Exploring Barriers to Sunscreen Development in the United States

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On my honor as a University Student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments

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Introduction

While sunscreens are made to protect against ultraviolet (UV) rays from the sun, Americans do not have easy access to technologically advanced sunscreens, which leave them more prone to the effects of sun exposure. Skin cancer is the most common cancer in the United States (Centers for Disease Control and Prevention [CDC], n.d.). It is currently estimated that every 1 in 5 Americans will develop skin cancer. Skin cancer can be attributed to long-term exposure to the sun. Other consequences include skin damage and premature aging. To avoid these risks, time spent in the sun should be limited. Otherwise, sunscreen should also be used and reapplied throughout the day. While sunscreen is associated with the summer, it should be used year-round to ensure proper UV protection.

Sunscreens are specially formulated to reflect or absorb UV rays to their maximum. They can also be formulated to be lightweight and invisible on the skin. However, sunscreens made in the United States (U.S.) may not offer the best protection from the sun. In a 2016 study, it was found that American sunscreens allow up to three times more UVA rays than European sunscreens (Diffey, 2016). They also tend to feel heavier and greasier on the skin compared to international products. A large reason is that ingredients that improve textures are not allowed in the U.S. but are in other countries.

As of 2025, the Food and Drug Administration (FDA) only has 16 approved ingredients that can be used as active ingredients in sunscreen (21 CFR § 352.10). The last time a new ingredient was approved was in 1999. Sunscreens made in the U.S. are required to adhere to FDA regulations. As a result, sunscreen formulations have not changed much since then. When looking at the European Union, its list contains 34 ingredients (Regulation 1223/2009). The difference in the length of lists reveals that the American sunscreens are limited in what they can

achieve. This raises the question: *Why is sunscreen development slower in the United States than in other countries?*

Background

The FDA has played a central role in regulating sunscreens since the 1970s, and this long-standing authority helps explain some of the challenges in sunscreen development today. As a result, the focus is directed to the FDA when understanding some of the problems that arise from sunscreens. A more common example may show how people of color are affected by sunscreens. There are two types of sunscreens available for purchase, chemical and mineral. Chemical sunscreens absorb UV radiation and convert it to heat, while mineral sunscreens use ingredients like zinc oxide to reflect UV rays off the skin. While both types offer protection, each has different formulation challenges and public perceptions. For example, one major problem with mineral sunscreens is that they can often leave a white cast. While this can affect everyone, it is more noticeable in those with darker complexions. When looking for the reason, many will turn to the FDA due to the lack of options to eliminate white cast. This may be due to the limited range of FDA-approved ingredients, which limits how these mineral sunscreens can be formulated for approved appearance. Examining the FDA overall, some experts argue that the FDA's strict process ensures the safety and efficacy of sunscreens before they reach consumers. However, others view these regulations as the main reason for major delays and a barrier to accessing ingredients already being used worldwide.

A key reason for the delays in American sunscreen development is how sunscreens are classified differently across countries. In the U.S., it is classified as an over-the-counter (OTC) drug since it is “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of

diseases" (21 CFR § 314.3). The FDA works to ensure that ingredients will not ultimately lead to any harm to users. This leads to a long process of ensuring the safety of ingredients and meeting specific requirements. In other parts of the world, sunscreen is classified as a cosmetic. Sunscreens are still held to high standards, but the requirements are different. This allows new filters to be approved faster and provides better sun protection to sunscreen users.

This regulatory contrast has drawn concern from researchers and industry experts. Printz (2015) argues that the FDA's outdated processes have created persistent innovation bottlenecks. Narla and Lim (2020) similarly observe that while systemic absorption of UV filters has prompted FDA caution, conclusive health risks remain unproven. Diffey (2016) adds that the European cosmetic-based system enables quicker approval of more effective UVA filters, which are currently unavailable to U.S. consumers. These perspectives suggest that the American regulatory approach, while rooted in precaution, may inadvertently compromise public access to superior sun protection.

To address delays in sunscreen approval, Congress has implemented several acts to reform the FDA's process, though these efforts have fallen short. One of the most well-known is the Sunscreen Innovation Act (2014), which aimed to reduce delays in the FDA's review process for new UV filters. Another recent example is the Coronavirus Aid, Relief, and Economic Security Act (2020). It aimed to streamline the approval process, but instead reinforced the FDA's stance on sunscreen. Although the act replaced the traditional rulemaking process with an administrative order system intended to modernize and speed up approvals, it did not change the FDA's underlying safety requirements. As a result, the FDA continued to request additional safety and efficacy data for sunscreen ingredients, which led to further delays instead of progress. No new active ingredients have been approved under this system, showing that the act

strengthened the FDA's preference for thorough evaluation over faster access.

Despite calls for reform, the FDA remains cautious about unresolved questions about the long-term safety of sunscreen ingredients. One of the concerns is the absorption of some chemicals into the skin, but the long-term effects are currently unknown. However, it raises some questions about whether the risk from absorption is more dangerous than the known risks of cancer from UV exposure. As mentioned earlier, skin cancer is one of the most common cancers in the U.S. New UV filters can offer higher levels of protection, but Americans do not have access to these yet. Experts argue that sun protection is more important than skin absorption, but regulatory frameworks do not reflect that.

While regulation is a major factor, sunscreen development in the U.S. is shaped by a broader network of actors and expectations. Sunscreen development is often discussed in the context of the FDA's slow approval process. However, the development of sunscreens is influenced by a network of regulatory agencies, manufacturers, scientific advancements, and consumer behavior. Regulatory agencies review products to ensure they are safe for consumers. In the U.S., sunscreens are regulated by the FDA. Their standards influence the sunscreen formulations possible, and regulations may be updated to reflect current scientific research. This may include how effective an ingredient may be or how an ingredient may lead to potential issues with long-term usage.

Manufacturers and consumers also play critical roles in shaping what sunscreens reach the market, often constrained by the regulatory environment. Manufacturers aim to provide standard-compliant products that are still high quality and align with consumer preferences. However, their goals can be discouraged due to the lengthy process of new drug approval. Especially smaller manufacturers who may not have the resources to fund the extensive testing

required, making it more practical to stick with already approved FDA ingredients. Consumers can also affect the market and regulations through their expectations for textures and performance while also wishing to save their health and the environment.

Since sunscreen is shaped by multiple interconnected factors, this paper will explore the different influences on sunscreen development in the U.S.

Methodology

Different primary and secondary sources were used to learn more about each actor and their relationships. To investigate more about the FDA and its practices, FDA regulations, policy documents, and public comments were examined to trace how regulatory frameworks evolved and why ingredient approvals have stalled. International regulatory frameworks from the European Union and Japan were analyzed to contrast ingredient classifications and consumer access. Academic literature and scientific studies were reviewed to assess the safety concerns behind FDA decisions, particularly regarding systemic absorption of UV filters. Public responses were evaluated through company announcements and news coverage to understand how regulatory constraints and scientific uncertainty influence product availability and innovation.

Results and Discussion

Regulatory Barriers

One major barrier to sunscreen innovation in the U.S. is the FDA's extensive safety testing requirements. This has significantly slowed the approval of new UV filters. As mentioned earlier, the FDA defines sunscreen as an OTC drug. OTC drugs are subject to tests to ensure the safety of consumers. These include evaluations for toxicity, stability, SPF performance, and

potential effects (*FDA Regulation of Over-the-Counter (OTC) Drugs*, 2021). In addition, the FDA often requires data on systemic absorption and long-term health effects, including concerns about hormone disruption or reproductive toxicity. These requirements are more extensive compared to some countries that treat sunscreen as a cosmetic, which generally results in faster ingredient approval. Together, these tests aim to confirm that sunscreens are both safe for long-term use and reliable in real-world conditions. Because of these rigorous standards and the lack of conclusive safety data on certain new ingredients, no new UV filters have been approved in the U.S. for decades.

This prolonged lack of approval can give the impression that unapproved UV filters are inherently unsafe. However, many of these ingredients have already passed safety evaluations and are widely used in European and Asian sunscreens. The continued delay in approval reflects the FDA's cautious approach rather than evidence that these ingredients are inherently harmful. To better understand why these delays persist in the U.S., it is useful to see how sunscreen is regulated in other countries.

Several ingredients have been awaiting FDA approval since 2002, but have not yet been approved (Printz, 2015). These include some ingredients already approved in Europe and some Asian countries, such as Mexoryl SX and Tinosorb S. A reason for this is that sunscreen is defined as a cosmetic ingredient. The European Commission (EC), the European Union's main executive body, specifically defines sunscreen as any preparation (cream, oils, gels) that is intended to protect the skin from UV radiation (Regulation 1223/2009). Sunscreens are mostly subject to testing to ensure they meet EC's UV protection standards. The Ministry of Health in Japan also views sunscreens as a quasi-drug (*Cosmetics and quasi-drug notification in Japan*, n.d.). This is the bridge between pharmaceuticals and beauty products. So, Japan acknowledges

the UV protection of its active ingredients, but it can still act as a cosmetic. Regardless, sunscreen is not treated like a full drug as it is in the U.S. While cosmetic regulations may appear to be a workaround, they are still held to high standards to ensure that sunscreens are safe and effective. This classification also allows users in Europe and Asia better protection against the sun since newer UV filters can be used.

While the international systems provide more regulatory flexibility, U.S. manufacturers remain limited by the FDA's drug-based framework. This framework adds cost, time, and uncertainty to the development process.

Manufacturers and Lengthy Approval Processes

In addition to regulatory classifications, sunscreen development is also constrained by the burdens placed on manufacturers. Manufacturers face high costs, lengthy timelines, and regulatory uncertainties when attempting to introduce new ingredients. Before a product can be approved, companies must provide extensive safety and efficacy data. While it is only helpful for their products, it can be time-consuming and places a financial burden on the company since research and development costs can be high. To address this issue, the Sunscreen Innovation Act (SIA) was enacted in 2014 to accelerate the approval process. SIA required the FDA to review new sunscreen ingredients within 300 days, or 180 days for existing applications. However, rather than streamline the process, it introduced more safety standards. For example, under SIA, the FDA began requiring additional testing on systemic absorption and potential endocrine disruption for UV filters. This includes long-term toxicology studies, which are expensive and could take months or even years. As a result, instead of accelerating approvals, the act increased the regulatory and financial burden on manufacturers. This financial burden can discourage

smaller companies from entering the market if they have new UV filters and deter larger companies from innovating new products.

When companies are looking to market new formulations, they have three regulatory options, each with its own barriers. The first is to follow the existing OTC administrative order that was created under the 2020 Coronavirus Aid, Relief, and Economic Security Act and finalized in 2022 with the FDA's Final Administrative Order (FDA, 2022). This order lists 16 active ingredients as generally recognized as safe and effective. The order also defines permitted dosages, labeling requirements, and combination rules for formulations. This path is the most straightforward since it avoids the need to seek out new approvals. However, this also limits innovation to the currently approved ingredients.

The second is to submit a Time and Extent Application (TEA) to add to the administrative order (21 CFR § 330.14). This application is designed to allow ingredients marketed abroad for at least five years to be evaluated and potentially added. The FDA then reviews available safety and efficacy data from international use, but often requires supplemental studies to meet U.S. standards. This is especially true for systemic absorption, long-term exposure, and potential hormonal effects. This process differs from foreign regulatory bodies that may accept more streamlined toxicology assessments or operate under different safety thresholds for cosmetic classification. While TEA is meant to facilitate bringing new UV filters into U.S. markets, delays have prevented the approval of new ingredients. This discourages companies from taking this approach and using currently approved ingredients on the list. Some UV filters, such as Tinosorb S, Tinosorb M, and Mexoryl SX, have been widely adopted in Europe (Regulation 1223/2009) but are unavailable in American sunscreens due to the lengthy FDA approval process.

The third, and most rigorous, is to submit a New Drug Application (NDA). This route treats sunscreen as a new pharmaceutical drug and requires full pre-clinical and clinical testing. An advantage of this method is that the FDA aims to review standard NDAs within 6-10 months. This offers a more predictable timeline compared to TEA, since TEA does not have a set timeline for approval. This method also allows companies to bring new formulations to the market. However, due to the high costs involved in finding the required safety and efficacy data, companies may opt for ingredients already on the administrative order. As a result, this limits the number of innovative sunscreens introduced to the market.

Scientific Findings and Concerns

Scientific uncertainty around ingredient safety has become one of the FDA's primary reasons for delaying the approval of new sunscreen ingredients, creating a significant barrier to innovation. The FDA's strict system serves to ensure consumer safety. A major concern that arises from products that go on the skin is absorption. Recent studies have shown that some commonly used sunscreen ingredients, such as oxybenzone and avobenzone, are absorbed into the bloodstream and exceed the FDA's recommended thresholds (Narla & Lim, 2020). The same studies have detected these ingredients in urine, blood, and breast milk. While this confirms that ingredients are systemically absorbed, the presence of these chemicals alone does not prove that they cause harm. Toxicological studies have yet to establish clear links between sunscreen absorption and adverse health outcomes, including hormone disruption and reproductive health. These findings can raise concerns about sunscreen usage. This gap in evidence creates regulatory uncertainties. Ingredients are absorbed, but without conclusive data on their health effects, it is unclear whether they should be restricted. As a result, these findings raise concerns for both

regulators and consumers about the long-term use of sunscreen.

The lack of safety data leads to regulatory hesitancy as the FDA continues to require more research on ingredients before they can be approved. While this is in the interest of American consumers, there can be an argument that the need for sun protection is greater than the unknown risks. There should be a more balanced approach that weighs the established dangers of UV exposure against unconfirmed risks associated with absorption.

The tension between innovation and safety is also evident in the divide between chemical and mineral sunscreens. Chemical sunscreens absorb UV light but raise concerns due to their proven absorption into the skin. Meanwhile, mineral sunscreens are generally recognized as safe, but are avoided due to aesthetic concerns, such as white cast. This is especially discouraging for users with darker complexions. This aesthetic issue becomes a barrier to equitable sunscreen use and drives demand for more elegant formulations.

A solution to this is the use of nanoparticles to make mineral sunscreens more transparent. It was found that nanoparticles below 30 nanometers do not absorb into the skin (Close, 2023). This suggests that they could address the white cast issue without introducing absorption risks. However, the public perception of nanoparticles remains cautious, often influenced by misinformation or general fears around nanotechnology. This has discouraged companies from pursuing these formulations despite their potential to improve aesthetics while staying within FDA-approved ingredients. As a result, both scientific and consumer skepticism contribute to a slowed pace of sunscreen development. While these scientific concerns create challenges on their own, the way the public responds to them can also influence what kinds of sunscreens are developed or avoided.

Public Responses and Environmental Concerns

The public response to chemical sunscreen absorption has been divided, with some consumers continuing to use these products without concern, while others have become more hesitant due to potential health risks. This growing caution has contributed to the rise of the "clear beauty" movement. This movement centers around transparency, safety, and sustainability in the skincare and beauty industry (Santoro, 2022). Consumers who are unsure about what ingredients do or how they are regulated may avoid products that contain chemical UV filters. This is significant because the new, more effective UV filters used internationally are chemical-based. This means that public concern over absorption may discourage their use even if they have not been proven harmful. The movement can also amplify fear-driven narratives through social media and influencer marketing by spreading misinformation or incomplete interpretations of scientific findings. While only two of the FDA-approved UV filters are mineral-based, chemical sunscreens make up most innovations. This means that public hesitation can indirectly limit the adoption of advanced formulations in the U.S.

Concerns about ingredient safety and slow regulatory updates have caused some consumers to lose trust in the FDA's ability to keep up with global sunscreen innovation. Frustration over outdated FDA regulations and limited ingredient options has led some consumers to seek more advanced sunscreen products from abroad, even if those products are not approved for sale in the U.S. In these cases, the concern is less about the safety of U.S. regulation and more about the lack of access to newer, more effective formulations already available in Europe or Asia. The rise of online retail has made it easier for consumers to bypass domestic regulations and purchase international sunscreens. While this gives consumers access to newer products, it also increases the risk of counterfeit products. Without strict regulatory

enforcement, consumers may unknowingly purchase sunscreens that do not meet safety or efficacy standards. This workaround highlights how consumer frustration can lead to riskier choices, weakening the influence of the FDA and reducing incentives for domestic innovation.

The recent FDA expansion under the Modernization of Cosmetics Regulation Act has further restricted U.S. access to some international sunscreen products, reinforcing existing regulatory barriers. While this act does not reclassify sunscreens, it gives the FDA more authority over companies that sell cosmetic products in the U.S., including international brands that market sunscreen as part of their skincare lines. Under this act, manufacturers are required to register with the FDA and follow good manufacturing practices. As a result, sunscreens with unapproved UV filters have faced closer scrutiny, even if they are widely used abroad. One company impacted by this is Beauty of Joseon, a major Korean cosmetics company known for its sunscreens. In 2025, they announced that they are no longer selling some of their most popular sunscreens due to them not being FDA-compliant and creating new formulations that do (Seo, 2025). This development highlights how regulatory expansion, even outside the OTC classifications, can limit U.S. access to advanced sunscreen products. This reinforces existing barriers to innovation and availability.

Environmental concerns, including coral reef safety, influence sunscreen regulations and product demand, creating additional challenges for manufacturers. In 2021, it was found that some sunscreen ingredients contribute to coral reef bleaching. These findings have led some states and U.S. territories to ban the use of these ingredients (Miller et al, 2021). This includes Hawaii and the U.S. Virgin Islands since they are close to aquatic ecosystems. As a result of this ban, these areas sell “reef-safe” sunscreens. However, it should be noted that there is no standard for what it means for a sunscreen to be “reef safe.” The term is often used to describe mineral

sunscreens, but its use in marketing can be inconsistent. This lack of standardization creates confusion for consumers. It also challenges manufacturers to formulate environmentally responsible products that still meet regulatory and consumer expectations.

The abundance of information leaves consumers with a difficult choice in how they may wish to balance personal health risks, environmental responsibility, and the need for sun protection. This uncertainty creates a fragmented market, where manufacturers struggle to meet overlapping expectations while staying within regulatory limits. This interplay complicates regulatory discussions and makes it difficult to establish clear guidelines for sunscreen usage.

Conclusion

Regulatory barriers, scientific uncertainties, and public perception challenges have hindered the development of sunscreens in the U.S. While the FDA has a cautious approach to sunscreen, it has inadvertently led to a limited selection of sunscreens that leave Americans more at risk of skin damage and cancer. Meanwhile, consumer concerns about absorption and environmental impacts complicate the narrative more and lead to shifts in product preferences.

These issues reach beyond sunscreen regulations and extend to larger concerns about how society balances scientific uncertainties with public health needs. Future works can explore more about how regulatory frameworks can be adapted to adopt a more balanced approach to ensure public safety and to innovate at a more reasonable rate. However, it should be acknowledged that there is still a lack of studies regarding the long-term effects of sunscreen. Without the knowledge, it is difficult to confirm whether the FDA's approach is valid. Regardless, it is still important to address all the barriers to sunscreen development, and it would require an approach that influences all these factors to improve access to more advanced sunscreens.

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