

SOMETHING'S FISHY: SALMON, CONGRESS AND FDA

RESearch and development in the field of sunscreens in the US has unfortunately taken a back seat to the ever-increasing development of government regulations. I cannot recount more than a few research projects worthy of notice in the field of sun care. Most originate from researchers overseas. The glaring, undeniable fact persists that real innovation in sunscreens in the US is at a standstill. The reason is quite simple. It is due to the cloud of uncertainty that looms as the US Food and Drug Administration (FDA) pursues a new path toward regulations for the industry.

First, a recap of recent regulatory developments, followed by a summary of the minor scientific developments in sunscreens.

Let us start at the top with the FDA leadership. Since Dr. Margaret Hamburg resigned her position almost a year ago, the agency has had an interim commissioner. President Barack Obama's FDA commissioner nominee, Dr. Robert Califf, cleared his hearings in the Senate HELP (Health, Education, Labor and



Media coverage has ebbed regarding reports of sunscreens damaging coral reefs

Pensions) Committee on Jan. 12, 2016. Unfortunately, the Senate has not set a date to vote on his nomination. Politics is obviously playing a major role in deciding who will be the next commissioner of the FDA. Senator Lisa Murkowski (R-AK) has expressed concerns about the nominee and has threatened a filibuster unless the FDA responds to her concerns about the oversight of genetically-engineered salmon! Apparently, in November 2015—two days after Califf's confirmation hearing—the FDA approved that fish for human consumption. Senator Bernie Sanders (I-VT) opposed Dr. Califf's nomination (by proxy, since he was busy campaigning in Iowa) for opposing the importation of lower-priced drugs from Canada. Even Sheldon Whitehouse (D-RI) raised the issue of drug prices at the hearing. After the hearing, Elizabeth Warren (D-MA), who supports Califf, "raised serious questions"

about how clinical trials are run in the US. The bottom line is that final sunscreen regulations are held hostage to lower drug prices from Canada, a perceived conflict of interest and the fate of genetically engineered salmon in the US!

In his final State of the Union address on Jan. 14, 2016, President Obama appointed Vice President Joe Biden to spearhead efforts to combat cancer in the US. This "moon shot" initiative to cure cancer will involve increasing resources, both private and public, to fight cancer. Biden worked last month with Congress to provide the National Institute of Health with its biggest budget in decades. Biden launched his initiative on Jan. 15, 2016 to find a cure for cancer by calling for more funding from individuals and governments while stressing the need for increased sharing of health research data by scientists. His efforts come eight months



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after the death of his son, former Delaware Attorney General Beau Biden, of brain cancer. That same day Biden said that President Obama will soon announce an executive order directing multiple agencies to act in a new federal task force to fight cancer. There will be a wide range of agencies involved in the effort including the Department of Health and Human Services, the National Institutes of Health, the Food and Drug Administration and the Department of Defense. Those agencies must lead a new push in sharing health data so that researchers can more easily see growing trends in the population, Vice President Biden said.

Order in the House?

In another regulatory development in the past few months, the FDA issued in November a draft guidance entitled “Over-The-Counter Sunscreens Safety and Effectiveness Data; Draft Guidance industry; availability.”¹ The notice announced the availability of draft guidance for the sunscreen industry and requested comments by Jan. 22, 2016. In early January, the FDA extended that deadline by 30 days to Feb. 22, 2016.² The Public Access to Safe Sunscreens (PASS) Coalition will respond to these draft guidelines. Interested scientists, advocates and consumers are encouraged to read the guidelines and to comment by Feb. 22, 2016.

Finally, in other regulatory developments, as the Congress unveiled in late December 2015 a \$1.2 trillion spending package to fund the government for the fiscal year ending September 2016, the House issued several bills including one entitled “Sunscreen Ingredient Application” which authorized the funding of an additional \$700,000 for the FDA to complete timely reviews of filed requests (TEAs) and to determine the safety and efficacy of sunscreen ingredients. Another House bill entitled “Sunscreen Ingredients Report” reminded everyone that no action has been taken by the FDA to approve new sunscreen ingredients which have been pending for more than 13 years. The House concluded that the FDA shall issue draft guidance for the cosmetics/sunscreen industry outlining data required for sunscreen active ingredients to meet the FDA’s safety and efficacy standards and to meet Sunscreen Innovation Act’s statutory deadlines for publication.³ The FDA dutifully issued this guidance memorandum on Nov. 23, 2015.

Other Research

Obviously, regulations dominate innovation in sunscreens in the US. Elsewhere, in recent months, a few publications appeared that addressed scientific studies pertaining to sunscreens. These publications include:

- A publication by B. Madretti and T. Karsili appeared in the publication *Physical Chemistry* in January 2016 entitled “Theoretical insights to the photo protective mechanism of natural biological sunscreen.” It is interesting reading.⁴
- A paper written by Eric Tan and coworkers was published in the *Journal of Physical Chemistry Letters* in December 2015. It is entitled “Excited-State Dynamics of Isolated and Microsolvated

Cinnamate-Based UVB Sunscreens.”⁵ In the same publication, Lewis Baker from the University of Warwick in the UK published a paper entitled “Ultrafast Protecting Sunscreen in Natural Plants.”⁶

- At the Consumer Electronics Association show in Las Vegas in January, L’Oréal revealed its “My UV Patch” that measures how much UV radiation to which the consumer has been exposed.⁷ (You can read more about the patch in this issue of Happi, p. 30).

- The Cancer Society of New Zealand distributed 100,000 bottles of SPF 50+ Sunscreen (50g) in November 2015. The group specifically targeted to kids to insure their protection from the sun’s harmful radiation.

- The issue of sunscreens damaging coral reefs resurfaced last fall. This issue dominated the internet and social media news for nearly two months. But in December 2015 another issue dominated

the Google headlines. A consumer advocacy group in Australia revealed that some popular sunscreens failed to deliver the SPF claims made on their labels. Also, US and UK Consumer Reports found different test results for sunscreens tested to those listed by the manufacturer. The furor regarding both issues, however, seems to have faded.

Regulation, or the lack of them in the field of sunscreens in the US dominates the headlines. While this vital issue remains in limbo, the lack of new regulations in the land has basically stymied and stifled innovative research and development. More importantly, the status-quo in regulations will continue to dominate the sunscreen scene for years to come. This is a bleak assessment for our goal in protecting our consumers from the rising incidence of skin cancer in the country. It is time to refocus our priorities in combating this rising epidemic. Perhaps Vice

President Biden could focus his efforts on skin cancer, which is the most common form of cancer in the US. ●

References:

1. Federal Register Nov. 23, 2015 (80FR72975).
2. Federal Register, Jan. 8, 2016 (81FR940).
3. House Report 114-205 (July 2015).
4. Barbara Madretti and Tolga Karsili, “Theoretical insights into the photo protective mechanism of natural biological sunscreens”, *Phys. Chem. Chem. Phys.* (2016).
5. Eric Tan, Michiel Hilbers and Wybren J. Buma, “Excited State Dynamics of Isolated Microsolvated Cinnamate UVB Sunscreens” *J. Phys. Chem. Letters* 17.12.2015.
6. Lewis A. Baker et al, “Ultrafast protecting sunscreens in natural plants”, *J.Phys.Chem. Letters* Vol 7, p.56-61 (2015).
7. Consumers Electronic Association (CEA).