No. _____

In The

Supreme Court of the United States

KRISTIN DICROCE, Individually and on Behalf of all Persons Similarly Situated,

Petitioner,

v.

MCNEIL NUTRITIONALS, LLC and JOHNSON & JOHNSON CONSUMER, INC.,

Respondents.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The First Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED FOR REVIEW

Whether the First, Eighth, and Ninth Circuits' holdings that state law claims based on violating the Federal Food, Drug and Cosmetic Act are impliedly preempted has misconstrued ***Medtronic, Inc. v. Lohr***, 518 U.S. 470 (1996), and ***Buckman Co. v. Plaintiffs' Legal Comm.***, 531 U.S. 341 (2001), and usurped the power of states to define the elements of their own state law causes of action.

PARTIES TO THE PROCEEDING

The names of all parties to the proceeding in this Court appear on the cover page. A corporate disclosure statement is not required because Plaintiff Kristin DiCroce is not a corporation. *See* Sup. Ct. R. 29.6.

STATEMENT OF RELATED CASES

Counsel is aware of no directly related proceedings arising from the same trial-court case as this case other than those proceedings appealed here.

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PETITION FOR WRIT OF CERTIORARI

At issue in this Petition is the constitutionally granted power to states to define their own state law causes of action. If allowed to stand, the *DiCroce* decision by the First Circuit, following decisions from the Eighth and Ninth Circuits, will impliedly preempt state law causes of action based in part on violations of the Food, Drug and Cosmetics Act, which is contrary to what this Court held in ***Medtronic, Inc. v. Lohr***, 518 U.S. 470 (1996), and ***Buckman Co. v. Plaintiffs' Legal Comm.***, 531 U.S. 341 (2001). Because these three circuit courts have upset the delicate balance of federalism by failing to follow controlling Supreme Court precedents, the Court should grant this Petition.

OPINIONS BELOW

DiCroce v. McNeil Nutritionals, LLC, et al., U.S. District Court for the District of Massachusetts is reported at 640 F.Supp.3d 182 (D. Mass. 2022). Judgment entered on November 10, 2022.

DiCroce v. McNeil Nutritionals, LLC, et al., U.S. Court of Appeals for the First Circuit is reported at 82 F.4th 35 (1st Cir. 2023). The judgment of the Court of Appeals was entered on September 18, 2023. A petition for rehearing or rehearing en banc was denied on December 7, 2023.

JURISDICTION

The judgment of the Court of Appeals was entered on September 18, 2023. A petition for rehearing or rehearing en banc was denied on December 7, 2023. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

The relevant statutes and regulations are at App. 31-61.

STATEMENT OF THE CASE

I. Introduction

This case presents a recurring question of great importance: how the doctrine of implied preemption should be applied in cases brought under state law based on allegations that Defendants had "violated FDA regulations"? The grant of this Petition will bring federal appellate courts' and district courts' application of federal law back into line with settled Supreme Court precedents.

II. Supreme Court Precedent At Issue In This Petition

In ***Medtronic, Inc. v. Lohr***, 518 U.S. 470, 484-487 (1996), the Court held that even an express-preemption

statute was to be construed narrowly in order to minimize its interference with state law remedies, thereby avoiding "a serious intrusion into state sovereignty." Part of minimizing that potential interference and serious intrusion was to allow state law claims based in part on the allegation that defendant's conduct had "violated FDA regulations." ***Medtronic***, 518 U.S. at 495.[1]

In ***Buckman Co. v. Plaintiffs' Legal Comm.***, 531 U.S. 341, 352 (2001), the Court found implied federal preemption in a case so extreme that its holding for defendant effectively reaffirmed ***Medtronic***, stating, *inter alia*, that the ***Medtronic*** decision "can be read to allow certain state-law causes of actions that parallel federal [regulations] . . ." *Id*. at 353. The Plaintiffs in ***Buckman*** had brought state law claims based on the allegation that Buckman had lied to the FDA during the approval process for certain medical devices, but the Court concluded that their claims presented the mirror image of the claims in ***Medtronic***.

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[1] *See also Wyeth v. Levine*, 555 U.S. 555, 574-75, 129 S.Ct. 1187, 173 L.Ed.2d 51 (2009), holding that there is no preemption where simultaneous compliance with state and federal law is possible, and the state law is not an obstacle to the realization of federal goals. "[T]he purpose of Congress is the ultimate touchstone in every pre-emption case." *Id*. at 565 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996)). " 'In all pre-emption cases, and particularly in those in which Congress has legislated in a field which the States have traditionally occupied, we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.' " *Id*. (citing *Medtronic*, 518 U.S. at 485, 116 S.Ct. 2240, quoting *Rice v. Santa Fe Elevator Corp*., 331 U.S. 218, 230, 67 S.Ct. 1146, 91 L.Ed. 1447 (1947)).

That is, ***Medtronic*** would have constituted a serious intrusion by federal law into state sovereignty and ***Buckman*** would constitute a serious intrusion by state law into federal jurisdiction.

To be decided by this Court in the event the Petition is granted is whether the First, Eighth, and Ninth Circuits have so misconstrued the doctrine of implied federal preemption as articulated in ***Medtronic, Inc. v. Lohr***, 518 U.S. 470 (1996), and ***Buckman Co. v. Plaintiffs' Legal Comm***., 531 U.S. 341 (2001), by holding that a state law claim for conduct violating the FDCA is impliedly preempted that they have usurped the power of state legislatures to define the elements of their own state law causes of action in violation of the bedrock principles of federalism.

III. Facts Relevant to this Petition

The U.S. Food and Drug Administration (the "FDA") treats dietary supplements as foods subject to the laws and regulations applicable to food. 1st Cir. App. at 17 (First Amended Complaint ("FAC") at ¶ 12).[2] The Federal Food, Drug, and Cosmetic Act (the "FDCA") provides that a statement on a dietary supplement's label or labeling "may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases." 21 U.S.C. § 343(r)(6). 1st Cir. App. at 18 (FAC at ¶ 15). A dietary supplement's label can

[2] "1st Cir. App." refers to the Record Appendix filed with the First Circuit. *See DiCroce v. McNeil Nutritionals, LLC, et al.*, First Cir. Docket No. 22-1910.

explain how the nutrients contained therein support the normal functioning of the body, whereas only an FDA approved drug can make disease claims explaining how it helps treat a non-normal condition. *See* 21 C.F.R. § 101.93(f). 1st Cir. App. at 18 (FAC at ¶¶ 14-15). Products such as the Lactaid Products claiming to treat diseases (even if labeled as "dietary supplements") are illegal, unapproved drugs. App. at 17 (trial court decision at 3).

Through both labeling and advertising, including on their website,[3] Defendants misrepresent that the Lactaid Products are effective to diagnose, prevent, treat, cure, or mitigate, or provide a beneficial effect for individuals who are lactose intolerant and/or experience the characteristic symptoms associated with being lactose intolerant. 1st Cir. App. at 19-20 (FAC at ¶ 17). Specifically, Defendants make the following virtually identical disease claims for each of the Lactaid Products at issue in this lawsuit (*i.e.*, Lactaid Fast Act Chewables, Lactaid Fast Act Caplets and Lactaid Original Strength Caplets), including that they treat people suffering from lactose intolerance "For the Prevention of • Gas • Bloating • Diarrhea associated with digesting diary," that by taking the Lactaid Products a consumer suffering from lactose intolerance can "Enjoy Dairy Again!", and "nothing can stop you from

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[3] Claims made on a company's website in connection with the products at issue are considered part of the label. *Kordel v. United States*, 335 U.S. 345, 349 (1948) ("labeling" as defined at 21 U.S.C. § 321(m) is "not restricted to labels that are on or in the article or package that is transported").

eating the foods you love. Our delicious vanilla chewables should be taken with your first bite of dairy, so that milk doesn't mess with you" (the "Disease Claims"). App. at 16-17 (trial court decision at 2); 1st Cir. App. at 19-20 (FAC at ¶¶ 17(a)-(c), 18) and 37-43 (Exhibits 1-3 to the FAC). Lactose Intolerance has been identified by the National Institute of Health as a disease. 1st Cir. App. at 20 (FAC at ¶ 19 and Exhibit 4 thereto at 44).

Plaintiff purchased the Lactaid Products in Massachusetts on multiple occasions within four years prior to bringing this lawsuit based on the mislabeled statements that they prevent and thus treat people suffering from lactose intolerance. App. at 18-19 (trial court decision at 4); 1st Cir. App. at 22 (FAC at ¶ 26). Had the Lactaid Products been labeled in compliance with applicable state and federal law discussed below, these Disease Claims would not have appeared on the Lactaid Products' labels, Plaintiff would not have been misled, and she would not have purchased the Lactaid Products but rather purchased a less expensive lactase supplement not making such claims. App. at 19 (trial court decision at 4-5);1st Cir. App. at 24 (FAC at ¶ 33). In contrast to Lactaid, other lactase supplements that did not make illegal disease claims were less expensive for treating lactose intolerance. 1st Cir. App. at 23 (FAC at ¶ 31).

On October 12, 2021, Plaintiff Kristin DiCroce ("DiCroce"), individually and on behalf of a class of similarly situated consumers, sued Defendants for misbranding the Lactaid Products. App. at 19 (trial

court decision at 5); 1st Cir. App. at 3 (*see* First Cir. Docket No. 22-1910). Specifically, Defendants have misbranded the Lactaid Products as dietary supplements when, in fact, the Lactaid Products are drugs because they are marketed and sold for the stated purpose of preventing and treating lactose intolerance. 1st Cir. App. at 16 (FAC at ¶¶ 2-5). Defendants have never sought nor obtained the required FDA approval for selling the Lactaid Products as drugs. App. at 17 (trial court decision at 3); 1st Cir. App. at 21-22 (FAC at ¶ 24). The original Complaint contained counts for violation of 93A (Count I), unjust enrichment (Count II), and false advertising in violation of ch. 266, Section 91 (Count III). 1st Cir. App. at 3. On April 8, 2022, after the Court dismissed the original Complaint on the grounds that Plaintiff had failed to show that she suffered any economic damages, 1st Cir. App. at 13-14, DiCroce filed her First Amended Complaint with the same counts, but this time alleging that she overpaid for the Lactaid Products because Defendants' materially misleading and illegal disease claims led her to reasonably believe they were worth more than basic, less expensive lactase supplements. App. at 18-19 (trial court decision at 4-5); 1st Cir. App. at 15, 24-25. Defendants moved to dismiss the FAC. On November 10, 2022, the District Court granted Defendants' Motion to Dismiss. App. 25, 28. Plaintiff then filed a timely Notice of Appeal on November 22, 2022. The U.S. Court of Appeals for the First Circuit affirmed the District Court decision, App. 1-12, and entered judgment on September 18, 2023. App. 13. Plaintiff filed a petition for

rehearing or rehearing en banc, which was denied on November 29, 2023. App. 29.

REASONS FOR GRANTING THE PETITION

To stop the further spread of federal circuits misinterpreting ***Medtronic*** and ***Buckman***, and usurping the power of state legislatures and state courts to define their own state law causes of action to include violations of the FDCA, this Court should reaffirm that Justice O'Connor's requirement-versus-remedy analysis applies here.

In ***Medtronic, Inc. v. Lohr***, 518 U.S. 470, 484-486 (1996), the Court held that even an express preemption statute was to be construed narrowly in order to minimize its interference with state law remedies, thereby avoiding "a serious intrusion into state sovereignty." Part of minimizing that potential interference and serious intrusion was to allow state law claims based in part on the allegation that defendant's conduct had "violated FDA regulations." ***Medtronic***, 518 U.S. at 495. Justice O'Connor comprehensively summed up the logic of that approach:

> Where a state cause of action seeks to enforce an FDCA requirement, that claim does not impose a requirement that is "different from, or in addition to" requirements under federal law. To be sure, the threat of a damages remedy will give manufacturers an additional cause to comply, but the requirements imposed on them under state and federal law do

> not differ. Section 360k does not preclude States from imposing different or additional ***remedies***, but only different or additional ***requirements***.

Medtronic, Inc. v. Lohr, 518 U.S. 470, 513 (1996) (O'Connor, J., concurring in part and dissenting in part) (emphasis in original).

In ***Buckman Co. v. Plaintiffs' Legal Comm.***, 531 U.S. 341, 352 (2001), this Court found implied federal preemption in a case so extreme that its holding for defendant had the effect of reaffirming ***Medtronic***. The Plaintiffs in ***Buckman*** had brought state law claims based on the allegation that Buckman had lied to the FDA during the approval process for certain medical devices, but the Court concluded that their claims presented the mirror image of the claims in ***Medtronic***. That is, ***Medtronic*** would have constituted a serious intrusion by federal law into state sovereignty and ***Buckman*** would constitute a serious intrusion by state law into federal jurisdiction:

> Given this analytical framework, we hold that the plaintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by federal law. The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Agency, and that this authority is used by the Agency to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Agency can be skewed by allowing fraud-on-the-FDA claims under state tort law.

Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 348 (2001) (footnote omitted).

The First Circuit (following the Eighth and Ninth Circuits) rejected ***Buckman's*** "somewhat delicate balance" and reached a conclusion that is precisely the opposite of the one Justice O'Connor had reached:

> More recently, we had the opportunity to consider *Buckman's* holding in the food-labeling context, in *Dumont v. Reily Foods Company*. 934 F.3d 35, 41-43 (1st Cir. 2019). There, we applied, without formally adopting, the Eighth and Ninth Circuits' test for deciding whether a state-law claim avoids preemption: "The plaintiff must be suing for conduct that violates the FDCA (or else his claim is expressly preempted by [the FDCA's medical device preemption provision, 21 U.S.C. § 360k], **but the plaintiff must not be suing because the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)**)." *Dumont*, 934 F.3d at 42 (alteration in original) (quoting *In re Medtronic, Inc.*, *Sprint Fidelis Leads Prod. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010)) (citing *Perez v. Nidek Co.*, 711 F.3d 1109, 1120 (9th Cir. 2013)). We explained that, based on this test, a "complaint is preempted unless the conduct it pleads: (1) violates FDCA labeling requirements and (2) would also violate [Massachusetts General Laws] chapter 93A even if the FDCA did not exist."

DiCroce v. McNeil Nutritionals, LLC, et al., 82 F.4th 35, 41 (1st Cir. 2023) (emphasis added). The Circuit

Court thus conflated a "fraud on the FDA" claim under *Buckman* with a state law claim alleging deceptive marketing as evidenced by a violation of the FDCA.

DiCroce is the latest circuit court decision gutting the "somewhat delicate balance" between state sovereignty and the federal statutory scheme that Congress and this Court have so carefully established, and Justice O'Connor has so cogently explained. The First Circuit has taken a US Supreme Court case preempting the specifically limited field of "fraud-on-the-FDA claims under state tort law," ***Buckman***, 531 U.S. at 352, and erroneously concluded that ***Buckman*** impliedly preempts ALL state law causes of action based at least in part on a violation of the FDCA. *See DiCroce*, 82 F.4th at 41. This is the opposite of Massachusetts state law. *See Loffredo v. Center for Addictive Behaviors*, 426 Mass. 541, 544 (1998) (observing the law in Massachusetts to be that "a defendant's violation of a statute that leads to a plaintiff's injury may figure as an element in an otherwise available cause of action") (footnote omitted).

The *DiCroce* court's test for implied preemption is impossible to interpret in a limited, logical manner. What does it even mean to say that a cause of action is preempted unless it "would also violate state law even if the FDCA did not exist"? The *DiCroce* test seems to imply that everything else in this parallel universe would remain the same, making the highly unlikely assumption, for example, that the Commonwealth of Massachusetts (and other states) would not have

enacted a state law equivalent of the FDCA if the FDCA had never existed. The more logical assumption is that Massachusetts would have enacted a state law equivalent of the FDCA and so the state law claims DiCroce brought here would have still been available to her.

Given this multiverse of alternative realities that could have come into existence if "the FDCA did not exist," *DiCroce*, 82 F.4th at 41, it would be impossible for manufacturers of drugs and/or dietary supplements to know their legal requirements as well as consumers to know their rights.

This case presents this Court with an opportunity to return the law of implied FDCA preemption to the land of sanity and certainty by reaffirming Justice O'Connor's conclusion that "[w]here a state cause of action seeks to enforce an FDCA requirement, that claim does not impose a requirement that is 'different from, or in addition to,' requirements under federal law," ***Medtronic***, 518 U.S. at 513, and therefore that cause of action is not impliedly preempted. Absent intervention by this Court, other federal circuit courts will likely adopt this erroneous analysis as well, giving federal courts virtually unfettered discretion to veto state legislatures.

CONCLUSION

For the foregoing reasons, Kristen DiCroce respectfully requests that this Court issue a writ of certiorari to review the *DiCroce* decision by the First Circuit Court of Appeals.

Respectfully submitted,

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