

**Testimony of Scott Faber**  
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**Before the**  
**Subcommittee on Health**  
**of the**  
**House Committee on Energy and Commerce**  
**on**  
**H.R. 4250, the Sunscreen Innovation Act**

**April 7, 2014**

Thank you for the opportunity to testify. My name is Scott Faber and I am the Senior Vice President for Government Affairs at EWG.

EWG welcomes the opportunity to testify on H.R. 4250, the Sunscreen Innovation Act. We share the goals of Representatives Whitfield and Dingell, and we look forward to working with the Committee to accelerate FDA's review and approval of sunscreen ingredients that may help reduce the troubling rise in skin cancer rates.

EWG has been recognized since 1993 as the nation's leading environmental health organization. Since 2007, EWG has published an annual sunscreen guide that rates the safety and efficacy of sunscreens, lotions, lip products and makeups that advertise sun

protection. We have also repeatedly urged the FDA to strengthen and finalize regulations governing the safety, effectiveness and labeling of OTC sunscreen products.

Simply put, skin cancer is a public health crisis. Every year, more and more Americans are diagnosed with it. More than 2 million of us develop skin cancer each year, including the most dangerous form, melanoma. In 2009, more than 61,000 people developed melanoma, and more than 9,000 died as a result.<sup>1</sup>

Over the past 35 years, the rate of new melanoma cases has tripled – from 7.89 per 100,000 in 1975 to 23.57 in 2010.<sup>2</sup> The melanoma death rate for white American men, the highest risk group, has increased from 2.64 to 4.10 deaths per 100,000. Since 2000, the rates of new melanoma cases for both men and women have been climbing by 1.9 percent per year,<sup>3</sup> including an especially troubling increase among teenagers.<sup>4</sup>

Sunlight produces two kinds of ultraviolet rays that can damage the skin and lead to skin cancer: ultraviolet A, which can penetrate the skin, and ultraviolet B, which does not penetrate the skin but is still harmful and is the primary cause of sunburn.<sup>5</sup> Although wearing protective clothing and avoiding intense sunlight are the best strategies for minimizing the risk of skin cancer, sunscreens that provide balanced UVA and UVB protection may reduce long term skin damage and aid in lowering the risk of skin cancer.

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<sup>1</sup><http://www.cdc.gov/cancer/skin/statistics/trends.htm>

<sup>2</sup>[http://seer.cancer.gov/csr/1975\\_2010/](http://seer.cancer.gov/csr/1975_2010/)

<sup>3</sup><http://www.cdc.gov/cancer/skin/statistics/trends.htm>

<sup>4</sup><http://www.ewg.org/2013sunscreen/skin-cancer-on-the-rise/>

<sup>5</sup><http://www.cdc.gov/cancer/skin/statistics/trends.htm>

Currently, however, sunscreens marketed in the United States have limited formulation options, and most products provide inadequate protection from UVA rays. That's largely because the FDA has failed to review and approve promising sunscreen ingredients that have been sold for years in Europe, Australia and other countries.

European sunscreen manufacturers can choose from 27 approved sunscreen chemicals, including seven that were expressly designed to filter UVA radiation. By contrast, US manufacturers can choose from only 17 chemicals, including just three that screen UVA rays.<sup>6</sup> The most common is avobenzene, which the FDA approved in 1972. Applications for approval of several promising chemicals that are photo-stable, offer stronger UVA protection, and are already in use in the EU and Australia – including Tinosorb S, Tinosorb M and Mexoryl SX – have been languishing at the FDA since 2005 and 2007, respectively.

To date, the FDA does not have a mechanism to quickly and efficiently review the safety of new active sunscreen ingredients. In 2002, the agency finalized rules for adding chemicals to its sunscreen monograph through a Time and Extent Application, with the intent of completing evaluations within 90 to 180 days.<sup>7</sup> Since then, however, not a single active ingredient has been approved through this process. Of eight chemicals currently under review, six have been under review for more than eight years. While it is imperative that FDA collect adequate health and safety information on new ingredients, long delays in evaluating this information are a detriment to public health.

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<sup>6</sup><http://www.ewg.org/2013sunscreens/europes-better-sunscreens/>

<sup>7</sup><http://www.gpo.gov/fdsys/pkg/FR-2002-01-23/pdf/02-1457.pdf>

The FDA has also failed to finalize its overall regulations governing sunscreens. In 1978, the agency announced its intention to develop a regulatory monograph governing the safety, effectiveness and labeling of OTC sunscreen products.<sup>8</sup> However, it took the FDA 15 years to develop a draft of its sunscreen monograph.<sup>9</sup> It has since issued a few regulations, but nearly four decades after the original announcement it has yet to finalize the monograph to ensure the safety and effectiveness of sunscreens.<sup>10</sup>

Furthermore, the FDA's recent rules fail to provide consumers with adequate protection. Almost all sunscreens marketed in the U.S. meet the new FDA rules for "broad spectrum" protection – suggesting that they offer adequate protection from both UVA and UVB rays – even though half of these products would likely not be sold in the EU under its stricter guidelines. What's more, the FDA has not restricted the use of Vitamin A as an inactive ingredient in sunscreens, even though it has been shown to hasten the development of skin tumors and lesions on sun-exposed skin,<sup>11</sup> or to consider the toxicity of oxybenzone, a common chemical in sunscreens that triggers allergic reactions and may disrupt the hormone system.<sup>12</sup>

In light of the seriousness of America's skin cancer crisis and the long history of delay, we believe that Congress should act to accelerate the review of sunscreen ingredients and

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<sup>8</sup>43 Fed. Reg. 38,206 (Aug. 25, 1978)

<sup>9</sup> 58 Fed. Reg. 28,194 (May 12, 1993)

<sup>10</sup> 76 Fed. Reg. 35,620 (June 17, 2011)

<sup>11</sup> Although the NTP found in 2012 that both retinylpalmitate and retinoic acid speed up the development of cancerous lesions and tumors on UV-treated animals, the FDA has refused to take action.

<sup>12</sup> Studies of several sunscreen chemicals indicate they may mimic hormones or disrupt the hormone system (Krause 2012, Schlumpf 2001, 2004b, 2008). Some research suggests that oxybenzone, 4-MBC, and octinoxate are toxic to reproductive systems or interfere with normal development. See <http://www.ewg.org/2013sunscreens/the-trouble-with-sunscreen-chemicals/>

require the FDA to finalize its sunscreen monograph. While we support the goals of the Sunscreen Innovation Act, we hope the Committee will address the following considerations:

- **Competent Regulatory Authority** – The Sunscreen Innovation Act would grant expedited review to sunscreen ingredients that have been in commerce for five years in another nation. However, H.R. 4250 does not address whether that nation must have a competent regulatory program capable of adequately assessing the safety and efficacy of sunscreen ingredients.
- **Use as Sunscreen Ingredient** – Because the use patterns of cosmetics and dietary supplements are different from use patterns of sunscreen, we believe that any ingredient assessment by the FDA or an expert panel should be based specifically upon its use as a sunscreen ingredient, not as a cosmetic or dietary supplement ingredient, as proposed in Sec 2 © (2) of H.R. 4250.
- **Role of Expert Panel** – The Sunscreen Innovation Act would require the FDA’s Nonprescription Drug Advisory Committee to review the safety and efficacy of sunscreen ingredients, including pending Time and Extent Applications and other ingredients FDA deems eligible for review. The NDAC is a 14-member Advisory Committee with broad representation that meets quarterly. EWG is concerned that the NDAC may not have the technical competency to review potential risks posed by sunscreen ingredients, including long-term risks posed by chemicals that

disrupt the endocrine system or cause severe allergic reactions. We look forward to working with the Committee to ensure that sunscreen ingredients are reviewed by an advisory panel composed of qualified experts.

- **Deadlines** – Although EWG shares the frustration of Reps. Whitfield and Dingell, we are troubled by the short deadlines contemplated by H.R. 4250. In particular, we are concerned about the ability of the NDAC to properly review all the ingredients subject to Time and Extent Applications within 180 days. Currently, there are eight Time and Extent applications pending at the FDA, and each of these chemicals poses unique safety and efficacy questions.<sup>13</sup> Furthermore, we believe that 45 days is insufficient time for the FDA to respond to an NDAC recommendation and do not believe that the FDA’s failure to act should result in the approval of an ingredient.
- **Role of the FDA** – As noted above, EWG believes the final determination of ingredient safety and efficacy should be made by the FDA. However, we are concerned that Sec. 4(2)(D) limits the ability of the Center for Drug Enforcement and Research (CDER) to seek further review by FDA staff, the NDAC or other experts. As currently drafted, H.R. 4250 would only allow CDER to approve an ingredient when FDA staff has failed to “provide reasonable and sufficient support” for a decision to disregard an NDAC recommendation. In essence, this provision would give the “supervisor” only one choice: to approve an ingredient.

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<sup>13</sup>Three ingredients -- Tinosorb S, Tinosorb M and Mexoryl SX – likely pose little or no risk to public health and should receive expedited review.

- **Availability of Data** – EWG is pleased the Sunscreen Innovation Act anticipates public involvement in NDAC and FDA reviews of ingredients. To better understand the safety and efficacy of sunscreen ingredients, we believe that applicants should be required to conduct a literature review and to submit both published and *unpublished* data about toxicity and use, so that the FDA, experts and consumers can fully assess the benefits and risks. We also look forward to working with the Committee to clarify when application information would be treated as confidential or trade secret.
- **Labeling** – Because of their unproven health benefits and because consumers are easily misled by “Sun Protection Factor” ratings, EWG strongly supports proposals to restrict the use of SPF claims greater than 50. While consumers may believe a sunscreen with an SPF of 30 provides twice the level of protection of a sunscreen with an SPF of 15, the reality is that this doubling of the SPF simply increases the ability of the sunscreen to filter UVB rays from 93 percent to 97 percent. A further increase to SPF 50 only blocks out 98 percent of UVB rays. Claims beyond SPF 50 are misleading and should be prohibited – a step already taken by many U.S. trading partners.<sup>14</sup> The FDA should be allowed to set an expedited and reasonable timeline for this review.

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<sup>14</sup>In addition, the SPF value does not reflect the product’s ability to filter out UVA rays. Studies suggest that high-SPF users are exposed to more UV rays because of the false sense of security created by misleading claims.

- **Aerosol Testing** – We are concerned that Section 3(1) of H.R. 4250 would require an FDA determination of the safety of sunscreens sold as an aerosol – which may pose serious inhalation risks – before adequate reviews have been completed. The FDA began to review the safety and efficacy of aerosol sprays in 2011 and should be granted more than 180 days to complete this important work.

EWG applauds Reps. Whitfield and Dingell for their efforts to accelerate review of the safety and efficacy of sunscreen ingredients and we look forward to working with the Committee to enact legislation that helps reduce the risk of skin cancer.