

United States Senate

WASHINGTON, DC 20510

May 17, 2012

Margaret A. Hamburg, M.D.
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner Hamburg:

We write to express our disappointment in a recent decision by the Food and Drug Administration (FDA) to delay compliance with the sunscreen regulations released last summer. Once again, the summer months are upon us and millions of Americans will be spending time outdoors without adequate protection from the sun. FDA's decision is a major step backward, and we strongly urge you to reverse it.

FDA's announcement last year that new sunscreen testing and labeling standards would be implemented this summer was a positive signal to Americans that they would not go another summer without critical protection from the sun. Unfortunately, delaying the implementation of these standards by six months (for some manufacturers and 18 months for others) will allow the deceptive practices of the industry to continue. Americans will continue to think they are truly protected from the sun, that a product is "waterproof" and "sweatproof," and provides "all day protection," when that isn't likely the case.

FDA first looked into the deceptive practices of sunscreen products over 30 years ago. Since then, the rate of melanoma in this country has doubled. According to the American Cancer Society, over two million individuals will be informed that they have a preventable form of skin cancer in 2012. When Americans purchase and use over-the-counter sunscreen products they assume they are protected from harmful UVA and UVB rays, but the current protection that they are afforded by these products could be misleading or worse inaccurate, according to the Environmental Working Group. Has FDA determined the effect that the delay in the new regulations will have on public health? Has FDA analyzed the potential for confusion among consumers due to conflicting announcements?

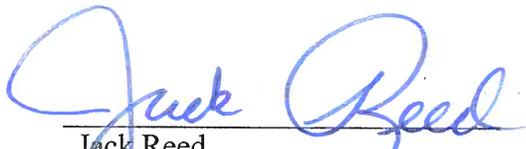
FDA's decision to delay the implementation of these critical regulations also draws attention to the agency's unfinished business regarding proposed regulations regarding the use of Sun Protection Factor (SPF) numbers over 50, as well as the testing and labeling of aerosol spray sunscreens. As you know, researchers have found significant variability in the SPF numbers listed on sunscreen products and products containing sun protection that make consumers believe that they are being adequately protected from the sun. For example, one product with an SPF of 30 was found to

protect against 98 percent of the sun's UVB rays, while a product labeled with a SPF of 100 may protect against 99 percent of the sun's rays. The larger the SPF number doesn't always result in significantly better protection. Similarly, aerosol-based products are becoming more popular among consumers, but may not provide the same level of protection from the sun as lotion-based products. It is critical that consumers have access to accurate information in order to know they are purchasing a product that provides adequate protection from the sun.

Once again, we urge you to reverse the recent decision to delay these critical regulations and to do more to ensure that consumers can purchase sunscreen products and products containing sun protection with the knowledge that they meet FDA's enforceable standards.

Thank you for your prompt attention to this matter. We look forward to your reply.

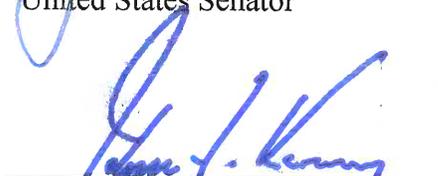
Sincerely,



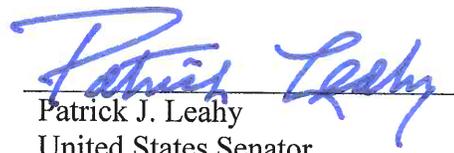
Jack Reed
United States Senator



Charles E. Schumer
United States Senator



John F. Kerry
United States Senator



Patrick J. Leahy
United States Senator



Kirsten E. Gillibrand
United States Senator



Bernard Sanders
United States Senator