FDLI'S FOOD *and* DRUG
POLICY FORUM

Finding the Right Benefit-Risk Balance in U.S. Sunscreen Regulation

Wendy K.D. Selig
Founder & CEO of WSCollaborative

VOLUME 5, ISSUE 5 // MAY 29, 2015

THE FOOD AND DRUG LAW INSTITUTE
1155 15TH STREET NW, SUITE 910 // WASHINGTON, DC 20005
www.fdli.org

FDLI

FOOD // DRUGS // ANIMAL DRUGS // BIOLOGICS // COSMETICS // DIAGNOSTICS // DIETARY SUPPLEMENTS // MEDICAL DEVICES // TOBACCO

INFORMATION FOR SUBSCRIBERS AND PURCHASERS

License Agreement (the "Agreement") and Terms of Use for End Users of FDLI Digital Publication Product Services (the "Services")

THIS IS AN AGREEMENT BETWEEN YOU, (THE "END USER"), AND THE FOOD AND DRUG LAW INSTITUTE ("FDLI"). FDLI IS THE PROVIDER OF THE SERVICES THAT PERMIT END USERS, (LIMITED TO FDLI MEMBERS OR NONMEMBER SUBSCRIBERS OR PURCHASERS OR OTHERS AS DETERMINED BY FDLI) TO LICENSE DIGITAL PUBLICATION PRODUCTS (THE "DIGITAL PUBLICATION PRODUCTS") FOR END USER USE ONLY UNDER THE TERMS AND CONDITIONS SET FORTH IN THIS AGREEMENT. PLEASE READ THIS LICENSE AGREEMENT AND TERMS OF USE, AND ALL RULES AND POLICIES FOR THE SERVICES (INCLUDING, BUT NOT LIMITED TO, ANY RULES OR USAGE PROVISIONS SPECIFIED ON THE FDLI WEBSITE) BEFORE USING THE PRODUCTS. BY USING THE PRODUCTS, YOU AGREE TO BE BOUND BY THE TERMS OF THIS AGREEMENT.

Digital Publication Products

FDLI website: The FDLI website enables the End User to download this Digital Publication Product to a personal computer or personal handheld device solely for personal use.

Use of Digital Publication Products: Upon your payment of the applicable fees, FDLI grants you the non-exclusive right to retain a permanent copy of the applicable Digital Publication Product and to view, print and use such Digital Publication Product an unlimited number of times, solely for your personal, non-commercial use.

Restrictions: The End User agrees that Digital Publication Products contain proprietary material that is owned by FDLI, and is protected by United States copyright laws. For reprint permissions or distribution inquiries, contact FDLI at (202) 371-1420.

For subscription or purchasing information, visit **www.fdli.org.**

Disclaimer

The Food and Drug Law Institute, founded in 1949, is a non-profit organization that provides a marketplace for discussing food and drug law issues through conferences, publications and member interaction.

The views, opinions and statements expressed in this article are those of the author(s). The Food and Drug Law Institute neither contributes to nor endorses Forum articles. *As a not-for-profit 501(c)(3) organization, FDLI does not engage in advocacy activities.*

FDLI

1155 15th Street NW, Ste. 910, Washington, D.C. 20005
Tel: (202) 371-1420; Fax: (202) 371-0649
email: comments@fdli.org
www.fdli.org

FDLI' S FOOD AND DRUG POLICY FORUM

Judy Rein JD, MA
FDLI, Director of Publications

FDLI'S FOOD AND DRUG POLICY FORUM EDITORIAL ADVISORY BOARD

TABLE OF CONTENTS

Finding the Right Benefit-Risk Balance in U.S. Sunscreen Regulation

Wendy Selig, Founder & CEO, WSCollaborative

I. INTRODUCTION

Finding the right balance in evaluating benefit and risk when it comes to cancer prevention is a difficult challenge. In the case of modernizing regulation of sunscreen ingredients in the US, stakeholders are still struggling to find balance, even when presented with the opportunity to advance innovation in preventing deadly skin cancer.

After years of frustration with the current regulatory framework for new sunscreen ingredients in the US, public health organizations, medical specialists, and ingredient manufacturers mobilized behind a legislative solution to streamline the review process. Championed by the Public Access to Sunscreens (PASS) Coalition, the Sunscreen Innovation Act (SIA), which President Obama signed into law in late 2014, (P.L. 113-195) sought to streamline the US Food and Drug Administration's (FDA) Time and Extent Application (TEA) process for Over-The-Counter (OTC) review of sunscreen ingredients. The bipartisan legislation passed the House and Senate with unanimous support as lawmakers moved to address barriers in the regulatory process that had created a virtual standstill in consideration and approval of new sunscreen technology. This new law took aim at the mounting public health crisis of rising skin cancer and melanoma rates in the US, designing a more transparent regulatory approach to review of products that have been widely available and used for five or more years by consumers in other countries.[1]

Enactment of the SIA brought with it the hope among proponents that FDA, once turning its attention to the eight pending applications that had languished for years without review, could expeditiously consider the safety and efficacy of those submissions and work cooperatively to enhance innovative options available to US consumers. However, FDA's recent actions seeking additional studies and data from the sponsors reflect the agency's concerns about potential long-term safety risks. Proponents of the new law, public health advocates and ingredient manufacturers, have expressed renewed frustration with the agency's approach, noting that the types of data requested for the pending applications were more akin to those required for a New Drug Approval process (NDA). This represents a significantly higher standard than that applied to ingredients currently available in sunscreens marketed in the US and appears to reflect a regulatory paradigm that prioritizes concern about risk over focus on benefit.[2]

This situation raises a key policy question: what is the appropriate balance in weighing benefit and risk in evaluating new tools designed for broad and repeated use by virtually everyone and intended to protect people from a known carcinogen, in this case providing additional options and choices for reducing UV exposure and with it the risk of contracting potentially deadly skin cancer? FDA is charged with determining the answer to this question, but has thus far struggled to do so in a manner that responds to the concerns of all stakeholders. Instead FDA has opted to allow its concern about *potential* health risks related to exposure to new ingredients to take precedence over any interest in allowing the use of new sunscreen filters by US consumers seeking to protect themselves from the *known* risks of UV exposure. The case of sunscreen ingredient regulation in the US touches on a range of important issues, including:

- the limitations of the current regulatory system for all OTC products,
- the challenges in the TEA process implemented in the 2000s, and, especially,
- the specific issues arising in the sunscreen case reflect the difficulty in balancing a known serious health risk (cancer-causing properties of UV radiation exposure) with a potential long-term exposure risk that might result from use of new sunscreen filters (or continued use of the filters currently widely used in the US, for that matter).

This article traces the history of the issues that led to enactment of the SIA and the FDA's actions in beginning to implement the new law, making recommendations to better meet the public health challenge of rising skin cancer and melanoma rates in the US.

POLICY RECOMMENDATIONS

1. Move beyond recriminations relating to the years of delay that stalled consideration of the eight pending applications. FDA should negotiate a reasonable science-based framework for considering the safety and efficacy of those specific ingredients, looking at existing data, relevant experience in other countries, and comparable standards to those used to assess current Monograph products in wide use within the US. By developing a moderated "grandfathering" approach to those applications caught up in the delay, which everyone agrees should not have occurred, the decks can be cleared for implementation of a more balanced prospective framework.
2. Find and apply prospectively a consensus approach in balancing benefit and risk by reassessing FDA's paradigm for evaluation of sunscreen ingredients (taking into account public preferences and appropriate long-term safety concerns);
3. Secure sustained additional resources for FDA to allow for adequate prioritization and conduct of these activities, including meeting the timelines set forth by the Sunscreen Innovation Act and finalizing the sunscreen Monograph; and
4. Although not discussed in-depth in this article, the experience with sunscreen regulation points to the need to prioritize efforts to develop more streamlined procedures for regulation of OTC products in general, including revisiting a proposal to engage advisory committee input for individual cases.

II. BACKGROUND

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 US. 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. Incidence of 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.[3]

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 remains high, and the incidence of this deadly disease continues to rise at alarming rates.[4]

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. People can reduce their risk of suffering and dying from this disease by limiting their exposure to dangerous UV rays, adopting a multi-faceted approach that includes: limiting exposure to the sun (seeking shade, covering up and using sunscreen), avoiding tanning beds, examining their skin to watch for changes, and seeing a dermatologist regularly, especially if they notice a change. All of these important steps were highlighted in 2014 as the US Surgeon General issued a Call to Action focused on the public health crisis of skin cancer. A central component of the public health messaging around skin cancer prevention is that people should use effective sunscreen protection all year round.[5]

FDA has recently approved several new drugs for skin cancer, and has been proactive in approving new therapies and hope for melanoma patients, especially those with late-stage disease. In the last five years, significant progress has been made on the treatment front—with eight therapies now available for use by the sickest of melanoma patients.[6] FDA is to be commended 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. New drugs are saving lives, while their approval and use are paving the way for continued investment by academia and industry in innovation that will bring about continued dramatic progress.

While FDA is moving forward with timely review and approvals for cutting-edge products to treat patients with melanoma, until very recently it had not fully reviewed and, as of this writing, it had not approved for US consumer use any of the latest submitted applications for products designed to reduce skin damage caused by the sun, with the goal of *preventing more* melanomas and skin cancers in the first place. The result is that, despite significant new knowledge and scientific discovery in the areas of skin biology, understanding of the complexity of UV radiation and its interaction with human skin, and the causes of melanoma and other skin cancers, US consumers continue to have limited choices of sunscreen filters, most of which were developed close to 20 years ago, even as people in countries around the world have access to more choices and newer sunscreen technology, especially in the realm of filters designed to block UVA rays, which have more recently been shown to be among the most damaging to the skin.[7]

While the sunscreens Americans use today can be effective for those who use them correctly (including sufficient application and reapplication, as well as year-round use), adherence to sunscreen recommendations

remains low in the US, a situation that could be addressed with improved formulations and better ingredient options. The newer products developed and used around the world offer important steps forward in the science of broad spectrum coverage, the length of efficacy of active ingredients and sensorial attributes. Among the innovations in newer sunscreen filters and products are novel means of expanding the broad spectrum efficacy, taking into account improvements in scientific understanding of the different wavelengths of UV rays—especially UVA rays—and the dangers they pose to human skin.[8]

Additionally, research has been ongoing to address issues of consumer preference and sensorial attributes (products that feel less heavy or sticky when applied correctly to the skin). Continued innovation in this area is important, because people may not use a product as directed for maximum efficacy if that product is uncomfortable to apply. As anyone who has tried to apply sunscreen to a squirming child knows, 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.

According to industry stakeholders, the history of inaction in reviewing pending applications and the lack of transparency in the regulatory framework have created strong disincentives for ongoing investment in sunscreen innovation for the U.S. market.[9]

A. The Sunscreen Innovation Act: Latest Chapter in a Long History

On November 26, 2014, President Obama signed into law the Sunscreen Innovation Act (SIA), bipartisan legislation designed to reform the sunscreen premarket review procedures in order to ensure more timely review and to enhance transparency and predictability in the process.

The legislation came about as a result of a two-year effort by a broad coalition of public health advocates, medical specialists, and sunscreen manufacturers to educate Congress and the public about the need to streamline the cumbersome US regulatory process, which had ground to a halt. No new sunscreen ingredients have been approved in the US under the OTC process since the late 1990s, despite the fact that several newer products pending FDA review were being widely used in other countries.[10]

The history of the OTC process spans more than 40 years. 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. In 1978 the FDA issued advanced notice of proposed rulemaking for sunscreens—the first FDA action truly focused on OTC sunscreens.[11] While several versions of a final monograph for sunscreen products have been developed since the 1993 tentative final monograph was issued,[12] a final monograph has not been implemented, although in 2011 FDA issued a regulation covering testing and labeling claims such as sweat proof, waterproof, and broad spectrum.[13]

In an attempt to enhance the process, 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." Several 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 that 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 five continuous years in the same country and in sufficient quantity. FDA has interpreted five continuous years of "use" as either in the US or in a foreign country.[14]

B. The TEA Process[15]

The TEA application process generally includes the following steps:

1. *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/extent of marketing, and detailed information about how the OTC drug component has been marketed.

2. *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.

3. *Public Comment.* The sponsor and other interested parties can submit public comments, including additional data to support or challenge safety and effectiveness.

4. *Determination.* FDA makes a determination regarding whether the OTC drug component is GRASE.

5. *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 US according to the terms of the final rule.

Despite predictions about its purpose and likely impact, a final rule approving a TEA application has never been issued for any new OTC drug component, including for sunscreen.

The SIA was designed to 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 new law provided much-needed transparency and predictability 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 was designed to ensure that all submissions are reviewed within a predictable timeframe by requiring that the current sunscreen backlog be reviewed within eight months and new submissions be reviewed within 11 months.

Initial versions of the SIA legislation incorporated the option of engaging the Nonprescription Drugs Advisory Committee (NDAC), as a means to respond to concerns about the highly technical nature of the submissions and ensure that FDA had access to the necessary expertise to make appropriate and timely review of pending applications. Proponents of this provision argued that it would help to ensure the deadlines envisioned by the SIA while maintaining FDA as the final arbiter in approving products for use in the US. The advisory

committee language was removed from the final legislation, however, in part due to concerns raised by certain stakeholders that the NDAC did not have sufficient expertise in the sunscreen arena.[16] Others raised concerns about establishing precedent. Rather than attempt to refine the advisory committee provision to address these concerns, it was removed before the bill was finalized. Despite calls from supporters of the legislation, the new law also did not include much-needed additional resources for the agency to allow it to maintain focus on this area of its mission.

Since enactment of the SIA, the FDA has met the letter of the law, adhering to the timetables and issuing proposed orders on all of the eight pending applications.[17] In each case, the agency found that it did not have sufficient data to determine whether the ingredient could be found to meet the GRASE standard, and requested additional studies regarding toxicity and systemic exposure.[18, 19] Notably, one of the ingredients reviewed among this group, Ecamsule, was previously the subject of a separate and successful New Drug Application (NDA) process in March 2008, yet FDA still concluded that it needed more data on this ingredient to evaluate it for GRASE under the OTC process. Subsequent to the issuance of these proposed orders FDA officials have met with the sponsors to discuss their views. This marked the very first time in the many years that the applications have been pending that FDA has provided any type of feedback to the sponsors. In a blog post explaining its actions to date, FDA officials cited discussions at the NDAC during a meeting in September 2014, during which members discussed the scope of testing that should be required in evaluating active sunscreen ingredients.[20]

As of this writing, there are ongoing discussions among the stakeholders, including Members of Congress who led the legislative effort to enact the SIA, regarding a path forward. In particular, it remains to be seen if and how manufacturers will respond to the new data requests from FDA and to what extent congressional interest may lead to further modifications to the OTC and TEA processes. What is clear is that despite progress made in elevating this issue as a priority for FDA, Congress, and the public through enactment of the SIA, the cumbersome nature of the regulatory process and the need for a more balanced benefit-risk framework for evaluation of sunscreen ingredients remain areas ripe for continued policy-focused discussion.

III. MAJOR ISSUES

The actions taken by FDA over the past four to five months, which were required by the SIA, are signs that the new law is having an effect in advancing a dialogue about the review process for sunscreen ingredients and providing sponsors with long-awaited agency feedback on pending applications under the TEA process. However, sponsors, public health advocates, journalists, and congressional leaders have all expressed frustration about an apparent "raising of the bar" for required data on these eight pending ingredients as compared to the monograph ingredients already widely available in the US.[21, 22]

In public statements and in meetings with advocates, FDA officials have repeatedly stated their concern about the potential for long-term harms to the health of the public that might occur as a result of systemic exposure to sunscreen ingredients.[23] Their comments suggest a decision to prioritize avoiding potential harms over a desire to enhance options available to consumers for preventing UV exposure risk for skin cancer.[24, 25] On September 4 – 5, 2015, an Advisory Committee meeting discussed a framework for balancing benefit and risk that reflects these concerns.[26] The agency's actions in evaluating the eight pending new filter applications signal a move to apply this new framework. However, these actions fall short of fully addressing the problem, given that the pending applications have already languished for many years, the ingredients under review have been widely used for many years in other countries, and those additional data

requirements appear to represent an overly stringent standard that had not been applied to the products currently in the monograph and widely used in the US.

It is important to note that FDA has a responsibility to carefully consider the safety of products approved for widespread use and, once considered GRASE, available for reformulation in a range of ways. The public health community has supported the need for careful review of new ingredient applications, especially in light of the concerns expressed by the potential for long-term, regular use of products on the skin to have latent health effects. However, these concerns must be carefully balanced with an equally—some might argue even more—important concern about the known negative health effects of UV exposure for people of all skin types and demographics. This is especially true for children and young adults, who have a much higher likelihood of developing skin cancer and deadly melanoma in their lifetimes if they suffer early overexposure to the sun (and sunburns).[27, 28] One of the issues confronting the public health community in seeking to combat melanoma and skin cancer lies in boosting adherence to the guidelines of virtually all major medical groups regarding sunscreen use as a proven tool to protect against UV exposure and its carcinogenic effects.[29] Studies have shown that people are sensitive to the sensorial qualities and methods of application of sunscreens, suggesting that enhanced adherence to proper sunscreen use could occur if consumers had more options to choose from that meet their lifestyle needs.[30]

There has long been consensus about the link between UV exposure and skin cancer incidence, and recent published studies have more directly demonstrated the strong correlation between UV exposure and melanoma specifically.[31] It is true that effective sunscreen, used properly and consistently, is only one of several strategies needed to reduce skin cancer risks, but it is a very important component of a public health strategy to combat these diseases. Other components include an avoidance of indoor tanning (a WHO-named carcinogen that, incidentally, historically has been only nominally regulated by FDA despite widespread availability in the US) and education/awareness to enhance early detection of skin cancer.[32]

The underlying policy questions to be addressed relate to balancing the benefits and risks of using sunscreens and determining the right level of evidence needed to evaluate both effectiveness in preventing UV exposure (and the skin cancers associated with it) and predicting future potential harms associated with regular application of sunscreen products. This balance should be achieved in a predictable, transparent, and timely manner to ensure that innovation in the sector is not stifled. A review of the statements made by FDA officials in a variety of settings suggests that the agency is concerned about potential downstream risk of systemic exposure to sunscreen ingredients to the point where it has determined that additional studies are needed before it will allow new ingredients into the US market via the OTC process.[33]

In the cancer treatment space, where there is no debate about the vital importance of offering new treatment options to seriously ill patients, FDA has demonstrated a proactive willingness to weigh risk and benefit in a manner that helps to incentivize innovation and accelerate approval of new therapies.[34] The development and enactment of the SIA, along with congressional, media, and public interest in the issues surrounding skin cancer prevention offer FDA an important opportunity to work with all stakeholders to develop a similarly proactive approach in providing tools to help people protect themselves from the effects of UV exposure, including skin cancer and melanoma.

The policy recommendations put forth in this article would help to lay the foundation for development of such an approach. First, by working with the sponsors to completely resolve the lingering frustrations surrounding the pending applications using reasonable standards for evaluating existing data, experience in other geographies, and a flexible approach based on those in place when the applications were originally

filed, FDA should be able to make GRASE decisions comparable to those made for products currently listed in the monograph and already in widespread use in the US.

Second, by defining and publicly articulating a balanced benefit-risk paradigm (with appropriate expert and public input) for consideration of new applications (those filed after enactment of the SIA), FDA will clearly signal to sponsors what type of studies and data, in what format, will be required for a timely GRASE review. This should minimize misaligned expectations by sponsors and reviewers in the future.

Third, it is clear that FDA continues to be under-funded and under-resourced to meet its extremely broad scope of work, forcing resource-allocation decisions that, in the past, have allowed sunscreen regulation to slide further down the priority list. FDA receives about $8 in funding for every American, despite the fact that its oversight covers roughly 25 percent of the US consumer economy.[35] If Congress provided enhanced funding for these important public health functions, FDA could ensure that it has the necessary staff and focus to meet the requirements of the SIA as well as complete final implementation of the existing monograph.

And, finally, the case of sunscreen ingredient regulation should provide insights and learnings that can lead toward a rational restructuring of the entire OTC process. One area ripe for further consideration is the question of ensuring sufficient expert input as FDA is weighing risk and benefit in the prevention arena. During legislative consideration of the SIA, a proposal was made to allow consultation with an Advisory Committee during review of specific applications, however this proposal was not ultimately included in the new law. Revisiting this idea in the broader context of OTC product review to provide appropriate expertise and allow for a more transparent review could provide enhanced stakeholder confidence in the overall process.

A concerted effort by all stakeholders can help bring the right balance to this important arena. Doing so is important to advancing the public health imperative of reducing incidence of skin cancer, and helping to realign our overall approach to prevention.

IV. SUGGESTED RESOURCES

General information on Skin Cancer & Melanoma:

http://www.skincancer.org/skin-cancer-information

http://www.curemelanoma.org/about-melanoma

http://www.melanoma.org/understand-melanoma/preventing-melanoma

http://www.cancer.org/cancer/cancercauses/sunanduvexposure/skincancerpreventionandearlydetection/skin-cancer-prevention-and-early-detection-toc

Background on OTC & TEA Processes:

http://www.raps.org/regulatoryDetail.aspx?id=18340

http://www.passcoalition.com/index.php/legislative-action

Background on SIA:

https://www.govtrack.us/congress/bills/113/s2141

http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/ucm434782.htm

http://www.fdli.org/docs/webinar/compiled-slide-show---sunscreen-innovation-act-2015.pdf?sfvrsn=0

ENDNOTES

1. https://www.govtrack.us/congress/bills/113/s2141.

2. http://www.passcoalition.com/index.php/media-info.

3. http://www.skincancer.org/skin-cancer-information.

4. http://www.curemelanoma.org/about-melanoma/.

5. http://www.surgeongeneral.gov/library/calls/prevent-skin-cancer/call-to-action-prevent-skin-cancer.pdf.

6. http://www.curemelanoma.org/assets/Uploads/MRA-Applauds-Latest-Melanoma-Drug-Approval.pdf.

7. http://www.ewg.org/2014sunscreen/does-europe-have-better-sunscreens/.

8. http://www.ewg.org/2014sunscreen/does-europe-have-better-sunscreens/, http://democrats.energycommerce.house.gov/sites/default/files/documents/Testimony-Faber-DEA-FDA-Regulation-2014-4-7.pdf.

9. http://www.delawareonline.com/story/money/business/2014/08/09/ashland-fda-holds-sunscreen-innovation/13798791/.

10. One new sunscreen ingredient was approved by FDA in this time period. L'Oreal submitted an NDA for approval of the active ingredient used in La Roche Posay sunscreen known as Mexoryl, which triggered a completely different review process than those envisioned by the TEA process. Manufacturers and supporters of the SIA have repeatedly stated that the NDA pathway is not a workable alternative to fixing the TEA process given the cost of pursuing an NDA and the inability to change formulations once a product is approved without having to resubmit additional NDA filings.

11. http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Over-the-CounterOTCDrugs/StatusofOTCRulemakings/ucm090127.pdf.

12. http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Over-the-CounterOTCDrugs/StatusofOTCRulemakings/ucm090174.pdf.

13. 21 CFR 201.327. For a summary see www.fda.gov/forconsumers/consumerupdates/ucm258416.htm.

14. http://www.raps.org/regulatoryDetail.aspx?id=18340.

15. http://www.raps.org/regulatoryDetail.aspx?id=18340.

16. http://democrats.energycommerce.house.gov/sites/default/files/documents/Testimony-Faber-DEA-FDA-Regulation-2014-4-7.pdf.

17. Two of the eight letters were issued in late 2014, before the SIA was enacted but as the legislation was completing its journey through Congress. The remaining six were issued in early 2015. In all cases FDA concluded it did not have sufficient information upon which to base a GRASE determination.

18. http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/ucm434782.htm.

19. http://blogs.fda.gov/fdavoice/index.php/2015/02/shedding-some-light-on-fdas-review-of-sunscreen-ingredients-and-the-sunscreen-innovation-act/.

20. http://blogs.fda.gov/fdavoice/index.php/2015/02/shedding-some-light-on-fdas-review-of-sunscreen-ingredients-and-the-sunscreen-innovation-act/.

21. http://www.wsj.com/articles/washingtons-skin-cancer-hostages-1426287044.

22. http://www.passcoalition.com/index.php/media-info.

23. http://www.regulations.gov/#!documentDetail;D=FDA-1978-N-0018-0773.

24. http://blogs.fda.gov/fdavoice/index.php/2015/02/shedding-some-light-on-fdas-review-of-sunscreen-ingredients-and-the-sunscreen-innovation-act/.

25. http://democrats.energycommerce.house.gov/sites/default/files/documents/Testimony-Woodcock-DEA-FDA-Regulation-2014-4-7.pdf.

26. http://www.fda.gov/AdvisoryCommittees/Calendar/ucm407137.htm.

27. http://www.skincancer.org/prevention/sunburn.

28. https://www.aap.org/en-us/about-the-aap/aap-press-room/news-features-and-safety-tips/pages/Sun-and-Water-Safety-Tips.aspx.

29. http://www.ncbi.nlm.nih.gov/pubmed/22271688.

30. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3774433/.

31. http://www.ncbi.nlm.nih.gov/pubmed/21135266,

32. http://jco.ascopubs.org/content/29/3/257.long.

33. http://www.cancer.org/acs/groups/cid/documents/webcontent/003184-pdf.pdf.

34. http://democrats.energycommerce.house.gov/sites/default/files/documents/Testimony-Woodcock-DEA-FDA-Regulation-2014-4-7.pdf.

35. http://www.ascopost.com/issues/november-1,-2013/a-look-ahead-how-the-fda-is-adapting-in-the-era-of-precision-medicine.aspx.

36. https://fdaalliance.files.wordpress.com/2011/03/fda_cornerstone_of_american_economy_finalforprint2.pdf.

ABOUT THE AUTHOR

Wendy K.D. Selig is Founder & CEO of WSCollaborative, working on cross-sector health collaborations. Previously, Selig was President & CEO of the Melanoma Research Alliance.

She is President of the National Coalition of Cancer Research, chaired United for Medical Research and One Voice Against Cancer, and served in the NCI Director's Consumer Liaison Group, the Clinical Trials Transformation Initiative, and the Public Access to Sunscreens Coalition.

She has held leadership staff positions for the American Cancer Society Cancer Action Network and Congress, and is a graduate of Princeton University and Northwestern University's Medill School of Journalism.

ABOUT THE FOOD AND DRUG POLICY FORUM

FDLI's *Food and Drug Policy Forum* provides a marketplace for the exchange of policy ideas regarding food and drug law issues. The *Forum* welcomes articles on cutting-edge state, national, and international policy issues related to food and drug law.

FDLI's *Food and Drug Policy Forum* is designed to provide a venue for the presentation of information, analysis, and policy recommendations in the areas of food, drugs, animal drugs, biologics, cosmetics, diagnostics, dietary supplements, medical devices, and tobacco.

Each issue of the *Forum* presents an important policy topic in the form of a question, provides background information and detailed discussion of the issues involved in the policy question, relevant research, pertinent sources, and policy recommendations. This publication is digital-only, peer-reviewed, and smartphone enabled.

The *Forum* is published monthly (12 times a year) and is provided as a complimentary benefit to FDLI members. Individual issues of the *Forum* are also available for separate purchase.

The *Food and Drug Policy Forum* Editorial Advisory Board, comprised of representatives of government and leading associations interested in food and drug law issues, as well as food and drug and healthcare professionals, provides peer review and guidance on articles considered for publication.

ABOUT FDLI

The Food and Drug Law Institute, founded in 1949, is a non-profit organization that provides a marketplace for discussing food and drug law issues through conferences, publications, and member interaction. FDLI's scope includes food, drugs, animal drugs, biologics, cosmetics, diagnostics, dietary supplements, medical devices, and tobacco. As a not-for-profit 501(c)(3) organization, FDLI does not engage in advocacy activities.

FDLI's mission is to provide education, training, and publications on food and drug law; act as a liaison to promote networking as a means to develop professional relationships and idea generation; and ensure an open, balanced marketplace of ideas to inform innovative public policy, law, and regulation.

In addition to the *Forum*, FDLI publishes the quarterly, peer-reviewed *Food and Drug Law Journal* presenting in-depth scholarly analysis of food and drug law developments; *Update* magazine, which provides members with concise analytical articles on cutting-edge food and drug issues; practical guides on contemporary food and drug law topics, and numerous comprehensive new books each year.