The question was taken.

The SPEAKER pro tempore. In the opinion of the Chair, two-thirds being in the affirmative, the ayes have it.

Mr. MEEHAN. Mr. Speaker, I object to the vote on the ground that a quorum is not present and make the point of order that a quorum is not present.

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, further proceedings on this question will be postponed.

The point of no quorum is considered withdrawn.

SUNSCREEN INNOVATION ACT

Mr. WHITFIELD. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 4250) to amend the Federal Food, Drug, and Cosmetic Act to provide an alternative process for review of safety and effectiveness of nonprescription sunscreen active ingredients and for other purposes, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 4250

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 ''Sunscreen Innovation Act''.

SEC. 2. REGULATION OF NONPRESCRIPTION SUNSCREEN ACTIVE INGREDIENTS.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

''Subchapter I—Nonprescription Sunscreen Active Ingredients

''SEC. 586. DEFINITIONS.

''In this subchapter:

''(1) The term 'Advisory Committee' means the Nonprescription Drug Advisory Committee or any successor to such Committee.

''(2) The terms 'generally recognized as safe and effective' and 'GRASE' mean generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the product's labeling, as described in section 201(p).

''(3) The term 'GRASE determination' means, with respect to a nonprescription sunscreen active ingredient or a combination of nonprescription sunscreen active ingredients, a determination of whether such ingredients or combination of ingredients is generally recognized as safe and effective and not misbranded for use under the conditions prescribed, recommended, or suggested in the product's labeling, as described in section 201(p).

''(4) The term 'nonprescription' means not subject to section 503(b)(1).

''(5) The term 'pending request' means each request submitted to the Secretary—

''(A) for consideration for inclusion in the over-the-counter drug monograph system;

''(B) that was deemed eligible for such review by publication of a notice of eligibility in the Federal Register prior to the date of enactment of the Sunscreen Innovation Act; and

''(C) for which safety and effectiveness data has been submitted to the Secretary prior to such date of enactment.

''(6) The term 'sponsor' means the person submitting the request under section 586A(a), including a time and extent application under section 586B, or the person that submitted the pending request.

''(7) The term 'sunscreen active ingredient' means an active ingredient that is intended for application to the skin of humans for purposes of absorbing, reflecting, or scattering radiation.

''(8) The term 'sunscreen' means a product containing one or more sunscreen active ingredients.

''SEC. 586A. GENERAL PROVISIONS.

''(a) REQUESTS.—Any person may submit a request to the Secretary for a determination of whether a nonprescription sunscreen active ingredient or a combination of nonprescription sunscreen active ingredients, for use under specified conditions, to be prescribed, recommended, or suggested in the labeling thereof (including dosage form, dosage strength, and route of administration) is generally recognized as safe and effective and not misbranded.

''(b) RULES OF CONSTRUCTION.—

''(1) CURRENTLY MARKETED SUNSCREENS.—Nothing in this subchapter shall be construed to affect the marketing of sunscreens that are lawfully marketed in the United States on or before the date of enactment of this subchapter.

''(2) ENSURING SAFETY AND EFFECTIVENESS.—Nothing in this subchapter shall be construed to alter the Secretary's authority to prohibit the marketing of a sunscreen that is not safe and effective or to impose restrictions on the marketing of a sunscreen to ensure safety and effectiveness.

''(3) OTHER PRODUCTS.—Nothing in this subchapter shall be construed to affect the Secretary's regulation of products other than sunscreens.

''(c) SUNSET.—This subchapter shall cease to be effective at the end of the 5-year period beginning on the date of enactment of this subchapter.

''SEC. 586B. ELIGIBILITY DETERMINATION.

''(a) IN GENERAL.—Upon receipt of a request under section 586A(a), not later than 60 days after the date of receipt of such request, the Secretary shall—

''(1) determine whether the request is eligible for further review under sections 586C and 586D, as described in subsection (b);

''(2) notify the sponsor of the Secretary's determination; and

''(3) make such determination publicly available in accordance with subsection (c).

''(b) CRITERIA FOR ELIGIBILITY.—

''(1) IN GENERAL.—To be eligible for review under sections 586C and 586D, a request shall be for a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients, for use under specified conditions, to be prescribed, recommended, or suggested in the labeling thereof, that—

''(A) is not included in the stayed sunscreen monograph in part 352 of title 21, Code of Federal Regulations; and

''(B) has been used to a material extent and for a material time, as described in section 201(p)(2).

''(2) TIME AND EXTENT APPLICATION.—A sponsor shall include in a request under section 586A(a) a time and extent application including all the information required to meet the standard described in paragraph (1)(B).

''(c) PUBLIC AVAILABILITY.—

''(1) REDACTIONS FOR CONFIDENTIAL INFORMATION.—If a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients is determined to be eligible for further review under subsection (a)(1), the Secretary shall make the request publicly available, with redactions for information that is treated as confidential under section 552(b) of title 5, United States Code, section 1905 of title 18, United States Code, or section 301(j) of this Act.

''(2) IDENTIFICATION OF CONFIDENTIAL INFORMATION BY SPONSOR.—Sponsors shall identify any information which the sponsor considers to be confidential information described in paragraph (1).

''(3) CONFIDENTIALITY DURING ELIGIBILITY REVIEW.—The information contained in a request under section 586A(a) shall remain confidential during the Secretary's consideration under this section of whether the request is eligible for further review.

''SEC. 586C. DATA SUBMISSION; FILING DETERMINATION.

''(a) IN GENERAL.—In the case of a request under section 586A(a) that is determined to be eligible under section 586B for further review under this section and section 586D—

''(1) the Secretary shall, in notifying the public under section 586B(a)(3) of such eligibility determination, invite the sponsor of the request and any other interested party to submit, in support of or otherwise relating to a GRASE determination—

''(A) published and unpublished data and other information related to the safety and effectiveness of the nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients for its intended nonprescription uses; or

''(B) any other comments; and

''(2) not later than 60 days after the submission of such data and other information by the sponsor, including any revised submission of such data and other information following a refusal to file under subparagraph (B), the Secretary shall—

''(A)(i) issue a written notification to the sponsor determining that the request under section 586A(a), together with such data and other information, is sufficiently complete to conduct a substantive review and make such notification publicly available; and

''(ii) file such request; or

''(B) issue a written notification to the sponsor refusing to file the request and stating the reasons for the refusal and why the data and other information submitted is not sufficiently complete to conduct a substantive review and make such notification publicly available;

''(3) the Secretary shall, in filing a request under paragraph (2)—

''(A) invite the public to submit further comments with respect to such filing; and

''(B) limit such public comment, and the comment period under paragraph (1), to the period ending on the date that is 60 days after such filing;

''(4) if the Secretary refuses to file the request—

''(A) the sponsor may, within 30 days of receipt of written notification of such refusal, seek a meeting with the Secretary regarding whether the Secretary should file the request; and

''(B) the Secretary shall convene the meeting; and

''(5) following any such meeting—

''(A) if the sponsor asks that the Secretary file the request (with or without amendments to correct any purported deficiencies to the request) the Secretary shall file the request over protest, issue a written notification of the filing to the sponsor, and make such notification publicly available; and

''(B) if the request is so filed over protest, the Secretary shall not require the sponsor to resubmit a copy of the request for purposes of such filing.

''(b) REASONS FOR REFUSAL TO FILE REQUEST.—The Secretary may refuse to file a request submitted under section 586A(a) if the Secretary determines the data or other information submitted by the sponsor under this section are not sufficiently complete to conduct a substantive review with respect to such request.

''(c) PUBLIC AVAILABILITY.—

''(1) REDACTIONS FOR CONFIDENTIAL INFORMATION.—The Secretary shall make data and other information submitted in connection with a request under section 586A(a) publicly available, with redactions for information that is treated as confidential under section 552(b) of title 5,

United States Code, section 1905 of title 18, United States Code, or section 301(j) of this Act.

''(2) IDENTIFICATION OF CONFIDENTIAL INFORMATION BY SPONSOR.—Sponsors or any other individual submitting data or other information under this section shall identify any information which the sponsor or individual considers to be confidential information described in paragraph (1).

''SEC. 586D. GRASE DETERMINATION.

''(a) REVIEW OF NEW REQUEST.—

''(1) PROPOSED ORDER BY CDER.—In the case of a request under section 586A(a), the Director of the Center for Drug Evaluation and Research shall—

''(A) not later than 300 days after the date on which the request is filed under section 586C(a), complete the review of the request and issue a proposed order determining that—

''(i) the nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients that is the subject of the request—

''(I) is GRASE; and

''(II) is not misbranded;

''(ii) the nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients that is the subject of the request—

''(I) is not GRASE; or

''(II) is misbranded; or

''(iii) additional information is necessary to allow the Director of the Center for Drug Evaluation and Research to complete the review of such request;

''(B) within such 300-day period, convene a meeting of the Advisory Committee to review the request under section 586A(a): and

''(C) if the Director fails to issue such proposed order within the 300-day period referred to in subparagraph (A), transmit the request to the Commissioner of Food and Drugs for review.

''(2) PROPOSED ORDER BY COMMISSIONER.—With respect to a request transmitted to the Commissioner of Food and Drugs under paragraph (1)(C), the Commissioner shall, not later than 60 days after the date of such transmission, issue—

''(A) a proposed order described in paragraph (1)(A)(i);

''(B) a proposed order described in paragraph (1)(A)(ii); or

''(C) a proposed order described in paragraph (1)(A)(iii).

''(3) PUBLICATION IN FEDERAL REGISTER; PUBLIC COMMENT PERIOD.—A proposed order issued under paragraph (1) or (2) with respect to a request shall—

''(A) be published in the Federal Register; and

''(B) solicit public comments for a period of not more than 45 days.

''(4) FINAL ORDER BY CDER.—In the case of a proposed order under paragraph (1)(A) or (2) with respect to a request, the Director of the Center for Drug Evaluation and Research shall—

''(A) issue a final order with respect to the request—

''(i) in the case of a proposed order under clause (i) or (ii) of paragraph (1)(A) or subparagraph (A) or (B) of paragraph (2), not later than 90 days after the end of the public comment period under paragraph (3)(B); or

''(ii) in the case of a proposed order under paragraph (1)(A)(iii) or paragraph (2)(C), not later than 210 days after the date on which the sponsor submits the additional information requested pursuant to such proposed order; or

''(B) if the Director fails to issue such final order within such 90- or 210-day period, as applicable, transmit such proposed order to the Commissioner of Food and Drugs for review.

''(5) FINAL ORDER BY COMMISSIONER.—With respect to a proposed order transmitted to the Commissioner of Food and Drugs under paragraph (4)(B), the Commissioner shall issue a final order with respect to such proposed order not later than 60 days after the date of such transmission.

''(b) REVIEW OF PENDING REQUESTS.—

''(1) IN GENERAL.—The review of a pending request shall be carried out by the Director of the Center for Drug Evaluation and Research in accordance with paragraph (3).

''(2) INAPPLICABILITY OF CERTAIN PROVISIONS.—Sections 586B and 586C shall not apply with respect to any pending request.

''(3) PROPOSED ORDER BY CDER.—The Director of the Center for Drug Evaluation and Research shall—

''(A) within the timeframe applicable under paragraph (4), complete the review of the request and issue a proposed order determining that—

''(i) the nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients that is the subject of the pending request—

''(I) is GRASE; and

''(II) is not misbranded;

''(ii) the nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients that is the subject of the pending request—

''(I) is not GRASE; or

''(II) is misbranded; or

''(iii) additional information is necessary to allow the Director of the Center for Drug Evaluation and Research to complete the review of the pending request; and

''(B) if the Director fails to issue such proposed order within the timeframe applicable under paragraph (4), transmit the pending request to the Commissioner of Food and Drugs for review.

''(4) TIMEFRAME FOR ISSUANCE OF PROPOSED ORDER BY CDER.—The Director of the Center for Drug Evaluation and Research shall issue a proposed order, as required by paragraph (3)(A)—

''(A) in the case of a pending request for which the Food and Drug Administration has issued a feedback letter before the date of enactment of the Sunscreen Innovation Act, not later than 45 days after such date of enactment; and

''(B) in the case of a pending request for which the Food and Drug Administration has not issued a feedback letter before the date of enactment of the Sunscreen Innovation Act, not later than 90 days after such date of enactment.

''(5) PROPOSED ORDER BY COMMISSIONER.—With respect to a pending request transmitted to the Commissioner of Food and Drugs under paragraph (3)(B), the Commissioner shall, not later than 60 days after the date of such transmission, issue—

''(A) a proposed order described in paragraph (3)(A)(i);

''(B) a proposed order described in paragraph (3)(A)(ii); or

''(C) a proposed order described in paragraph (3)(A)(iii).

''(6) PUBLICATION IN FEDERAL REGISTER; PUBLIC COMMENT PERIOD.—A proposed order issued under paragraph (3) or (5) with respect to a pending request shall—

''(A) be published in the Federal Register; and

''(B) solicit public comments for a period of not more than 45 days.

''(7) ADVISORY COMMITTEE.—For a proposed order issued under paragraph (3)(A)(iii) or (5)(C) requesting additional information, an Advisory Committee meeting shall be convened if the sponsor requests, or the Director of the Center for Drug Evaluation and Research or the Commissioner of Food and Drugs decides, to convene such a meeting for the purpose of reviewing the pending request.

''(8) FINAL ORDER BY CDER.—In the case of a proposed order under paragraph (3)(A) or (5) with respect to a request, the Director of the Center for Drug Evaluation and Research shall—

''(A) issue a final order with respect to the request—

''(i) in the case of a proposed order under clause (i) or (ii) of paragraph (3)(A) or subparagraph (A) or (B) of paragraph (5), not later than 90 days after the end of the public comment period under paragraph (3)(B); or

''(ii) in the case of a proposed order under paragraph (3)(A)(iii) or paragraph (5)(C)—

''(I) if the Advisory Committee is not convened pursuant to paragraph (7), not later than 210 days after the date on which the sponsor submits the additional information requested pursuant to such proposed order; or

''(II) if the Advisory Committee is convened pursuant to paragraph (7), not later than 270 days after date on which the sponsor submits such additional information; or

''(B) if the Director fails to issue such final order within such 90-, 210-, and 270-day period, as applicable, transmit such proposed order to the Commissioner of Food and Drugs for review.

''(9) FINAL ORDER BY COMMISSIONER.—With respect to a proposed order transmitted to the Commissioner of Food and Drugs under paragraph (8)(B), the Commissioner shall issue a final order with respect to such proposed order not later than 60 days after the date of such transmission.

''(c) ADVISORY COMMITTEE.—

''(1) LIMITATIONS.—The Food and Drug Administration—

''(A) shall not be required to convene the Advisory Committee—

''(i) more than once with respect to any request under section 586A(a) or any pending request; or

''(ii) more than twice in any twelve month period with respect to the review of submissions under this section; and

''(B) shall not be required to submit more than 3 submissions to the Advisory Committee per meeting.

''(2) MEMBERSHIP.—In appointing the members of the Advisory Committee, the Secretary may select to serve temporarily as voting members on the Advisory Committee—

''(A) members of other Federal advisory committees; or

''(B) consultants from outside of the Department of Health and Human Services who have substantive expertise regarding sunscreen active ingredients.

''(d) NO DELEGATION.—Any responsibility vested by this section in the Commissioner of Food and Drugs is not delegable.

''(e) EFFECT OF FINAL ORDER.—

''(1) CONTENT.—A final order under subsection (a)(4), (a)(5), (b)(8), or (b)(9) with respect to a request under section 586A(a) or a pending request shall determine that the nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients that is the subject of the request—

''(A) is GRASE and is not misbranded; or

''(B) is not GRASE or is misbranded.

''(2) ACTIVE INGREDIENTS DETERMINED TO BE GRASE.—Upon issuance of a final order determining that a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients is GRASE and is not misbranded, the active ingredient or combination of active ingredients shall be permitted to be introduced or delivered into interstate commerce, for use under the conditions subject to the final order, in accordance with all requirements applicable to drugs not subject to section 503(b)(1).

''(3) ACTIVE INGREDIENTS DETERMINED NOT TO BE GRASE.—Upon issuance of a final order determining that the nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients is not GRASE or is misbranded, the active ingredient or combination of active ingredients shall not be introduced or delivered into interstate commerce, for use under the conditions subject to the final order, unless an application submitted pursuant to section 505(b) with respect to such active ingredient or combination of active ingredients is approved.

''SEC. 586E. REPORTS.

''(a) GAO REPORT.—Not later than 1 year after the date of enactment of the Sunscreen Innovation Act, the Comptroller General of the United States shall—

''(1) submit a report reviewing the overall progress of the Secretary in carrying out this subchapter to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives; and

''(2) include findings on—

''(A) the progress made in completing the review of pending requests; and

''(B) the role of the Office of the Commissioner of Food and Drugs in issuing determinations with respect to pending requests, including the number of requests transferred to the Office of the Commissioner under section 586D.

''(b) SECRETARY'S REPORT.—

''(1) IN GENERAL.—Not later than 1 year after the date of enactment of the Sunscreen Innovation Act, and every 2 years thereafter, the Secretary shall issue a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives describing actions taken under this section. Each report under this subsection shall be posted on the Internet site of the Food and Drug Administration.

''(2) CONTENTS.—The reports under this subsection shall include—

''(A) a review of the progress made in issuing GRASE determinations for pending requests, including the number of pending requests—

''(i) reviewed and the decision times for each request, measured from the date of the original request for an eligibility determination submitted by the sponsor;

''(ii) resulting in a determination that the nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients is GRASE and not misbranded;

''(iii) resulting in a determination that the nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients is not GRASE and is misbranded and the reasons for such determinations; and

''(iv) for which a determination has not been made, an explanation for the delay, a description of the current status of each such request, and the length of time each such request has been pending, measured from the date of original request for an eligibility determination by the sponsor;

''(B) a review of the progress made in issuing in a timely manner GRASE determinations for requests submitted under section 586A(a), including the number of such requests—

''(i) reviewed and the decision times for each request;

''(ii) resulting in a determination that the nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients is GRASE and not misbranded;

''(iii) resulting in a determination that the nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients is not GRASE and is misbranded and the reasons for such determinations; and

''(iv) for which a determination has not been made, an explanation for the delay, a description of the current status of each such request, and the length of time each such request has been pending, measured from the date of original request for an eligibility determination by the sponsor;

''(C) a description of the staffing and resources relating to the costs associated with the review and decisionmaking pertaining to requests under this subchapter;

''(D) a review of the progress made in meeting the deadlines with respect to processing requests under this subchapter;

''(E) to the extent the Secretary determines appropriate, recommendations for process improvements in the handling of pending and new requests, including the advisory committee review process; and

''(F) recommendations for expanding the applicability of this subchapter to nonprescription active ingredients that are not related to the sunscreen category of over-the-counter drugs.

''(c) METHOD.—The Secretary shall publish the reports required under subsection (b) in the manner the Secretary determines to be the most effective for efficiently disseminating the report, including publication of the report on the Internet website of the Food and Drug Administration.''.

SEC. 3. GUIDANCE.

(a) IN GENERAL.—

(1) ISSUANCE.—Not later than one year after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue guidance, in accordance with good guidance practices, on the implementation of, and compliance with, subchapter I of chapter V of the Federal Food, Drug, and Cosmetic Act, as added by section 2, including guidance on—

(A) the criteria for determining whether a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients has been used to a material extent and for a material time, as described in section 201(p)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(p)(2));

(B) the format and content of a safety and effectiveness data submission; and

(C) the safety and efficacy standards for determining whether a nonprescription sunscreen active ingredients or combination of nonprescription sunscreen active ingredients is generally recognized as safe and effective, as defined in section 586 of such subchapter I.

(2) INAPPLICABILITY OF PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code, shall not apply to collections of information made for purposes of guidance under this subsection.

(b) SUBMISSIONS PENDING ISSUANCE OF FINAL GUIDANCE.—Irrespective of whether final guidance under subsection (a) has been issued—

(1) persons may, beginning on the date of enactment of this Act, make submissions under subchapter I of chapter V of the Federal Food, Drug, and Cosmetic Act, as added by section 2; and

(2) the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall review and act upon such submissions in accordance with such subchapter.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Kentucky (Mr. WHITFIELD) and the gentleman from Michigan (Mr. DINGELL) each will control 20 minutes.

The Chair recognizes the gentleman from Kentucky.

GENERAL LEAVE

Mr. WHITFIELD. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and insert extraneous materials on the bill into the RECORD.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Kentucky?

There was no objection.

Mr. WHITFIELD. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise today in support of H.R. 4250, the Sunscreen Innovation Act, which seeks to address an important area of public concern by strengthening the sunscreen ingredient review process at the Food and Drug Administration.

I would like to remind everyone that skin cancer is the most prevalent kind of cancer in America. Each year, there are more new cases of skin cancer than breast, prostate, lung, and colon cancer combined. By 2015, it is estimated that one in 50 Americans will develop melanoma in their lifetime. Melanoma also happens to be one of the most common forms of cancer in young adults, particularly young women.

Even though the Food and Drug Administration has listed action on sunscreen ingredient applications as a priority since 2008, no new sunscreen ingredients have been approved by the FDA. In fact, none have been approved in 15 years. This is despite the fact that eight sunscreen applications have been pending at the FDA, some as far back as 2002.

I might add that we find ourselves in this predicament, even though in Europe and other places around the world, new sunscreen ingredients are being introduced into sunscreen products.

This past April, the Energy and Commerce Committee held a hearing on the Sunscreen Innovation Act, where all of the expert witnesses, including the FDA, were in agreement that the current approval process is broken and in need of reform.

So the objective of the Sunscreen Innovation Act is twofold: first, to expedite the review of pending applications at FDA; and, second, to create a timely and transparent process for new applications to be reviewed and acted on.

The framework outlined in this legislation strikes an appropriate balance between consumer safety and access to the very best sunscreen product. The bill we have before us today reflects a bipartisan agreement reached in consultation with the Food and Drug Administration and outside stakeholders, such as the PASS Coalition and Environmental Working Group.

I want to give a particular thanks to my colleague from Michigan (Mr. DINGELL) for sponsoring this legislation with me. I would also like to thank Chairman UPTON, who worked with us closely throughout the entire process, and Ranking Member WAXMAN for their assistance in reaching the agreement that allowed this legislation to come to the floor.

I urge all my colleagues to support the bill. At this time, I reserve the balance of my time.

Mr. DINGELL. I yield myself such time as I may consume.

(Mr. DINGELL asked and was given permission to revise and extend his remarks.)

Mr. DINGELL. Mr. Speaker, I rise in support of H.R. 4250, the Sunscreen Innovation Act. This legislation proves that this body can work together, not only across the aisle but with the agencies under our jurisdiction and also with the industries concerned. This legislation has the support of everyone.

□ 1745

There is no opposition to it, and that includes the industry, it includes the

health people, it also includes the environmentalists, and it includes the administration. UV rays from the Sun are, it is understood, increasing the amount of melanoma amongst our people enormously—800 percent amongst young women, and 400 percent amongst young men over the past 40 years.

Sunscreens sold in the United States today do not offer the same level of protection as sunscreen sold in Europe, Canada, Australia, and other countries. In fact, the last over-the-counter sunscreen ingredient was approved by FDA in the 1990s. Some sunscreen ingredients have been waiting review by FDA for over a decade.

This is inexcusable, and it should not be permitted because FDA has taken so long to review these applications. It is clear that increased accountability is needed at the agency to ensure these pending sunscreen applications are reviewed in a timely and speedy manner.

I want to commend and congratulate my colleague, Mr. WHITFIELD, for his leadership and fine work on this, and also Chairman UPTON for his outstanding work, and I want to congratulate my friends, Mr. PALLONE and Mr. WAXMAN, for the good work which they have done on this legislation.

Indeed, the staffs on both sides of the committee have been remarkable in what it is they have done on this matter, and it is interesting to note that we have the strong support of the American Academy of Dermatology, the American Cancer Society Cancer Action Network, the Melanoma Research Alliance, the Environmental Working Group, and the Melanoma Research Foundation.

Mr. Speaker, I insert letters from those agencies into the RECORD.

AMERICAN ACADEMY OF DERMATOLOGY ASSOCIATION,
Washington, DC, July 21, 2014.

Hon. ED WHITFIELD,
U.S. House of Representatives, Washington, DC.
Hon. JOHN DINGELL,
U.S. House of Representatives, Washington, DC.

DEAR REPRESENTATIVE WHITFIELD AND REPRESENTATIVE DINGELL: The American Academy of Dermatology Association (Academy), which represents more than 13,000 dermatologists nationwide, commends you for working together to amend H.R. 4250, the Sunscreen Innovation Act, which would ensure that sunscreen ingredients are reviewed by the U.S. Food and Drug Administration (FDA) within a predictable timeframe. The Academy applauds you for your work with stakeholders on this legislation and is pleased to offer its support for the Committee-passed amended bill, which has the potential to reduce Americans' risk for skin cancer by ensuring that they have access to the safest, most effective sunscreens available.

Skin cancer is the most common cancer in the United States and one in five Americans will develop skin cancer in their lifetime. Dermatologists diagnose more than 3.5 million cases and treat more than 2.2 million people with skin cancer every year in the U.S. Research has shown that sunscreen helps reduce the risk of skin cancer and is essential to protecting the public from UV radiation. Proper use of sunscreen combined with access to the safest, most effective ingredients available will go a long way toward reducing these statistics.

We applaud you for working together to amend this legislation, which will ensure that sunscreen ingredients are thoroughly and expeditiously reviewed in a timely manner. We support allowing the Nonprescription Drugs Advisory Committee (NDAC) to provide recommendations on sunscreen ingredients to the FDA, and are pleased to see a provision under the amended bill that would allow the Secretary to appoint members of other federal advisory committees or outside consultants with substantive expertise regarding sunscreen active ingredients to the NDAC when sunscreen ingredients are reviewed. We are also in favor of the provisions within the amended legislative language that strengthen Congressional oversight by requiring reporting of FDA's activities and progress in the review of sunscreen ingredients.

We appreciate your continued leadership on this issue and look forward to working with you in the fight against skin cancer. If you have any questions or if we can provide any additional information, please contact Christine O'Connor, the Academy's Associate Director, Congressional Policy at coconnor@aad.org or (202) 609–6330; or Niva Haynes, the Academy's Manager, Congressional Policy at nhaynes@aad.ord or (202) 712–2608.

Sincerely,
BRETT M. COLDIRON, MD, FAAD,
President, American Academy of Dermatology Association.

AMERICAN CANCER SOCIETY CANCER ACTION NETWORK,
Washington, DC, May 6, 2014.

Re Letter of support for legislation to improve the FDA process for approving new sunscreen ingredients

Hon. JACK REED,
U.S. Senate, Washington, DC.
Hon. ED WHITFIELD,
U.S. House of Representatives, Washington, DC.
Hon. JOHNNY ISAKSON,
U.S. Senate, Washington, DC.
Hon. JOHN DINGELL,
U.S. House of Representatives, Washington, DC.

DEAR SENATOR REED, SENATOR ISAKSON, REPRESENTATIVE WHITFIELD AND REPRESENTATIVE DINGELL, On behalf of the American Cancer Society Cancer Action Network (ACS CAN), I am writing to express my support for legislation to reform the current Food and Drug Administration sunscreen approval process. ACS CAN is the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society.

As you know, despite dramatic increases in rates of melanoma and skin cancer, the last time the FDA approved a new sunscreen ingredient was during the 1990's. H.R. 4250, now pending in the House Energy and Commerce Committee, provides a solid basis for coming to an agreement on a new and workable FDA review process for approving new sunscreen ingredients. Ultimately the goal is to provide Americans with access to the most up-to-date, safe and effective sunscreen technology now available in Europe while preserving FDA's important authority to ensure the safety of over the counter products like sunscreen. The review process in place today does not work.

We believe that it is important for Americans to have access to the latest sunscreen technology to help curb the current skin cancer epidemic in the United States and that is why ACS CAN has joined the Public Access to SunScreens (PASS) Coalition. The PASS Coalition is a multi-stakeholder coalition formed to advocate for a regulatory pathway to market for new, safe and effective sunscreen ingredients. Specifically, the purpose of the Coalition is to develop reforms that guarantee a timely review by the Food & Drug Administration (FDA) of pending Time and Extent Applications (TEAs) for over-the-counter (OTC) sunscreen ingredients.

ACS CAN would like to thank you for supporting H.R. 4250, and we look forward to working with you to resolve any concerns regarding the legislation so that Americans have access to the most effective and safe sunscreens.

If you should have any questions or concerns, please do not hesitate to contact me. Thank you.

Sincerely,
CHRISTOPHER W. HANSEN,
President, American Cancer Society Cancer Action Network.

BASF,
May 5, 2014.

Re Letter of Support for the Sunscreen Innovation Act (S. 2141/H.R. 4250)

Hon. JACK REED,
U.S. Senate, Washington, DC.
Hon. JOHNNY ISAKSON,
U.S. Senate, Washington, DC.
Hon. ED WHITFIELD,
U.S. House of Representatives, Washington, DC.
Hon. JOHN DINGELL,
U.S. House of Representatives, Washington, DC.

DEAR SENATOR REED, SENATOR ISAKSON, REPRESENTATIVE WHITFIELD AND REPRESENTATIVE DINGELL: On behalf of BASF Corporation, I am writing to express support for the Sunscreen Innovation Act (S. 2141 and H.R. 4250) and thank you for your leadership on this important issue. BASF Corporation is the North American affiliate of BASF SE. Our portfolio includes chemicals, plastics, crop protection products and performance products. Through science and innovation, we enable our customers in nearly every industry to meet the current and future needs of society. We sum up this contribution in our corporate purpose: We create chemistry for a sustainable future.

Among the products in BASF's portfolio are sunscreen filters. BASF is a leading innovator and manufacturer of sunscreen filters. We currently have three applications for sunscreen filters pending at the Food and Drug Administration (FDA)—including one since 2002. These ingredients have been available to consumers globally since the 1990s. Moreover, there are additional sunscreen filters we would like to submit for FDA approval. Given the amount of time the current applications have been pending, you can understand why it is important that the current process for consideration of new sunscreen ingredients needs to be improved.

BASF Corporation supports the Sunscreen Innovation Act because it creates a transparent and predictable review process of new sunscreen ingredients and guarantees a decision by FDA on applications for new ingredients within a defined timeframe. We believe Americans should have access to the latest sunscreen technology to help curb the current skin cancer epidemic in the United States. This is why we joined the Public Access to SunScreens (PASS) Coalition, a multi-stakeholder coalition formed to advocate for a regulatory pathway to market for new, safe and effective sunscreen ingredients.

We look forward to working with you to enact this legislation as expeditiously as possible.

Sincerely,

STEVEN J. GOLDBERG,
Vice President and Associate General Counsel, Regulatory and Government Affairs, BASF Corporation.

MELANOMA RESEARCH ALLIANCE,
Washington, DC, May 2, 2014.

Re Letter of Support for H.R. 4250, the Sunscreen Innovation Act

Hon. JACK REED,
U.S. Senate, Washington, DC.
Hon. ED WHITFIELD,
U.S. House of Representatives, Washington, DC.
Hon. JOHNNY ISAKSON,
U.S. Senate, Washington, DC.
Hon. JOHN DINGELL,
U.S. House of Representatives, Washington, DC.

DEAR SENATOR REED, SENATOR ISAKSON, REPRESENTATIVE WHITFIELD AND REPRESENTATIVE DINGELL: On behalf of the Melanoma Research Alliance (MRA), I am writing to convey MRA's support for the Sunscreen Innovation Act (5. 2141 and H.R. 4250). MRA supports the Sunscreen Innovation Act because it will reform the current sunscreen approval process and encourages Congress to enact this critical legislation as soon as possible.

As you know, despite dramatic increases in rates of melanoma and skin cancer, the last time the FDA approved a new sunscreen ingredient is the 1990s. The Sunscreen Innovation Act will provide Americans access to the latest sunscreen technology, which addresses America's growing skin cancer epidemic and fosters innovation in sunscreen. Its provisions create a transparent and predictable review process and guarantees that safe and effective products reach consumers within a defined timeframe.

MRA is a public charity that accelerates the pace of scientific discovery and its translation in order to eliminate suffering and death due to melanoma by funding innovative research programs to improve melanoma prevention, diagnosis, staging, and treatment. In addition, MRA works with allies in government, non-profit, and industry to promote awareness about melanoma among the public.

As you know, in the U.S., one person dies every hour from melanoma and the numbers of skin cancer cases have risen dramatically. Sadly, many skin cancers could be prevented simply by reducing exposure to UV radiation, the leading environmental factor in the development of skin cancer.

We believe that it is important for Americans to have access to the latest sunscreen technology to help curb the current skin cancer epidemic in the United States and that is why we joined the Public Access to SunScreens (PASS) Coalition. The PASS Coalition is a multi-stakeholder coalition formed to advocate for a regulatory pathway to market for new, safe and effective sunscreen ingredients. Specifically, the purpose of the Coalition is to develop reforms that guarantee a timely review by the Food & Drug Administration (FDA) of pending Time and Extent Applications (TEAs) for over-the-counter (OTC) sunscreen ingredients.

There is unprecedented opportunity to make a difference in the future course of melanoma and other skin cancers. We are especially grateful for your leadership in the fight against melanoma. Despite recent progress in the field, much more needs to be done until melanoma prevention is effectively addressed.

MRA would like to thank you for introducing the Sunscreen Innovation Act. We look forward to working with you to enact this legislation this summer.

If you should have any questions or concerns, please do not hesitate to contact me. Thank you.

Sincerely,

WENDY K.D. SELIG,
MRA President and Chief Executive Officer.

MELANOMA RESEARCH FOUNDATION,
Washington, DC, April 29, 2014.

Re Letter of Support for H.R. 4250, the Sunscreen Innovation Act

DEAR SENATOR REED, SENATOR ISAKSON, REPRESENTATIVE WHITFIELD AND REPRESENTATIVE DINGELL: On behalf of The Melanoma Research Foundation (MRF) I am writing to express my support for the Sunscreen Innovation Act (S. 2141 and H.R. 4250). The MRF supports the Sunscreen Innovation Act because it will reform the current sunscreen approval process and encourages Congress to enact this critical legislation as soon as possible.

As you know, despite dramatic increases in rates of melanoma and skin cancer, the last time the FDA approved a new sunscreen ingredient is the 1990s. The Sunscreen Innovation Act will provide Americans access to the latest sunscreen technology, which addresses America's growing skin cancer epidemic and fosters innovation in sunscreen. Its provisions create a transparent and predictable review process and guarantees that safe and effective products reach consumers within a defined timeframe.

The Melanoma Research Foundation (MRF) is the largest independent organization devoted to melanoma. The MRF is a 501(c) (3) nonprofit organization. Committed to the support of medical research in finding effective treatments and eventually a cure for melanoma, the MRF also educates patients, caregivers and physicians about the prevention, diagnosis and treatment of melanoma.

Just one blistering sunburn at an early age can double a person's chance of developing melanoma. Regular use of sunscreen can greatly reduce the risk. The FDA's inaction over the past 12 years has prevented consumers from having access to new sunscreen products that could potentially save their lives.

We believe that it is important for Americans to have access to the latest sunscreen technology to help curb the current skin cancer epidemic in the United States and that is why we joined the Public Access to SunScreens (PASS) Coalition. The PASS Coalition is a multi-stakeholder coalition formed to advocate for a regulatory pathway to market for new, safe and effective sunscreen ingredients. Specifically, the purpose of the Coalition is to develop reforms that guarantee a timely review by the Food & Drug Administration (FDA) of pending Time and Extent Applications (TEAs) for over-the-counter (OTC) sunscreen ingredients.

The MRF would you like to thank you for introducing the Sunscreen Innovation Act. We look forward to working with you to enact this legislation this summer.

If you should have any questions or concerns, please do not hesitate to contact me. Thank you.

Sincerely,

MARY ANTONUCCI,
National Director of Advocacy and Volunteer Services, The Melanoma Research Foundation.

Mr. DINGELL. I would like to observe that the staff has performed extraordinary work on this matter. I want to congratulate and thank Greg Sunstrum on my staff, as well as Taylor Booth, John Stone, Carly McWilliams, and Eric Flamm for their hard work on the legislation, and I want to recognize members of the PASS Coalition for their hard work and advocacy on behalf of this important issue.

Mr. Speaker, I reserve the balance of my time.

Mr. WHITFIELD. Mr. Speaker, at this time, I would like to yield 5 minutes to my colleague from Michigan (Mr. UPTON), the chairman of the Energy and Commerce Committee.

Mr. UPTON. Mr. Speaker, I rise today in support of this very important bipartisan legislation to indeed help protect the public health. H.R. 4250, the Sunscreen Innovation Act, is just that.

The growing rate of skin cancer in the U.S., including melanoma, is indeed alarming. According to the American Cancer Society, more Americans are diagnosed with skin cancer every year than breast, prostate, lung, and colon cancer combined, and in 2015, this year, one in every 50 of our constituents is going to be diagnosed with melanoma. We have got to take every step that we can to combat this public health crisis.

Sadly, advancements in sunscreen have failed to keep pace with the increased awareness of the harm overexposure to the Sun can cause. The FDA has not approved a new nonprescription sunscreen ingredient for nearly 20 years, despite the fact that several applications have been pending at the agency for products that have been used safely and effectively in Europe and other parts of the world.

The review process that these products have to go through at the FDA is, quite simply, broken. It needs to be fixed, and that is what this legislation does.

I particularly want to commend the work that my good friend from the great State of Michigan (Mr. DINGELL) and Mr. WHITFIELD and members of our entire committee, as this bill passed with unanimous support as we moved through the process. We wanted to come up with a solution to allow the FDA to fix the problem, and that is what this bill does.

The Sunscreen Innovation Act is going to address the current backlog of applications pending at the FDA, as well as establish a predictable and transparent review process for new applications, incorporating meaningful input from experts and the public.

The bill also establishes the number of timeframes for decisionmaking at the FDA and remove administrative hurdles identified by the FDA to the sunscreen approval process. More importantly, it is going to allow Americans to benefit from these products sooner, while ensuring that they are indeed safe and effective.

We have had great success in our Energy and Commerce Committee this Congress, with over a dozen public health bills that have already been signed into law, obviously all bipartisan, and I am confident that this commonsense bill which received, again, unanimous support at our committee will soon be part of our strong record of results.

In fact, I am told that this is the 61st bill that our committee has reported

out that will be approved on the House floor. That is a pretty good record of achievement.

This one really, like the others, has a real impact on all of our constituents. It gives the FDA the rightful tools, so that we can get to the bottom of the problem which impacts one in 50 Americans.

So, again, I want to compliment Mr. DINGELL, Mr. WHITFIELD, Mr. PALLONE, Mr. WAXMAN, and others for helping deliver this bill to the House floor, and I look forward to a strong vote—hopefully voice—in a few minutes.

Mr. DINGELL. Mr. Speaker, I have no further requests for time, so if the gentleman, my good friend, Mr. WHITFIELD, is ready, I am prepared to yield back with the strong urging to my colleagues to support this bill—which is strongly bipartisan—unanimously brought forward to the Congress and which has the strong support of both industry, government, and health groups.

Mr. Speaker, I yield back the balance of my time.

Mr. WHITFIELD. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I want to, once again, thank Mr. DINGELL, and I appreciate his naming the staff because there was a lot of negotiations with FDA on this bill, and Taylor Booth on my staff and other members of the Energy and Commerce Committee staff, as named by Mr. DINGELL, I want to give special thanks to them, and also, we appreciate the efforts of Mr. PITTS, who is the chairman of the Health Subcommittee.

Without the help of him, Mr. PALLONE, and their staffs, we would not have been able to bring this bill to the floor. So I would urge everyone to support it, and with that, I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Kentucky (Mr. WHITFIELD) that the House suspend the rules and pass the bill, H.R. 4250, as amended.

The question was taken; and (two-thirds being in the affirmative) the rules were suspended and the bill, as amended, was passed.

A motion to reconsider was laid on the table.

PAUL D. WELLSTONE MUSCULAR DYSTROPHY COMMUNITY ASSISTANCE, RESEARCH AND EDUCATION AMENDMENTS OF 2014

Mr. BURGESS. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 594) to reauthorize and extend the Paul D. Wellstone Muscular Dystrophy Community Assistance, Research, and Education Amendments of 2008, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 594

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 ''Paul D. Wellstone Muscular Dystrophy Community Assistance, Research and Education Amendments of 2014''.

SEC. 2. INITIATIVE THROUGH THE DIRECTOR OF THE NATIONAL INSTITUTES OF HEALTH.

Section 404E of the Public Health Service Act (42 U.S.C. 283g) is amended—

(1) in subsection (a)(1)—

(A) by striking ''Muscoskeletal'' and inserting ''Musculoskeletal''; and

(B) by inserting ''Becker, congenital muscular dystrophy, limb-girdle muscular dystrophy,'' after ''Duchenne,'';

(2) in subsection (b)—

(A) in paragraph (2)—

(i) by striking ''genetics,'' at the second place it appears; and

(ii) by inserting ''cardiac and pulmonary function, and'' after ''imaging,''; and

(B) in paragraph (3), by inserting ''and sharing of data'' after ''regular communication'';

(3) in subsection (d)—

(A) in paragraph (2)—

(i) in the matter preceding subparagraph (A), by striking ''15'' and inserting ''18''; and

(ii) in subparagraph (A)—

(I) by striking ''and the Food and Drug Administration'' and inserting '', the Food and Drug Administration, and the Administration for Community Living'';

(II) by inserting ''and adults'' after ''children''; and

(III) by striking ''such as the Department of Education'' and inserting ''including the Department of Education and the Social Security Administration''; and

(B) in paragraph (4)(B), by inserting '', but shall meet no fewer than two times per calendar year'' before the period; and

(4) in subsection (e)—

(A) in paragraph (1)—

(i) in the matter preceding subparagraph (A), by striking ''through the national research institutes'' and inserting ''through the agencies represented on the Coordinating Committee pursuant to subsection (d)(2)(A)''; and

(ii) in subparagraph (A)—

(I) by inserting ''public services,'' before ''and rehabilitative issues''; and

(II) by inserting '', studies to demonstrate the cost-effectiveness of providing independent living resources and support to patients with various forms of muscular dystrophy, and studies to determine optimal clinical care interventions for adults with various forms of muscular dystrophy'' after ''including studies of the impact of such diseases in rural and underserved communities''; and

(B) in paragraph (2)(D), by inserting after ''including new biological agents'' the following: ''and new clinical interventions to improve the health of those with muscular dystrophy''.

SEC. 3. SURVEILLANCE AND RESEARCH REGARDING MUSCULAR DYSTROPHY.

The second sentence of section 317Q(b) of the Public Health Service Act (42 U.S.C. 247b–18(b)) is amended by inserting before the period the following: ''and, to the extent possible, ensure that data be representative of all affected populations and shared in a timely manner''.

SEC. 4. INFORMATION AND EDUCATION.

Section 5(c) of the Muscular Dystrophy Community Assistance, Research and Education Amendments of 2001 (42 U.S.C. 247b–19(c)) is amended—

(1) in paragraph (2)—

(A) by inserting ''for pediatric and adult patients, including acute care considerations,'' after ''issuance of care considerations'';

(B) by inserting ''various'' before ''other forms of muscular dystrophy''; and

(C) by striking ''and'' at the end;

(2) by redesignating paragraph (3) as paragraph (4);

(3) by inserting after paragraph (2) the following:

''(3) in developing and updating care considerations under paragraph (2), incorporate strategies specifically responding to the findings of the national transitions survey of minority, young adult, and adult communities of muscular dystrophy patients; and''; and

(4) in paragraph (4), as redesignated, by inserting ''various'' before ''other forms of muscular dystrophy''.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Texas (Mr. BURGESS) and the gentleman from New York (Mr. ENGEL) each will control 20 minutes.

The Chair recognizes the gentleman from New York.

GENERAL LEAVE

Mr. BURGESS. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and insert extraneous materials in the RECORD on the bill.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Texas?

There was no objection.

Mr. BURGESS. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, thank you for the recognition to discuss this bipartisan, bicameral legislation that was introduced with Mr. ENGEL of New York, H.R. 594, the Muscular Dystrophy Community Assistance, Research and Education Amendments of 2014, or the MD CARE Act.

H.R. 594 has 113 bipartisan cosponsors. This bill makes targeted updates and improvements to legislation first passed by Congress in 2001 and then reauthorized in 2008. In each instance, these bills, including H.R. 594, have passed both subcommittee and full committee on voice votes and passed overwhelmingly on the floor under suspension, a trend I hope we can continue today.

Mr. Speaker, this legislation is supported by the totality of the muscular dystrophy community with over 20 organizations writing letters of support, including the Muscular Dystrophy Association and the Parent Project Muscular Dystrophy.

In short, the underlying law is a success story. Since its enactment, this law has successfully targeted limited Federal resources to improve clinical care across the muscular dystrophies.

Muscular dystrophy is not a single disease. It is a group of genetic disorders characterized by progressive weakness and the loss of voluntary muscles that control movement.

Muscular dystrophy affects hundreds of thousands of children and adults throughout the United States and worldwide. Some forms of muscular dystrophy are seen in infancy or childhood, while others may not appear until adulthood. The extent of muscle weakness, as well as rate of progression, varies based on where among a spectrum of muscular dystrophies a patient falls.

Since 2001, this law has successfully changed the lives of families impacted