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Federal Court Finds State Law Claims Preempted By FDA Monograph

by Andrew Reissaus and Alexandra Stubblefield

On January 17, 2025, a California federal court held that putative class action claims surrounding disclosures, warnings, and the safety and efficacy of a product were preempted by the Food, Drug, and Cosmetic Act ("FDCA"). *Eisman v. Johnson & Johnson Consumer, Inc.*, No. 2:24-CV-01982-ODW (AJRX), 2025 WL 241024, at *2 (C.D. Cal. Jan. 17, 2025).

The therapeutic over-the-counter ("OTC") shampoo products at issue contained the active ingredient Coal Tar, a component of which is benzene. *Id.* at *1. Plaintiff, a consumer who purchased the shampoo, argued that defendants, Johnson & Johnson Consumer, Inc. and Kenvue, Inc., should have disclosed the presence of benzene in their products and that they misrepresented their products as safe and effective when they failed to do so. *Id.* Defendants argued that the FDCA expressly preempted plaintiff's state law claims. *Id.* at *2.

The court dismissed plaintiff's claims with prejudice finding them preempted because they aimed to place different or additional requirements beyond those imposed by FDA.[1] *Id.* at *4, *6.

The court explained the legal concept of express preemption and the FDA monograph to which defendants were required to adhere in this case.[2] *Id.* at *2-4. Products containing Coal Tar are "generally recognized as safe and effective and [are] not misbranded if [they] meet[] each of the conditions" in 21 C.F.R. §§ 358.701 and 330.1. *Id.* at *3.

First, the court explained that "the monograph does not require defendants to include benzene on the label, and imposing such a requirement would be inconsistent with the FDA's regulations." *Id.* at *4. FDA's monograph for OTC Coal Tar products regulates the product labeling and does not require benzene disclosures or warnings. *Id.* Thus, additional disclosures are preempted. *Id.* Further, benzene need not be included as a component "because it is not a purposefully added component of the drug." *Id.*

Second, the court reasoned that "FDA Guidance does not impose on defendants an obligation to eliminate benzene from the Products, and [plaintiff's] claims seeking to do so are not parallel

[1] The court determined that amendment would be futile as preemption generally cannot be cured by amendment. *Id.* at *6.

[2] For a fulsome explanation of express preemption and FDA monographs, please refer to our previous article: Andrew Reissaus & Alexandra Stubblefield, *Preemption and Standing Defenses Succeed in OTC Decongestant Multidistrict Litigation* (Dec. 16, 2024), https://www.wlf.org/2024/12/16/publishing/preemption-and-standing-defenses-succeed-in-otc-decongestant-multidistrict-litigation/.

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to federal requirements." *Id.* at *5. The removal of benzene is contradictory to FDA's monograph because FDA knew that OTC Coal Tar products contain some level of benzene and still approved the monograph. *Id.* Plaintiff also cited guidance from FDA stating that "benzene should not be present in drug products" *Id.* The court rejected this argument because FDA's recommendations were specific to a different class of products—those containing carbomers. *Id.* Additionally, the court explained that even if the FDA's guidance was applicable, "it is non-binding guidance lacking the force of law." *Id.*

This decision reflects the role courts play in ensuring that state law tort claims do not impermissibly conflict with the monograph regime established by Congress in the FDCA.

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