SUNSCREEN FILTER

Will FDA Commissioner Califf Make Sunscreen a Priority?

A
ter many months of Congress-
ional hearings, there is finally
a new FDA commissioner: Dr.
Robert Califf, a cardiologist
who served as the FDA chief
during the Obama Administration, was confirmed
on February 15 by a very small majority
(50-46) in the Senate. He was opposed
by five key Democratic senators (Sand-
ers, Manchin, Hassan, Blumenthal and
Markey) for his prior work with the
pharmaceutical industry and his lax re-
cord on opioids.

The issue of opioids had derailed
the nomination of Dr. Janet Woodcock, the
Acting Commissioner, earlier and she
will now serve as the Principal Deputy
Commissioner (second in command).
The FDA currently faces major issues
with the decisions to approve addi-
tional new corona vaccines, especially for
children younger than five years old,
and a host of other controversial issues
including the abortion pill, flavored e-
cigarettes, an Alzheimer drug and the
opioid crisis. But nowhere in the nomi-
nation hearings were the controversial
issues related to sunscreens ever exten-
sively addressed!

The FDA regulates 20% of the dollars
spent by consumers (prescription drugs,
most of the nation’s food supply, and cos-
metics including sunscreens, etc.) but has
given sunscreen regulations an extremely
low priority. Hawaii has consistently
usurped the responsibilities of the FDA
by unilaterally requiring both drug prescrip-
tions to use sunscreens and banning most
currently approved UV filters from use
(see Happi, February 2022, p. 48). These
two functions are obviously FDA functions
and not state functions. Hawaii today has
numerous bills to ban and regulate ultra-
violet filters on the basis that they harm
the coral reefs. These include HB 1519,
SB 2319, SB 2850, SB 2910, SB 2949 and
SB 3001. If passed, they would ban all
non-GRASE (Generally Regarded as Safe
and Effective) ultraviolet filters from being
sold in Hawaii. This effectively means that
sunscreens with only mineral titanium and
zinc oxide filters would be allowed in Ha-
waii in the future. Of course, if the FDA
would ever get to issue the “Sunscreens
Deemed Final Order” (which refused to
make determinations regarding whether
many ingredients commonly found in
sunscreens are GRASE) and eventually
allow the use of the other 12 traditional
non-mineral UV filters, then perhaps that
would change the landscape in Hawaii
and other worldwide municipalities advo-
cating only mineral sunscreens.

A QUIET FEW MONTHS

The sunscreen category has been relative-
ly quiet of late. However, an interesting
study conducted at Griffith University in
Queensland, Australia, found that aerosol
sunscreens did not adequately deliver sun-
screen in mildly windy conditions leading
to poor protection against UV radiation.
Researchers tested five aerosol sunscreens
and found that at a moderate speed of
12 mph, 28-93% sunscreen was lost and

Xavier Becerra, Secretary of Health and Human Services, ceremonially swears in Dr. Robert M. Califf as
FDA’s Commissioner of Food and Drugs during a ceremony at the Health and Human Services head-
quarters in Washington, DC on Feb. 22, 2022. Califf was joined by his spouse, Lydia Califf.

The ceremonial event followed Califf’s official swearing in that occurred Feb. 17, 2022.

(US Food and Drug Administration photo by Matthew MacRoberts)
at low speeds of 6 mph the loss was 32-79%. Despite the wide range of loss based on these initial findings reported in the study, the Cancer Council, the Radiation Program, and the Nuclear Safety Agency of Australia strongly urged Australians against using aerosol sunscreens for sun protection this summer!

In other news, the National Cancer Institute in the US relaunched its “moonshot” effort to reduce incidence of all cancers by 50%. The campaign was introduced by then Vice President Joe Biden during the Obama Administration. I hope this program funds US researchers to document the efficacy of sunscreens’ ability to protect from skin cancer. Very little research on this subject has been carried out in US universities and pharmaceutical companies. Australian researchers have led the way in this endeavor. The role of sunscreens in real protection from skin cancers must be properly documented!

Research into new, more effective safe ultraviolet filters has been seriously lacking worldwide. Here are a few attempts today. Russian chemists (in the Journal of Materials Chemistry B) revealed that tetravalent cerium phosphates were comparable in protection to commercial titanium and zinc oxides. In a previous column (February 2021) I reported on a bacterium (bacillus lysate) with excellent SPF boosting capabilities. The bacterium was discovered on the International Space Station. Attempts to commercialize this material are underway.

While some researchers search the heavens, others scour the ocean for sunscreen solutions. Their research has focused on micro algae, cyanobacteria, sea cucumbers, seagrass, mangroves, planktons and, most recently, Zebrafish. Several of these marine materials have potential in UV protection. However, due to issues of cultivation, purification and isolation, the ability to yield commercially available safe and effective UV filters is still years away. When, and if, these new ingredients are finally harnessed and commercialized, convincing the FDA to approve them as GRASE filters for sunscreen human use will be a major challenge!

A seismic shift in priorities at the FDA is required to give sunscreen regulations a higher priority to enable us to create superior UV filters and ultimately better and safer sunscreen products to decrease the incidences of skin cancer observed today. I’ll close with some good news. After two years, FDA has agreed to meet with PCPC.