Congress of the United States Washington, DC 20515

July 20, 2015

The Honorable Barack Obama President of the United States of America The White House 1600 Pennsylvania Ave, NW Washington, DC 20500

Dear Mr. President:

On July 29, 2014, the U.S. Surgeon General's *Call to Action to Prevent Skin Cancer* concluded "We must act with urgency to stop the ever-increasing incidence of skin cancers in the United States." The Centers for Disease Control (CDC) have similarly called for an increased focus on skin cancer prevention. Unfortunately, the Food and Drug Administration (FDA) recently announced it was delaying consideration of eight new sunscreen ingredients that have been used all over the world, many for several years. We are writing to express concerns over the implementation of the bipartisan Sunscreen Innovation Act and ask for your help to ensure the Administration is united in its effort to ensure Americans have access to the latest sunscreens to prevent skin cancer.

According to the *Call to Action to Prevent Skin Cancer*, nearly 5 million Americans are treated for skin cancer every year at an estimated cost of \$8.1 billion to U.S. taxpayers. That figure does not include the cost in human suffering for the families of the nearly 9,000 Americans that die every year from melanoma, more than one every hour of every day. It doesn't have to be this way.

Eight sunscreens have been pending at FDA for many years - some for over 13 years - without final decisions. In 2014, Congress enacted the bipartisan Sunscreen Innovation Act to establish a transparent and timely application process that addressed the existing process issues raised by FDA. This legislation was drafted in consultation with FDA, the public health community, the physician community and sunscreen manufacturers and was enacted on a bipartisan basis — in fact it passed by unanimous consent.

Despite this bipartisan action to enact historic reforms and an Administration-wide focus on prevention, FDA has failed to approve any new sunscreen ingredients. The FDA has even failed to approve an over-the-counter sunscreen ingredient that it already approved as safe and effective in 2006 under a New Drug Application (NDA).

Instead of acting according to the Surgeon General's plea "with urgency to stop the ever-increasing incidence of skin cancers in the United States," FDA instead stated publicly "U.S.

¹ U.S. Department of Health and Human Services. *The Surgeon General's Call to Action to Prevent Skin Cancer*. Washington, DC: Office of the Surgeon General; page 65, July 29, 2014, *available at* http://www.surgeongeneral.gov/library/calls/prevent-skin-cancer/call-to-action-prevent-skin-cancer.pdf.

consumers currently have access to a great number of sunscreen products."³ This approach creates a huge disincentive to innovation because it suggests FDA does not view new skin cancer prevention innovations as urgent.

The best way to survive skin cancer is to prevent it in the first place. We urge you to ensure that your Administration's calls for urgency in skin cancer prevention are heeded at the FDA so that Americans have access to the latest skin cancer prevention technology as soon as possible. The 5 million Americans that will be diagnosed with skin cancer in 2015 expect us all to work together to solve this public health epidemic.

Thank you for your help in addressing this urgent and bipartisan issue.

Sincerely,

ED WHITFIELD

Member of Congress

TEVE STIVERS

Member of Congress

MARSHA BLACKBURN

Member of Congress

SAM FARR

Member of Congress

DEBBIE DINGELL

Member of Congress

CHARLIE RANGEL

Member of Congress

THOMAS J. ROONEY

Member of Congress

BRETT GUTHRIE

Member of Congress

³ Michele, Theresa, FDA is Systematically Screening For Safe Sunscreens, *Wall Street Journal*, March 30, 2015, available at http://www.wsj.com/articles/fda-is-systematically-screening-for-safe-sunscreens-letters-to-the-editor-1427649129.

ANDY BARR
Member of Congress

HAROLD ROGERS Member of Congress

PATRICK TIBERI Member of Congress

ROBERT LATTA
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JAMES P. McGOVERN Member of Congress

JOHN CARNEY
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