Congress of the United States Washington, DC 20515

June 21, 2024

The Honorable Robert Califf, MD, MACC Commissioner U.S. Food and Drug Administration 10903 New Hampshire Avenue Silver Springs, MD 20993

Dear Commissioner Califf:

We write to strongly encourage the Food and Drug Administration (FDA) to employ its regulatory authority and discretion to remove barriers that hinder Americans' access to safe and effective sunscreens.

As you know, the public health challenges posed by increasing incidence of skin cancer are significant. These issues are not new. Ten years ago, the U.S. Surgeon General issued a Call to Action to prevent, the most prevalent cancer in the country, skin cancer. Congress shortly thereafter unanimously enacted the Sunscreen Innovation Act. Yet, the FDA has still not approved a new sunscreen active ingredient for broad application in the United States since the 1990s. Although strides have been made in skin cancer awareness, early detection, and treatment, the U.S. continues to lag far behind other countries in terms of sunscreen access and protecting people from harmful U.V. rays.

There is no one-size-fits-all skin cancer prevention tool for all skin types, tones, and conditions because sunscreens have varying properties and protections. Americans require a range of sunscreens to better serve their varied lifestyles and allow them to spend more time outdoors for improved mental and physical health. Not only is it critical that the American public have access to as many of the active sunscreen ingredients on the U.S. market as possible, but also that they have access to the new, safe, and efficient products like those already available to consumers in other parts of the world.

We urge FDA to prioritize access to sunscreen and sunscreen choice, including sunscreen active ingredients that have demonstrated safety and efficacy in the U.S. marketplace for decades and are proven skin cancer prevention tools. Any regulatory framework for the review and evaluation of sunscreen active ingredients must recognize the important role sunscreens play in preventing skin cancer.

Additionally, to promote access to the largest number of safe and effective sunscreen active ingredients available to protect as many people as possible from the sun's harmful rays, we are asking that the FDA outline the steps it is taking to reform its sunscreen active ingredient testing

¹ Scott, A., & Amin, A. (2022, July 13). Why the U.S. doesn't have the best sunscreens in the world. Marketplace. https://www.marketplace.org/2022/07/13/why-the-u-s-doesnt-have-best-sunscreens-in-the-world/

requirements to leverage real-world evidence and internally-accepted testing methodologies, such as non-animal testing, which, taken together, can provide expedited review and approval of new and innovative sunscreen ingredients. The FDA should align its safety testing requirements for sunscreen ingredients with modern science and internationally accepted testing standards appropriate to sunscreens as a topical skin cancer prevention tool.

More must be done to ensure that Americans are equally protected from a known carcinogen as people in other countries. This was Congress' intent when it unanimously enacted the Sunscreen Innovation Act ten years ago. The FDA has a mandate to protect Americans against skin cancer by bringing new sunscreens to market, yet the agency has failed to meet this mandate. Hundreds of thousands of new cases of skin cancer have been diagnosed in the intervening decade, while no new sunscreen ingredients have been approved. We have now entered another sun season without any demonstrable progress to show for it and little to no transparency on what the agency is doing to protect the American people against skin cancer. We call on the FDA to take appropriate action.

Thank you for your attention to this important issue.

Sincerely,

David Joyce Member of Congress

Sand P Ju

Debbie Dingell

John Joyce Member of Congress

Debbie Dingell Member of Congress Deborah K. Ross Member of Congress

ahkm