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BLOG

FDCA Preemption Has Teeth for Benzene Failure-to-Warn Claims

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The Central District of California recently shut down, on preemption grounds, a group of class-action plaintiffs' second attempt to assert claims alleging that benzoyl peroxide (BPO) in over-the-counter (OTC) acne treatments unavoidably degrades into the carcinogen benzene.

The case is one of many filed in the wake of a citizen's petition to FDA by the controversial testing lab Valisure, which alleged benzene contamination in BPO-based products.[1] Specifically, plaintiffs allege that BPO degrades into benzene under normal use, handling, and storage conditions.[2] Although plaintiffs contend that benzene is harmful "even in trace amounts," they do not seek damages for physical injury. Instead, they assert economic-loss claims under state law based on the theory that manufacturers failed to warn of BPO's potential to degrade into benzene.[3]

Two decisions from Judge Stanley Blumenfeld, Jr., of the U.S. District Court for the Central District of California, have dealt significant setbacks to plaintiffs pursuing these benzene-related claims. Both decisions turned on the express preemption provision of the Food, Drug, and Cosmetic Act (FDCA), which applies to OTC drugs, 21 U.S.C. § 379r(a). That provision preempts any state-law "requirement . . . (1) that relates to the regulation of a [OTC drug]; and (2) that is different from or in addition to, or that is otherwise not identical with, a requirement under" the FDCA.

Last year, in *Howard v. Alchemee, LLC*, claims that OTC acne products containing BPO were misbranded were dismissed by the court as preempted by the FDCA.[4] As the court explained, FDA expressly permits BPO to be used as an active ingredient under a "comprehensive set of FDA regulations called a monograph," which sets labeling requirements and mandates specific warnings and directions.[5] Notably, though, the monograph does not require warnings about benzene.[6] The court therefore held that plaintiffs' claims were "fundamentally at odds with the FDA's monograph" and expressly preempted by § 379r(a).[7] Requiring defendants "to make disclosures not required under the FDCA," the court explained, "would conflict with the FDA's conclusion that BPO is safe and effective."[8]

Following their loss in *Howard,* plaintiffs reframed their claims to allege that not all benzene levels are inherently unsafe, but rather that degradation of products containing BPO to "more than 2 parts per million (ppm) of benzene during the [products'] shelf lives" was the problem.[9] In late April, in *O'Dea v. RB Health (US) LLC*,[10] Judge Blumenfeld held that those newly framed state-law claims were still expressly preempted. This time, plaintiffs' theory

ran into "a different preemption problem: it depends on the premise that the FDA limits the benzene that may be present in BPO-based acne medications to 2 ppm."[11] But plaintiffs pointed to no "provision of the FDCA or any FDA regulation prohibiting benzene in excess of 2 ppm in BPO-based acne medications."[12]

The court rejected plaintiffs' claims because their reliance on the Q3C Guidance—a 2017 FDA document offering nonbinding recommendations on acceptable levels of residual solvents in pharmaceuticals—did not constitute a valid FDCA or FDA regulatory requirement.[13] The court gave two primary reasons for doing so. First, the court noted that the FDA guidance plaintiffs relied on was "nonbinding" and "does not establish any rights for any person and is not binding on FDA or the public," and thus "does not impose a legal limit on the benzene in Defendants' products."[14] Second, the court held that even if the guidance had binding effect, it was "inapplicable on its face" because "Defendants do not use benzene as a solvent in manufacturing their acne treatments," and "any benzene [the products] contain comes from degradation of the BPO."[15] Because no binding federal requirement establishes a 2 ppm benzene limit, the court held, plaintiffs effectively sought to impose labeling obligations that were "different from, in addition to, or otherwise not identical with the requirements of the FDCA."[16] The court therefore held that those claims were preempted.[17]

Judge Blumenfeld's rulings illustrate the potential breadth of the FDCA's express preemption provision as applicable to OTC drugs, particularly in failure-to-warn cases. When faced with similar allegations, OTC drug manufacturers should assess whether their product is subject to an FDA monograph or another binding regulatory framework that sets forth labeling requirements. If so, courts may find state-law failure-to-warn claims preempted where they seek to impose labeling obligations that do not closely parallel the federal requirements. The rulings also underscore the importance of scrutinizing the purpose and scope of regulatory guidance on acceptable contaminant levels—which plaintiffs have increasingly targeted in recent cases—to determine whether such guidance truly sets the safety limits alleged.

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[1] *Howard v. Alchemee, LLC*, 2024 WL 4272931, at *1 (C.D. Cal. Sep. 19, 2024). FDA has recently cast doubt on the lab's methods and findings. *See It's About Time – FDA Calls Foul on Valisure*, Drug & Device Law (Apr. 4, 2025), https://www.druganddevicelawblog.com/2025/04/its-about-time-fda-calls-foul-on-valisure.html.

[2] *Howard*, 2024 WL 4272931, at *1.

[3] *Id.* at *1-2.

[4] *Id.* at *1.

[5] *Id.* at *6.

[6] *Id*. at *6-7.

[7] *Id*. at *7.

[8] *Id*. at *10.

[9] *Id.* at *1.

[10] 2025 WL 1212835, at *5 (C.D. Cal. Apr. 22, 2025).

[11] *Id.* at *5.

[12] *Id.*

[13] *Id.*

[14] *Id.* at *6 (internal citations and quotations omitted).

[15] *Id*.

[16] *Id.* at *7 (internal quotations omitted).

[17] *Id.*

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Rand Brothers

Patrick Hogan

Jacqueline Ju

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