

BLOG



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Key Takeaway

In December 2022, the Modernization of Cosmetics Regulation Act (MoCRA) directed the FDA to conduct research into the effects of PFAS use in cosmetics. Cosmetic companies that are sued over PFAS use could move to dismiss or stay those cases while the FDA research is ongoing under the primary-jurisdiction doctrine.

On December 29, 2022, President Biden signed the Modernization of Cosmetics Regulation Act (MoCRA) into law. [1] One provision of MoCRA charges the FDA to conduct research into the use of perfluoroalkyl and polyfluoroalkyl substances—better known as PFAS—in the cosmetic industry, and to publish a report containing its findings by December 29, 2025. [2] The ongoing FDA assessment opens the door for companies sued by consumers over PFAS to assert new jurisdiction-based defenses.

PFAS, sometimes known as "forever chemicals," are liquid-resistant chemicals used in a wide range of commercial products, including nonstick baking pans, firefighting foam, and cosmetics. Due to their ubiquity in popular products, and their resistance to biodegrading, many people have raised concerns about potential deleterious effects on human health. However, research indicating the dangers of PFAS is limited, as is data about the concentration of PFAS in commercial products.

MoCRA's directive for the FDA to research PFAS is consistent with a general recent governmental push for regulation of PFAS use. For example, a number of states have worked to ban or limit PFAS use in commercial products, and the EPA has been working on various initiatives to study and limit the impact of environmental exposure to PFAS. [3] Indeed, in February 2022, the FDA announced it would be monitoring scientific studies on PFAS. [4]

The ongoing MoCRA review of PFAS use in cosmetic products opens up new defenses for companies sued in PFAS-related class actions. For instance, defendants may wish to invoke the primary-jurisdiction doctrine in an effort to stay plaintiffs' claims until the FDA has completed its PFAS report.

The primary-jurisdiction doctrine is the notion that when a court and an agency have concurrent jurisdiction over an issue, the courts will often hold that the agency has primary jurisdiction over the issue, and the court will therefore refuse to hear the case until the agency has made some sort of determination regarding the issue at hand. [5] Primary-jurisdiction doctrine is widely applied in U.S. courts to either dismiss or stay litigation, and has been cited several times by the Supreme Court. [6]

A recent decision from the Northern District of New York provides a roadmap for what successful invocation of primary jurisdiction might look like for PFAS defendants. In that case, *In re: Beech-Nut Nutrition Company Baby Food Litigation*, ^[Z] plaintiffs sued a baby food company, alleging that the defendant's products contained dangerous and toxic heavy metals. The suit was filed in February 2021, and in April 2021, the FDA announced a plan to research the presence of heavy metals in baby foods and then decide on regulatory actions. In light of that, the court granted the defendant's motion to dismiss, holding that under the primary-jurisdiction doctrine, since the case turned on questions about the harmfulness of heavy metals in baby food, the FDA has primary jurisdiction. The court held that the plaintiffs' suit must be put on hold until the results of the FDA's rule-making process are known. In its decision, the court emphasized that it did not want to contribute to the development of a confusing and contradictory body of law across various states that will then potentially be undone by the FDA's determination. The court also argued that the costs of delaying the plaintiffs' lawsuit was outweighed by concerns that the case, if allowed to proceed, would involve extensive costs, only for the court's decision to ultimately be rendered moot by the FDA.

Cosmetics companies that are sued under theories about the presence of PFAS in their products will likely want to consider moving for dismissal or stay on the basis of the pending FDA research report. Potentially, the results of the FDA's research might render the claims against them moot. At the very least, they can argue, based on the primary-jurisdiction doctrine, that the FDA's forthcoming report will be helpful to the parties and court in resolving the dispute.

Modernization of Cosmetics Regulation Act of 2022, Pub. L. 117-328, §§ 3501-3508, https://www.congress.gov/117/bills/hr2617/BILLS-117hr2617enr.pdf.

2 Id., § 3506.

3 See, e.g., Environmental Protection Agency, PFAS Strategic Roadmap: EPA's Commitments to Action 2021–2024, https://www.epa.qov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf.

U.S. Food & Drug Administration, Per and Polyfluoroalkyl Substances (PFAS) in Cosmetics, https://www.fda.gov/cosmetics/cosmetic-ingredients/and-polyfluoroalkyl-substances-pfas-cosmetics.

E Primary-Jurisdiction Doctrine, Black's Law Dictionary (11th ed. 2019).

§ See, e.g., Pharm. Rsch. & Mirs. of Am. v. Walsh, 538 U.S. 644, 673 (2003); Port of Bos. Marine Terminal Ass'n v. Rederiaktiebolaget Transatlantic, 400 U.S. 62, 68 (1970); United States v. W. Pac. R.R. Co., 352 U.S. 59, 63−64 (1956).

 $\underline{{}_{\!\!\!/}}$ No. 1:21-CV-133, 2023 WL 350818 (N.D.N.Y. Jan. 19, 2023).

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