

United States Senate

WASHINGTON, DC 20510

May 25, 2011

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

Jacob J. Lew
Director
Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Dear Commissioner Hamburg and Director Lew:

Once again, the summer months are upon us and millions of Americans will be spending time outdoors without adequate protection from the sun. It has now been nearly four years since the Food and Drug Administration (FDA) proposed comprehensive standards for sunscreen products and products claiming to contain sun protection in *Sunscreen Drug Products for Over-the-Counter Human Use; Proposed Amendment of Final Monograph* (72 Fed. Reg. 49070). We strongly urge you to finalize this monograph without further delay so that Americans will no longer be deceived into thinking they are truly protected from the sun when that isn't the case.

The 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. This year, 2 million individuals will be informed that they have a preventable form of skin cancer.

We continue to be disappointed that the FDA has not prioritized the implementation of meaningful, enforceable standards for sunscreen products and products containing sun protection that includes standards for both UVA and UVB protection. Millions of Americans purchase and use over-the-counter sunscreen products and 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.

Researchers have found significant variability in the numbers, words, ratings, colors, and symbols that sunscreen products and products containing sun protection use to make consumers believe that they are being protected from the sun. For example, one product with a Sun Protection Factor (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. Additionally, there is currently no confirmed method of determining if a product protects against UVA rays, and claims that a product is "waterproof" or provides "all day protection" from the sun are unsubstantiated. Clearly and accurately labeled sunscreen products, containing comprehensive information that includes UVA and UVB protection would help keep Americans safer from the sun's harmful rays.

In the past, when Congress inquired about the status of the final monograph regulation, we were told that the number of written comments that the agency received to the proposed monograph delayed its finalization, but that it would be released in the fall of 2010. That time frame has come and gone, and now we need action.

As such, we urge you to issue this final monograph immediately. Once again, we look forward to hearing from you about when this proposed monograph will be finalized and when consumers will be able to 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.

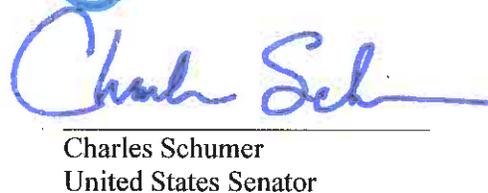
Sincerely,



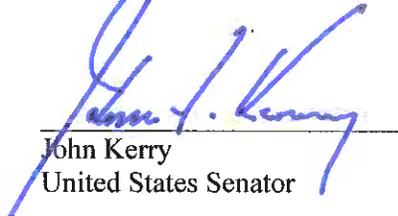
Jack Reed
United States Senator



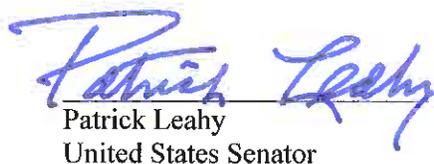
Tom Harkin
United States Senator



Charles Schumer
United States Senator



John Kerry
United States Senator



Patrick Leahy
United States Senator