### 112TH CONGRESS 1ST SESSION

# H. R. 1676

To help prevent the occurrence of cancer resulting from the use of ultraviolet tanning lamps by imposing more stringent controls on the use of such devices, and for other purposes.

## IN THE HOUSE OF REPRESENTATIVES

May 2, 2011

Mrs. Maloney (for herself, Mr. Dent, and Mr. Jackson of Illinois) introduced the following bill; which was referred to the Committee on Energy and Commerce

# A BILL

- To help prevent the occurrence of cancer resulting from the use of ultraviolet tanning lamps by imposing more stringent controls on the use of such devices, 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 "Tanning Bed Cancer
  - 5 Control Act of 2011".
  - 6 SEC. 2. FINDINGS.
  - 7 Congress finds as follows:

- 1 (1) Two million Americans—approximately 70 2 percent of whom are girls and women—visit a tan-3 ning salon each day.
  - (2) In July 2009, the World Health Organization International Agency for Research on Cancer Monograph Working Group raised the classification of the use of UV-emitting tanning devices to Group 1, "carcinogenic to humans".
    - (3) The new carcinogen classification places tanning beds alongside tobacco smoke, asbestos, and uranium as known cancer-causing agents.
    - (4) The World Health Organization reports that the risk of cutaneous melanoma is increased by 75 percent when use of tanning devices starts before 30 years of age.
    - (5) According to the American Academy of Dermatology, there were over 120,000 new melanomas diagnosed in the United States during 2009 and approximately 8,650 people were estimated to die from melanoma during 2009.
    - (6) In a December 2008 Report to Congress, FDA determined, through its own analysis, that the current warning labels for indoor tanning devices do not effectively communicate the risks associated with indoor tanning and is therefore reviewing modifica-

- tions to the labeling requirements in an effort to better inform consumers about the risks associated with
- 3 sunlamp products.
- 4 (7) According to section 514 of the Federal 5 Food, Drug, and Cosmetic Act (21 U.S.C. 360d), 6 the Secretary of Health and Human Services deter-7 mines that a performance standard is necessary to 8 provide reasonable assurance of the safety and effec-9 tiveness of the device.
- 10 (8) If tanning devices do not provide reasonable
  11 assurances of safe and effective performance, the
  12 Secretary shall seek to reclassify these devices as is
  13 most appropriate based on the scientific evidence
  14 and to put in place safeguards for consumer access
  15 to these devices.

#### 16 SEC. 3. RECLASSIFICATION.

- 17 (a) Study.—Not later than 1 year after the date of
- 18 enactment of this Act, the Commissioner of Food and
- 19 Drugs (hereinafter in this Act referred to as the "Commis-
- 20 sioner") shall complete a study to examine the classifica-
- 21 tion of ultraviolet tanning lamps as class I devices.
- 22 (b) Reclassification.—Not later than 1 year after
- 23 the completion of the study under subsection (a), the Com-
- 24 missioner shall, based on the results of such study—

1	(1) issue a rule providing for the reclassification
2	under section 513(e) of the Federal Food, Drug, and
3	Cosmetic Act (21 U.S.C. 260c(e)) of an ultraviolet
4	tanning lamp as a class II or class III device; or
5	(2) submit to the Congress a report that pro-
6	vides a justification for not issuing such a rule.
7	SEC. 4. PERFORMANCE STANDARDS.
8	(a) STUDY.—Not later than 1 year after the date of
9	enactment of this Act, the Commissioner shall complete
10	a study on performance standards established under sec-
11	tion 514 of the Federal Food, Drug, and Cosmetic Act
12	(21 U.S.C. 360d) for ultraviolet tanning lamps to examine
13	the adequacy of such performance standards.
14	(b) Revision of Performance Standards.—Ex-
15	cept as provided in subsection (c), the Commissioner,
16	based on the results of the study under subsection (a),
17	shall, not later than 1 year after the completion of such
18	study—
19	(1) issue a rule providing for more stringent
20	performance standards for ultraviolet tanning lamps,
21	including with respect to the strength of ultraviolet
22	rays emitted by such devices and the amount of time
23	a user should remain exposed to such devices; or
24	(2) submit to the Congress a report that pro-
25	vides a justification for not issuing such a rule.

1	(c) Labeling Requirements.—The Commissioner
2	shall carry out the recommendations made in the report
3	submitted under section 230 of the Food and Drug Ad-
4	ministration Amendments Act of 2007 (Public Law 110-
5	85) regarding the labeling of ultraviolet tanning lamps.
6	SEC. 5. NO LIMITATION ON RECALL AUTHORITY.
7	Nothing in this Act shall be construed to limit the
8	authority of the Commissioner under section 518(e) of the
9	Federal Food, Drug, and Cosmetic Act (21 U.S.C.
10	360h(e)) with regard to an ultraviolet tanning lamp.
11	SEC. 6. DEFINITIONS.
12	In this Act:
13	(1) The term "ultraviolet tanning lamp"—
14	(A) refers to an ultraviolet ray-emitting de-
15	vice for purposes of tanning, including indoor
16	tanning devices and sunlamps for tanning; and
17	(B) notwithstanding subparagraph (A)
18	does not include an ultraviolet ray-emitting de-
19	vice for purposes of use as part of a treatment
20	regimen prescribed by a licensed health care
21	professional.
22	(2) The terms "class I", "class II", and "class
23	III" have the meanings given such terms in section
24	513(h) of the Federal Food, Drug, and Cosmetic
25	Act (21 II S.C. 360c(h))

1 (3) The terms "device", "interstate commerce",
2 "label", and "labeling" have the meanings given
3 such terms under section 201 of the Federal Food,
4 Drug, and Cosmetic Act (21 U.S.C. 321).

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