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October 31, 2024

Dr. Robert Califf
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Commissioner Califf,

I am alarmed by recent reports and a new study that found high levels of benzene, a known hormone disruptor and carcinogen,¹ in popular acne treatment products from brands like Clearasil, Proactiv, and CVS Health.^{2,3} In March 2023 a study from Valisure, an independent quality assurance company, revealed that products containing benzoyl peroxide (BPO) “are fundamentally unstable and can generate unacceptably high levels of benzene”.^{4,5} Some of the products tested by Valisure contained levels “18 times the amount of the potent carcinogen allowed [conditionally] in U.S. drugs” when tested at room temperature in off-the-shelf products, and “over 800 times the [conditional]... limit” when tested at elevated temperatures. I call on the Food and Drug Administration (FDA) to take action to update industry guidelines for manufacturers using BPO as an active ingredient and immediately inform consumers of the significant health risks posed by benzene in degraded BPO products. For example, leading dermatologists⁶ and medical associations like the American Acne and Rosacea Society have

¹ [CDC | Facts About Benzene](#)

² Kucera et. al. *Evaluation of Benzene Presence and Formation in Benzoyl Peroxide Drug Products*, Journal of Investigative Dermatology, [https://www.jidonline.org/article/S0022-202X\(24\)02155-9/fulltext](https://www.jidonline.org/article/S0022-202X(24)02155-9/fulltext) (October 7, 2024)

³ *Second Study Finds Cancer Risk in Proactiv, Clearasil and Other Acne Creams*, Bloomberg News, <https://www.bloomberg.com/news/articles/2024-10-07/proactiv-clearasil-contain-cancer-risk-second-study-finds>, (October 7, 2024)

⁴ *Valisure Detects Benzene in Benzoyl Peroxide*, Valisure, <https://www.valisure.com/valisure-newsroom/valisure-detects-benzene-in-benzoyl-peroxide>, (March 6, 2024).

⁵ Kucera et. al. *Benzoyl Peroxide Drug Products Form Benzene*, Environmental Health Perspectives, <https://ehp.niehs.nih.gov/doi/10.1289/EHP13984> (March, 14, 2024)

⁶ *Benzoyl Peroxide Acne Drugs Lack Stability and Degrade into Carcinogenic Benzene Including When Kept at Room Temperature, New Study Finds*, Elsevier, <https://www.elsevier.com/about/press-releases/benzoyl-peroxide-acne-drugs-lack-stability-and-degrade-into-carcinogenic> (October 7, 2024)

already advised consumers to store “ BPO products... at refrigerator temperature which at least theoretically can reduce degradation of BPO to benzene.”⁷

As you know, benzene is one of the most commonly used chemicals in the United States but it is also strongly linked to higher risks of cancer, specifically leukemia and other blood related conditions.⁸ In the short term, exposure to benzene can lead to problems with the nervous system causing drowsiness, headaches, or tremors. In addition to its links to cancer, long-term benzene exposure can also cause anemia and low white blood cell counts.⁹ As such, the use of benzene is highly regulated by the FDA, Environmental Protection Agency, and the Occupational Health and Safety Administration.^{10, 11} Last year, the FDA warned manufacturers to avoid using benzene in the manufacturing process but issued a conditional limit of 2 parts per million when its use is unavoidable to produce a drug product with a significant therapeutic advance.¹² However, it appears that some manufacturers are improperly taking this guidance out of context. For example, the manufacturer of Banana Boat sunscreen recently argued that “products containing less than 2 ppm of benzene are safe”, but the Ninth Circuit Court of Appeals disagreed, ruling that “characterizing such products as safe runs counter to the [FDA’s] caveat-laden guidance.”¹³ The FDA must update and better clarify its guidance to prevent manufacturers from using misguided loopholes on the presence of benzene in drug products.

On March 6, 2024, Valisure released the results of a comprehensive study testing the stability of BPO in acne products. They tested 175 acne treatment products, 99 containing BPO and 76 without BPO as an active ingredient.¹⁴ The 76 products without BPO did not contain benzene levels outside of FDA’s conditional limit of 2 ppm. However, 94 out of the 99 BPO containing products had levels of benzene that significantly increased with exposure to heat.¹⁵ Further, the testing confirmed that high levels of benzene can leak from the container into the surrounding air, increasing the risk of inhalation.¹⁶

Valisure has previously conducted testing on the presence of benzene in other products like sunscreen, hand sanitizer, and dry shampoo.¹⁷ In those cases, the benzene was linked to

⁷ *Response Statement from the American Acne & Rosacea Society to the Valisure Citizen Petition on Benzene in Benzoyl Peroxide Drug Products*, American Acne & Rosacea Society, <https://acneandrosacea.org/uncategorized/american-acne-rosacea-society-aars-responds-to-citizen-petition-submitted-by-valisure-regarding-benzene-in-benzoyl-peroxide-drug-products/> (March 20, 2024)

⁸ *Benzene and Cancer Risk*, The American Cancer Society, <https://www.cancer.org/cancer/risk-prevention/chemicals/benzene.html>, (February 1, 2023)

⁹ *Id*

¹⁰ *Benzene*, The Occupational Safety and Health Administration, <https://www.osha.gov/benzene> (last accessed October 17, 2024).

¹¹ *Gasoline Mobile Source Air Toxics*, The Environmental Protection Agency, <https://www.epa.gov/gasoline-standards/gasoline-mobile-source-air-toxics>, (October 9, 2024).

¹² *FDA alerts drug manufacturers to the risk of benzene contamination in certain drugs*, Food and Drug Administration, <https://www.fda.gov/drugs/pharmaceutical-quality-resources/fda-alerts-drug-manufacturers-risk-benzene-contamination-certain-drugs>, (December 27, 2023).

¹³ *Ninth Circuit rescues Banana Boat false advertising suit*, Courthouse News Service, <https://www.courthousenews.com/ninth-circuit-rescues-banana-boat-false-advertising-suit/> (October 13, 2024)

¹⁴ *Valisure Detects Benzene in Benzoyl Peroxide*, Valisure, <https://www.valisure.com/valisure-newsroom/valisure-detects-benzene-in-benzoyl-peroxide>, (March 6, 2024).

¹⁵ *Id*

¹⁶ *Id*

¹⁷ *Scientists Are Finding Out Just How Toxic Your Stuff Is*, TIME Magazine, <https://time.com/6975046/toxic-chemicals-in-products-valisure/> (May 9, 2024)

contamination from raw materials during the manufacturing process. In this case, there is no raw material contamination and the benzene is accumulating from the degradation of the BPO active ingredient. This raises significant concerns over the safety of these products and the use of BPO altogether.

While the FDA has released information on benzene contamination in other consumer products, the agency has not addressed the safety risk caused by the degradation of BPO into benzene.¹⁸ In the meantime, these products continue to be sold and used by countless Americans on a daily basis. This is especially true for young people that may be seeking treatment for the acne they develop during puberty. Exposure to benzene could be detrimental to their health and development.

It is imperative that FDA take immediate action to address these troubling findings and prevent future health issues. In light of these test results, it is clear that FDA must conduct a thorough review of BPO products and promulgate clearer regulations on the use of BPO, its storage protocols, and generally regarding benzene in consumer products. Additionally, FDA must take the necessary actions to ensure that consumers are made aware of the risk that these products pose and ensure that manufacturers are likewise taking the appropriate actions to investigate and recall products with unacceptable levels of benzene. Valisure has filed a citizen's petition urging the agency to recall and suspend the sale of products containing benzoyl peroxide given the drug's propensity to form the known carcinogen benzene, they have also asked FDA to conduct an investigation regarding these products, provide information to the public on potential harms, update industry guidance, support the increasing number of independent drug quality testing programs in the United States including by the Department of Defense,¹⁹ and more.²⁰ We urge FDA to heed these suggestions to protect public health.

Thank you for your attention to this urgent matter.

Sincerely,



Richard Blumenthal
United States Senate

¹⁸ *FDA alerts drug manufacturers to the risk of benzene contamination in certain drugs*, The Food and Drug Administration, <https://www.fda.gov/drugs/pharmaceutical-quality-resources/fda-alerts-drug-manufacturers-risk-benzene-contamination-certain-drugs>, (December 27, 2023).

¹⁹ *Tainted Medication Fears Spur US Defense Department to Seek Outside Testing*, Bloomberg News, <https://www.bloomberg.com/news/articles/2023-08-08/tainted-medication-fears-spur-us-defense-department-to-seek-outside-testing> (August 8, 2023)

²⁰ *Citizen Petition on Benzene in Benzoyl Peroxide Drug Products*, Valisure, <https://www.regulations.gov/document/FDA-2024-P-1130-0001> (March 5, 2024)