Testimony of Michael Werner, JD
Partner, Holland & Knight
On behalf of
The Public Access to SunScreens (PASS) Coalition
House Committee on Energy and Commerce
Subcommittee on Health
September 13, 2017
Summary

The Public Access to SunScreens (PASS) Coalition is a multi-stakeholder coalition composed of public health groups, dermatologists, sunscreen manufacturers, and leading advocates for skin cancer patients. The PASS Coalition was formed to ensure Americans have access to the latest sunscreen technology to curb the skin cancer epidemic in the United States.

According to the U.S. Surgeon General, over 5 million Americans are treated for skin cancer every year, costing American taxpayers $8.1 billion annually. Based on the skin cancer epidemic in the U.S., Americans must have access to all available safe and effective sunscreen products, especially those that have been available for years in Europe and elsewhere and have been shown to offer a public health benefit to the populations that have been using these products.

In a joint effort to address the skin cancer epidemic, Congress, FDA, the PASS Coalition, and other stakeholders came together to enact the bipartisan Sunscreen Innovation Act (SIA; Public Law 113-195) in 2014, which included several provisions to improve Americans' access to OTC sunscreen ingredients. FDA has met all the timelines required by the SIA. Unfortunately, none of the eight pending sunscreen ingredients have yet received a final decision.

The PASS Coalition supports the efforts to enact reforms to the OTC drug approval process. As Congress considers OTC reform legislation, the PASS Coalition has several principles for this Committee to consider in drafting your reform legislation. These principles have been developed based on feedback from the FDA, Congress, and other public health groups and industry stakeholders.

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Good morning, Chairman Burgess, Ranking Member Green, and members of the Subcommittee, my name is Michael Werner. I am a partner at the law firm of Holland & Knight and a public policy advisor to the Public Access to SunScreens Coalition (PASS Coalition). Thank you for inviting me to testify today regarding efforts to improve and strengthen the approval process for over-the-counter (OTC) products, including sunscreens.

The PASS Coalition is a multi-stakeholder coalition composed of public health groups, dermatologists, sunscreen manufacturers, and leading advocates for skin cancer patients. The PASS Coalition was formed to ensure Americans have access to the latest sunscreen technology to curb the skin cancer epidemic in the United States. The PASS Coalition's mission is to work collaboratively with all stakeholders, including the FDA, the White House, Congress, health providers, consumer organizations, and sunscreen manufacturers, to establish a transparent review within a predictable timeframe for pending time and extent applications (TEAs) for OTC sunscreen ingredients. We are also committed to ensuring that FDA has the resources it needs to conduct the pre-market review of sunscreen ingredients.

In a joint effort to address the skin cancer epidemic, Congress, FDA, the PASS Coalition, and other stakeholders came together to enact the bipartisan Sunscreen Innovation Act (SIA; Public Law 113-195) in 2014. By working together and across the aisle, Congress, FDA and stakeholders identified a number of regulatory barriers to the consideration of OTC sunscreen ingredients and created historic reforms to address these barriers for sunscreen ingredients. The SIA was ultimately enacted by both the House and Senate by voice vote.

The PASS Coalition supports the efforts of the House Energy & Commerce Committee, and your counterparts in the Senate, to extend similar reforms achieved for sunscreens to other OTC product categories. We also support the establishment of a user fee program to provide FDA with the resources to implement these reforms. Based on our experience over the last three years implementing the SIA and productive conversations with Dr. Woodcock and Deputy Commissioner Anna Abram, we also believe that there are several improvements that are necessary to help continue to improve the review process for pending sunscreen ingredients. The OTC reform legislation being considered by the Subcommittee provides the opportunity to codify these improvements to finally achieve the promise of the SIA.

Public Health Impact of Skin Cancer

Mr. Chairman, skin cancer is a public health crisis in the United States. On July 29, 2014, the U.S. Surgeon General issued *A Call to Action to Prevent Skin Cancer* stating: "Even though most skin cancers can be prevented, rates of skin cancer, including melanoma, are increasing in the United States." According to the U.S. Surgeon General, over 5 million Americans are treated for skin cancer every year, costing American taxpayers $8.1 billion annually.

The alarming rate of skin cancer means that each year there are now more new cases of skin cancer than the combined incidence of breast cancer, prostate cancer, lung cancer, and colon cancer. Melanoma, attributed primarily to UV exposure, is the deadliest of the skin cancers as a result of its ability to move quickly and spread to distant organs in the body and is rising dramatically across demographics. In the United States, a patient is diagnosed with melanoma every eight minutes and an American loses her life every hour from the disease. Despite recent tremendous advancements in treatment science, the melanoma death rate for patients with metastatic disease has remained static over the past 30 years, and according to the American Cancer Society the incidence of this deadly disease continues to rise at alarming rates. From 1975-2011, rates of melanoma in young men and women ages 20-39 years increased by 34% in men and by 84% in women.

These figures show that Americans must have access to all available safe and effective sunscreen products, especially those that have been available for years in Europe and elsewhere and have been shown to offer a public health benefit to the populations that have been using these products.

The Surgeon General's 2014 *Call to Action* concludes with this powerful recommendation: "We must act with urgency to stop the ever-increasing incidence of skin cancers in the United States."

United States Sunscreen Backlog

The last time a new OTC sunscreen ingredient was approved in the United States was the 1990s. Since 2002, eight new sunscreen ingredients have been submitted for review under the FDA's TEA process. Meanwhile, these ingredients have been widely available in Europe, Asia, and Central and South America for decades. That's why the PASS Coalition supported enactment of

the bipartisan SIA by the Congress. Clearing the backlog of sunscreen applications will ensure that Americans have greater access to broad-spectrum sunscreens, which provide better protection against both UVA and UVB rays.

Overview of Sunscreen Innovation Act Reforms

The SIA represented the culmination of fruitful collaboration between external stakeholders, including the PASS Coalition, the FDA, and Congress, who all saw the need to improve Americans' access to OTC sunscreen products to reduce the incidence of cancer in this country. As a brief reminder, the SIA incorporated several major provisions, including:

- allowing FDA to make scientific decisions on OTC ingredients with administrative orders instead of rulemaking;
- establishing timelines for FDA review of the safety and efficacy of sunscreen active ingredients;
- allowing robust opportunities for public comment and the submission of safety and effectiveness data;
- ensuring a sunscreen ingredient with at least five years of safe and effective use in a comparable jurisdiction is eligible for consideration as under existing FDA regulations;
- requiring FDA to issue final guidance on the safety and effectiveness data required for FDA to review new sunscreen ingredients.

FDA has met all the timelines required by the SIA. Unfortunately, none of the eight pending sunscreen ingredients have yet received a final decision.

In 2016, the PASS Coalition contracted with two independent scientists, Edward Sargent, Ph.D., M.P.H., a toxicologist, and Jeffrey B. Travers, M.D., Ph.D., F.A.A.D., a dermatologist, to review FDA's draft guidance and examine proposed orders for the eight pending sunscreen ingredients. The purpose of the independent scientific review was to provide the Coalition with an analysis of FDA's actions and to help the Coalition develop recommendations for an appropriate testing regimen based on the risk profile of the pending sunscreen ingredients and the growing incidence of skin cancer. The independent scientific review resulted in recommendations with validated testing procedures to balance the benefits of additional broad spectrum sunscreen protection versus the risk of skin cancer in addition to those described in FDA's draft guidance. The conclusions of Drs. Sargent and Travers were peer reviewed and published in the Journal of Regulatory Toxicology and Pharmacology in August 2016 and was entitled "Examining the differences in current regulatory processes for sunscreens and proposed safety assessment paradigm."

Based on recent conversations with FDA, there is agreement that some changes to the SIA for the eight pending ingredients would be beneficial to establish an opportunity for meetings with sponsors of new sunscreen ingredients to discuss validated testing procedures that would support a determination of general recognition of safety and effectiveness.

OTC Reform Legislation

The PASS Coalition supports the efforts to enact reforms to the OTC drug approval process. Many of the same structural issues that the SIA sought to address for sunscreens also apply to other categories of products, particularly the requirement for FDA to make OTC drug decisions through rulemaking and the need for a predictable and transparent review process.

As Congress considers OTC reform legislation, the PASS Coalition has several principles for this Committee to consider in drafting your reform legislation. These principles have been developed based on feedback from the FDA, Congress, and other public health groups and industry stakeholders.

First, the eight sunscreen ingredients that already have received proposed sunscreen administrative orders should continue to be considered under the SIA. The first of these pending sunscreen ingredients was submitted in 2002 and has been under FDA review for 15 years. Each ingredient was required to be approved for at least 5 years in a comparable jurisdiction, which means that some of the pending ingredients have over 20 years of international experience. OTC reform legislation should allow sponsors of the eight pending to complete consideration of its ingredients under the SIA. New sunscreen ingredients, as with all other OTC drugs, should go through the OTC reform framework.

Second, any new OTC drug approval pathways must be flexible enough to accommodate new sunscreen ingredients with U.S. or international experience. The OTC reform process should allow sponsors to use U.S. or international safety and effectiveness data as the basis to meet FDA's standard for products generally recognized as safe and effective, similar to the framework established in the TEA process and codified in eligibility requirements of the SIA.

Third, any new OTC drug approval pathway should not require the sponsor of a sunscreen application to file a New Drug Application (NDA) for its active ingredient to be considered for an OTC administrative order. We believe that the NDA process is particularly burdensome for new sunscreen ingredients, and the FDA should have alternate pathways at their disposal to consider these new applications to maximize the ability of safe and effective products to come to

market as soon as possible. For instance, the NDA process evaluates only finished products, however sunscreen active ingredients are included in a variety of seasonal finished products to block UVA and/or UVB radiation from the sun. This is the same rationale used by FDA when it established the TEA process.

Fourth, any OTC reform legislation should authorize FDA to meet individually on a confidential basis with sponsors of sunscreen ingredients to allow for open discussions of confidential commercial information or trade secrets. FDA has expressed a willingness to consider validated alternative testing procedures in support of a determination of general recognition of safety and effectiveness outside of what the agency included in its final guidance on safety and effectiveness data. An individual meeting will also assist in the establishment of testing protocols for tests that have never been performed on a sunscreen ingredients before.

Finally, given the importance of innovation in the OTC space for getting patients the safe and effective products they require, the FDA's testing standards for these products should be periodically reviewed and assessed. As I mentioned previously, independent studies have already concluded that improvements to the testing regimes for sunscreen ingredients can and should be made to incorporate new scientific evidence and appropriately reflect the potential risks of these ingredients with the proven public health benefits of skin cancer prevention.

Ultimately, we believe that the OTC legislation currently being developed by Congress is the proper vehicle for these and other changes to be made to the current OTC framework. Inclusion of provisions that incorporate these principles will ensure Americans have access to sunscreen ingredients that are available across the world. Given the number of new products, labeling changes, and other issues pending regarding the tens of thousands of OTC products in the United

States, the time is now for Congress to act to improve the way these products are considered and approved.

Thank you for the opportunity to testify before you today. I look forward to your questions.