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Preemption and Standing Defenses Succeed in OTC Decongestant Multidistrict Litigation

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The federal district court handling nationwide Multidistrict Litigation involving over-the-counter ("OTC") nasal decongestants recently granted defendant drug manufacturers' motion to dismiss nearly one hundred cases. *In re Oral Phenylephrine Mktg. & Sales Pracs. Litig.*, No. 23-MD-3089-BMC, --- F. Supp. 3d ---, 2024 WL 4606818 (E.D.N.Y. Oct. 29, 2024). The OTC medications at issue all contained phenylephrine, which the FDA initially approved as a "safe and effective" nasal decongestant nearly forty years ago. *Id.* at *1. Plaintiffs, who purchased OTC phenylephrine products, claimed that by 2016, defendants knew "that oral phenylephrine is no better than placebo" and engaged in a scheme to defraud the public and the FDA into believing that phenylephrine is an effective decongestant. *Id.* Plaintiffs brought state law tort and federal civil Racketeer Influenced and Corrupt Organizations Act ("RICO") claims. The court held that plaintiffs' state law claims were preempted by the Federal Food, Drug, and Cosmetic Act ("FDCA") and that plaintiffs lacked standing to assert their RICO claims. *Id.* The opinion recognizes (1) important preemption principles that prevent state tort law from interfering with the FDA's statutory authority to regulate medications, and (2) constraints based on standing that limit the scope of who can pursue civil RICO claims.

Plaintiffs' state law claims are preempted by the FDCA.

Plaintiffs brought four types of claims under New York state law: mislabeling, false-advertising, false-concealment, and express warranty. *Id.* at *2, *7. The court found these claims were "expressly preempted" because all were based on a core allegation that the defendants should have updated their products' labeling regarding efficacy, despite the FDA's approval of phenylephrine as "safe and effective."[1] *Id.* at *2. As the court dismissed plaintiffs' claims based on express preemption and plaintiffs did not contend there were safety issues, it did not evaluate separate additional bases for implied preemption. *Id.* at *6. Implied preemption defenses commonly arise in the pharmaceutical context. *See e.g., Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299 (2019) (holding claims preempted if clear evidence exists that FDA would not have approved labeling change plaintiffs sought). The court also acknowledged that plaintiffs could not premise their claims on the preempted theory that the manufacturers should have stopped selling their products. *In re Oral Phenylephrine*,

[1] The week after the MDL court's opinion, the FDA opened the public comment period on a proposed administrative order that would withdraw oral phenylephrine's OTC nasal decongestant monograph approval. FDA News Release, *FDA Proposes Ending Use of Oral Phenylephrine as OTC Monograph Nasal Decongestant Active Ingredient After Extensive Review* (Nov. 7, 2024), https://www.fda.gov/news-events/press-announcements/fda-proposes-ending-use-oral-phenylephrine-otc-monograph-nasal-decongestant-active-ingredient-after. The MDL court determined that its express preemption holding survives this development, as "the fact that the FDA might change the monograph in the future would not change this analysis." Order Granting Letter Motion to Judge Cogan Regarding Entry of Judgment, *In re Oral Phenylephrine Mktg. & Sales Pracs. Litig.*, No. 1:23-md-03089 (E.D.N.Y. Nov. 12, 2024). Plaintiffs filed a notice of appeal to the Second Circuit on December 9, 2024.

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2024 WL 4606818, at *7. "[A]n actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability." *Mutual Pharm. Co., Inc. v. Bartlett*, 570 U.S. 472, 488 (2013).

The FDCA establishes two systems to determine whether OTC drugs are safe and effective: the New Drug Application system and the monograph system. *In re Oral Phenylephrine*, 2024 WL 4606818, at *3. The monograph system, at issue here, allows manufacturers to bypass the FDA's review of certain OTC drugs when the drug and its labeling conform to an FDA-issued monograph—which the FDA promulgates through the notice-and-comment rulemaking process, as Congress expressly authorized in the FDCA. If a drug and label match the information contained in the monograph, then the drug is generally recognized as safe and effective. *Id.*

The court examined whether plaintiffs' state claims were preempted by deciding "whether they would enforce a requirement different [than] the federal OTC drug labelling requirements." *Id.* at *3. While, in general, the FDCA is supplemented by state law absent a conflict, state law may not differ from the FDCA's OTC drug provisions. *Id.* Thus, the court held that a state's drug labeling requirement must be "parallel" to federal law to avoid express preemption. *Id.*

The court's analysis focused on plaintiffs' claim that the labels' "Indications" section needed to be updated to "truthfully" describe the products' efficacy. *Id.* Indications must be included on the phenylephrine product label and must use the specific monograph language or "truthful and non-misleading statements describing the monograph language." *Id.* at *4. While the court recognized that the FDA permits some flexibility in the language to promote efficiency, the regime does not create a duty upon the manufacturer to update the label to remove an approved indication. *Id.* The court warned that manufacturers may not be able to change the product's indications section drastically "without misbranding the product." *Id.*

Plaintiffs also claimed that defendants' labeling about phenylephrine's effectiveness for nasal decongestion was false and misleading in violation of the FDCA's misbranding provision. *Id.* at *5. The court rejected plaintiffs' attempt to evade preemption on two bases. *Id.* First, the FDA has sole authority to determine whether a drug is "effective." *Id.* Thus, if defendants' label is consistent with the monograph's statements about efficacy, then the label cannot be false or misleading. *Id.* Further, the court criticized plaintiffs' attack on the labels' "Indications" section as "nonsensical." *Id.* Using plaintiffs' logic, "[phenylephrine] manufacturers would still be allowed to sell products labelled as 'nasal decongestants,' so long as the products' labels do not state that the products are effective." *Id.*

Plaintiffs sought to escape preemption by arguing that the phenylephrine monograph requires truthful statements on its labels and incorporates the anti-misbranding statute. *Id.* at *6. The Court discounted this argument as "completely divorced from the text of the regulations, which does not reference any duty to revise indications based on newly discovered scientific information." *Id.* (citing *Critcher v. L'Oreal USA Inc.*, 959 F.3d 31 (2d Cir. 2020) (holding FDA's authority to determine contents of labeling for cosmetics warranted preemption)). The court noted that the regulation plaintiffs referenced only permits sponsors of NDAs to revise *safety* labeling (i.e., the Warnings and Precautions section), not *efficacy* information (i.e., the "Indications" section). *Id.* at *6; *see also Albrecht*, 587 U.S. at 305 (label change without FDA's prior approval permitted only where "newly acquired information" exists regarding "risk of harm"); *Wyeth v. Levine*, 555 U.S. 555, 571 (2009) (same). The court explained its view of the clear distinction between efficacy and safety: Congress allows extra protections by the states to ensure the safety of consumers; however, efficacy "remains within the exclusive purview of the FDA." *In re Oral Phenylephrine*, 2024 WL 4606818, at *6. As plaintiffs' claims "focus on efficacy, not safety," the court held there was no non-preempted duty to amend the label. *Id.* at *7.

Plaintiffs lack standing to assert RICO claims.

Plaintiffs alleged that defendants violated RICO by engaging in mail and wire fraud to further their scheme to defraud the public and mislead the FDA about phenylephrine's efficacy. *Id.* The court applied the direct-purchaser requirement to plaintiffs' RICO claim and dismissed the claim for lack of standing. *Id.* The "direct purchaser" rule "bars downstream indirect purchasers from bringing an antitrust claim." *Id.* (citing *Ill. Brick Co. v. Illinois*, 431 U.S. 720 (1977)). A direct purchaser is an immediate buyer who has purchased a product from the alleged violator. *Id.* (citing *Apple Inv. v. Pepper*, 587 U.S. 273, 280 (2019)). As plaintiffs did not dispute that they were indirect purchasers of phenylephrine products, the court addressed whether this rule, originating in antitrust cases, also applies to civil RICO claims. *Id.* The court held that the same rules regarding standing apply in both the antitrust and RICO framework, as Congress intended the words used in the RICO statute to have the same meaning as in the antitrust context. *Id.* at *8.

The court also rejected plaintiffs' argument that they met their burden to establish standing by alleging defendants' conduct was a proximate cause of their injuries. While Article III standing requires a showing of causation, the court held that RICO separately and additionally requires "analytically distinct aspects of standing," including the direct-purchaser requirement. *Id.*

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This opinion preempting state law claims that would seek to second-guess the FDA's determinations regarding the efficacy of medications represents an important application of express preemption in the context of OTC medications. The court's holding that plaintiffs must be direct purchasers to have standing to assert civil RICO claims also serves to limit attempts by plaintiffs' bar to use the treble damages available under RICO to circumvent state tort reform laws limiting available remedies in product liability cases. *See* Br. of Atl. Legal Found. & DRI Ctr. for Law & Pub. Pol'y as *Amici Curiae* in Supp. of Pet'rs at 8, *Medical Marijuana, Inc. v. Horn*, No. 23-365 (U.S. Nov. 2023), https://atlanticlegal.org/wp-content/uploads/2023/11/Medical-Marijuana-Inc.-v.-Horn-23-365.pdf.

