

106TH CONGRESS  
2D SESSION

# S. 2333

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

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## IN THE SENATE OF THE UNITED STATES

MARCH 30, 2000

Mr. REED (for himself and Mr. BINGAMAN) 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 amend the Federal Food, Drug, and Cosmetic Act to grant the Food and Drug Administration the authority to regulate the manufacture, sale, and distribution 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.**

4 This Act may be cited as the “Tobacco Regulatory  
5 Fairness Act of 2000”.

1 **SEC. 2. FINDINGS.**

2 Congress makes the following findings:

3 (1) Cigarette smoking and tobacco use cause  
4 approximately 450,000 deaths each year in the  
5 United States.

6 (2) Cigarette smoking accounts for approxi-  
7 mately \$65,000,000,000 in lost productivity and  
8 health care costs.

9 (3) In spite of the well-established dangers of  
10 cigarette smoking and tobacco use, there is no Fed-  
11 eral agency that has any authority to regulate the  
12 manufacture, sale, distribution, and use of tobacco  
13 products.

14 (4) The tobacco industry spends approximately  
15 \$4,000,000,000 each year to promote tobacco prod-  
16 ucts.

17 (5) Each day 3,000 children try cigarettes for  
18 the first time, many of whom become lifelong ad-  
19 dicted smokers.

20 (6) There is no minimum age requirement in  
21 Federal law that an individual must reach to legally  
22 buy cigarettes and other tobacco products.

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

1           (8) It is inconsistent for the Food and Drug  
2           Administration to regulate the manufacture, sale,  
3           and distribution of other nicotine-containing prod-  
4           ucts used as substitutes for cigarette smoking and  
5           tobacco use and not be able to regulate tobacco  
6           products in a comparable manner.

7 **SEC. 3. DEFINITIONS.**

8           Section 201 of the Federal Food, Drug, and Cosmetic  
9           Act (21 U.S.C. 321) is amended by adding at the end the  
10          following:

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

14          “(ll) 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          “(mm) 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          “(nn) The term ‘tar’ means mainstream total articu-  
24          late matter minus nicotine and water.”.

1 **SEC. 4. ENFORCEMENT.**

2 Section 301 of the Federal Food, Drug, and Cosmetic  
3 Act (21 U.S.C. 331) is amended—

4 (1) in subsections (a), (b), (c), (g), and (k), by  
5 striking “or cosmetic” and inserting “cosmetic, or  
6 tobacco product”; and

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

8 “(u) The manufacture, sale, distribution, and adver-  
9 tising of tobacco products in violation of regulations pro-  
10 mulgated by the Secretary pursuant to chapter X.”.

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

12 The Federal Food, Drug, and Cosmetic Act (21  
13 U.S.C. 301 et seq.) is amended by adding at the end the  
14 following:

15 **“CHAPTER X—TOBACCO PRODUCTS**

16 **“SEC. 1000. REGULATION OF TOBACCO PRODUCTS.**

17 “(a) REGULATIONS.—Not later than 1 year after the  
18 date on which the Secretary receives the recommendations  
19 described in section 1003(f), the Secretary shall promul-  
20 gate regulations governing the manufacture, sale, and dis-  
21 tribution of tobacco products in accordance with the provi-  
22 sions of the chapter.

23 “(b) FOOD AND DRUG ADMINISTRATION.—Regula-  
24 tions promulgated under subsection (a) shall designate the  
25 Food and Drug Administration as the Federal agency that

1 regulates the manufacture, distribution, and sale of to-  
2 bacco products.

3 “(c) LIMITATION.—Regulations promulgated under  
4 subsection (a) may not prohibit the manufacture, distribu-  
5 tion, or sale of a tobacco product solely on the basis that  
6 such product causes a disease.

7 “(d) SALE OR DISTRIBUTION.—Under regulations  
8 promulgated under subsection (a) it shall be unlawful to—

9 “(1) sell a tobacco product to an individual  
10 under the age of 18 years;

11 “(2) sell a tobacco product to an individual if  
12 such tobacco product is intended for use by an indi-  
13 vidual under the age of 18 years; and

14 “(3) sell or distribute a tobacco product if the  
15 label of such product does not display the following  
16 statement: ‘Federal Law Prohibits Sale To Minors’.

17 “(e) MANUFACTURING.—Regulations promulgated  
18 under subsection (a) governing the manufacture of to-  
19 bacco products shall—

20 “(1) require that all additives used in the man-  
21 ufacture of tobacco products are safe; and

22 “(2) classify as a drug any nicotine-containing  
23 product that does not meet the definition of a to-  
24 bacco product.

1 **“SEC. 1001. ADULTERATED TOBACCO PRODUCTS.**

2 “(a) IN GENERAL.—A tobacco product shall be  
3 deemed to be adulterated—

4 “(1) if such product consists in whole or in part  
5 of any filthy, putrid, or decomposed substance, or is  
6 otherwise contaminated by any poisonous or deleterious  
7 substance that may render such product injurious  
8 to health;

9 “(2) if such product has been prepared, packed,  
10 or held under insanitary conditions in which such  
11 product may have been contaminated with filth, or  
12 in which such product may have been rendered injurious  
13 to health; and

14 “(3) if the container for such product is composed,  
15 in whole or in part, of any poisonous or deleterious  
16 substance that may render the contents of  
17 such product injurious to health.

18 “(b) REGULATIONS.—The Secretary may by regulation  
19 prescribe good manufacturing practices for tobacco  
20 products. Such regulations may be modeled after current  
21 good manufacturing practice regulations for other products  
22 regulated under this Act.

23 **“SEC. 1002. MISBRANDED TOBACCO PRODUCTS.**

24 “A tobacco product shall be deemed to be  
25 misbranded—

1           “(1) if the labeling of such product is false or  
2           misleading in any particular;

3           “(2) if in package form unless such product  
4           bears a label containing—

5                   “(A) the name and place of business of the  
6           tobacco product manufacturer, packer, or dis-  
7           tributor; and

8                   “(B) an accurate statement of the quantity  
9           of the contents in terms of weight, measure, or  
10          numerical count,

11          except that under subparagraph (B) of this para-  
12          graph reasonable variations shall be permitted, and  
13          exemptions as to small packages shall be established,  
14          by regulations promulgated by the Secretary;

15          “(3) if any word, statement, or other informa-  
16          tion required by or under authority of this chapter  
17          to appear on the label or labeling is not prominently  
18          placed thereon with such conspicuousness (as com-  
19          pared with other words, statements or designs in the  
20          labeling) and in such terms as to render it likely to  
21          be read and understood by the ordinary individual  
22          under customary conditions of purchase and use;

23          “(4) if such product has an established name,  
24          unless its label bears, to the exclusion of any other  
25          nonproprietary name, its established name is promi-

1 nently printed in type as required by the Secretary  
2 by regulation;

3 “(5) if the Secretary has issued regulations re-  
4 quiring that the labeling of such product bear ade-  
5 quate directions for use, or adequate warnings  
6 against use by children, that are necessary for the  
7 protection of users unless the labeling of such prod-  
8 uct conforms in all respects to such regulations; and

9 “(6) if such product was manufactured, pre-  
10 pared, propagated, or processed in an establishment  
11 not duly registered as required under section 1004.

12 **“SEC. 1003. ADVISORY COMMITTEE.**

13 “(a) ESTABLISHMENT.—There is established in the  
14 Food and Drug Administration a Tobacco and Nicotine  
15 Products Advisory Committee (hereafter referred to as the  
16 ‘advisory committee’).

17 “(b) PURPOSE.—The advisory committee shall assist  
18 the Secretary in developing the regulations described in  
19 section 1000.

20 “(c) MEMBERSHIP.—

21 “(1) IN GENERAL.—Not later than 60 days  
22 after the date of enactment of this chapter, the Sec-  
23 retary shall appoint to the advisory committee 10 in-  
24 dividuals who are qualified by training and experi-  
25 ence to evaluate and make recommendations regard-

1       ing regulations governing the manufacture, distribu-  
2       tion, sale, labeling and advertising of tobacco prod-  
3       ucts.

4               “(2) EXPERTS.—The members described under  
5       paragraph (1), not including the chairperson of such  
6       advisory committee, shall consist of—

7               “(A) one expert in the field of nicotine ad-  
8       diction;

9               “(B) one expert in the field of pharma-  
10      cology;

11              “(C) one expert in the field of food and  
12      drug law;

13              “(D) one expert in the field of public edu-  
14      cation;

15              “(E) one expert in the field of toxicology;

16              “(F) two experts representing the interests  
17      of family medicine, internal medicine, or pediat-  
18      rics; and

19              “(G) two consumer representatives from  
20      the public health community.

21              “(3) EX OFFICIO.—The advisory committee  
22      shall have the following as ex officio members:

23              “(A) The Director of the National Cancer  
24      Institute.

1           “(B) The Director of the National Heart,  
2 Lung, and Blood Institute.

3           “(C) The Director of National Institute on  
4 Drug Abuse.

5           “(D) The Director of the Centers for Dis-  
6 ease Control and Prevention.

7           “(E) The Surgeon General of the Public  
8 Health Service.

9           “(4) CHAIRPERSON.—The chairperson of the  
10 advisory committee shall be appointed by the Sec-  
11 retary with the advice and consent of the Commis-  
12 sioner of Food and Drugs.

13          “(d) FUNCTION.—The advisory committee shall—

14           “(1) review the available scientific evidence on  
15 the effects of tobacco products on human health;

16           “(2) review the manufacturing process of to-  
17 bacco products, including the use of additives,  
18 sprayed on chemicals, product development, and  
19 product manipulation;

20           “(3) review the role of nicotine as part of the  
21 smoking habit, including its addictive properties and  
22 health effects; and

23           “(4) review current Federal, State, and local  
24 laws governing the manufacture, distribution, sale,  
25 labeling and advertising of tobacco products.

1       “(e) **AUTHORITY.**—The advisory committee may hold  
2 hearings and receive testimony and evidence as the com-  
3 mittee determines to be appropriate.

4       “(f) **RECOMMENDATIONS.**—Not later than 1 year  
5 after the Secretary has appointed all members to the advi-  
6 sory committee, such committee shall prepare and submit  
7 recommendations regarding regulations to be promulgated  
8 under section 1000 to the Secretary.

9       **“SEC. 1004. REGISTRATION.**

10       “Not later than 120 days after the date of enactment  
11 of this chapter, any manufacturer directly or indirectly en-  
12 gaged in the manufacture, distribution, or sale of tobacco  
13 products shall register with the Secretary the name and  
14 place of business of such manufacturer.

15       **“SEC. 1005. ADVERTISING.**

16       “(a) **REGULATIONS.**—The Federal Trade Commis-  
17 sion, after consultation with the Secretary and upon re-  
18 ceipt of approval by the Secretary, shall promulgate regu-  
19 lations governing the advertising of all tobacco products.

20       “(b) **LABELS.**—The Federal Trade Commission,  
21 after consultation with the Secretary and upon receipt of  
22 approval by the Secretary, may promulgate regulations  
23 that—

24               “(1) modify the warning labels required by the  
25       Federal Cigarette Labeling and Advertising Act (15

1 U.S.C. 1331 et seq.) and the Comprehensive Smoke-  
2 less Tobacco Health Education Act of 1986 (15  
3 U.S.C. 4401 et seq.) if the modification in the con-  
4 tent of the label does not weaken the health message  
5 contained in the label and is in the best interests of  
6 the public health as determined by the Secretary;  
7 and

8 “(2) increase the size and placement of such re-  
9 quired labels.”.

10 **SEC. 6. CONFORMING AMENDMENTS.**

11 (a) RECORDS.—Section 703 of the Federal Food,  
12 Drug, and Cosmetic Act (21 U.S.C. 373) is amended—

13 (1) by striking “or cosmetics” each place it ap-  
14 pears and inserting “cosmetics, or tobacco prod-  
15 ucts”; and

16 (2) by striking “or cosmetic” each place it ap-  
17 pears and inserting “cosmetic, or tobacco product”.

18 (b) FACTORY INSPECTIONS.—Section 704 of the Fed-  
19 eral Food, Drug, and Cosmetic Act (21 U.S.C. 374) is  
20 amended—

21 (1) in subsection (a)(1)—

22 (A) by striking “or cosmetics” each place  
23 it appears and inserting “cosmetics, or tobacco  
24 products”; and

1                   (B) by striking “or restricted devices” each  
2                   place it appears and inserting “restricted de-  
3                   vices, or tobacco products”; and  
4                   (2) in subsection (b), by striking “or cosmetic”  
5                   and inserting “cosmetic, or tobacco product”.

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