A Hot Topic: Is the FDA's Approach to Sunscreen Regulation Failing Consumers?

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INTRODUCTION

Sunscreen has many benefits for the health of human bodies. It protects us from harmful ultraviolet (UV) rays, lowers the incidence of skin cancer, improves the health of our skin, and prevents signs of premature aging.[1] "Skin cancer is the most common type of cancer in the United States,"[2] and about 90% of skin cancer cases are associated with sun exposure.[3] Therefore, sunscreen serves as our defense against sun exposure's negative impacts on our health and beauty. Consumers' increased attention to sunscreen and its importance for human health has led to a call for the Food and Drug Administration (FDA)[4] to update its regulation over sunscreen to ensure its safety and to align the United States with countries that have evolved more quickly in the creation of sunscreen technology.[5] As it stands, the FDA has been slow to update its sunscreen regulation and approve new sunscreen technology and has, in turn, left American consumers with a limited selection of sunscreen products they will actually use.[6] Because of the fundamental role sunscreen plays in safeguarding the public's health from the short and long-term consequences of unprotected sun exposure, it is crucial that the FDA, through its regulation, promote consumer trust in sunscreen as a safe, effective, and desirable product.

Sunscreen products are not only important for health and beauty but also have become an integral part of the American economy as one of the fastest-growing skincare categories on the market.[7] Notably, the market size for sun care products was $13.03 billion in 2019 and is expected to reach $16.84 billion by 2027.[8] Furthermore, although makeup sales

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1. Shreya Shanbhag, Akshatha Nayak, Reema Narayan & Usha Yogendra Nayak, *Anti-Aging and Sunscreens: Paradigm Shift in Cosmetics*, 9 ADVANCED PHARM. BULL. 348, 351–52 (2019).

2. Amanda Mull, *You're Not Allowed to Have the Best Sunscreens in the World*, ATLANTIC (July 1, 2022), https://www.theatlantic.com/technology/archive/2022/07/us-sunscreen-ingredients-outdated-technology-better-eu-asia/661433/ [https://perma.cc/J8Z6-P96V].

3. Shanbhag, Nayak, Narayan & Yogendra Nayak, *supra* note 1, at 351.

4. The FDA is a federal agency "responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation." *What We Do*, FDA (Mar. 28, 2018), https://www.fda.gov/about-fda/what-we-do [https://perma.cc/JT4W-AAYP].

5. *See, e.g.*, Mull, *supra* note 2.

6. *Id.* "The FDA hasn't added a new active ingredient to its sunscreen monograph—the document that details what is legally allowed in products marketed in the U.S.—in decades." *Id.*

7. *Sun Care Products Market to Reach USD 16.84 Billion by 2027; Development of Devices to Measure Sunlight Intensity Will Boost Growth, Says Fortune Business Insights™*, GLOBE NEWSWIRE (Oct. 9, 2020), https://www.globenewswire.com/news-release/2020/10/09/2106263/0/en/Sun-Care-Products-Market-to-Reach-USD-16-84-Billion-by-2027-Development-of-Devices-to-Measure-Sunlight-Intensity-will-Boost-Growth-Says-Fortune-Business-Insights.html [https://perma.cc/7UVR-HKDL] [hereinafter *Sun Care Products Market to Reach USD 16.84 Billion by 2017*].

8. *Id.*

decreased during the first year of the COVID-19 pandemic, skincare sales remained steady as people focused on enhancing the look of their natural skin.[9] Brands formerly focused on makeup have thus started moving into the skincare market to capitalize on the expanding interest in skincare.[10] The U.S. skincare market was "valued at $26.92 billion in 2018 and is projected to reach $37.13 billion by 2026."[11] As Americans spend more money on skincare products and beauty products generally,[12] the FDA's oversight and regulation over these products is becoming increasingly important.

A significant contributor to the FDA moving slowly to approve new sunscreen ingredients is the way it categorizes sunscreen ingredients. Sunscreen prevents two types of ultraviolet rays, UVA and UVB, from penetrating the skin.[13] The ingredients in sunscreen that protect against these rays are called filters and generally fall into one of two categories: physical or chemical.[14] While mineral filters block UVA and UVB rays, chemical filters absorb either UVA or UVB rays and are combined together to supply full-spectrum protection.[15] The FDA treats all filters, mineral and physical, as active ingredients that must be individually tested and approved before they can enter the market because the United States regulates sunscreen as an over-the-counter (OTC) drug.[16] Whether a consumer buys their sunscreen from a drug store or a high-end skincare retailer, the product will have at least one filter that has gone through the FDA approval process.[17]

By classifying sunscreen as an OTC drug, the FDA has made it so sunscreen products must pass rigorous, time-consuming, and expensive

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9. *See* Cheryl Wischhover, *How the Beauty Industry Is Surviving the Pandemic*, VOX (Aug. 11, 2020), https://www.vox.com/the-goods/21352703/beauty-industry-pandemic-cosmetics-makeup-skincare-lipstick-nuface [https://perma.cc/NXQ7-BZSE].

10. *See id.*

11. *US Skincare Market Size and Forecast*, VERIFIED MKT. RESEARCH (Nov. 2021), https://www.verifiedmarketresearch.com/product/us-skincare-market/ [https://perma.cc/X9L9-5MQ9].

12. REILLY ROBERTS, COMMON THREAD, 2022 BEAUTY INDUSTRY TRENDS & COSMETICS MARKETING: STATISTICS AND STRATEGIES FOR YOUR ECOMMERCE GROWTH (2022), https://commonthreadco.com/blogs/coachs-corner/beauty-industry-cosmetics-marketing-ecommerce#statistics [https://perma.cc/NBE5-XQ94].

13. Mull, *supra* note 2.

14. *Id.*

15. *Id.*

16. *Id.* Per the FDA, "Over-the-counter medicine is also known as OTC or nonprescription medicine. All these terms refer to medicine that you can buy without a prescription. They are safe and effective when you follow the directions on the label and as directed by your health care professional." *Understanding Over-the-Counter Medicines*, U.S. FOOD & DRUG ADMIN. (May 16, 2018), https://www.fda.gov/drugs/buying-using-medicine-safely/understanding-over-counter-medicines [https://perma.cc/WW95-AEN8].

17. Mull, *supra* note 2.

testing.[18] This testing is particularly cumbersome because it provides extensive procedural requirements without adequate resources.[19] Unlike the review of new prescription drugs, review for OTC products are given no additional resources.[20] Therefore, because of its strict classification and the FDA's limited resources, the FDA struggles to vigorously protect consumers, while still allowing for crucial innovation.[21]

Because of the FDA's regulation, American sunscreen manufacturers have access to fewer active ingredients.[22] In Europe, Australia, and much of Asia, sunscreens are treated as cosmetics or "health-bolstering goods" and, in turn, these countries regulate sunscreen ingredients with simpler safety standards as compared to the United States.[23] For instance, while Europe has approved twenty-seven substances for use in sunscreen products, the FDA has only approved sixteen active ingredients for the same use.[24] Of the filters available for use in American sunscreens, the eight that are commonly used in products[25] have left sunscreen formulas uncomfortable because of their unpleasant textures and unsightly because of their chalky white undertones.[26] While consumers may put up with the undesirable feel or look of sunscreen occasionally, the products currently on the market in the United States effectively discourage daily use of sunscreen, which is widely recommended by dermatologists.[27] Consequently, unlike consumers in other countries with more efficient sunscreen regulation and advanced sunscreen technology, many consumers in the United States are choosing not to wear sunscreen as often as necessary to protect against the dangers of the sun.[28]

In an additional consequence of the FDA moving slowly on sunscreen regulation, instead of foregoing sunscreen, other consumers

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18. *Id.*

19. *See* Emily Davidson, *Time for Reapplication: A Review of FDA Sunscreen Regulation & Why It Needs an Update*, 20 U. PITTSBURGH J. TECH. L. & POL'Y 212, 216–17 (2020).

20. *Id.* at 216.

21. *Id.* at 216–17.

22. Sarah Aswell, *Why You Need to Reconsider That Sunscreen You're Using,* HEALTHLINE (Aug. 12, 2019), https://www.healthline.com/health/the-best-sunscreen-isnt-from-america [https://perma.cc/9GHL-QJA6].

23. Mull, *supra* note 2.

24. Aswell, *supra* note 22.

25. Many of the filters approved for use in the United States are not used by sunscreen manufacturers because they have undesirable side effects and fail to blend into the products consumers like to purchase. Mull, *supra* note 2.

26. *Id.* When filters are used in the amount necessary to achieve high levels of SPF protection, it is particularly hard for American sunscreen manufacturers to create formulas that are desirable for consumer use. "Maximum protection can sometimes mean maximum chalkiness or oiliness." *Id.*

27. *Id.*

28. *Id.*

have begun to look outside of the United States to purchase sunscreen products from supply lines that evade FDA notice.[29] Several dozen active ingredients, not approved by the FDA, are contained in several "cult favorite[]" sunscreen products available for purchase through third-party sellers on Amazon.[30] This consumer behavior can put public health at risk because of the lack of FDA oversight over products entering the American market without testing and approval.[31]

Moving quickly and comprehensively on sunscreen regulation will benefit the health of American bodies and the American economy. Unfortunately, the slow speed at which the FDA is moving on sunscreen and its rigid testing regime has resulted in consumers having fewer safe and effective sunscreen products to choose from and experiencing less trust in their safety and efficacy.[32]

There is a better balance to be struck between allowing sunscreen innovation and protecting the public from unsafe products. However, the FDA is not effectively striking this balance to benefit and protect consumers. Part I of this Note will review the factual background of the public's attention to sunscreen, explain the current sunscreen issues in the news, and highlight the different actors involved in the growing discourse surrounding sunscreen. Part I will also show that the actors involved in the sunscreen industry—scientific researchers, social media influencers, and the public at large—have considerable influence on consumers' trust in sunscreen, their buying habits, and the FDA's approach to sunscreen regulation. Part II of this Note will outline the history of sunscreen regulation by Congress and the FDA. It will focus on the key issues included in the pending order the FDA proposed on November 12, 2021. Finally, Part III will examine how the FDA can utilize the information provided by both other countries and social media influencers to create sunscreen regulation that promotes consumer safety and vital innovation. Additionally, Part III will show that using this information will enhance consumer trust and benefit consumers' health and producers' profit.

29. *Id.*

30. *Id.*

31. *See, e.g.*, Michelle Wong, *Purito Sunscreen and All About SPF* Testing, LAB MUFFIN BEAUTY SCI. (Dec. 10, 2020), https://labmuffin.com/purito-sunscreen-and-all-about-spf-testing-with-video/ [https://perma.cc/XSR6-LCLA].

32. Aswell, *supra* note 22.

I. FACTUAL BACKGROUND

Sunscreen has long made headlines for the various dangers it poses.[33] Today, the most recent sunscreen news has centered on two new issues posed by sunscreen products: potentially harmful ingredients and incorrect Sun Protection Factors (SPF) labeling.[34] These issues have led to numerous sunscreen product recalls, which has led consumers to lose trust in sunscreen products as they watch their favorite products disappear.[35] This Part will examine some of the key players contributing to the conversation surrounding sunscreen and the high-profile stories concerning the possible dangers presented by sunscreen products.

A. Social Media's Influence on Sunscreen

Social media can be a key venue in educating a large number of people about the importance of sunscreen.[36] Social media influencers, also known as "content creators" or simply "influencers," have large social media followings and often receive payment from companies for advertising products.[37] While most social media influencers do not have a medical background, they do have an impact on their many followers' health decisions.[38] Social media influencers have contributed to a sizeable increase in the rates of skin cancer worldwide by promoting recreational tanning and the perceived social desirability of having tanned skin.[39] The number of adults treated for skin cancers increased from 3.4 million between 2002–2006 to almost 5 million between 2007–2011.[40] Despite the

33. *See, e.g.*, Jamie Ducharme, *Almost Every Doctor Recommends Sunscreen. So Why Don't We Know More About Its Safety?*, TIME (Aug. 2, 2021), https://time.com/6084625/sunscreen-safety-regulations/ [https://perma.cc/GT2V-JVPL].

34. *Id.*

35. *See* Laura Cohen, Comment Letter on Proposed Order to Amending Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use (Nov. 11, 2021), https://www.regulations.gov/comment/FDA-1978-N-0018-15845 [https://perma.cc/MR3U-W4VF] ("There is a rapid disappearance of UV filters occurring due to the public's concerns regarding 'Reef Damage', hormonal disruption or possible carcenoginic [sic] threats. The citizens of this country are left with less choices for sunscreens. People get accustomed to a product and tend to repeat the purchase their favorite branded products. With sunscreen brands either disappearing quickly or being recalled, some consumers tend to discontinue protection or look for a more convenient method of application.").

36. *See generally* Henriette De La Garza, Mayra B. C. Maymone & Neelam A. Vashi, *Impact of Social Media on Skin Cancer Prevention*, 18 INT'L J. ENV'T RSCH. & PUB. HEALTH 5002 (2021).

37. Jenna Wortham, *The Well-Followed on Social Media Cash In on Their Influence*, N.Y. TIMES (June 8, 2014), https://www.nytimes.com/2014/06/09/technology/stars-of-vine-and-instagram-get-advertising-deals.html?searchResultPosition=5 [https://perma.cc/95MW-6SPV].

38. De La Garza, Maymone & Vashi, *supra* note 36, at 5006.

39. *Id.*

40. *Id.*

extensive studies showing the direct connection between sun exposure and skin cancer, about 7.8 million Americans still regularly use tanning beds.[41]

Recently, however, there has been a shift in the social media influencer world from encouraging sun exposure to demonizing it and highlighting the importance of sunscreen.[42] Because the skin is the most easily visible indicator of general health and aging,[43] it is not a surprise that many social media influencers, who focus on beauty topics, now promote the use of sunscreen.[44] Given the sizeable market sunscreen generates, companies who sell sunscreen products are also increasingly able to pay influencers to promote their sunscreen products.[45] With the attention of millions of social media followers, influencers from a wide variety of platforms, such as Instagram, TikTok, Twitter, and Facebook, have begun to police companies that create sunscreen products.[46] This newfound attention on sunscreen from influencers is significant because consumers increasingly use social media to gain health information.[47] With over 4.20 billion social media users worldwide in 2021, social media influencers indeed do influence what issues the public pays attention to,[48] and numerous influencers have decided to target sunscreen as the topic they post about the most.[49]

B. Gwyneth Paltrow and Sunscreen Skepticism

Many influencers who focus on beauty and skincare seek to educate followers about the importance of sunscreen and speak out against those in the beauty community whom they believe are not sending the correct message about sunscreen.[50] For example, Gwyneth Paltrow, the founder of Goop, an online "wellness shop,"[51] recently faced significant backlash

41. *Indoor Tanning*, AM. ACADEMY OF DERMATOLOGY ASS'N, https://www.aad.org/media/stats-indoor-tanning [https://perma.cc/BNK4-DA4J].

42. *See, e.g.*, Skincarebyhyram, TIKTOK, https://www.tiktok.com/@skincarebyhyram/video/6895871388020706566. As of February 2023, the hashtag for sunscreen on TikTok, has over 5.6 billion views and is used by many influencers to advocate for sunscreen use. *#sunscreen*, TIKTOK, https://www.tiktok.com/tag/sunscreen?lang=en [https://perma.cc/AG53-3QFV] [hereinafter *#sunscreen on TikTok*]. Similarly, as of February 2023, the hashtag for sunscreen on Instagram has over 3.3 million posts. #sunscreen, INSTAGRAM, https://www.instagram.com/explore/tags/sunscreen/?hl=en [https://perma.cc/2955-W8SN] [hereinafter *#sunscreen on Instagram*].

43. De La Garza, Maymone & Vashi, *supra* note 36, at 5006.

44. *See, e.g.*, *#sunscreen on TikTok*, *supra* note 42; *#sunscreen on Instagram, supra* note 42.

45. *See, e.g.*, *#sunscreen on TikTok*, *supra* note 42; *#sunscreen on Instagram, supra* note 42.

46. *See, e.g.*, *#sunscreen on TikTok*, *supra* note 42; *#sunscreen on Instagram, supra* note 42.

47. *See generally* De La Garza, Maymone & Vashi*, supra* note 36.

48. *Id.* at 5002.

49. *See, e.g.*, *#sunscreen on TikTok*, *supra* note 42; *#sunscreen on Instagram*, *supra* note 42.

50. *See, e.g.*, *#sunscreen on TikTok*, *supra* note 42; *#sunscreen on Instagram*, *supra* note 42.

51. *What's Goop*, GOOP, https://goop.com/whats-goop/ [https://perma.cc/34YR-VQHH].

for a video she made with Vogue detailing her morning beauty routine.[52] In the video, Paltrow admitted to only using sunscreen on a small portion of her face, stating "There are a lot of really harsh chemicals in conventional sunscreens so that's a product that I really want to avoid that isn't certified by the EWG [Environmental Working Group]."[53] Because of Paltrow's widespread impact, whether real or perceived, on the behavior of consumers, many beauty influencers voiced concerns over her comments and saw it as a setback in promoting proper and widespread use of sunscreen.[54] Specifically, Paltrow's critics decried her comments as contributing to the skepticism of science they saw as an increasingly prevalent force in United States culture.[55] That skepticism affects consumer trust in and willingness to use sunscreen.[56] Thus, Paltrow's comments contributed to the mistrust of this critical healthcare product.[57]

C. Valisure Discovery

Regardless of the science concerning sunscreen's risks and benefits, news stories have contributed to consumer skepticism about sunscreen's safety and efficacy. According to a survey from the cosmetic procedures database RealSelf, almost half of Americans report they never wear sunscreen, and only 11% wear it every day.[58] The lack of FDA guidance, combined with negative news stories about sunscreen, has left many Americans feeling it is better to go without than risk wearing a product that is incredibly important to human health.[59]

A recent increase in concern regarding the potentially harmful chemicals found in sunscreen products has resulted in researchers filing petitions with the FDA to recall certain sunscreens, or remove them from the market altogether.[60] In May 2021, one such petition was filed after the independent testing lab, Valisure, found benzene, a chemical known to cause cancer in humans, in seventy-eight sunscreen and after-sun

52. Taylor Bryant, *Sun Protection Brands View Gwyneth Paltrow's Spotty Sunscreen Application Going Viral as a Teaching Moment*, BEAUTY INDEP. (Apr. 8, 2021), https://www.beautyindependent.com/sun-protection-brands-gwyneth-paltrow-spotty-sunscreen-application/ [https://perma.cc/23R3-B8K3].

53. *Id.*

54. *Id.*

55. *Id.*

56. *Id.*

57. *Id.*

58. Madison Phillips, *RealSelf Report: 62% of Americans Use Anti-Aging Products Daily, But Only 11% Wear Sunscreen Daily*, REALSELF (May 1, 2020), https://www.realself.com/news/2020-realself-sun-safety-report [https://perma.cc/EN23-ER78].

59. *See id.*

60. Anna Edney, *Why the FDA Is Looking at the Chemicals in Sunscreens*, BLOOMBERG (Aug. 9, 2021), https://www.bloomberg.com/news/articles/2021-08-09/why-the-fda-is-looking-at-the-chemicals-in-sunscreens-quicktake-ksxy6xpf [https://perma.cc/CSN5-WC5Q].

products.[61] Valisure asked for a recall of the contaminated sunscreen products and requested the FDA more clearly define the limits of how much benzene contamination is permittable in drug and cosmetic products.[62] After this research emerged, in July 2021, Johnson & Johnson voluntarily recalled five sunscreen products after it found benzene in samples of its products.[63] In its announcement, Johnson & Johnson did not disclose how much benzene it detected during testing. Instead, it highlighted that the benzene levels discovered "would not be expected to cause adverse health consequences."[64] The company notified the FDA of the recall announcement and urged its customers to discontinue using the five sunscreen products listed.[65]

That said, the sunscreen industry pushed back on the degree of danger chemicals, like benzene, pose to consumers.[66] Johnson & Johnson is the only sunscreen producer to halt sales of its sunscreens containing benzene following Valisure's research, and it reportedly did so only in an "abundance of caution."[67] There are still sunscreen products on the market that contain Benzene.[68]

D. KraveBeauty Scandal

Many sunscreen consumers have opted to purchase products outside of the United States, especially from Asian manufacturers, because most of the newest sunscreen technology has not been approved by the FDA and is, therefore, not available to purchase from American manufacturers.[69] While daily sunscreen wear is very typical in many parts of Asia, the vast majority of people in western countries only wear sunscreen for special occasions, such as going to the beach.[70] This

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61. *Valisure Detects High Levels of Known Human Carcinogen Benzene in Several Sunscreen Products and Requests FDA Actions*, VALISURE (May 25, 2021), https://www.valisure.com/blog/valisure-news/valisure-detects-benzene-in-sunscreen/ [https://perma.cc/H9W7-RYGR].

62. *Id.*

63. *Johnson & Johnson Consumer Inc. Issues Voluntary Recall of Specific NEUTROGENA® and AVEENO® Aerosol Sunscreen Products Due to the Presence of Benzene*, JOHNSON & JOHNSON (July 14, 2021), https://www.jnj.com/johnson-johnson-consumer-inc-issues-voluntary-recall-of-specific-neutrogena-and-aveeno-aerosol-sunscreen-products-due-to-the-presence-of-benzene [https://perma.cc/MYV2-UVHB].

64. *Id.*

65. Timothy Bella & Janna Mandell, *Johnson & Johnson Recalls Five Neutrogena, Aveeno Sunscreen Products Containing Traces of Benzene*, WASH. POST (July 16, 2021), https://www.washingtonpost.com/health/2021/07/15/johnson-johnson-sunscreen-recall-benzene/ [https://perma.cc/5Z6H-GPEK].

66. Edney, *supra* note 60.

67. Bella & Mandell, *supra* note 65.

68. Edney, *supra* note 60.

69. *See, e.g.*, Mull, *supra* note 2.

70. Wong, *supra* note 31.

disparity is partly why Asian countries have made greater efforts to produce sunscreen that is as light and comfortable as possible.[71] In contrast, many sunscreens on the market in the United States are still seen as heavy and uncomfortable.[72]

The controversy surrounding the brand KraveBeauty, and its product "Beet the Sun," recently provided an example of how the FDA's restrictions on new sunscreen technology have impacted the sunscreen market and the safety of sunscreen consumers. Beet the Sun, a chemical sunscreen with SPF 50+, was created by KraveBeauty with advanced sun filters widely used and tested in Asia.[73] Because the FDA has not yet approved these filters, the brand renamed and sold the exact same product in the United States without the SPF label to work around the FDA regulations.[74] Known in the United States as "The Beet Shield," KraveBeauty marketed the product as an "antioxidant day fluid" but made clear to consumers it had the same exact formulation as the original product.[75] The Beet Shield became exceedingly popular in the United States because of its desirable consistency and lack of white cast.[76]

Following reports that several Korea-based manufacturers and independent testing labs had produced faulty results that led to products advertising incorrect SPF claims, KraveBeauty commissioned independent testing to verify its SPF claims.[77] Unfortunately, the test results showed the product's formula "performed below" KraveBeauty's standards[78] and, as such, the brand discontinued sales of Beet the Sun and The Beet Shield from all markets.[79] KraveBeauty reported it legally could not disclose the exact results of their independent testing, but they did assure customers that the product had some level of SPF.[80] The KraveBeauty mishap underscores the need for the FDA to work more

71. *Id.*

72. *Id.*

73. Ali Oshinsky, There's No Good Excuse to Skip SPF Anymore, INTO THE GLOSS, https://intothegloss.com/2020/07/new-sunscreens-summer-2020/ [https://perma.cc/FMG6-7BF5].

74. *Id.*

75. Michelle Wong, *Sunscreen Reviews: Krave Beauty, Lagom, Pestlo*, LAB MUFFIN BEAUTY SCI., https://labmuffin.com/sunscreen-reviews-krave-beauty-lagom-pestlo [https://perma.cc/RKZ5-RF3A].

76. *Id.*

77. *Beet the Sun Statement*, KRAVEBEAUTY (2022), https://kravebeauty.com/pages/beet-the-sun-statement [https://perma.cc/HB8S-85RA].

78. KraveBeauty did not announce the standards it used to conduct the testing, stating: "Unfortunately, due to legal and privacy constraints, we're not able to release our exact results or testing documentation to the public." *Id.*

79. *Id.*

80. Aamina Khan, *Krave Beauty Discontinues Beet the Sun Sunscreen, Offers Explanation*, TEENVOGUE (Apr. 13, 2021), https://www.teenvogue.com/story/krave-beauty-discontinues-beet-the-sun-sunscreen [https://perma.cc/QEF4-VM6C].

quickly to review new sunscreen technology so consumers are not harmed by companies who attempt to sidestep regulation.

E. Purito Backlash

In another recent case involving a cult-classic Korean sunscreen product, Centella Green Level Unscented Sun, the brand Purito faced backlash after discovering that the product's SPF levels were well below the advertised level of SPF 50+.[81] News of this issue spread quickly after INCIDecoder, an ingredient database founded by a cosmetic chemist, published the results of its independent testing of the SPF levels in Centella Green Level Unscented Sun.[82] Soon after, Purito reacted by discounting the product.[83]

Unlike KraveBeauty's sunscreen, Purito's sunscreen was marketed as having SPF even though the FDA had not approved its SPF technology.[84] In 2018, the FDA filed a warning letter against the company manufacturing Purito's sunscreen for failing to ensure the drugs it made had "the identity, strength, quality, and purity they claim to possess."[85] Therefore, while the FDA had warned Purito about the issues with their product, it took a third-party to protect consumers from the dangerous consequences of SPF mislabeling.

The Purito scandal once again demonstrates the FDA's crucial role in actively ensuring sunscreen consumers are protected from false advertising and able to trust the effectiveness of their sunscreen products.

II. SUNSCREEN REGULATION AT THE FEDERAL LEVEL

Although sunscreen has garnered widespread media attention in recent years, sunscreen regulation is not new to Congress or the FDA. Thus, Part II of this Note first examines the history of Congress and the FDA's attempts to regulate sunscreen and then explains the FDA's most recent proposed order regarding sunscreen regulation.

A. Sunscreens Regulated as Drugs

The Food, Drugs, and Cosmetic Act (FDCA) delegates authority to the FDA to regulate food, drugs, cosmetics, and medical devices.[86] In the

81. Rio Viera-Newton, *What Went Wrong with Purito's Centella Green?*, N.Y. MAGAZINE (Dec. 15, 2020), https://nymag.com/strategist/2020/12/what-went-wrong-with-puritos-sunscreen.html [https://perma.cc/JH98-62N2].

82. *Id.*

83. *Id.*

84. *Id.*

85. *Id.*

86. *See* Federal Food Drug and Cosmetic Act, 21 U.S.C. §§ 301–399a (2010).

1970s, the FDA started to regulate sunscreens as OTC drugs.[87] Because the FDA regulates sunscreen as a drug, unlike other countries' regulatory bodies that regulate sunscreen as a cosmetic, the United States requires every ingredient in sunscreen products to pass rigorous, time-consuming, and expensive testing.[88]

Before a sunscreen manufacturer can market a product containing a new active ingredient, it must submit a New Drug Application (NDA) to the FDA, showing the product is safe and effective.[89] The FDA's Center for Drug Evaluation and Research (CDER) determines whether to allow new drugs to be marketed in the United States.[90] If the CDER decides the drug's known risks outweigh its benefits, it will deny the application.[91] Additionally, the FDA may accept an OTC drug into the United States market under an OTC monograph.[92] The OTC monograph is similar to a "recipe book" as it includes approved "ingredients, doses, formulations, labeling, and, in some cases, testing parameters."[93] If they conform to a monograph, sunscreen manufacturers outside the United States can introduce their products into the OTC marketplace without FDA approval.[94]

However, a growing number of active ingredients and sunscreen products used abroad cannot be legally used in sunscreens sold in the United States without FDA approval. Despite the FDA's well-established process for OTC drug review, it has been slow to approve new active ingredients for sunscreen products that have been long approved for use abroad.[95]

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87. Emily Jones, *Stripped from Sunscreen, but Fine for Foundation: How the Regulatory Dichotomy of Topically Applied Skin Products Endangers Women*, 35 WIS. J. L., GENDER & SOC'Y 143, 156 (2020).

88. Theresa M. Michele, *From Our Perspective: Helping to Ensure the Safety and Effectiveness of Sunscreens*, U.S. FOOD & DRUG ADMIN. (Nov. 21, 2016), https://www.fda.gov/drugs/news-events-human-drugs/our-perspective-helping-ensure-safety-and-effectiveness-sunscreens [hereinafter *From Our Perspective*] [https://perma.cc/2M6K-WXM6].

89. *How Drugs Are Developed and Approved*, U.S. FOOD & DRUG ADMIN (Jan. 7, 2019), https://www.fda.gov/drugs/development-approval-process-drugs/how-drugs-are-developed-and-approved [https://perma.cc/9PJR-VAY9].

90. *Id.*

91. *Id.*

92. *Id.*

93. *Id.*

94. *Id.*

95. *See* Edward Hale*, Bringing Sunscreen into the 21st Century*, REGUL. REV. (May 27, 2019), https://www.theregreview.org/2019/05/27/hale-sunscreen-regulation-proposed-rule/ [https://perma.cc/6R6Q-EL2L].

In 2002, the FDA created Time and Extent Applications (TEAs) in an effort to modernize sunscreen regulation.[96] If a sunscreen ingredient had a five-year history of extensive and safe OTC use in another country, then the ingredient would be eligible for a fast-track application process with the FDA.[97] That said, this change did not result in any additional approvals,[98] a disappointing result leading some critics to believe the FDA simply does not consider sunscreen regulation a priority.[99]

B. The Sunscreen Innovation Act

Discouraged sunscreen manufacturers joined with cancer prevention organizations and others interested in the sunscreen market to form the Public Access to Sun Sunscreens (PASS) coalition.[100] With ending the sunscreen drought in mind, PASS lobbied Congress, and the Sunscreen Innovation Act (SIA) was enacted in November 2014.[101] The SIA supplemented TEA regulation with new statutory procedures and a new process for reviewing the safety and effectiveness of nonprescription sunscreen active ingredients.[102] Further, the SIA required the FDA to streamline approval of new ingredients in OTC sunscreen and update the sunscreen monograph by November 2019.[103] However, the SIA never meaningfully reached its goal because it failed to provide the FDA with additional resources or flexibility in the review process.[104]

Under the SIA, the FDA proposed sunscreen orders for eight sunscreen active ingredients available in other countries but only available in the United States following an approved new drug application (NDA).[105] The FDA concluded it needed additional research and pointed

96. Marc S. Reisch, *After More than a Decade, FDA Still Won't Allow New Sunscreens*, CHEM. & ENG'G NEWS (May 18, 2015), https://cen.acs.org/articles/93/i20/Decade-FDA-Still-Wont-Allow.html [https://perma.cc/J7U5-N88T].

97. *Id.*

98. Jones, *supra* note 87, at 157.

99. Reisch, *supra* note 96.

100. *Id.*

101. *Id.*; *see also* Sunscreen Innovation Act, Pub. L. No. 113-195, § 586, 128 Stat. 2035 (2014) (codified as amended at 21 U.S.C. § 360fff).

102. *From Our Perspective*, *supra* note 88; *see also* Sunscreen Innovation Act § 586, 128 Stat. at 2035.

103. Jones, *supra* note 87, at 157–58; *see also* § 586, 128 Stat. at 2045.

104. Davidson, *supra* note 19, at 217.

105. *From Our Perspective*, *supra* note 88; *see also New Drug Application (NDA)*, U.S. FOOD & DRUG ADMIN. (Jan. 21, 2022), https://www.fda.gov/drugs/types-applications/new-drug-application-nda [https://perma.cc/L68E-CEZR] ("The NDA application is the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing in the U.S.").

to outstanding data gaps for each active ingredient.[106] That said, the FDA did not move forward in this process because it never received the data.[107]

Then, in February 2019, the FDA proposed a new rule, under the SIA, to make safe sunscreens more available to the public.[108] This rule, entitled "Sunscreen Drug Products for Over-the-Counter Human Use," proposed conditions the FDA would follow to determine whether OTC sunscreen products are generally recognized as safe and effective (GRASE) and not misbranded.[109] The FDA recognized that there had been a substantial increase in sunscreen use and critical research on sunscreen ingredients since the 1999 Final Monograph.[110]

C. CARES Act

Despite the progress it made, the FDA's proposed order in 2019 was cancelled by the 2020 Coronavirus Aid, Relief, and Economic Security (CARES) Act. Through the CARES Act, Congress established a "final administrative order," referred to by the FDA as the "deemed final order,"[111] for OTC sunscreens and set the current requirements.[112] The provisions in the CARES Act "establish[ed] conditions under which the FDA [may] permit certain OTC drugs to be marketed without approved new drug applications because they are . . . (GRASE), so long as they comply with all other applicable requirements."[113] The CARES Act replaced the rulemaking process for OTC monograph drugs with an administrative process for issuing, revising, and amending the OTC monographs.[114] This new process was intended to help the FDA respond to new scientific advances and safety issues more quickly than it had been able to in the past.[115] The CARES Act also required the FDA to issue a

106. *Id.*

107. *Id.*

108. Jones, *supra* note 87, at 157–58.

109. Sunscreen Drug Products for Over-the-Counter Human Use, 84 Fed. Reg. 6,204, 6,206 (proposed Feb. 26, 2019).

110. *Id.*

111. *Questions and Answers: FDA Posts Deemed Final Order and Proposed Order for Over-the-Counter Sunscreen*, U.S. FEED & DRUG ADMIN. (Nov. 16, 2021), https://www.fda.gov/drugs/understanding-over-counter-medicines/questions-and-answers-fda-posts-deemed-final-order-and-proposed-order-over-counter-sunscreen [hereinafter *Questions and Answers*] [https://perma.cc/3ZJ4-VMVS].

112. *FDA Takes Steps Aimed at Improving Quality, Safety and Efficacy of Sunscreens*, U.S. FEED & DRUG ADMIN. (Sept. 24, 2021), https://www.fda.gov/news-events/press-announcements/fda-takes-steps-aimed-improving-quality-safety-and-efficacy-sunscreens [https://perma.cc/QDZ5-PA47].

113. *Id.*

114. *Id.*

115. *Id.*

revised proposed order by September 27, 2021, to revise the deemed final order for sunscreens.[116]

D. 2021 Proposed Rule

On November 12, 2021, the FDA announced a proposed order entitled "Amending Over-the-Counter (OTC) Monograph M020: Sunscreen Drug Products for OTC Human Use."[117] The proposed order is supposed to be used as a "vehicle" to transition the FDA's ongoing considerations surrounding requirements for OTC sunscreens marketed without approved applications from the previous rulemaking process to a new rulemaking process.[118] The FDA has relied mainly on the same scientific data from the 2019 proposed rule.[119] Therefore, the proposed rule requirements are substantively the same as those included in the 2019 proposed rule.[120] Like the 2019 proposed order, this proposed order advances proposals addressing the other conditions of use for sunscreen drug products marketed without an approved application, including broad-spectrum protection, maximum SPF requirements, dosage forms, labeling, final formulation testing and recordkeeping, sunscreen-insect repellent combinations, and more.[121] However, the FDA hopes the comment period will shed light on new scientific data that was not previously available for the 2019 proposed rule.[122] Specifically, the FDA is seeking additional scientific data on the active ingredients commonly found in sunscreen products.[123]

The proposed order includes a few key differences from the CARES Act deemed final order. First, the deemed final order concluded sunscreens containing sixteen specified sunscreen active ingredients were GRASE by incorporating the ingredients from the 1999 sunscreen monograph.[124] In contrast, the proposed order recommends GRASE status for only two active ingredients.[125] Additionally, unlike the deemed final order, which

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116. *Id.*

117. Amending Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use; Over the Counter Monograph Proposed Order, 86 Fed. Reg. 53,322 (proposed Sept. 27, 2021).

118. *Id.* at 53,323.

119. *Id.*

120. *Id.* at 53,323–24.

121. *Id.* at 53,323.

122. *Id.* at 53,324.

123. *Id.*

124. Theresa M. Michele, *An Update on Sunscreen Requirements: The Deemed Final Order and the Proposed Order*, U.S. FOOD & DRUG ADMIN. (Dec. 16, 2022), https://www.fda.gov/drugs/news-events-human-drugs/update-sunscreen-requirements-deemed-final-order-and-proposed-order [https://perma.cc/NH8G-PKFJ].

125. *Id.*

does not require broad-spectrum, the proposed order includes a requirement that all sunscreens with SPF values of fifteen and above satisfy broad-spectrum requirements.[126] These proposals, according to the FDA, "are designed to ensure that consumers have access to sunscreens with adequate ultraviolet A rays (UVA) protection, given the growing body of data linking UVA exposure to skin cancers and other harms."[127]

The proposed order also includes updates regarding how sunscreen products are labeled so consumers can identify key product information easily on sunscreen packaging.[128] Products that have not been shown to protect against the harms of sun exposure would be required to say so on the product's packaging.[129] Because accurate and transparent labeling impacts whether consumers will purchase a product and how they will use a product, the FDA's proposed changes in this area aim to protect consumers from relying on ineffective sunscreen products.[130] In another change to labeling requirements, the proposed order also includes a limit on the SPF value sunscreen products can claim to have.[131] Ideally, this requirement will protect consumers from over relying on sunscreen products with large SPF values, which can provide consumers with a false sense of security.[132]

III. HOW THE FDA CAN EFFECTIVELY USE ITS AUTHORITY TO PROMULGATE AN EFFECTIVE FINAL RULE

The bottom line in the fight over sunscreen regulation is that consumers need to be confident the FDA is regulating sunscreen products in a way that ensures safety and effectiveness. In its final regulation, the FDA needs to build public trust in sunscreen products by providing clear standards, to which sunscreen manufacturers must adhere. As of now, the debate over the safety of certain sunscreen ingredients is unclear because of a dearth of scientific studies and FDA resources. Consumers can feel they are currently presented with the decision to use sunscreen, and possibly face the adverse consequences of harmful ingredients, or forgo

126. *Id.*

127. *FDA Takes Steps Aimed at Improving Quality, Safety and Efficacy of Sunscreens*, *supra* note 112.

128. *Questions and Answers*, *supra* note 111.

129. *Id.*

130. *See* Jeanette Contreras, Dir. of Health Pol'y, Nat'l Consumers League, Comment Letter on Docket No. FDA-1978-N-0018-15815 (Nov. 11, 2021), https://www.regulations.gov/comment/FDA-1978-N-0018-15842 [https://perma.cc/R2HN-WAU5].

131. Amending Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use, 86 Fed. Reg. at 53324.

132. James Hamblin, *How SPF Ratings Can Do More Harm than Good*, ATLANTIC (Aug. 15, 2016), https://www.theatlantic.com/health/archive/2016/08/psychology-of-spf/495542/ [https://perma.cc/WM65-G36K].

sunscreen, and risk harmful sun exposure. The FDA can give consumers a better choice than that.

As previously mentioned, the FDA is specifically seeking safety data on twelve chemicals commonly found in sunscreen products to determine whether those ingredients are safe for everyday use. Currently, it is unknown whether the FDA has received enough evidence through the notice and comment period to determine whether the relevant chemicals are in fact GRASE. With its failure to finalize timely and effective regulation in mind, the FDA should not allow an expansive extension in its rulemaking process like it repeatedly has in the past. Although the FDA has limited resources to allocate, the pending final rule should be a priority for the FDA because of its long history of failing to regulate sunscreen products and corresponding lack of public confidence. In addition, Congress should increase the FDA's funding to give it the resources to move quickly and definitively on issuing a final rule.

A. The FDA Should Look to Social Media to Understand How Consumers Are Interacting with Sunscreen Products

The FDA can inspire confidence in the safety of sunscreen and increase sunscreen use by paying attention to current sunscreen trends. Consumers are no longer willing to wear a sunscreen product that leaves an uncomfortable and unappealing white residue.[133] Thus, the FDA needs to be aware of where the sunscreen market is going so it can encourage the innovation of products consumers are excited to wear and protect consumers from new products that may be untested and dangerous.

Social media influencers in the beauty community are on the cutting edge of sunscreen trends.[134] These influencers are in touch with what kinds of sunscreen products consumers are interested in buying and wearing daily.[135] While the FDA and social media influencers are unlikely friends, the FDA can utilize influencers' knowledge and market-creating power to tailor their rulemaking in a way that covers the types of sunscreen products consumers actually use.

The FDA should also use social media influencers to understand new sunscreen products overlooked in its previous regulation. Manufacturers have quickly and creatively transformed the form sunscreen products take, using sunscreen in the form of mists, powders, serums, and other

133. *See, e.g.*, Wong, *supra* note 31; Mull, *supra* note 2.

134. *See, e.g.*, *#sunscreen on TikTok*, *supra* note 42; *#sunscreen on Instagram*, *supra* note 42.

135. *See, e.g.*, *#sunscreen on TikTok*, *supra* note 42; *#sunscreen on Instagram*, *supra* note 42.

innovative skincare products.[136] These new products put aside traditional formulas by providing lightweight, comfortable, and aesthetically-pleasing sunscreen options.[137] The FDA needs to act more quickly moving forward to review new sunscreen technology to protect consumers from the potential dangers posed by this fast-moving industry and allow effective forms of sunscreen to enter the market.

There is a difficult balance to strike between innovation and protection, and social media influencers can offer valuable information to the FDA about how consumers are engaging with sunscreen use. Consequently, influencers may help the FDA find ways to improve public trust in sunscreen because of the connection and power they have over millions of social media users. For example, the FDA can utilize social media influencers to understand the key sunscreen ingredients that worry consumers and the new sunscreen products that are exciting consumers. Understanding consumers' main concerns and preferences will aid the FDA in their rulemaking process because it will better be able to address the critical obstacles, still in play, for consumer daily use of and trust in sunscreen.

B. The FDA Can Rely More Heavily on Foreign Innovation in Sunscreen

To further encourage safe and desirable sunscreen products entering the American market, the FDA should put more resources into analyzing foreign innovation in sunscreen formulation.[138] As seen in the KraveBeauty and Purito sunscreen scandals, other countries, especially those in Asia and Europe, have progressed much farther than the United States in terms of sunscreen innovation.[139] Other countries have already formulated and tested new sunscreen technologies, which have been proven safe and effective.[140]

The FDA should streamline its new sunscreen ingredients review process by accepting foreign market experience data.[141] Foreign data can be highly beneficial to the FDA's understanding of how sunscreen products are performing abroad and can contribute to its effort to enhance consumer trust. The FDA can also mitigate the costs for sunscreen manufacturers, who would otherwise have to duplicate the efforts of other countries. Innovative sunscreen technology, especially being marketed by

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136. Jessica Schiffer, *Sunscreen Gets a Glow Up*, N.Y. TIMES (Jul. 28, 2021), https://www.nytimes.com/2021/07/28/fashion/sunscreen-gets-a-glow-up.html?searchResultPosition=1 [https://perma.cc/LRS6-9FVC].

137. *See, e.g.*, *#sunscreen on TikTok*, *supra* note 42; *#sunscreen on Instagram*, *supra* note 42.

138. *See, e.g.*, Davidson, *supra* note 19.

139. Mull, *supra* note 2.

140. *Id.*

141. Jones, *supra* note 87, at 157–58.

smaller or newer businesses, would not be kept out of the American market because of the expensive cost and time to gain FDA approval.[142] This approach does involve more risk than the current FDA approach; however, without a significant shift in the way the FDA regulates sunscreen, it is unlikely the FDA will be able to avoid the pattern of failure it has experienced in regulating sunscreen products for decades.[143]

Before deciding how to classify the active ingredients being considered under the proposed rule, the FDA should consider the history of how these ingredients have performed in foreign markets. As of now, the proposed order recommends that twelve UV filters be reclassified from GRASE Category I to GRASE Category III, which would require additional data to support GRASE status.[144] However, most of these filters have a long history of being safe for consumer use internationally, as proven by extensive studies conducted in other regions of the world.[145] If the FDA moves forward with reclassifying these filters without first taking into account all available data, it could further contribute to public mistrust of sunscreen.[146] When working to regulate a product that is so essential to public health, the FDA needs to consider the lasting impact of reclassification without proper evaluation.[147]

After the proposed order is adopted, the FDA should look to how other countries have implemented sunscreen regulation to ensure sunscreen manufacturers have adequate time to adjust to the order's new requirements.[148] Once the proposed order goes into effect, sunscreen manufacturers will be burdened with updating their formulas, labeling, and packaging, and with performing new tests on their products.[149] Consumers will likely see sunscreen products increase in price and decrease in availability during this time-consuming and expensive process.[150] If sunscreen manufacturers have to increase prices and pull products off the shelves, public health could be negatively impacted as consumer access to sunscreen is depleted.[151] With that said, the FDA can mitigate some of these negative consequences by looking to the EU's

142. *Id.* at 333.

143. *Id.*

144. Gerald Renner, Dir. Tech. Regul. & Int'l Affs., Cosmetics Eur., Comment on WTO Notification Proposed Order Amending Over-the-Counter Monograph 020: Sunscreen Drug Products for Over-the-Counter Human Use, at 2 (Nov. 5, 2021), https://www.regulations.gov/comment/FDA-1978-N-0018-15826 [https://perma.cc/N3R4-DC7A].

145. *Id.*

146. *Id.*

147. *Id.*

148. *Id.*

149. *Id.*

150. *Id.* at 4.

151. *Id.*

experience with implementation.[152] According to experience in the EU, the FDA should allow "an implementation time of at least [twenty-four] months and a sell-through period for existing stock of at least [four] years."[153]

The FDA's careful approach to sunscreen regulation has been generally beneficial to consumers, but the slow progress towards increasing the availability of effective and desirable sunscreen products can be significantly helped by adopting the practices seen abroad.

CONCLUSION

The FDA is currently presented with a pivotal opportunity to promulgate sunscreen regulation that encourages consumers to use sunscreen. After failing to provide definitive sunscreen regulation for decades, despite the substantial increase in sunscreen innovation abroad and the growing research on the dangers some sunscreen ingredients pose to consumers, the FDA has damaged the public's trust in sunscreen and put the health of many Americans at risk .[154] Many Americans are excited about using sunscreen and adding it to their daily skincare routine,[155] but consumers are no longer willing to use traditional undesirable sunscreen products.[156] Therefore, the FDA has a unique opportunity to change the way sunscreen is viewed by updating its regulation to be safer and more innovative.

The FDA must work to make their review process of sunscreen products and ingredients more efficient and effective. One critical step is for the FDA to increase the amount of resources it allocates to review and approve new sunscreen products. Congress should provide the FDA with more funding for this purpose. The FDA can also look to social media influencers focused on creating sunscreen content to understand consumer trends and fears. Further, the FDA should look to other countries with more advanced sunscreen regulations and products as a model. Overall, whatever path the FDA takes to finalize its rule on sunscreen, it is apparent that the United States is in critical need of effective sunscreen regulation to ensure that Americans have access to safe sunscreen that is actually used.

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152. *Id.*

153. *Id.*

154. *See, e.g.*, Davidson, *supra* note 19, at 217; Ducharme, *supra* note 33.

155. *See Sun Care Products Market to Reach USD 16.84 Billion by 2027, supra* note 7.

156. *See, e.g.*, *#sunscreen on TikTok*, *supra* note 42; *#sunscreen on Instagram*, *supra* note 42; Wong, *supra* note 31.