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Time for Reapplication: A Review of FDA Sunscreen Regulation & Why it Needs an Update

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Abstract

Sunscreen is a staple in melanoma prevention and foreign innovation in formulation and application provide consumers with methods of sun protection. Nevertheless, FDA regulations designed to protect American consumers from ineffective sunscreens often act as a barrier to entry for these innovative, foreign sunscreens from reaching American consumers. This Note will address balancing concerns between consumer protection and promoting product innovation. The Note outlines the history of sunscreen regulation in the United States. Then it discusses the current regulatory framework and what sunscreen filters are currently available to American consumers before providing examples of foreign innovation in sunscreen formulation.

Time for Reapplication: A Review of FDA Sunscreen Regulation & Why it Needs an Update

Emily Davidson*

I. INTRODUCTION

Be honest—the word sunscreen calls to mind the pasty, white goop applied poolside. The traditional sunscreen from the summers of childhood probably contained Oxybenzone, a UV filter that the FDA classifies as safe for use.[1] Nevertheless, environmental groups disagree due to the potential environmental threats of Oxybenzone.[2] This led to the question of what American consumers can do to find sunscreen options that they want to use, that offer broad-spectrum protection, and that do not cause environmental damage. Foreign cosmeceutical companies and researchers offer solutions: through technological innovation, they have concocted new sunscreen filters and methods designed for greater protection. The only problem is these filters are not available to American consumers (or available in the American market) yet because of the FDA's regulation of sunscreen as an over-the-counter drug. This Note will first examine the FDA's scheme of regulation and why it needs to be updated to accommodate new technologies and innovation. Next it will elucidate new and emerging technologies in the formulation of sunscreen and emphasize which ones are available to American consumers under the current FDA regulations. Lastly, this will advocate for the benefits to U.S. consumers if the regulatory barriers were removed.

II. BACKGROUND: SUNSCREEN IN THE AMERICAN MARKET

Before we can discuss the FDA regulations, it is important to note why the FDA regulated sunscreens to begin with. Prior to the 1940s, suntan lotions and the sunscreen business did not exist.[3] It was not until the increased demand for sunscreen

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[1] Jennifer Brescoll Mancuso et al., *Sunscreens: An Update*, 18 AM. J. CLINICAL DERMATOLOGY 643, 645 (2017).

[2] Antonio Tovar-Sánchez et al., *Sunscreen Products as Emerging Pollutants to Coastal Waters*, 8 PLOS ONE 6 (2013).

[3] KERRY SEGRAVE, SUNTANNING IN 20TH CENTURY AMERICA 74 (2005).

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coupled with the incorporation of sunscreen ingredients into everyday products, like makeup and skincare, that the FDA subjected sunscreen to heightened regulatory scrutiny.[4]

Consumers' Research (now better known as *Consumer Reports*) began publishing their evaluations of sunscreens in the 1950s.[5] In their 1954 evaluation, Consumers' Research noted that all products claiming to prevent sunburn contained a sunscreen substance or chemical, as these were defined by the provisions of the Federal Food, Drug, and Cosmetics Act to declare their essential ingredients.[6]

Sunscreens have also been historically linked to the cosmetics market. In 1957, journalist, John Aberle, reported "the suntanned look has become increasingly desirable, whether as a sign of health . . . or as tacit proof of a good vacation."[7] Many cosmetics companies at the time sold suntan lotions: Revlon, Elizabeth Arden, and Avon.[8] Many of these companies circumvented the process of FDA regulation by claiming only to "aid in the tanning process," rather than "preventing sunburn," to avoid classification of drugs under the FDA.[9] This kept prices lower and allowed the cosmetics companies to get their products to consumers faster.

Tactics like this continued until the 1970s when the FDA mandated a coding system for sun care products under which sunscreens were regulated as an over-the-counter (OTC) drug.[10] Once the coding system was enforced, manufacturers of sun care products adapted their marketing and advertising strategies to emphasize the sunscreen aspect of their products over the tanning benefits.[11]

In 1980, the FDA began the labeling requirement still in use today—SPF.[12] The sun protection factor (SPF) was intended to indicate what level of sun protection a product contained.[13] In the mid-1980s, cosmetics companies like Avon and Lancôme

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[4] Patrick R. Jones, *Protecting the Consumer From Getting Burned: The FDA, the Administrative Process, and the Tentative Final Monograph on Over-the-Counter Sunscreens*, 20 AM. J.L. & MED. 317, 317 (1994).

[5] SEGRAVE, *supra* note 3, at 76–77.

[6] *Id.*

[7] *Id.* at 77.

[8] *Id.*

[9] *Id.* at 80.

[10] *Id.* at 88.

[11] *Id.*

[12] *Id.* at 89.

[13] *Id.*

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began including sunscreen filters in their cosmetics and marketed the products to consumers as protection from aging.[14] This trend continues today with many cosmetics companies labeling their products with an SPF as anti-aging to draw in new customers with products aimed at preventing signs of aging.[15]

III. CURRENT FDA REGULATORY PROVISIONS

From the perspective of the manufacturers, the critical requirements for a sunscreen include efficient protection against acute and long-term UV damage; stability against heat and UV radiation; user-friendly to encourage application; and cost effectiveness.[16]

All sunscreen filters must be approved by the local regulatory agency for the area in which the products are to be marketed.[17] For the American market, this requires FDA approval of any UV filters. The FDA defines "sunscreen" as a "drug containing one or more active sunscreen ingredients," and "sunscreen active ingredient" as "an active ingredient that is intended for application to the skin of humans for the purposes of absorbing, reflecting, or scattering ultraviolet radiation."[18]

Ultraviolet filters (UV filters) are chemicals that scatter and absorb ultraviolet (UV) radiation.[19] UV filters can be classified as either organic filters (also called physical filters) or inorganic filters (also called chemical filters).[20] The organic filters can exist in either liquid or solid form and absorb photons from both UVA and UVB rays.[21] There are five main types of organic filters: para-aminobenzoic acid (PABA) derivatives, benzophenones, salicylates, cinnamates, and "other."[22] The PABA derivatives are highly effective UVB absorbers but cause severe photodegradation

[14] *Id.* at 93.

[15] Shreya Shanbhag et al., *Anti-aging and Sunscreens: Paradigm Shift in Cosmetics*, 9 ADV. PHARM. BULL. 348, 350 (2019).

[16] Serge Forestier, *Rationale for Sunscreen Development*, 58 J. AM. ACAD. DERMATOL. S133 (2008).

[17] Mancuso et al., *supra* note 1, at 643.

[18] 21 U.S.C. § 360fff.

[19] Mancuso et al., *supra* note 1, at 644.

[20] *Id.*

[21] *Id.*

[22] *Id.* at 645.

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when used in conjunction with oxybenzone.[23] PABA derivatives are also a common contact allergen and therefore rarely used in formulations.[24]

Benzophenones are better UVA absorbers.[25] Oxybenzone is the most frequently used form because it absorbs both UVA and UVB.[26] However, it is the most common cause of photoallergic reaction among UV filters and because of this in the European Union, sunscreens containing oxybenzone must include a warning on the label.[27] Despite this, oxybenzone is still commonly used in the United States because of the lack of other U.S. FDA-approved filters that provide both photostabilization of avobenzone and UVA2 and UVB protection.[28]

Salicylates are relatively weak UVB absorbers and therefore are generally used in combination with other organic absorbers to increase UV absorption.[29] The most common cinnamate is octinoxate, which is a strong UVB absorber that also destabilizes Avobenzone.[30] Lastly, the other filters that do not cleanly fit into the four previous categories of organic filters fall into the fifth miscellaneous category.[31]

Inorganic filters, such as titanium dioxide and zinc oxide, are opaque particles that primarily absorb but also reflect and scatter UV photons that reach the skin.[32] Generally, these are cosmetically disfavored because of the severe white cast they leave on the skin.[33] Both titanium dioxide and zinc oxide are FDA approved filters.[34]

In 2012, the FDA determined that sunscreens blocking a broad spectrum of UV radiation with a SPF of 15 or greater could be marketed as reducing the risk of skin cancer.[35] However, the FDA did not remove sunscreens with a SPF of lower than 15

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[23] *Id.*

[24] *Id.*

[25] *Id.*

[26] *Id.*

[27] *Id.*

[28] *Id.*

[29] *Id.*

[30] *Id.*

[31] *Id.*

[32] *Id.* at 645–46 (2017).

[33] *Id.*

[34] *Id.*

[35] Joshua M. Sharfstein, M.D., *A Spotlight on Sunscreen Regulation*, 373 NEW ENG. J. MED. 101 (2015).

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from the market.[36] This is problematic because some Americans may be purchasing sunscreens without knowing that there is no evidence to suggest that they protect against skin cancer, and even worse, many Americans still fail to use sunscreen altogether.[37] In 2015, the FDA declined to permit use of eight new sunscreen ingredients without additional data, although these same ingredients have been used in Europe for over five years and despite the recent passage of the Sunscreen Innovation Act (SIA) in 2014, designed to expedite the approval process for such new products.[38] However, the SIA requires that the sunscreen active ingredient submitted for review meet the "generally recognized as safe and effective" standard, otherwise known as GRASE.[39] GRASE determinations mean that qualified, scientific experts with both training and experience have evaluated the safety and effectiveness of the product for its prescribed purpose.[40]

With new prescription drugs, the FDA generally moves faster than European regulatory agencies, and it approved 41 products in 2014, the record for the previous 18 years.[41] Nevertheless, the speed must be carefully balanced with safety to ensure consumer protection.[42] OTC products, including sunscreens, are regulated through an entirely different process designed for products posing little to no risk, under the "generally recognized as safe and effective" standard.[43] This process has no product-specific approval decision; instead, the agency must issue proposed and final rules, with multiple opportunities for public comment before authorizing each class of products.[44] Unlike review of new prescription drugs, the pathway for OTC products has no additional resources.[45]

Between procedural requirements and inadequate resources, OTC product regulation proceeds in slow motion as compared with the rest of the agency.[46] These

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[36] *Id.* at 101–03.

[37] *Id.* at 101.

[38] *Id.*; *see also* Sunscreen Innovation Act, Pub. L. No. 113-195, § 586D, 128 Stat. 2044 (2014).

[39] Sunscreen Innovation Act, Pub. L. No. 113-558, § 586.

[40] *Id.*

[41] Joshua M. Sharfstein, M.D., *A Spotlight on Sunscreen Regulation*, 373 NEW ENG. J. MED. 101, 102 (2015).

[42] Vincent J. Roth, *The mHealth Conundrum: Smartphones & Mobile Medical Apps—How Much FDA Medical Device Regulation is Required?*, 15 N.C. J.L. & TECH. 359, 407 (2014).

[43] Sharfstein, *supra* note 35, at 102.

[44] *Id.*

[45] *Id.*

[46] *Id.*

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limitations lead to a cautious approach in approving products, like sunscreen, that are designed for long-term use by millions of children and adults in the absence of disease.[47] The Sunscreen Innovation Act (SIA), set deadlines for FDA review and removed several procedural requirements for agency action.[48] The SIA provided no new resources, no new authority for post-marketing safety, and little new flexibility for the agency in the review process.[49]

The complex regulatory framework of the FDA makes compliance challenging for even the most diligent and careful sunscreen formulators.[50] In general, these companies are out of compliance to some extent because complete compliance with FDA regulation is difficult.[51] The assumption is that if a company makes an effort to comply with FDA regulations, the effort will prevent an unsafe or ineffective product from entering the market.[52] Nevertheless the difficult regulations also hinder innovation in the marketplace, which makes it necessary to strike a balance between adequate consumer product safety and room for innovation and technology.[53]

IV. New Technology in Sunscreens: What Is Available to American Consumers?

Some innovation in sun protection, like clothing with an SPF of 50, is currently available to American consumers.[54] Nevertheless, some sunscreens used extensively abroad, like Parasol 1789 in Europe, are not available to American consumers, despite pressures from manufacturers.[55] The regulatory scheme currently in place under the SIA is slow to adapt to new sunscreen ingredients, even those commonly used internationally, and provides for greater barriers to less traditional, and more innovative, sunscreens.

Physical UV filters, including titanium dioxide and zinc oxide, are already approved by the FDA as effective sunscreens but tend to be disfavored by consumers

[47] *Id.*

[48] *Id.*; *see also* Sunscreen Innovation Act, Pub. L. No. 113-195.

[49] Sharfstein, *supra* note 35, at 103.

[50] Roth, *supra* note 42, at 407.

[51] *Id.*

[52] *Id.*

[53] *Id.*

[54] *Fabric Innovation*, Coolibar, https://www.coolibar.com/mission/fabric-innovation.html (last visited Apr. 17, 2020).

[55] Jones, *supra* note 4, at 327.

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due to the unsightly white cast.[56] A considerable effort has been made to overcome the "cosmetic shortcomings" of these filters by minimizing the particle size to the nano range.[57] The concern with the use of nanoparticles is that since they exhibit different chemical and optical properties than the normal sized particles, there could be negative health implications.[58] However, the currently available evidence of nanoparticles does not demonstrate that they are toxic to healthy, intact skin.[59] The FDA does not currently have regulations in place regarding the labeling of products containing nanoparticles, and since they are derived from already approved FDA filters, these products are currently available to American consumers.[60] This innovation falls within provisions of the SIA that do not require currently available sunscreen ingredients to reapply for GRASE determination.[61]

Another current area of innovation in sunscreen is in the development of an oral sunscreen pill. One issue with a sunscreen pill is that it would be a supplement under FDA regulation and the FDA does not currently regulate supplements, so the manufacturers would not need to prove the effectiveness of such a pill.[62] So long as the manufacturer does not make false or misleading claims, and there is no health threat, the manufacturers are permitted to sell whatever supplements they choose.[63] Despite significant research in developing a sunscreen pill, the problems of moving antioxidants through the human body make it tricky to develop a pill that would completely replace sunscreen lotion.[64] Dr. Henry Lim, a dermatologist at the Henry Ford Hospital in Detroit, Michigan, notes "if you think about taking a pill by mouth, it has to go through multiple steps . . . it has to be absorbed, go through the blood and then through the liver before it gets to the skin."[65] This process is particularly problematic for antioxidant-based sunscreen pills because of the instability of antioxidants.[66] Many of the current pills are based on an antioxidant-rich extract from

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[56] Mark E. Burnett & Steven Q. Wang, *Current Sunscreen Controversies: A Critical Review*, 27 PHOTODERMATOL., PHOTOIMMUNOL. & PHOTOMED. 58, 63 (2010).

[57] *Id.*

[58] *Id.*

[59] *Id.*

[60] *Id.* at 64.

[61] Sunscreen Innovation Act (2014), Pub. L. No. 113-558, § 586A.

[62] Erin Biba, *The Sunscreen Pill*, 515 NATURE S124 (Nov. 19, 2014).

[63] *Id.*

[64] *Id.*

[65] *Id.*

[66] *Id.*

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the tropical fern, *polypodium leucotomos*, although one U.K. researcher is trying to patent an extract from an algae found in coral.[67] In August 2013, the American Academy of Dermatology said in a statement on oral sunscreens that there is "no scientific evidence that oral supplements alone can provide an adequate level of protection from the sun's damaging ultraviolet rays."[68] So the pill may still be used in conjunction with traditional topical sunscreen but it is not advisable to use alone and expect full protection from UV rays. Even if such a pill was submitted to the FDA for approval, it would fail to meet the standard for GRASE determination because the standard set by the FDA allows *only* for those ingredients "generally recognized as safe and effective."[69] This benchmark provides a bar to innovative sunscreen formulations, like oral pills, because they have no such general recognition of safety and effectiveness.

One prescription sunscreen has been created by Clinuvel Pharmaceuticals, based in Melbourne, Australia, known as Scenesse (afamelanotide) and is currently awaiting FDA approval for marketing in the United States.[70] Scenesse is derived from a naturally occurring hormone that is released into the body upon exposure to ultraviolet radiation.[71] This hormone triggers skin cells to release melanin, the dark pigment in skin, and the drug triggers the same reaction, causing the skin to create a tan when exposed to the sun.[72] Tanned skin acts as a natural shield against the sun; melanin acts as a filter to screen out some wavelengths of sunlight that would otherwise induce skin damage.[73] Any person taking Scenesse would eventually become very tanned and therefore much less likely to burn from sun exposure.[74] While this seems like a great alternative to topical sunscreens, Scenesse is not being marketed to general consumers.[75] If approved by the FDA, Scenesse would be available only as a prescription drug to treat people with diseases, such as vitiligo, that make them extremely photosensitive.[76] Also, Scenesse is not administered as an oral pill: Scenesse would be available as an implant, the size of a grain of rice,

[67] *Id.*

[68] *Id.* at S124–S125.

[69] Sunscreen Innovation Act, Pub. L. No. 113-558, § 586.

[70] Biba, *supra* note 62, at S124–S125.

[71] *Id.*

[72] *Id.*

[73] *Id.*

[74] *Id.*

[75] *Id.*

[76] *Id.*

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injected under the skin where it would begin working within two days of the injection and last up to two months before a new implant is required.[77] This process makes Scenesse an impractical option for most American consumers.[78] Even if Scenesse became an option without a prescription, it would most likely fails to meet the GRASE determination for the same reason as the sunscreen pills.[79] While the GRASE benchmark serves to protect American consumers, it also undermines innovation, like Scenesse, that would benefit those with UV sensitivity.

Other recent research at Paul Long's lab at King's College London has examined the feasibility of sunscreen made from compounds naturally found in algae that live on coral.[80] Long has spent over five years studying mycosporine-like amino acids (MAAs), these are naturally occurring sunscreens produced by organisms that live in clear, shallow water and so are exposed to high levels of ultraviolet radiation.[81] Both these organisms and the fish that feed on them are protected by the MAAs, which absorb ultraviolet radiation before it can cause damage.[82] This research on MAAs seems promising but like many sun-protective compounds found in nature, they are not fully effective in blocking the sun.[83] Therefore, any sunscreen formulated with MAAs would need to be supplemented with other UV protection for complete protection from UV exposure. Again, MAAs present such a new and innovative form of sunscreen that they are not generally recognized as safe and effective. MAAs would fail to meet GRASE under the SIA regulations.[84]

The current FDA regulation of sunscreen through the SIA intends to protect consumers through thorough review of product safety and effectiveness before new sunscreen ingredients reach American consumers. Nevertheless, the regulatory scheme also hinders innovative sunscreen ingredients and formulations from benefitting American consumers. Since its passage in 2014, the SIA has allowed ingredients currently on the market to persist while stifling any innovation from entering the marketplace.

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[77] *Id.*

[78] *Id.*

[79] Sunscreen Innovation Act, Pub. L. No. 113-558, § 586.

[80] Biba, *supra* note 62, at S124–S125.

[81] *Id.*

[82] *Id.*

[83] *Id.*

[84] Sunscreen Innovation Act, Pub. L. No. 113-558, § 586.

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V. THE IMPACT OF FDA REGULATION ON AMERICAN CONSUMERS AND ALTERNATIVE REGULATORY FRAMEWORKS

Because the U.S. sunscreen manufacturers do not have access to these new UV filters, there is concern that U.S. sunscreen may not offer broad-spectrum protection comparable to those available in other markets.[85] Joshua Sharfstein of the Johns Hopkins Bloomberg School of Public Health notes, "understanding the FDA means recognizing that the framework for over-the-counter products is not designed to promote innovation with potential public health benefits."[86] Sharstein suggests that Congress "should try again and pass legislation establishing an alternative approval pathway that combines the flexibility of the new drug pathway with the ability to simultaneously approve multiple formulations and concentrations."[87] Sharfstein also suggests that the FDA "should be able to negotiate with sponsors to get the right data without years of rulemaking, establish postmarketing data requirements, consult with other countries' regulators to establish consistent standards where possible, and move quickly in the event that safety concerns emerge."[88] Congress ought to provide additional resources for timely review.[89] Timely review of sunscreens is critical to expand sunscreen options for American consumers and would help ameliorate the prevalence of melanoma in the United States.[90]

Other countries offer alternative solutions to regulate sunscreen. In the European market, sunscreens are classified as cosmetics and are therefore not held to the same regulatory norms used in the United States.[91] This ameliorates the process of manufacturing by allowing companies to quickly get their products to consumers. Nevertheless, the European framework raises concerns about the effectiveness of the products. Effectiveness is particularly important for sunscreens because ineffective sunscreens could be detrimental to consumers falsely relying on SPF claims. In Japan, sunscreens are regulated as "quasi-drugs" where regulations on the types of UV filters and concentrations are permitted.[92] This system would be a better option because it allows for more consumer protection than the European

[85] Mancuso et al., *supra* note 1, at 646.

[86] Sharfstein, *supra* note 35, at 103.

[87] *Id.*

[88] *Id.*

[89] *Id.*

[90] *Id.*

[91] Mancuso et al., *supra* note 1, at 646.

[92] *Id.*

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method. However, in Australia, sunscreen regulation will vary based on the intended use of the product: beach sunscreens are regulated as therapeutic drugs, whereas daily-wear moisturizer sunscreens are regulated as cosmetics.[93] The Australian method appears the most rational because it correlates the amount of regulation to the amount of direct UV exposure. Beachgoers lounge directly in sunlight for long periods of time and therefore need the highest degree of sun protection and regulatory protections. Whereas sunscreen integrated into skincare, like moisturizers or foundations, are intended for the daily use of an average person who may be exposed to UV rays for short, intermittent periods.

Note that the United States has the least and Europe and Australia have the most UV filters available when formulating sunscreen.[94] The United States only has 16 approved filters and the list has not been updated in the last 10 years.[95] There are currently 8 new filters that the industry has been urged to approve and they passed the SIA to approve them, but as of 2017 they have not been approved.[96] It might seem unrealistic to say that these unapproved sunscreen filters are life changing and lifesaving. Nevertheless, if these can help at least one person to wear sunscreen regularly, then that is one less melanoma patient. By changing their regulatory practices to allow more sunscreens into the market, the FDA will protect more American consumers from skin cancer. The FDA is responsible for the public health by ensuring product safety and efficacy, and updating sunscreen regulations will uphold that mission.[97]

[93] *Id.*

[94] *Id.*

[95] *Id.*

[96] *Id.*

[97] *What We Do*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/about-fda/what-we-do (last visited Apr. 17, 2020).

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