105TH CONGRESS 2D SESSION

H. R. 3889

To amend the Federal Food, Drug, and Cosmetic Act to strengthen controls over tobacco.

IN THE HOUSE OF REPRESENTATIVES

May 14, 1998

Mr. UPTON introduced the following bill; which was referred to the Committee on Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to strengthen controls over 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 "Teen Tobacco Use Pre-
- 5 vention Act of 1998".
- 6 SEC. 2. TOBACCO PRODUCT REGULATION.
- 7 (a) Amendment.—The Federal Food, Drug, and
- 8 Cosmetic Act (21 U.S.C. 301 et seq.) is amended—
- 9 (1) by redesignating chapter IX as chapter X;

1	(2) by redesignating sections 901, 902, 903,
2	904, and 905 as sections 1001, 1002, 1003, 1004,
3	and 1005, respectively; and
4	(3) by adding after chapter VIII the following
5	new chapter:
6	"CHAPTER IX—HEALTH AND SAFETY REGU-
7	LATORY REQUIREMENTS RELATING TO TO-
8	BACCO PRODUCTS
9	"SEC. 900. DEFINITIONS.
10	"In this chapter:
11	"(1) Cigarette.—The term 'cigarette' means
12	any product which contains nicotine, is intended to
13	be burned under ordinary conditions of use, and con-
14	sists of—
15	"(A) any roll of tobacco wrapped in paper
16	or in any substance not containing tobacco; and
17	"(B) any roll of tobacco wrapped in any
18	substance containing tobacco which, because of
19	its appearance, the type of tobacco used in the
20	filler, or its packaging and labeling, is likely to
21	be offered to, or purchased by, consumers as a
22	cigarette described in subparagraph (A).
23	"(2) Cigarette tobacco.—The term 'ciga-
24	rette tobacco' means any product that consists of
25	loose tobacco that contains or delivers nicotine and

- is intended for use by persons in a cigarette. Unless otherwise stated, the requirements of this title pertaining to cigarettes shall also apply to cigarette to-
- 4 bacco.

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

- 5 "(3) NICOTINE.—The term 'nicotine' means the 6 chemical substance named 3-(1-Methyl-2-7 pyrrolidinyl)pyridine or C₁₀H₁₄N₂, including any salt 8 or complex of nicotine.
 - "(4) SMOKELESS TOBACCO.—The term 'smokeless tobacco' means any product that consists of cut, ground, powdered, or leaf tobacco that contains nicotine and that is intended to be placed in the oral or nasal cavity.
 - "(5) TAR.—The term 'tar' means mainstream total particulate matter minus nicotine and water.
 - "(6) Tobacco additive.—The term 'tobacco additive' means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in the substance becoming a component of, or otherwise affecting the characteristics of, any tobacco product, including any substance that may have been removed from the tobacco product and then readded in the substance's original or modified form.

- 1 "(7) Tobacco product.—The term 'tobacco
- 2 product' means cigarettes and smokeless tobacco
- 3 products.

4 "Subchapter A—Tobacco Product Regulation

- 5 "SEC. 902. CONSTITUENT LABELING.
- 6 "(a) IN GENERAL.—The Secretary shall by regula-
- 7 tion require the manufacturer of tobacco products to in-
- 8 clude, in accordance with subsection (c), on a label on the
- 9 package of the products the amount of tar and nicotine
- 10 in the tobacco products and the amount of carbon mon-
- 11 oxide produced by such products.
- 12 "(b) Regulations.—The Secretary may by regula-
- 13 tion require the manufacturer of tobacco products to in-
- 14 clude, in accordance with subsection (c), on a label on the
- 15 package of the products constituents in addition to the
- 16 constituents described in subsection (a) if the Secretary
- 17 determines that identification of such constituents is nec-
- 18 essary for the protection of the public health.
- 19 "(c) COMMON OR USUAL NAMES.—The Secretary
- 20 shall promulgate regulations requiring the disclosure to
- 21 the public of the common or usual name of each ingredient
- 22 (other than tobacco, water, or reconstituted tobacco sheet
- 23 made wholly from tobacco) contained in a tobacco product
- 24 in descending order of predominance by weight, except
- 25 that such regulations—

1	"(1) may provide for the disclosure of spices,
2	flavorings, and colorings without naming each spice,
3	flavoring, or coloring; and
4	"(2) may exempt from disclosure incidental ad-
5	ditives, including processing aids and chemical pre-
6	servatives, that are present in a tobacco product at
7	insignificant levels that the Secretary determines do
8	not have any functional effect or health risk.
9	"SEC. 903. TOBACCO PRODUCT LABELING, WARNING, AND
10	PACKAGING STANDARDS.
11	"(a) Cigarettes.—
12	"(1) Packaging.—It shall be unlawful for any
13	person to manufacture, package, or import for sale
14	or distribution within the United States any ciga-
15	rettes the package of which fails to bear, in accord-
16	ance with the requirements of this subsection, one of
17	the following statements:
18	"WARNING: Cigarettes Are Addictive.
19	"WARNING: Tobacco Smoke Can Harm Your
20	Children.
21	"WARNING: Cigarettes Cause Fatal Lung
22	Disease.
23	"WARNING: Cigarettes Cause Cancer.
24	"WARNING: If You Think Smoking Is Cool,
25	You Are Dead Wrong.

1	"WARNING: Cigarettes Cause Strokes And
2	Heart Disease.
3	"WARNING: Smoking During Pregnancy Can
4	Harm Your Baby.
5	"WARNING: Smoking Can Kill You.
6	"WARNING: Tobacco Smoke Causes Fatal
7	Lung Disease In Nonsmokers.
8	"WARNING: Quitting Smoking Now Greatly
9	Reduces Serious Risks To Your Health.
10	"(2) Requirements for label state-
11	MENTS.—
12	"(A) LOCATION.—Each label statement re-
13	quired by paragraph (1) shall be located on the
14	upper portion of the front panel of the cigarette
15	package (or carton) and occupy not less than
16	25 percent of such front panel.
17	"(B) Type and color.—With respect to
18	each label statement required by paragraph (1),
19	the phrase 'WARNING' shall appear in capital
20	letters and the label statement shall be printed
21	in 17 point type with adjustments as deter-
22	mined appropriate by the Secretary to reflect
23	the length of the required statement. All the
24	letters in the label statement shall appear in
25	conspicuous and legible type, in contrast by ty-

pography, layout, or color with all other printed material on the package, and be printed in an alternating black-on-white and white-on-black format as determined appropriate by the Secretary.

"(C) EXCEPTION.—Paragraph (1) shall not apply in the case of a flip-top cigarette package (offered for sale on the date of enactment of this title) where the front portion of the flip-top does not comprise at least 25 percent of the front panel. In the case of such a package, the label statement required by subparagraph (A) of paragraph (1) shall occupy the entire front portion of the flip top.

"(3) Requirements for advertising.—

"(A) IN GENERAL.—It shall be unlawful for any manufacturer or importer of cigarettes to advertise or cause to be advertised within the United States any cigarette unless the advertising bears, in accordance with the requirements of this subsection, one of the following statements:

"WARNING: Cigarettes Are Addictive.

"WARNING: Tobacco Smoke Can Harm Your Children.

1	"WARNING: Cigarettes Cause Fatal Lung
2	Disease.
3	"WARNING: Cigarettes Cause Cancer.
4	"WARNING: If You Think Smoking Is
5	Cool, You Are Dead Wrong.
6	"WARNING: Cigarettes Cause Strokes
7	And Heart Disease.
8	"WARNING: Smoking During Pregnancy
9	Can Harm Your Baby.
10	"WARNING: Smoking Can Kill You.
11	"WARNING: Tobacco Smoke Causes
12	Fatal Lung Disease In Nonsmokers.
13	"WARNING: Quitting Smoking Now
14	Greatly Reduces Serious Risks To Your
15	Health.
16	"(B) Location.—Each label statement re-
17	quired by subparagraph (A) shall occupy not
18	less than 20 percent of the area of the adver-
19	tisement involved.
20	"(C) Type and color.—
21	"(i) Type.—With respect to each
22	label statement required by subparagraph
23	(A), the phrase 'WARNING' shall appear
24	in capital letters and the label statement
25	shall be printed in the following types:

1	"(I) With respect to whole page
2	advertisements on broadsheet news-
3	paper—45 point type.
4	"(II) With respect to half page
5	advertisements on broadsheet news-
6	paper—39 point type.
7	"(III) With respect to whole page
8	advertisements on tabloid news-
9	paper—39 point type.
10	"(IV) With respect to half page
11	advertisements on tabloid news-
12	paper—27 point type.
13	"(V) With respect to DPS maga-
14	zine advertisements—31.5 point type.
15	"(VI) With respect to whole page
16	magazine advertisements—31.5 point
17	type.
18	"(VII) With respect to $28 \mathrm{cm} \times 3$
19	column advertisements—22.5 point
20	type.
21	"(VIII) With respect to $20 \mathrm{cm} \times 2$
22	column advertisements—15 point
23	type.

The Secretary may revise the required type sizes as the Secretary determines appropriate within the 20 percent requirement.

"(ii) Color.—All the letters in the label statement under this subparagraph shall appear in conspicuous and legible type, in contrast by typography, layout, or color with all other printed material in the advertisement, and be printed in an alternating black-on-white and white-on-black format as determined appropriate by the Secretary.

"(4) ROTATION OF LABEL STATEMENTS.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), the label statements specified in paragraphs (1) and (2)(A) shall be rotated by each manufacturer or importer of cigarettes quarterly in alternating sequence on packages of each brand of cigarettes manufactured by the manufacturer or importer and in the advertisements for each such brand of cigarettes in accordance with a plan submitted by the manufacturer or importer and approved by the Secretary. The Secretary shall approve a plan submitted by a manufacturer or importer

1	of cigarettes which will provide the rotation re-
2	quired by this paragraph and which assures
3	that all of the label statements required by
4	paragraphs (1) and (2)(A) will be displayed by
5	the manufacturer or importer at the same time.
6	"(B) Application of other rotation
7	REQUIREMENTS.—
8	"(i) In general.—A manufacturer
9	or importer of cigarettes may apply to the
10	Secretary to have the rotation schedule de-
11	scribed in clause (iii) apply with respect to
12	a brand style of cigarettes manufactured
13	or imported by such manufacturer or im-
14	porter if—
15	"(I) the number of cigarettes of
16	such brand style sold in the fiscal year
17	of the manufacturer or importer pre-
18	ceding the submission of the applica-
19	tion is less than ½ of 1 percent of all
20	the cigarettes sold in the United
21	States in such year; and
22	"(II) more than $\frac{1}{2}$ of the ciga-
23	rettes manufactured or imported by
24	such manufacturer or importer for
25	sale in the United States are pack-

12 1 aged into brand styles which meet the 2 requirements of subclause (I). 3 If an application is approved by the Secretary, the rotation schedule described in clause (iii) shall apply with respect to the 6 applicant during the 1-year period begin-7 ning on the date of the application ap-8 proval. 9 "(ii) Plan.—An applicant under 10 clause (i) shall include in its application a 11 plan under which the label statements 12 specified in subparagraph (A) of paragraph 13 (1) will be rotated by the applicant manu-

label rotation described in clause (iii).

"(iii) OTHER ROTATION REQUIREMENTS.—Under the rotation schedule
which the manufacturer or importer with
an approved application may put into effect, each of the label statements specified
in paragraph (1) shall appear on the packages of each brand style of cigarettes with
respect to which the application was ap-

proved an equal number of times within

the 12-month period beginning on the date

facturer or importer in accordance with the

14

15

16

17

18

19

20

21

22

23

24

1	of the approval by the Secretary of the ap-
2	plication.
3	"(5) Application of requirement.—Para-
4	graph (1) does not apply to a distributor or retailer
5	of cigarettes who does not manufacture, package, or
6	import cigarettes for sale or distribution within the
7	United States.
8	"(6) Television and radio advertising.—It
9	shall be unlawful to advertise cigarettes and little ci-
10	gars on any medium of electronic communications
11	subject to the jurisdiction of the Federal Commu-
12	nications Commission.
13	"(b) Smokeless Tobacco Products.—
14	"(1) In general.—
15	"(A) Packaging.—It shall be unlawful for
16	any person to manufacture, package, or import
17	for sale or distribution within the United States
18	any smokeless tobacco product the package of
19	which fails to bear, in accordance with the re-
20	quirements of this subsection, one of the follow-
21	ing statements:
22	"WARNING: This Product May Cause
23	Mouth Cancer.
24	"WARNING: This Product May Cause
25	Gum Disease And Tooth Loss.

1	"WARNING: This Product Is Not A Safe
2	Alternative To Cigarettes.
3	"WARNING: Smokeless Tobacco Is Ad-
4	dictive.
5	"(B) Advertising.—It shall be unlawful
6	for any manufacturer or importer of smokeless
7	tobacco products to advertise or cause to be ad-
8	vertised within the United States any smokeless
9	tobacco product unless the advertising bears, in
10	accordance with the requirements of this sub-
11	section, one of the following statements:
12	"WARNING: This Product May Cause
13	Mouth Cancer.
14	"WARNING: This Product May Cause
15	Gum Disease And Tooth Loss.
16	"WARNING: This Product Is Not A Safe
17	Alternative To Cigarettes.
18	"WARNING: Smokeless Tobacco Is Ad-
19	dictive.
20	"(2) Requirements for label state-
21	MENTS.—
22	"(A) LOCATION.—Each label statement re-
23	quired by subparagraph (A) of paragraph (1)
24	shall be located on the principal display panel

of the product and occupy not less than 25 percent of such panel.

"(B) Type and color.—With respect to each label statement required by subparagraph (A) of paragraph (1), the phrase 'WARNING' shall appear in capital letters and the label statement shall be printed in 17 point type with adjustments as determined appropriate by the Secretary to reflect the length of the required statement. All the letters in the label statement shall appear in conspicuous and legible type in contrast by typography, layout, or color with all other printed material on the package and be printed in an alternating black on white and white on black format as determined appropriate by the Secretary.

- "(3) ADVERTISING AND ROTATION.—The provisions of paragraphs (3) and (4)(A) of subsection (a) shall apply to advertisements for smokeless tobacco products and the rotation of the statements required under paragraph (1)(A) on such products.
- "(4) APPLICATION OF REQUIREMENT.—Paragraph (1) does not apply to a distributor or retailer of smokeless tobacco products who does not manu-

facture, package, or import such products for sale or
 distribution within the United States.

"(5) Television and radio advertising.—It shall be unlawful to advertise smokeless tobacco on any medium of electronic communications subject to the jurisdiction of the Federal Communications Commission.

"(c) STATEMENT OF INTENDED USE.—

"(1) Requirement.—Each manufacturer, distributor, and retailer advertising or causing to be advertised, disseminating or causing to be disseminated advertising concerning, tobacco products otherwise permitted under this chapter shall include, in a type size and format as the Secretary may prescribe in a regulation promulgated under subsection (d), the established name of the product and a statement of the intended use of the product as provided for in paragraph (2).

"(2) Intended use statements.—

"(A) CIGARETTES.—A statement of intended use for cigarettes or cigarette tobacco is as follows (whichever is appropriate):

"Cigarettes—A Dangerous Tobacco Product Intended For Use Only By Persons 18 or Older.

1	"Cigarette Tobacco—A Dangerous Tobacco
2	Product Intended For Use Only By Persons 18
3	or Older.
4	"(B) Smokeless tobacco.—A statement
5	of intended use for a smokeless tobacco product
6	is as follows (whichever is appropriate):
7	"Loose Leaf Chewing Tobacco—A Dangerous
8	Tobacco Product Intended For Use Only By
9	Persons 18 or Older.
10	"Plug Chewing Tobacco—A Dangerous To-
11	bacco Product Intended For Use Only By Per-
12	sons 18 or Older.
13	"Twist Chewing Tobacco—A Dangerous To-
14	bacco Product Intended For Use Only By Per-
15	sons 18 or Older.
16	"Moist Snuff—A Dangerous Tobacco Product
17	Intended For Use Only By Persons 18 or
18	Older.
19	"Dry Snuff—A Dangerous Tobacco Product In-
20	tended For Use Only By Persons 18 or Older.
21	"(d) Regulations.—
22	"(1) In general.—Not later than 180 days
23	after the date of the enactment of this Act, the Sec-
24	retary shall promulgate such regulations as may be
25	necessary to implement subsections (a), (b), and (c).

1	"(2) Authority to revise tobacco product
2	LABELING STATEMENTS.—The Secretary may by
3	rule change the text of any of the statements re-
4	quired under subsections (a) and (b). A rule promul-
5	gated under this subparagraph shall not become ef-
6	fective prior to the expiration of the 1-year period
7	beginning on the date on which the final rule is pub-
8	lished in the Federal Register.
9	"(e) Preemption.—No statement relating to the use
10	of cigarettes or smokeless tobacco products and health,
11	other than the statements required by subsections (a), (b),
12	or (c), shall be required on any package or in any adver-
13	tisement of cigarettes or a smokeless tobacco product.
14	"(f) Exports.—Packages of cigarettes or smokeless
15	tobacco products manufactured, imported, or packaged—
16	"(1) for export from the United States; or
17	"(2) for delivery to a vessel or aircraft, as sup-
18	plies, for consumption beyond the jurisdiction of the
19	internal revenue laws of the United States;
20	shall be exempt from the requirements of this chapter, but
21	such exemptions shall not apply to cigarettes or smokeless
22	tobacco products manufactured, imported, or packaged for
23	sale or distribution to members or units of the Armed
24	Forces of the United States located outside of the United
25	States.

"SEC. 904. VENDING MACHINES.

- 2 "(a) In General.—No manufacturer, distributor, or
- 3 retailer may distribute or cause to be distributed any to-
- 4 bacco product through a vending machine, except that dis-
- 5 tribution may be made through vending machines that are
- 6 located in facilities where the retailer ensures that no indi-
- 7 viduals under 18 years of age are present or permitted
- 8 to enter at any time.
- 9 "(b) Monitoring.—The Secretary shall, during the
- 10 2 year period beginning on the effective date of this Act,
- 11 monitor compliance with subsection (a). The Secretary
- 12 may propose additional restrictions on vending machine
- 13 sales if there is evidence that individuals under the age
- 14 of 18 are continuing to purchase tobacco products from
- 15 vending machines.

16 "SEC. 905. MINIMUM AGE.

- 17 "(a) Prohibition.—No person shall sell or distrib-
- 18 ute a tobacco product to an individual under the age of
- 19 18 or such higher age as may be prescribed by applicable
- 20 State law.
- 21 "(b) Verification.—A retailer of tobacco products
- 22 shall verify that an individual is 18 or older by checking
- 23 identification that includes the individual's date of birth
- 24 and photograph. Such verification shall be made of any
- 25 individual age 26 or younger. If a State has in effect a
- 26 law which prohibits the sale of tobacco products to individ-

- 1 uals under age 18, the Secretary may not take enforce-
- 2 ment action against a retailer of tobacco products for the
- 3 sale in such State of tobacco products without checking
- 4 identification as required by this subsection if such a sale
- 5 is a face-to-face transaction and is conducted in accord-
- 6 ance with such State law to an individual who is of legal
- 7 age.
- 8 "(c) Notice.—The Secretary shall notify any retailer
- 9 who is found not to be routinely complying with subsection
- 10 (b) of such failure of the retailer and of the penalties
- 11 under this section.
- 12 "(d) Penalties.—For a violation of subsection
- 13 (a)—
- 14 "(1) if it is a first offense, the Secretary shall
- notify the retailer of the violation and warn the re-
- tailer of penalties for subsequent violations;
- 17 "(2) for the second violation, be subject to a
- civil penalty of \$250; and
- 19 "(3) for each subsequent violation, be subject to
- a civil penalty which is twice the amount of the pre-
- ceding civil penalty.
- 22 "(e) Enforcement.—A State shall—
- "(1) enforce the law described in subsection (a)
- 24 systematically and conscientiously and in a manner
- 25 that can reasonably be expected to reduce the extent

1	to which tobacco products are available in such
2	State to individuals under the age of 18;
3	"(2) certify that the State requires enforcement
4	of such law to be treated as a priority by State and
5	local law enforcement authorities;
6	"(3) conduct random, unannounced inspections
7	to ensure compliance with the law described in sub-
8	section (a); and
9	"(4) annually submit to the Secretary a report
10	describing—
11	"(A) the activities carried out by the State
12	to enforce such law;
13	"(B) the steps taken by the State to en-
14	sure that enforcement of such law was treated
15	as a priority by State and local law enforcement
16	authorities;
17	"(C) the extent of success the State has
18	achieved in reducing the availability of tobacco
19	products to individuals under the age of 18;
20	and
21	"(D) the strategies to be utilized by the
22	State for enforcing such law
23	If a State does not comply with this subsection, the
24	Secretary may reduce the amount of a grant that the
25	State is eligible for under section 1926 of the Public

- 1 Health Service Act. The reduction shall stay in effect until
- 2 the State demonstrates to the Secretary that it is comply-
- 3 ing with this subsection.
- 4 "SEC. 906. SMALL SALES AND SAMPLES.
- 5 "(a) Prohibition.—No person may distribute or sell
- 6 a cigarette individually or in packages of less than 20 and
- 7 no person may distribute samples of cigarettes.
- 8 "(b) Penalties.—The penalties prescribed by sec-
- 9 tion 905(d) shall apply to violations of subsection (a).
- 10 "SEC. 907. DISTRIBUTION THROUGH THE MAIL.
- 11 "(a) IN GENERAL.—No person may distribute a to-
- 12 bacco product through the mail.
- 13 "(b) Authority to Use Mail.—A person who
- 14 wants to distribute a tobacco product through the mail
- 15 shall submit to the Secretary a plan which will ensure that
- 16 the tobacco product will only go to individuals who are
- 17 18 or older. If the Secretary approves the plan, such per-
- 18 son may make such distribution.
- 19 "(c) Monitoring.—The Secretary shall after 2 years
- 20 after the effective date of this Act review distributions of
- 21 tobacco products through the mail to determine if individ-
- 22 uals under the age of 18 are receiving tobacco products
- 23 so distributed.
- 24 "(d) Penalties.—The penalties prescribed by sec-
- 25 tion 905(d) shall apply to violations of subsection (a).

1 "SEC. 908. TOBACCO PRODUCT USE REDUCTION TARGETS.

- 2 "(a) In General.—The Secretary shall determine
- 3 the average annual incidence of the daily use of tobacco
- 4 products by individuals who are under 18 years of age and
- 5 the Secretary shall determine the underage use base per-
- 6 centage for tobacco products which shall be a percentage
- 7 determined by the Secretary, weighted by the population
- 8 of the age group involved as determined using data com-
- 9 piled in 1995 by the Bureau of the Census. The Secretary
- 10 shall report to the Congress the average annual incidence
- 11 and underage use base percentage.
- "(b) Goals.—With respect to the average annual in-
- 13 cidence of the daily use of tobacco products by individuals
- 14 who are under 18 years of age, it shall be the national
- 15 goals of the United States that such use be reduced as
- 16 follows:
- 17 "(1) in the fifth calendar year after the date of
- enactment of this Act the percentage decrease in the
- use of tobacco products shall be at least 35 percent;
- 20 "(2) in the seventh calendar year after the date
- of enactment of this Act the percentage decrease in
- 22 the use of tobacco products shall be at least 50 per-
- cent; and
- 24 "(3) in the tenth and subsequent calendar years
- 25 after the date of enactment of this Act the percent-

- 1 age decrease in the use of tobacco products shall be
- 2 at least 80 percent.
- 3 "(c) Determination.—The Secretary shall deter-
- 4 mine whether the required percentage reduction in the un-
- 5 derage use of tobacco products in the fifth calendar year
- 6 after the date of enactment of this Act (based on sub-
- 7 section (b)) has been achieved for the year involved. If it
- 8 has not, the Secretary may make recommendations to the
- 9 Congress with respect to a different goal of reduction in
- 10 underage use of tobacco products."
- 11 (b) Effective Date.—The amendment made by
- 12 subsection (a) shall take effect January 1, 1999.

 \bigcirc