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110TH CONGRESS
1ST SESSION

H. R. 3084

To require the Food and Drug Administration to establish a standard for broad-spectrum protection in sunscreen products, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 18, 2007

Mrs. LOWEY introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To require the Food and Drug Administration to establish a standard for broad-spectrum protection in sunscreen products, 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 ''Skin Cancer Prevention, Education, and Consumer Right-To-Know Act''.

SEC. 2. FINDINGS.

The Congress finds as follows:

(1) Skin cancer is a growing epidemic in the United States with more than 1,000,000 new cases diagnosed each year.

(2) About 10,000 Americans die each year from skin cancer.

(3) The most deadly form of skin cancer, melanoma, has tripled among Caucasians since 1980.

(4) One in 5 Americans and one in 3 Caucasians will develop skin cancer in the course of a lifetime.

(5) A person's risk for skin cancer doubles if he or she has had 5 or more sunburns.

(6) More than 90 percent of all skin cancers are caused by sun exposure, yet fewer than 33 percent of adults, adolescents, and children routinely use sun protection.

(7) Most skin cancer is caused by prolonged exposure to the ultraviolet rays from the sun. This invisible radiation is classified as UVA radiation and UVB radiation.

(8) UVB radiation is the chief cause of sunburn and skin cancer.

(9) UVA radiation is more constant, year-round, and penetrates the skin more deeply, causing both premature aging and skin cancer.

(10) Current United States sunscreen standards set by the Food and Drug Administration

(FDA) require protection from UVB radiation but not UVA radiation.

(11) The current United States sunscreen standards provide a false sense of security to Americans, since their sunscreen is protecting successfully against sunburn, but not adequately against other forms of skin damage, including skin cancers. Consumers may wrongly believe that their sunscreen is sufficiently protecting them and therefore stay in the sun longer.

SEC. 3. BROAD-SPECTRUM SUNSCREEN STANDARD.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended—

(1) in section 502, by adding at the end the following:

''(y) If it is a drug that is a sunscreen product and its labeling is in violation of section 566 .''; and

(2) by inserting after section 565 the following:

''SEC. 566. BROAD-SPECTRUM SUNSCREEN STANDARD.

''(a) LABELING.—The labeling of a drug that is a sunscreen product and fails to meet the standard adopted under subsection (b)(1) shall not—

''(1) describe the product using the term 'broad-spectrum' (or any variant of such term); or

''(2) include the symbol described in subsection (b)(2).

''(b) STANDARD; SYMBOL.—The Secretary shall—

''(1) adopt a standard for broad-spectrum protection in sunscreen products in order to better protect Americans from skin cancer and premature aging; and

''(2) adopt an easily recognized symbol for inclusion in the labeling of sunscreen products meeting such standard.

''(c) MINIMUM REQUIREMENTS.—

''(1) MINIMUM REQUIREMENTS.—In establishing the standard under subsection (b)(1), the Secretary shall require—

''(A) a minimum ratio 1 to 3 of UVA protection factor (UVA–PF) to sun protection factor (SPF);

''(B) a critical wavelength of 370 nanometers, as obtained in application of the critical wavelength testing method;

''(C) a minimum level of UVB radiation protection of sun protection factor 6 as obtained in application of the International Sun Protection Factor Test Methods (2006) or an

equivalent degree of protection obtained with any in vitro method; and

"(D) truth in labeling requirements such that—

"(i) claims of broad-spectrum protection from ultraviolet radiation can only be made in cases where the product meets the requirements established under this section; and

"(ii) labels claiming broad-spectrum protection include the symbol described in subsection (b)(2) only if the sunscreen product meets the standard adopted under subsection (b)(1).

"(2) MEASUREMENT OF PROTECTION LEVELS.—The protection factors described in paragraph (1) shall be measured using standardized, reproducible testing methods that take photo-degradation into account. In considering such methods, the Secretary shall give preference to in vitro testing methods.

"(d) REGULATIONS.—Not later than December 31, 2007, the Secretary shall issue comprehensive final regulations for carrying out this section with respect to sunscreen products.

''(e) DEFINITIONS.—

''(1) BROAD-SPECTRUM PROTECTION.—The term 'broad-spectrum protection' means protection from both UVA radiation and UVB radiation.

''(2) SUN PROTECTION FACTOR.—The term 'sun protection factor' is the ratio between the ultraviolet dose required to produce minimal erythema reaction (redness) in protected skin (skin with sunscreen) compared to unprotected skin (skin without any sunscreen). The number indicates how many times longer a person can stay in the sun before beginning to burn while wearing sun protection than if he or she were not wearing any sunscreen at all.

''(3) UVA PROTECTION FACTOR.—The term 'UVA protection factor' means the ratio of the minimum UVA radiation dose necessary to induce a persistent pigment darkening on the skin protected by a sunscreen product to the minimal UVA radiation dose necessary to induce the minimal darkening effect on the same unprotected skin.

''(4) UVA RADIATION.—The term 'UVA radiation' means sun radiation in the spectrum of 320 to 400 nanometers.

''(5) UVB RADIATION.—The term 'UVB radiation' means sun radiation in the spectrum of 290 to 320 nanometers.''.

(b) EFFECTIVE DATE.—The requirements of sections 502(y) and 566(a) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), shall take effect on the earlier of—

(1) the date determined appropriate by the Secretary of Health and Human Services; or

(2) the date that is 1 year after the date of the enactment of this Act.

SEC. 4. EDUCATION.

(a) EDUCATION.—Upon issuing the regulations required by subsection (d) of section 566 of the Federal Food, Drug, and Cosmetic Act, as added by section 3, the Secretary of Health and Human Services shall implement a general, nationwide education campaign identifying the risks posed by sun exposure without the use of a sunscreen providing broad-spectrum protection.

(b) CONTENTS.—The education campaign under this section shall be designed to increase the level of knowledge and awareness among the general public of the causes of skin cancer, the risks posed by unprotected sun exposure, the respective roles of UVA radiation and UVB radiation (as defined in such section 566) in the development of skin

cancer, the effective application of sunscreen, and the release of the standard requiring broad-spectrum protection (as defined in such section 566) in sunscreen products.

(c) DURATION.—The education campaign under this section shall be implemented for not less than one year.

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