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On behalf of
The Public Access to SunScreens (PASS) Coalition
House Committee on Energy and Commerce
Subcommittee on Health
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Good afternoon. Mr. Chairman, Ranking Member Pallone, and members of the Subcommittee, my name is Wendy Selig. I am President and CEO of the Melanoma Research Alliance (MRA). Thank you for inviting me to testify today on behalf of the Public Access to SunScreens Coalition (PASS Coalition) in support of HR 4250, the Sunscreen Innovation Act, bipartisan legislation co-sponsored by Congressmen Whitfield and Dingell.

The PASS Coalition is a multi-stakeholder group formed to advocate for a regulatory pathway to market for new, safe and effective sunscreen ingredients. Specifically, the purpose of the Coalition is to address a breakdown in the current process for consideration by the Food & Drug Administration (FDA) of pending Time and Extent Applications (TEAs) for over-the-counter (OTC) sunscreen ingredients. The goal of the PASS Coalition 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 and predictable process for pre-market review of sunscreen components.

MRA is a unique non-profit organization whose mission is to end suffering and death due to melanoma by collaborating with all stakeholders to accelerate powerful research, advance cures for all patients, and prevent more melanomas. Our organization, founded by Debra and Leon Black in 2007 under the auspices of the Milken Institute, is the leading private funder of melanoma research, having awarded more than $51 million in cutting edge research around the world. MRA is proud to be an active member of the PASS Coalition.

The Public Health Problem

Mr. Chairman, skin cancer has become a public health crisis in the United States. Today, skin cancer is the most common form of cancer diagnosed in the U.S. Each year there are more new cases of skin cancer -- including melanoma -- than the combined incidence of breast cancer, prostate cancer, lung cancer and colon cancer. Melanoma, which is the deadliest of the skin cancers as a result of its ability to move quickly and spread to distant organs in the body, is rising dramatically across demographics.

In the United States each year, more than 76,000 Americans are diagnosed with melanoma - one every eight minutes - and more than 9,400 Americans die of melanoma - one every hour. 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 the incidence of this deadly disease continues to rise at alarming rates.

MRA's mission is to accelerate the progress of science and innovation with the ultimate goal of defeating this deadly disease. And we have made real strides on the treatment front – especially in the last several years where four new drugs have been approved for use by the sickest of melanoma patients. We commend the FDA for its work in this area, including landmark efforts to evaluate and approve new modalities of treatment in immunotherapy, companion diagnostics for biomarker-driven targeted therapies, combination therapies, and activating the new Breakthrough Therapy designation to speed review processes. We see the agency as a vital partner in our fight against melanoma. These drugs are saving lives, while their approval and use are paving the way for continued investment by our academic and industry partners in innovation that will bring about continued dramatic progress.

Still, we know that more effective options for prevention, diagnosis, prognosis, and treatment of melanoma are urgently needed.

That's why I'm here today. Everyone is at risk for developing melanoma, regardless of demographics. One of the risk factors for skin cancer, and specifically melanoma, is exposure to UV radiation. In fact, one blistering sunburn during childhood can double an individual's chance of developing melanoma later in life. We know that people can reduce their risk of suffering and dying from this disease by limiting their exposure to dangerous UV. Along with others in the field, we take every opportunity to urge people to protect themselves and their loved ones by reducing their exposure to UV (from the sun and tanning beds), to examine their skin and watch for changes, and to see a dermatologist regularly, especially if they notice a change. **A central component of our message to the public is that people should use effective sunscreen protection all year round.**

As an organization that is committed to the best science and accelerating innovation, MRA has become increasingly concerned that the current regulatory environment in the U.S. is a barrier to enhanced innovation in the area of bringing the most effective products forward to the public.

As you know Mr. Chairman, FDA is responsible for ensuring the safety and effectiveness of all drugs. FDA's authority over drugs includes medical claims related to sunscreens and sunscreen ingredients. FDA estimated that it would take 90-180 days to evaluate TEA applications and approve approximate 30 new OTC products each year under the TEA process. Despite a number of sunscreen applications pending FDA review and approval -- some that were filed over 10 years ago -- FDA has not completed the review of, or approved, any new sunscreen component under its existing OTC process since the 1990s. As a result, U.S. consumers have not had the benefit of accessing the most cutting edge science and innovation in this field.

I'd like to reiterate my earlier point, Mr. Chairman, about treatments for melanoma. The FDA has recently approved several new drugs for melanoma patients. Unfortunately, while the FDA

is moving forward with timely review and approvals for cutting edge products to treat patients with melanoma -- and we all commend the agency for doing so -- it hasn't fully reviewed or approved any of the latest products that have been designed to *prevent* melanoma and skin cancer in the first place. Mr. Chairman, we can do better.

It's clear the current sunscreen pre-market review process needs to be reformed to ensure timely review and to add transparency and predictability. The general public agrees. A U.S. National poll conducted in 2013 found that 86 percent of Americans support reforms that ensure the United States has access to the latest sunscreen technology.

It is important to point out that the sunscreens Americans use today can be effective for those who use them correctly, which includes sufficient application and re-application, as well as year-round. However, the latest products developed and used around the world, some of which remain pending at FDA for over 10 years, offer important steps forward in the science of broad spectrum coverage, the length of efficacy of active ingredients and sensorial attributes. These should be made available in the U.S. if found to be safe and effective. Picture this scenario as a point of comparison -- imagine if melanoma patients in the United States were told that although new scientific advances in treatment of melanoma are being made available in the rest of the world, in the U.S. they could only have access to treatments available more than a decade ago. It is hard to imagine that we would accept that situation, yet this is precisely where we are today when it comes to sunscreen regulation.

Among the innovations that the companies have been making in sunscreen filters and products are new ways of expanding the broad spectrum efficacy, taking into account improvements in scientific understanding of the different wavelengths of UV rays and the dangers they pose to our skin. Additionally, companies have been working to address issues of consumer preference and sensorial attributes (products that feel less heavy or sticky when applied correctly to the skin.) This is important as people may not use a product as directed for maximum efficacy if that product is uncomfortable to apply. As those of us with children know all too well when our kids squirm when we approach with a tube of sunscreen, finding innovative ways to make these products more user friendly can help improve the rate at which people are using them properly and to maximum effect. Unfortunately, given the history of stalled reviews under the FDA's current process, there is a strong disincentive for companies to invest in sunscreen innovation in the U.S. market.

FDA's Regulatory Approval Approach

Let me provide some background information on the FDA review process for these products. In 1972, FDA began reviewing OTC products already on the market not covered by a New Drug Application (NDA). FDA established review panels to evaluate OTC drugs on the market pre-1972 by category and began developing monographs for each category of drug product. If an OTC drug meets the criteria established in a monograph, it is considered "generally recognized as safe and effective," or GRASE, and does not need independent premarket approval. The existing OTC drug monographs are codified in regulation. Although several versions of a final monograph for sunscreen products have been developed, a final monograph has not been implemented.

In January 2002, FDA published a final rule establishing the TEA process to consider new applications for OTC products that were not covered by existing OTC monographs and to allow for changes to the monographs to include new products or creation of new monographs. The final rulemaking stated that FDA "will strive to complete TEA evaluations in 90-180 days." Sunscreen ingredients were put in the category of products to be reviewed under this process.

The criteria for a product to be eligible for the TEA process are:

- It must be marketed for OTC purchase by consumers; and
- It must have been marketed for use as an OTC product for a minimum of 5 continuous years in the same country and in sufficient quantity.

FDA interpreted 5 continuous years of "use" as either in the US or in a foreign country.

The TEA Process

The TEA application process follows the following timeline:

- **Application.** A sponsor submits an application with a description of the OTC drug component and its basic chemical make-up, a list of all the countries in which the OTC drug component has been marketed, the duration of marketing, and detailed information about how the OTC drug component has been marketed.
- **Notice of Eligibility.** If FDA considers the drug eligible for consideration in the OTC monograph system, it publishes a Notice of Eligibility in the Federal Register and accepts public comment on the application.
- **Public Comment.** The sponsor and other interested parties can submit public comments, including additional data to support or challenge safety and effectiveness.
- **Determination.** FDA makes a determination regarding whether the OTC drug component is GRASE.
- **Rulemaking.** If an application is determined to be GRASE, FDA publishes a proposed rulemaking to either add the OTC drug component to an existing OTC monograph or create a new monograph. After a public comment period, FDA publishes a final rule and the OTC drug component may be marketed in the U.S. according to the terms of the final rule.

Unfortunately, a final rule approving a TEA application has never been issued for any new OTC drug component, including for sunscreen. Some sunscreen applications have been pending since the TEA process was established in 2002. And remember, to be eligible for the TEA program, these products had to have been marketed for at least 5 years prior to eligibility. Therefore, some of the pending sunscreen products were developed in the 1990s and have been used all over the world since then; however, FDA has not completed a review or approved any of these products in the United States.

Imagine our lives if we were living with 1990s technology. Cell phones would still be the size of a briefcase, iPods would not exist, and air bags would still be an optional feature on luxury cars.

Below is a list of the current -- and still pending -- sunscreen ingredient applications:

Pending Sunscreen Ingredient Time and Extent Applications			
Ingredient	**Date of Submission**	**Eligibility Determination**	**Docket**
Amiloxate	8/14/2002	7/11/2003	FDA-2003-N-0196
Enzacamene	8/21/2002	7/11/2003	FDA-2003-N-0196
Octyl Triazone	8/21/2002	7/11/2003	FDA-2003-N-0196
Bemotrizinol	4/11/2005	12/5/2005	FDA-2005-N-0453
Bisoctrizole	4/11/2005	12/5/2005	FDA-2005-N-0453
Iscotrizinol	9/16/2005	7/26/2006	FDA-2006-O-0314
Ecamsule	9/18/2007	9/12/2008	FDA-2008-N-0474
Drometrizole Trisiloxane	1/21/2009	6/2/2010	FDA-2003-N-0196

A Proposal for Reform

The PASS Coalition supports the Sunscreen Innovation Act. This bipartisan/bicameral proposal will improve the TEA process to expedite the approval of applications for components of OTC sunscreen products. While maintaining the basic structure and eligibility standards of the current review process, the Act provides transparency and predictability.

The Act streamlines the TEA process by codifying a timeframe for review and providing FDA with the authority to make a final scientific decision on the application instead of through rulemaking. It ensures that all submissions are reviewed within a predictable timeframe by requiring that the current sunscreen backlog be reviewed within 8 months and new submissions be reviewed within 11 months.

While keeping the existing process whereby FDA makes an eligibility determination, the Act says an existing Advisory Committee of experts, the Nonprescription Drugs Advisory Committee (NDAC), will review the safety and efficacy data. Under the Act, NDAC will make a recommendation to FDA regarding whether the product is safe and effective. But importantly, this is only a recommendation. FDA remains the final arbiter about whether a product is approved for marketing in the United States. FDA has the authority to review every product before it goes to market.

The Act also requires FDA to submit a report regarding the progress of the new review and approval process to Congress 12 months following passage of the bill and every two years thereafter.

The legislation is a pragmatic way of alleviating the current backlog of sunscreen ingredients and streamlining the TEA process for all sunscreen ingredients. Its enactment would be a victory for all parties -- FDA would be administering a process that ensures safe and effective products reach the market as soon as possible; manufacturers would know that their product application would receive a timely review and would be incentivized to invest in innovation to prevent more

melanomas; and most importantly, Americans could get access to the most innovative sunscreen products.

Mr. Chairman, and members of the Subcommittee, I commend you for your leadership in holding this hearing today. May is Melanoma Awareness Month. As the weather improves and people are once again making plans for outdoor activities, MRA and the PASS Coalition strongly urge you to support and enact the Sunscreen Innovation Act. Doing so will bring overdue and needed reforms to the FDA review process and provide a commonsense approach to empowering Americans to reduce their risk for melanoma by providing a responsible path for new, effective products to reach the American consumer.

The PASS Coalition looks forward to working collaboratively with Congress and FDA to further improve the Sunscreen Innovation Act and ensure it is signed by the President this year.

Thank you. I'd be happy to answer any questions you might have.