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BLOG

A Potential Shield: FDCA Preemption in Product Liability and Mass Torts Litigation

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The Food, Drug, and Cosmetic Act (FDCA or the Act) governs safety, efficacy, and labeling over drugs, cosmetics, dietary supplements, medical devices, and other consumer products. 21 U.S.C. § 393(b). The FDCA grants the Food and Drug Administration (FDA) the primary power to enforce the Act (*id.* § 393(a)), including whether drugs, cosmetics, dietary supplements, and medical device manufacturers properly label their products to avoid misleading their customers. *See, e.g.*, *id.* §§ 343, 352, 362, 387c. The FDCA expressly precludes a private right of action to enforce the Act (*id.* § 337(a)). Based on this provision, courts have held that express preemption occurs when the FDCA "imposes a federal requirement on the device and the contested state or local rule imposes any obligation that differs from or adds to those in the FDCA." *Plourde v. Sorin Grp. USA, Inc.*, 23 F.4th 29, 33 (1st Cir. 2022). Express preemption does not apply to state-law claims that merely have "parallel duties" to FDA regulations promulgated under the Act. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008).

Simultaneously, courts have been grasping with the contours of implied preemption under the FDCA. Several recent decisions by district and circuit courts have held that conflict preemption (a type of implied preemption) blocks state-law claims when those claims are "ultimately dependent on the existence of violations of federal law." *Collyer v. Catalina Snacks Inc.*, 2024 U.S. Dist. LEXIS 9637, at *17 (N.D. Cal. Jan. 18, 2024); *see also Nexus Pharms., Inc. v. Cent. Admixture Pharm. Servs.*, 48 F.4th 1040 (9th Cir. 2022) (holding that a state law claim that prohibited the sale of a drug was preempted because it was based on an allegation of a violation of the FDCA).

The most recent high-profile case on conflict preemption is *DiCroce v. McNeil Nutritionals, LLC*, where the First Circuit addressed a putative class action claim by plaintiff-appellant Kristin DiCroce (DiCroce) against McNeil Nutritionals, LLC and Johnson & Johnson Consumer, Inc. (collectively, Appellees). 82 F.4th 35 (1st Cir. 2023). DiCroce claimed that Appellees violated FDA labeling requirements by misbranding their product, Lactaid. They alleged that Lactaid was marketed as a dietary supplement instead of a drug, even though it was marketed as a treatment for lactose intolerance, a medical condition. Additionally, the lawsuit alleged that the product's labeling violated state law claims related to unfair or deceptive trade practices, false advertising, and unjust enrichment, and was misleading to consumers. The district court dismissed DiCroce's complaint on the grounds that "no reasonable consumer could find Lactaid's product labels deceptive[.]" *Id.* at 38.

The First Circuit affirmed the district court's holding, but was "not tied to the district court's reasoning." *Id.* at 39. Instead, the First Circuit upheld the district court's ruling because "DiCroce's claims are impliedly preempted by the

FDA's statutory enforcement authority." *Id.* at 40. The First Circuit made clear that "§ 337(a) preempts any state-law claim that exists 'solely by virtue' of an FDCA infraction." *Id.* Stated otherwise, a plaintiff bringing a state-law claim must sue for "conduct that **violates** the FDCA" rather than sue for "conduct **because** it violates the FDCA." *Id.* at 41. Here, the First Circuit found that DiCroce's "claim that Lactaid's label is misleading is premised entirely on her belief that said label violates the FDCA" and states "no other grounds on which her claims could survive." *Id*. Therefore, her state-law claims were impliedly preempted because "the FDCA 'is a critical element in [DiCroce's] case.'" *Id.* at 42.

On April 15, 2024, the Supreme Court denied certiorari, letting the First Circuit's decision stand. *DiCroce v. McNeil Nutritionals, LLC*, 2024 WL 1607964, at *1 (U.S. Apr. 15, 2024).

The Supreme Court's decision to deny cert affirms that conflict preemption with the FDCA may bar some state-law product liability claims. In terms of whether a conflict exists between the claim and the FDCA, the underlying allegations will be dispositive. Thus, defendants facing state-law claims such as failure to warn, deceptive practice, or misrepresentation should conduct a conflict analysis to determine whether the alleged conduct is tortious solely because it violates the FDCA. If so, implied preemption could be a tool to dismiss those claims.

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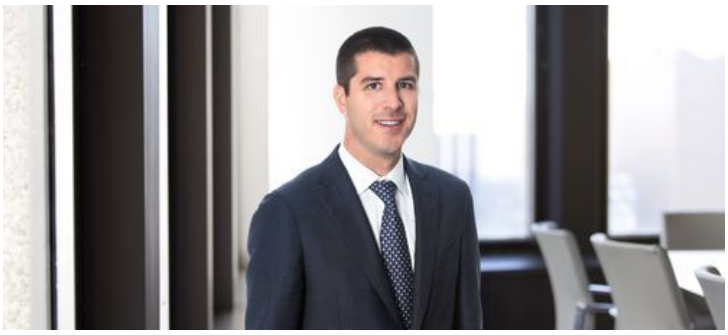

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