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May 28, 2021

Janet Woodcock  
Acting Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, Maryland 20993

Dear Acting Commissioner Woodcock:

I write to urge the Food and Drug Administration (FDA) to use its new authorities to issue and finalize an administrative order to update sunscreen regulation in a timely manner. The previously proposed sunscreen rule—which I supported—would have ensured that non-prescription, commercially-available sunscreens are safe, effective, and properly labeled. The public deserves safe and effective sunscreens that reduce the risk of cancer and long-term skin damage. FDA must provide clear public guidance for these largely unregulated products and their impacts on public health.

Additionally, earlier this week, the Connecticut-based independent testing lab Valisure announced that company tests detected the cancer causing chemical benzene at high levels in 78 sunscreen and after-sun products.<sup>1</sup> This includes household name brands such as Neutrogena, CVS Health, and Banana Boat. On May 24, 2021, Valisure sent a Citizen Petition<sup>2</sup> to FDA outlining the company's findings and urging a recall of contaminated product batches. FDA must work with Valisure and manufacturers to immediately recall these products and investigate this contamination. FDA should also issue import alerts for products manufactured in foreign facilities to stop these products from flowing into the United States.

Over 90 percent of the 5 million skin cancer diagnoses each year have been linked to ultraviolet (UV) ray exposure.<sup>3</sup> Experts agree that sunscreen is a life-saving product that protects skin from the sun's potentially harmful UV rays, which can increase the risk of skin cancer and

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<sup>1</sup> Team Valisure, "Valisure Detects Benzene in Sunscreen," Valisure News (New Haven, Connecticut), May, 25, 2021, <https://www.valisure.com/blog/valisure-news/valisure-detects-benzene-in-sunscreen/>

<sup>2</sup> Valisure to Food and Drug Administration, May 24, 2021, <https://www.valisure.com/wp-content/uploads/Valisure-Citizen-Petition-on-Benzene-in-Sunscreen-and-After-sun-Care-Products-v9.7.pdf>

<sup>3</sup> Consumer Reports, "What you need to know about the chemicals in your sunscreen," *Washington Post* (Washington, D.C.), June 17, 2019, [https://www.washingtonpost.com/health/what-you-need-to-know-about-the-chemicals-in-your-sunscreen/2019/06/14/3840042c-8ca3-11e9-adf3f70f78c156e8\\_story.html?utm\\_term=.9ff1441b18cf&wpisrc=nl\\_lean&wpmm=1\\_](https://www.washingtonpost.com/health/what-you-need-to-know-about-the-chemicals-in-your-sunscreen/2019/06/14/3840042c-8ca3-11e9-adf3f70f78c156e8_story.html?utm_term=.9ff1441b18cf&wpisrc=nl_lean&wpmm=1_)

sunburn.<sup>4</sup> When combined with other proactive methods like limiting time spent in direct sunlight and wearing protective clothing, most sunscreens decrease the prevalence of short- and long-term effects of sun exposure.

However, a curious paradox has emerged: sunscreen is more widely used than ever, but the rate of skin cancer cases in the United States is increasing.<sup>5</sup> Two recent FDA studies found that many sunscreen ingredients are absorbed through the skin into the bloodstream, and some experts are concerned about that exposure over time and the potential increased risk of hormone disruption, skin irritation, or even skin cancer.<sup>6,7</sup> In large part, the cumulative effects of most sunscreen ingredients on human health<sup>8</sup> and the natural environment<sup>9</sup> remain uncertain, leaving consumers with a dizzying array of conflicting information. Given the increased vulnerability of children, pregnant women, and other populations to chemical exposure,<sup>10</sup> rigorous testing on the systemic absorption and toxicity of sunscreen ingredients is needed to ensure that these products are safe for routine long-term use. This should include examination of both cancer endpoints, as well as non-cancer endpoints, such as developmental and reproductive toxicity.

Congress has long been concerned about the lack of consumer protections regarding sunscreen and in 2014 it passed the Sunscreen Innovation Act which modified the process by which FDA reviews the safety and effectiveness of nonprescription sunscreen active ingredients and established timelines for FDA review. The Sunscreen Innovation Act also directed FDA to amend and finalize not later than five years after enactment, regulations concerning nonprescription sunscreen, which had been stayed indefinitely.

As a result, the FDA released a proposed rule entitled “Sunscreen Drug Products for Over-the-Counter Human Use,” also known as the sunscreen rule, in February 2019.<sup>11</sup> This proposed rule, if finalized, would have brought OTC sunscreens up-to-date with the latest science, helping to keep the public well-informed and healthy. The Coronavirus Aid, Relief, and Economic Security (CARES) Act modernized the way that OTC drugs such as sunscreen are regulated. The CARES Act modified FDA’s OTC drug monograph development and review process, replacing the rulemaking process with a new administrative order process, withdrawing the proposed sunscreen rule.

Consumers deserve transparent, truthful information regarding their sunscreen products. As such, it is critical that FDA take expeditious action to address the safety and efficacy of

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<sup>4</sup> “Sunscreen FAQ,” American Academy of Dermatology, July 17, 2019, <https://www.aad.org/media/stats/prevention-and-care/sunscreen-faqs>.

<sup>5</sup> <https://www.ewg.org/sunscreen/report/skin-cancer-on-the-rise/>.

<sup>6</sup> Aaron Carroll, “How Safe Is Sunscreen,” *New York Times* (New York, New York) June. 10, 2019, <https://www.nytimes.com/2019/06/10/upshot/how-safe-is-sunscreen.html>.

<sup>7</sup> Consumer Reports, “What you need to know about the chemicals in your sunscreen,” *Washington Post* (Washington, D.C.), July. 17, 2019, [https://www.washingtonpost.com/health/what-you-need-to-know-about-the-chemicals-in-your-sunscreen/2019/06/14/3840042c-8ca3-11e9-adf3-f70f78c156e8\\_story.html?utm\\_term=.9ff1441b18cf&wpsrc=nl\\_lean&wpmm=1](https://www.washingtonpost.com/health/what-you-need-to-know-about-the-chemicals-in-your-sunscreen/2019/06/14/3840042c-8ca3-11e9-adf3-f70f78c156e8_story.html?utm_term=.9ff1441b18cf&wpsrc=nl_lean&wpmm=1).

<sup>8</sup> “FDA advances new proposed regulation to make sure that sunscreens are safe and effective,” Food and Drug Administration, <https://www.fda.gov/news-events/press-announcements/fda-advances-new-proposed-regulation-make-sure-sunscreens-are-safe-and-effective>.

<sup>9</sup> Julia Calderone, “The Truth About ‘Reef Safe’ Sunscreen,” Consumer Reports, *Washington Post* (Washington, D.C.), February 7, 2019, <https://www.consumerreports.org/sunscreens/the-truth-about-reef-safe-sunscreen/>.

<sup>10</sup> Consumer Reports, “What you need to know about the chemicals in your sunscreen,” *Washington Post* (Washington, D.C.), July. 17, 2019, [https://www.washingtonpost.com/health/what-you-need-to-know-about-the-chemicals-in-your-sunscreen/2019/06/14/3840042c-8ca3-11e9-adf3-f70f78c156e8\\_story.html](https://www.washingtonpost.com/health/what-you-need-to-know-about-the-chemicals-in-your-sunscreen/2019/06/14/3840042c-8ca3-11e9-adf3-f70f78c156e8_story.html).

<sup>11</sup> Food and Drug Administration, *Sunscreen Drug Products for Over-the Counter Human Use*, proposed rule 2019-03019, National Archives and Records Administration (2019), <https://www.federalregister.gov/documents/2019/02/26/2019-03019/sunscreen-drug-products-for-over-the-counter-human-use>.

sunscreens to keep consumers safe and informed—this includes getting potentially dangerous products off of store shelves. I strongly urge FDA to use its administrative order authority to update sunscreen regulation to ensure that these products are safe and effective, while rejecting any attempts to weaken this critically important effort, specifically with regard to ingredient evaluations and clearer sunscreen labels. FDA must also work with manufacturers to recall sunscreen and after-sun lotion batches potentially contaminated with unsafe levels of benzene.

Thank you for your attention to this important matter.

Sincerely,

A handwritten signature in blue ink that reads "Richard Blumenthal". The signature is written in a cursive, flowing style.

Richard Blumenthal  
United States Senate