What's Keeping the U.S. From Allowing Better Sunscreens?

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When dermatologist Adewole "Ade" Adamson sees people spritzing sunscreen as if it's cologne at the pool where he lives in Austin, Texas, he wants to intervene. "My wife says I shouldn't," he said, "even though most people rarely use enough sunscreen."

At issue is not just whether people are using enough sunscreen, but what ingredients are in it.

The Food and Drug Administration's ability to approve the chemical filters in sunscreens that are sold in countries such as Japan, South Korea, and France is hamstrung by a 1938 U.S. law that requires sunscreens to be tested on animals and classified as drugs, rather than as cosmetics as they are in much of the world. So Americans are not likely to get those better sunscreens — which block the ultraviolet rays that can cause skin cancer and lead to wrinkles — in time for this summer, or even the next.

Sunscreen makers say that requirement is unfair because companies including BASF Corp. and L'Oréal, which make the newer sunscreen chemicals, submitted safety data on sunscreen chemicals to the European Union authorities some 20 years ago.

Steven Goldberg, a retired vice president of BASF, said companies are wary of the FDA process because of the cost and their fear that additional animal testing could ignite a consumer backlash in the European Union, which bans animal testing of cosmetics, including sunscreen. The companies are asking Congress to change the testing requirements before they take steps to enter the U.S. marketplace.

In a rare example of bipartisanship last summer, Sen. Mike Lee (R-Utah) thanked Rep. Alexandria Ocasio-Cortez (D-N.Y.) for urging the FDA to speed up approvals of new, more effective sunscreen ingredients. Now a bipartisan bill is pending in the House that would require the FDA to allow non-animal testing.

"It goes back to sunscreens being classified as over-the-counter drugs," said Carl D'Ruiz, a senior manager at DSM-Firmenich, a Switzerland-based maker of sunscreen chemicals. "It's really about

giving the U.S. consumer something that the rest of the world has. People aren't dying from using sunscreen. They're dying from melanoma."

Every hour, at least two people die of skin cancer in the United States. Skin cancer is the most common cancer in America, and 6.1 million adults are treated each year for basal cell and squamous cell carcinomas, according to the Centers for Disease Control and Prevention. The nation's second-most-common cancer, breast cancer, is diagnosed about 300,000 times annually, though it is far more deadly.

Though skin cancer treatment success rates are excellent, 1 in 5 Americans will develop skin cancer by age 70. The disease costs the health care system $8.9 billion a year, according to CDC researchers. One study found that the annual cost of treating skin cancer in the United States more than doubled from 2002 to 2011, while the average annual cost for all other cancers increased by just 25%. And unlike many other cancers, most forms of skin cancer can largely be prevented — by using sunscreens and taking other precautions.

But a heavy dose of misinformation has permeated the sunscreen debate, and some people question the safety of sunscreens sold in the United States, which they deride as "chemical" sunscreens. These sunscreen opponents prefer "physical" or "mineral" sunscreens, such as zinc oxide, even though all sunscreen ingredients are chemicals.

"It's an artificial categorization," said E. Dennis Bashaw, a retired FDA official who ran the agency's clinical pharmacology division that studies sunscreens.

Still, such concerns were partly fed by the FDA itself after it published a study that said some sunscreen ingredients had been found in trace amounts in human bloodstreams. When the FDA said in 2019, and then again two years later, that older sunscreen ingredients needed to be studied more to see if they were safe, sunscreen opponents saw an opening, said Nadim Shaath, president of Alpha Research & Development, which imports chemicals used in cosmetics.

"That's why we have extreme groups and people who aren't well informed thinking that something penetrating the skin is the end of the world," Shaath said. "Anything you put on your skin or eat is absorbed."

Adamson, the Austin dermatologist, said some sunscreen ingredients have been used for 30 years without any population-level evidence that they have harmed anyone. "The issue for me isn't the safety of the sunscreens we have," he said. "It's that some of the chemical sunscreens aren't as broad spectrum as they could be, meaning they do not block UVA as well. This could be alleviated by the FDA allowing new ingredients."

Ultraviolet radiation falls between X-rays and visible light on the electromagnetic spectrum. Most of the UV rays that people come in contact with are UVA rays that can penetrate the middle layer of the skin and that cause up to 90% of skin aging, along with a smaller amount of UVB rays that are responsible for sunburns.

The sun protection factor, or SPF, rating on American sunscreen bottles denotes only a sunscreen's ability to block UVB rays. Although American sunscreens labeled "broad spectrum" should, in theory, block UVA light, some studies have shown they fail to meet the European Union's higher UVA-blocking standards.

"It looks like a number of these newer chemicals have a better safety profile in addition to better UVA protection," said David Andrews, deputy director of Environmental Working Group, a nonprofit that researches the ingredients in consumer products. "We have asked the FDA to consider allowing market access."

The FDA defends its review process and its call for tests of the sunscreens sold in American stores as a way to ensure the safety of products that many people use daily, rather than just a few times a year at the beach.

"Many Americans today rely on sunscreens as a key part of their skin cancer prevention strategy, which makes satisfactory evidence of both safety and effectiveness of these products critical for public health," Cherie Duvall-Jones, an FDA spokesperson, wrote in an email.

D'Ruiz's company, DSM-Firmenich, is the only one currently seeking to have a new over-the-counter sunscreen ingredient approved in the United States. The company has spent the past 20 years trying to gain approval for bemotrizinol, a process D'Ruiz said has cost $18 million and has advanced fitfully, despite attempts by Congress in 2014 and 2020 to speed along applications for new UV filters.

Bemotrizinol is the bedrock ingredient in nearly all European and Asian sunscreens, including those by the South Korean brand Beauty of Joseon and Bioré, a Japanese brand.

D'Ruiz said bemotrizinol could secure FDA approval by the end of 2025. If it does, he said, bemotrizinol would be the most vetted and safest sunscreen ingredient on the market, outperforming even the safety profiles of zinc oxide and titanium dioxide.

As Congress and the FDA debate, many Americans have taken to importing their own sunscreens from Asia or Europe, despite the risk of fake products.

"The sunscreen issue has gotten people to see that you can be unsafe if you're too slow," said Alex Tabarrok, a professor of economics at George Mason University. "The FDA is just incredibly slow. They've been looking at this now literally for 40 years. Congress has ordered them to do it, and they still haven't done it."

Dermatologists Offer Tips on Keeping Skin Safe and Healthy

– Stay in the shade during peak sunlight hours, 10 a.m. to 4 p.m. daylight time.
– Wear hats and sunglasses.
– Use UV-blocking sun umbrellas and clothing.
– Reapply sunscreen every two hours.

You can order overseas versions of sunscreens from online pharmacies such as Cocooncenter in France. Keep in mind that the same brands may have different ingredients if sold in U.S. stores. But importing your sunscreen may not be affordable or practical. “The best sunscreen is the one that you will use over and over again,” said Jane Yoo, a New York City dermatologist.

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