

111TH CONGRESS  
2D SESSION

# H. R. 4520

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.

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## IN THE HOUSE OF REPRESENTATIVES

JANUARY 26, 2010

Mrs. MALONEY (for herself, Mr. DENT, Mr. GRIJALVA, and Mr. BRADY of Pennsylvania) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## 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 2010”.

6 **SEC. 2. FINDINGS.**

7 Congress finds as follows:

1           (1) One million Americans—70 percent of  
2 whom are girls and women—visit a tanning salon  
3 each day.

4           (2) In July 2009, the World Health Organiza-  
5 tion International Agency for Research on Cancer  
6 Monograph Working Group raised the classification  
7 of the use of UV-emitting tanning devices to Group  
8 1, “carcinogenic to humans.”

9           (3) The new carcinogen classification places  
10 tanning beds alongside tobacco smoke, asbestos, and  
11 uranium as known cancer-causing agents.

12           (4) The World Health Organization reports  
13 that the risk of cutaneous melanoma is increased by  
14 75 percent when use of tanning devices starts before  
15 30 years of age.

16           (5) According to the American Academy of Der-  
17 matology, there were over 120,000 new melanomas  
18 diagnosed in the United States during 2009 and ap-  
19 proximately 8,650 people were estimated to die from  
20 melanoma during 2009.

21           (6) In a December 2008 Report to Congress,  
22 FDA determined, through its own analysis, that the  
23 current warning labels for indoor tanning devices do  
24 not effectively communicate the risks associated with  
25 indoor tanning and is therefore reviewing modifica-

1 tions to the labeling requirements in an effort to bet-  
2 ter 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 performance standards are established by pro-  
8 viding that a drug or device allows for the reason-  
9 able assurance of safe and effective performance.

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 U.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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