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What We Still Don't Know About Sunscreens

By THE EDITORS

Updated, July 6, 1:40 p.m. | Lenora Felderman, a dermatologist, joins the discussion.

Americans dutifully slather on sunscreens every summer, hoping to stave off aging, wrinkles and cancer. But with each passing season, more questions are raised about whether the labeling and safety guidelines for sunscreens, created in 1978, are adequate or misleading. The Food and Drug Administration, meanwhile, has been criticized for failing to approve new ingredients that are available in Europe.

Research is also questioning the safety of certain ingredients that have been widely used for years. Just recently, Senator Charles Schumer of New York called on the Food and Drug Administration to investigate reports suggesting a possible link between skin cancer and retinyl palmitate, now found in many sunscreen products.

What should the F.D.A. do about sunscreens? And what do consumers need to keep in mind even if they cover themselves with a SPF 70 sunblock?

- Darrell S. Rigel, clinical professor of dermatology
- Sonya Lunder, Environmental Working Group
- Michael K. Hansen, Consumers Union
- Kerry Hanson, chemist, University of California, Riverside
- Lenora Felderman, dermatologist

Approve Better Ingredients

Darrell S. Rigel *is a clinical professor of dermatology at New York University Langone Medical Center and a former president of the American Academy of Dermatology. He does efficacy testing for sunscreen makers.*

There are three important things the Food and Drug Administration should do about sunscreen. First, it needs to make sunscreen labels more clear. Right now consumers have no way of knowing what sort of ultraviolet A (UVA) protection a sunscreen offers — SPF, or sun protection factor, only measures protection from ultraviolet B rays (UVB). The F.D.A. needs to agree on a label format and make it uniform and understandable to consumers.

> Americans are clearly deprived of better sunscreen agents that exist in other countries.

Second, F.D.A. officials need to start approving sunscreen agents that they have been sitting on for too long. There is a method for rapid approval, and agents that are being considered under this method need to be evaluated for approval. In the U.S., there are 17 approved sunscreen agents, Europe has 28, and Japan has more than 40. We are clearly deprived in the U.S. of the better sunscreen agents that exist in other countries all because the F.D.A. has not approved them.

Third, the F.D.A. needs to move forward with the 2007 draft regulations, known as the "sunscreen monograph," which has been worked on since 1978 with no final version yet written.

One of the reasons those regulations have not yet been approved is because of controversy over how best to conduct UVA testing. UVB testing is easy because it simply involves testing the skin for burn rates. UVA testing is more difficult. That said, there are a number of different ways to test in the lab, and the F.D.A. needs to agree upon a test or series of tests and approve the guidelines. The simplest thing to do would be to adopt European standards for testing UVA.

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The Vitamin A Issue

Sonya Lunder *is a senior analyst at the Environmental Working Group, where she does research on a variety of human health topics, including mercury in fish, bisphenol-A, flame retardants and phthalates. She was a contributing researcher to E.W.G.'s 2010 Sunscreen Guide.*

A yearlong study by the Food and Drug Administration has produced sobering data indicating that a form of vitamin A, retinyl palmitate, may accelerate development of skin tumors and lesions when applied in the presence of sunlight. That wouldn't be a problem if the substance weren't an active ingredient in more than 40 percent of all sunscreens available in the United States.

> The F.D.A. should investigate the potential link between vitamin A and skin cancer.

The cosmetics industry aggressively markets products with Vitamin A ingredients claiming they rejuvenate skin. This may be safe for products used indoors, but there is a real possibility of harm when used on sun-exposed skin. In the study, tumors and lesions developed up to 21 percent sooner in sun-exposed lab animals coated with a vitamin A-laced cream than among animals treated with a vitamin-free cream.

Concerns about vitamin A are just one indication that the F.D.A. faces a lot of unfinished business when it comes to assuring consumers that sunscreens are in safe. It's been 32 years since the agency announced plans to issue rules governing sun products. It has never finished the job. That gives the industry leeway when making and marketing sunscreens, leading to products that overpromise and underperform.

While manufacturers are voluntarily complying with government recommendations in Europe that set a high threshold for UVA protection and restrict marketing claims, U.S. consumers are being offered poorer-quality products.

The F.D.A. should improve sun protection. But it should also investigate the potential link between vitamin A and skin cancer, and address the toxicity of other ingredients before it can do what it promised back when Jimmy Carter was president: give consumers reason to feel confident that their sunscreens are safe.

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Put Facts on the Bottle

Michael K. Hansen *is a senior scientist with Consumers Union, the publisher of Consumer Reports. He has worked on food safety and environmental health issues.*

Americans know that when they head to the beach they need to protect their skin, which usually means putting on sunscreen. But consumers need to know more than just the SPF (sunburn protection factor) rating on the bottle and the F.D.A. needs to do much more to ensure that sunscreen products provide safe and effective protection.

> Consumers need to know if sunscreens actually protect them from cancer-causing UVA rays.

It's been three years since the F.D.A. proposed important changes in how it regulates sunscreen products. Yet it has delayed those changes despite continuing public confusion about these products.

Sunscreens are used to protect against two types of ultraviolet radiation (UV), UVA and UVB, which can cause sunburn, skin cancer and other skin damage.

Our tests have found that products may provide very different levels of protection against UVB and UVA, which is not reflected on the product label. Currently, sunscreens are only required to label and test for protection against UVB (that's the SPF). But UVA exposure is also extremely damaging, and yet at this point, some sunscreens can have a very high SPF but offer little or no UVA protection. This has to change.

The F.D.A.'s 2007 proposed rule would require sunscreen manufacturers to test for UVA as well as UVB protection and provide information on both on the label.

In addition, a new "warning" statement would be required to indicate that UV exposure increases the risk of skin cancer and other skin damage and that besides using sunscreen, consumers should reduce exposure by staying out of the sun and wearing protective clothing. Consumers Union generally supports that rule and thinks the F.D.A. should issue it in final form as soon as possible.

We also believe the agency should investigate health concerns that have been raised about various sunscreen ingredients. The F.D.A.'s own research has suggested that retinyl palmitate — which is added to sunscreens and other cosmetics to help prevent signs of aging — may increase the rate of skin tumors when exposed to UV, but the F.D.A. has not released the full study.

The agency should release this study immediately. Other ingredients, such as oxybenzone or octyl methoxycinnamate (OMC), have been shown to penetrate the skin and/or may act to disrupt the endocrine system. The F.D.A. needs to re-evaluate such ingredients in the context of both the safety and efficacy of the specific sunscreen formulations they are used in.

Finally, studies are finding that nanoparticles of titanium dioxide (TiO2) and/or zinc oxide (ZnO), common in many products, may be more harmful than larger forms of these chemicals. They may reach different parts of the body, cross the placenta and affect the developing fetus, or cause DNA damage linked to cancer.

The F.D.A. should treat nanoparticles like new ingredients, demand complete safety data for these substances, and require that nanoscale ingredients be identified as such on product labels.

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What We Don't Know

Kerry Hanson *is a senior research scientist in the department of chemistry at the University of California at Riverside. She studies the effects of UV light upon reactive oxygen species generation in the skin. Dr. Hanson has consulted for the sunscreen industry.*

The information out there currently on sun protection can be confusing, but one thing we do know for sure is that sunscreens do an outstanding job at preventing sunburn when used correctly, through either the absorption or scattering of UV light by molecules called UV-filters.

Our research found that in some conditions sunscreens can damage the skin.

One thing researchers aren't so sure about is if our concept of sun protection (or photoprotection) needs to be redefined. When sunscreens were first introduced we wanted UV-filters that would block as much UVB light as possible while meeting specific safety standards. Every sunscreen that we can purchase in the U.S. today is still based on this model, which has to meet the SPF labeling requirements as well as photoallergy, phototoxicity and contact irritancy safety standards put forth by F.D.A..

Advances in research now shows that this traditional concept of photoprotection (preventing sunburn by UVB rays) is inadequate. New labeling rules, which will go into effect soon, will for the first time provide the consumer with information about UVA protection. This is an important public health step because it informs the consumer that UVA rays are just as damaging as UVB rays.

Research is also beginning to show a need for an even deeper understanding of what "photoprotection" should mean. For example, our lab determined that under certain conditions some UV-filters can generate reactive oxygen species (ROS) in the skin. These are highly reactive forms of oxygen that have the ability to react with anything in their paths, including cell membranes, collagen, and DNA, among others.

We have also found that the addition of antioxidants can reduce the number of UV-induced ROS in the skin. Should sunscreens protect against ROS, generated both by intrinsic skin molecules and potentially some UV-filters? Can antioxidants provide a simple fix to UV-induced ROS reactions in the skin? Perhaps the amount of ROS generated naturally or by certain UV-filters is negligible, or perhaps it's a significant source of concern.

Others are studying the effects of UV light upon the immune system, cellular function and integrity, and nuclear damage. It's a beginning, and an exciting one at that, but one thing the consumer may be unaware of is that this is a research area that is not that well-funded.

Companies don't have the research resources, including equipment, to study some of these basic questions, and so our government science agencies, like the F.D.A., the National Science Foundation and the National Institutes of Health, could push this area forward with a funding stream to our academic labs. In fact, this is a prime example of an area where government funded research could have a significant public health impact since every single person spends time in the sun.

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A False Sense of Security

***Lenora Felderman**, an assistant clinical professor of dermatology at Weill Cornell College of Medicine and New York-Presbyterian Hospitals, is in private practice in Manhattan.*

Since sunscreens are under F.D.A. control, it should be the role and commitment of this agency to regulate and inform the physician, patient and consumer with full, honest disclosure of the efficacy of sunscreen products. The F.D.A. should require pharmaceutical companies to label not only the SPF value, which addresses UVB protection, but also include a rating system for UVA protection as well.

> Furthermore, the F.D.A. should monitor and evaluate the use of retinyl palmitate in sunscreens.

Our knowledge has increased about the deleterious effects of UVA exposure — more than 95 percent of the sun's ultraviolet light reaches us as UVA rays. This UVA exposure has been increasingly implicated as an important factor in photoaging, photosensitive disorders, photoimmune suppression and carcinogenesis. Therefore, the growing need for adequate UVA protection in sunscreens is tantamount.

Sunscreens allow for a false sense of security and protection. Most sunscreens in the United States do not adequately block the UVA range. Research has shown that the ingredients Tinosorb M and Meroxyl TM XL, are extremely effective in broader ultraviolet protection. The F.D.A. should push forward the approval of these beneficial ingredients, which are currently used in sunscreens in Europe.

The 2007 proposed F.D.A. regulations for sunscreen labeling should be streamlined and instituted. The UVA rating system of 1 to 4 stars and warning labels addressing the increased medical risk of ultraviolet exposure is necessary to develop clear and truthful consumer understanding about the potential risks of sun exposure. Furthermore, it is important for the F.D.A. to monitor and evaluate the use of the ingredient retinyl palmitate. Retinyl palmitate, found in many sunscreens, remains controversial in its potential link to skin cancer.

The sun can be either a friend or foe, but it is up to us to determine our relationship.