

Annual Skin Check: Examining the Dermatology Headlines of 2019



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RESIDENT PEARLS

- Chemical sunscreen made headlines in 2019 due to concerns over coral reef toxicity and systemic absorption in humans.
- With a total of 654 cases, New York City's largest measles outbreak in nearly 30 years ended in September 2019.
- From dupilumab for adolescent atopic dermatitis to apremilast for Behçet disease, the US Food and Drug Administration approved several therapies for pediatric dermatology and rare dermatologic conditions in 2019.
- Two popular skin care products—the Neutrogena Light Therapy Acne Mask and Johnson's Baby Powder—were involved in recalls in 2019.

As the calendar year comes to an end, this article reviews unique issues in dermatology that made the news in 2019: chemical sunscreen, the measles outbreak, drug approvals for pediatric dermatology and orphan diseases, and recalls of popular skin care products.

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From chemical sunscreen to the measles outbreak and drug approvals to product recalls, dermatology experienced its share of firsts and controversies in 2019.

Chemical Sunscreen Controversies

Controversial concerns about the effects of chemical sunscreen on coral reefs took an unprecedented turn in

the United States this last year. On February 5, 2019, an ordinance was passed in Key West, Florida, prohibiting the sale of sunscreen containing the organic UV filters oxybenzone and/or octinoxate within city limits.¹ On June 25, 2019, a similar law that also included octocrylene was passed in the US Virgin Islands.² In so doing, these areas joined Hawaii, the Republic of Palau, and parts of Mexico in restricting chemical sunscreen sales.¹ Although the Key West ordinance is set to take effect in January 2021, opponents, including dermatologists who believe it will discourage sunscreen use, currently are trying to overturn the ban.³ In the US Virgin Islands, part of the ban went into effect in September 2019, with the rest of the ban set to start in March 2020.² Companies have started to follow suit. On August 1, 2019, CVS Pharmacy announced that, by the end of 2020, it will remove oxybenzone and octinoxate from some of its store-brand chemical sunscreens.⁴

On February 26, 2019, the US Food and Drug Administration (FDA) proposed that there are insufficient data to determine if 12 organic UV filters—including the aforementioned oxybenzone, octinoxate, and octocrylene—are generally recognized as safe and effective (GRASE).⁵ Although these ingredients were listed as GRASE by the FDA in 2011, the rise in sunscreen use since then, as well as changes in sunscreen formulations, prompted the FDA to ask manufacturers to perform additional studies on safety parameters such as systemic absorption.^{5,6} One study conducted by the FDA itself was published in May 2019 and showed that maximal use of 4 sunscreens resulted in systemic absorption of 4 organic UV filters above 0.5 ng/mL, the FDA's threshold for requiring nonclinical toxicology assessment. The study

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authors concluded that “further studies [are needed] to determine the clinical significance of these findings. [But] These results do not indicate that individuals should refrain from the use of sunscreen.”⁷ Some in the industry have suggested it may take at least 5 years to generate all the data the FDA has requested.⁶

End of the New York City Measles Outbreak

On September 3, 2019, New York City’s largest measles outbreak in nearly 30 years was declared over. This announcement reflected the fact that 2 incubation periods for measles—42 days—had passed since the last measles patient was considered contagious. In total, there were 654 cases of measles and 52 associated hospitalizations, including 16 admissions to the intensive care unit. Most patients were younger than 18 years and unvaccinated.⁸

The outbreak began in October 2018 after Orthodox Jewish children from Brooklyn became infected while visiting Israel and imported the measles virus upon their return home.^{8,9} All 5 boroughs in New York City were ultimately affected, although 4 zip codes in Williamsburg, a neighborhood in Brooklyn with an undervaccinated Orthodox Jewish community, accounted for 72% of cases.^{8,10} As part of a \$6 million effort to stop the outbreak, an emergency order was placed on these 4 zip codes, posing potential fines on people living or working there if they were unvaccinated.⁸ In addition, a bill was passed and signed into law in New York State that eliminated religious exemptions for immunizations.¹¹ In collaboration with Jewish leaders, these efforts increased the administration of measles-mumps-rubella vaccines by 41% compared with the year before in Williamsburg and Borough Park, another heavily Orthodox Jewish neighborhood in Brooklyn.⁸

Drug Approvals for Pediatric Dermatology

On March 11, 2019, the IL-4/IL-13 inhibitor dupilumab became the third biologic with a pediatric dermatology indication when the FDA extended its approval to adolescents for the treatment of atopic dermatitis.¹² The FDA approval was based on a randomized, double-blind, placebo-controlled trial in which 42% (34/82) of adolescents treated with dupilumab monotherapy every other week achieved 75% or more improvement in the Eczema Area and Severity Index at week 16 compared with 8% (7/85) in the placebo group ($P < .001$).¹³

In October 2019, trifarotene cream and minocycline foam were approved by the FDA for the treatment of acne in patients 9 years and older.^{14,15} As such, both became the first acne therapies to include patients as young as 9 years in their studies and indication—a milestone, considering the fact that children have historically been excluded from clinical trials.¹⁶ The 2 topical treatments also are noteworthy for being first in class: trifarotene cream is the only topical retinoid to selectively target the retinoic acid receptor γ and to have been studied specifically for both

facial and truncal acne,^{14,17} and minocycline foam is the first topical tetracycline.¹⁵

Drug Approvals for Rare Dermatologic Diseases

On July 19, 2019, apremilast, a phosphodiesterase 4 inhibitor, became the first medication approved by the FDA for the treatment of adults with oral ulcers due to Behçet disease, a rare multisystem inflammatory disease.¹⁸ The FDA approval was based on a double-blind, randomized, placebo-controlled trial in which 53% (55/104) of patients receiving apremilast monotherapy were ulcer free at week 12 compared to 22% (23/103) receiving placebo ($P < .0001$) (ClinicalTrials.gov Identifier NCT02307513).¹⁹

On October 8, 2019, afamelanotide was approved by the FDA to increase pain-free light exposure in adults with erythropoietic protoporphyria, a rare metabolic disorder associated with photosensitivity.²⁰ A melanocortin receptor agonist, afamelanotide is believed to confer photoprotection by increasing the production of eumelanin in the epidermis. The FDA approval was based on 2 randomized, double-blind, placebo-controlled trials, both of which found that patients given afamelanotide spent significantly more time in direct sunlight without pain compared to patients in the placebo group ($P = .005$ and $P = .04$).²¹

Recalls of Popular Skin Products

On July 5, 2019, Neutrogena recalled its cult-favorite Light Therapy Acne Mask. The recall was driven by rare reports of transient visual side effects due to insufficient eye protection from the mask’s light-emitting diodes.^{22,23} Reported in association with 0.02% of masks sold at the time of the recall, these side effects included eye pain, irritation, tearing, blurry vision, seeing spots, and changes in color vision.²⁴ In addition, a risk for potentially irreversible eye injury from the mask was cited in people taking photosensitizing medications, such as doxycycline, and people with certain underlying eye conditions, such as retinitis pigmentosa and ocular albinism.^{22,24,25}

Following decades of asbestos-related controversy, 1 lot of the iconic Johnson’s Baby Powder was recalled for the first time on October 18, 2019, after the FDA found subtrace levels of asbestos in 1 of the lot’s bottles.²⁶ After the recall, Johnson & Johnson reported that 2 third-party laboratories did not ultimately find asbestos when they tested the bottle of interest as well as other bottles from the recalled lot. Three of 5 samples prepared in 1 room by the third-party laboratories initially did test positive for asbestos, but this result was attributed to the room’s air conditioner, which was found to be contaminated with asbestos. When the same samples were prepared in another room, no asbestos was detected.²⁷ The FDA maintained there was “no indication of cross-contamination” when they originally tested the implicated bottle.²⁸

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