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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.

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Tanning Bed Cancer Control Act of 2010''.

SEC. 2. FINDINGS.

Congress finds as follows:

(1) One million Americans—70 percent of whom are girls and women—visit a tanning 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 sunlamp products.

(7) According to section 514 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d), the Secretary of Health and Human Services determines performance standards are established by providing that a drug or device allows for the reasonable assurance of safe and effective performance.

(8) If tanning devices do not provide reasonable assurances of safe and effective performance, the Secretary shall seek to reclassify these devices as is most appropriate based on the scientific evidence and to put in place safeguards for consumer access to these devices.

SEC. 3. RECLASSIFICATION.

(a) STUDY.—Not later than 1 year after the date of enactment of this Act, the Commissioner of Food and Drugs (hereinafter in this Act referred to as the ''Commissioner'') shall complete a study to examine the classification of ultraviolet tanning lamps as class I devices.

(b) RECLASSIFICATION.—Not later than 1 year after the completion of the study under subsection (a), the Commissioner shall, based on the results of such study—

(1) issue a rule providing for the reclassification under section 513(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 260c(e)) of an ultraviolet tanning lamp as a class II or class III device; or

(2) submit to the Congress a report that provides a justification for not issuing such a rule.

SEC. 4. PERFORMANCE STANDARDS.

(a) STUDY.—Not later than 1 year after the date of enactment of this Act, the Commissioner shall complete a study on performance standards established under section 514 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d) for ultraviolet tanning lamps to examine the adequacy of such performance standards.

(b) REVISION OF PERFORMANCE STANDARDS.—Except as provided in subsection (c), the Commissioner, based on the results of the study under subsection (a), shall, not later than 1 year after the completion of such study—

(1) issue a rule providing for more stringent performance standards for ultraviolet tanning lamps, including with respect to the strength of ultraviolet rays emitted by such devices and the amount of time a user should remain exposed to such devices; or

(2) submit to the Congress a report that provides a justification for not issuing such a rule.

(c) LABELING REQUIREMENTS.—The Commissioner shall carry out the recommendations made in the report submitted under section 230 of the Food and Drug Administration Amendments Act of 2007 (Public Law 110–85) regarding the labeling of ultraviolet tanning lamps.

SEC. 5. NO LIMITATION ON RECALL AUTHORITY.

Nothing in this Act shall be construed to limit the authority of the Commissioner under section 518(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360h(e)) with regard to an ultraviolet tanning lamp.

SEC. 6. DEFINITIONS.

In this Act:

(1) The term ''ultraviolet tanning lamp''—

(A) refers to an ultraviolet ray-emitting device for purposes of tanning, including indoor tanning devices and sunlamps for tanning; and

(B) notwithstanding subparagraph (A), does not include an ultraviolet ray-emitting device for purposes of use as part of a treatment regimen prescribed by a licensed health care professional.

(2) The terms ''class I'', ''class II'', and ''class III'' have the meanings given such terms in section 513(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(h)).

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

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