

Blame the FDA for Your Outmoded Sunscreen



By Henry Miller — September 19, 2019



Credit: Andrew Steele/Wikipedia [1]

By Henry I. Miller and Renata H. Mullen

As we've just passed the dog days of summer, when people were outside at swimming pools, the beach, and elsewhere, physicians like us were rightly concerned about sunscreens, which are critical for people exposed to the sun. It's a complex subject.

Earlier this year, the FDA proposed a [rule](#) [2] that describes the conditions under which over-the-counter (that is, nonprescription) sunscreen products are "generally recognized as safe and effective (GRASE)." It requests manufacturers of sunscreens on the market to provide information on the absorption through the skin of their products by November, or else some ingredients now used to prevent sunburn will have to be withdrawn from the market.

According to FDA regulators, if the active ingredients in sunscreens are absorbed into the bloodstream at a level of 0.5 nanograms per milliliter or higher, they should be tested to determine whether they increase the risk of cancer, birth defects, or other adverse effects. There is reason to believe that some commercially available sunscreens fall into this category: In a pilot study [published in May](#) [3], the active ingredients in four commercially available sunscreens exceeded that threshold.

Fortunately, the FDA isn't recommending that people stop using sunscreens while the data are being accumulated, because Americans are also getting skin cancer—and sometimes dying from it—at an alarming rate. What's also alarming, however, is that the FDA doggedly refuses to approve state-of-the-art sunscreens that could do a much better job protecting us from the sun's cancer-causing rays than the ones currently available in this country.

Meanwhile, the rest of the world has not been out snoozing in the sun. Since the 1990s, advanced

new sunscreens have been widely sold in Europe, Latin America, Asia, and Australia. But Americans have access only to older generations of sunscreen that prevent sunburn—but *not* the deeper damage that can cause skin cancer.

The delay in approving sunscreens that could prevent many skin cancers and save lives has to do with the complex and outmoded way the FDA approves new over-the-counter drugs, the category of medical products that includes sunscreens. It is long past time for the FDA to modernize and speed up its approval process.

Sun damage to the skin is an epidemic. Skin cancer will strike one in five Americans over the course of their lives, and the rates of all types of skin cancer—including melanoma and keratinocyte cancers (basal cell and squamous cell carcinoma)—are increasing. Melanomas are often deadly. Approximately [160,000 people in the United States are diagnosed with them annually, and one American dies every hour of every day](#) ^[4]—amounting to about 10,000 per year. About 65 percent of melanomas and 90 percent of keratinocyte cancers worldwide are attributable to sun exposure.

In 2014, the U.S. surgeon general declared skin cancer a public health emergency—yet, even five years later, the FDA is not responding as if it were dealing with an emergency. Astonishingly, the last time a new sunscreen ingredient was introduced in the United States was in 2002?—before smartphones, Facebook, and Twitter. The FDA's unwillingness to approve state-of-the-art sunscreens is condemning many Americans to get skin cancers they otherwise could avoid.

A sunscreen with SPF 50 bought in the United States allows three times as much ultraviolet light to enter the skin as sunscreens with the same SPF available abroad.

A little background is necessary to understand sun damage to skin and its prevention. There are two major wavelengths of ultraviolet light beaming down on us from the sun that are believed to damage the skin and lead to skin cancer as well as premature skin aging—types A and B, commonly referred to as UVA and UVB.

Most U.S. sunscreens are fairly effective against UVB light, which is what causes immediate sunburn. And a sunburn, of course, is noticeable after a short period of time. It's a signal your body gives you to get out of the sun before your burn worsens.

UVA light penetrates deeper into the skin and is in many ways more damaging?—and this is the light that can cause cancer. And unlike UVB that causes sunburn, the more serious damage that can be caused by UVA is not something we notice. It can take many years—even decades?—of exposure to UVA light to cause skin cancer.

U.S. sunscreens fail to provide adequate protection against cancer-causing UVA light.

Americans therefore are being hit with a double whammy. Because sunscreens offer protection from sunburn caused by UVB light, many people stay in the sun longer, understandably thinking they are safe. As a result, they are exposed for a longer period of time to more harmful UVA light.

Most Americans mistakenly believe that they are getting state-of-the-art skin protection from sunscreen. However, a sunscreen with SPF 50 bought in the United States allows [three times as much ultraviolet light](#)

[5] to enter the skin as sunscreens with the same SPF available abroad.

Inadequate sunscreen is not only killing Americans?—it is also costing us a bundle in health care expenditures. In the era of rising health care costs, prevention is critical. Allowing access to highly effective sunscreens would be much cheaper than paying for repeated costly and sometimes disfiguring removal of precancerous and cancerous lesions.

In a large, randomized prospective trial conducted in Australia?—where state-of-the-art sunscreen is available—regular use of this advanced sunscreen significantly reduced the number of precancerous lesions, as well as non-melanoma and melanoma skin cancers that people suffered.

Another wrinkle in this story is that Americans are spending unprecedented amounts on products and procedures to inhibit or reverse skin aging, which is accelerated by sun damage. Skin aging and wrinkling are drastically reduced by the regular use of newer-generation sunscreens. In fact, there is recent evidence that using the new and more effective sunscreens can even *reverse* [6] some skin aging.

Measures to protect the skin from sun damage should also include avoidance of tanning, whether outdoors or in tanning facilities; reducing peak sunlight exposure—between 10 a.m. and 4 p.m.—when possible; and wearing protective clothing and hats.

We also need access to the best available sunscreens, and the FDA must do its part.

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[2] https://www.govinfo.gov/content/pkg/FR-2019-02-26/pdf/2019-03019.pdf?mod=article_inline

[3] https://jamanetwork.com/journals/jama/article-abstract/2733085?mod=article_inline

[4] <https://www.melanoma.org/understand-melanoma/what-melanoma/melanoma-facts-and-stats>

[5] <https://jamanetwork.com/journals/jamadermatology/fullarticle/2491692>

[6] <http://www.skincancer.org/healthy-lifestyle/anti-aging/what-is-photoaging>

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