IN THE SUPERIOR COURT OF NEW JERSEY APPELLATE DIVISION

Docket No. A-001501-23

ALISON BEAVAN, Plaintiff-Respondent, v. ALLERGAN USA, INC., *et al.*, Defendant-Appellant.	On Appeal from: SUPERIOR COURT OF NEW JERSEY, LAW DIVISION, MORRIS COUNTY DOCKET NO.: MRS-L-151-21 Sat Below: Hon. Louis S. Sceusi, J.S.C. Civil Action

***AMICI CURIAE* BRIEF OF THE PRODUCT LIABILITY ADVISORY COUNCIL, INC. AND THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA IN SUPPORT OF DEFENDANT-APPELLANT**

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I. PRELIMINARY STATEMENT

Amici curiae agree with defendant Allergan USA, Inc. ("Allergan") that, whatever plaintiff now chooses to call her claims, they necessarily depend on a purported "duty to recall" an FDA-approved medicine that does not exist under either the common law or New Jersey's Product Liability Act ("PLA").

Throughout the proceedings in the trial court, plaintiff pursued a claim rooted in what her complaint explicitly pleaded as the defendant not issuing a recall sooner of the medicine at issue (an injectable eye treatment). That claim is necessarily premised on a purported duty to recall.

However, no "failure-to-recall" claim exists at common law, in New Jersey or elsewhere. Many states' laws reject such claims in many contexts. Nor did the PLA create any recall-based cause of action. No New Jersey precedent allows any failure-to-recall claim under the PLA. This is why, on appeal, plaintiff strenuously attempts to distance herself from what she alleged in her complaint.

Even if a failure-to-recall claim did exist, it would be preempted by federal law. A failure-to-recall claim inherently asserts, under State law, that the defendant cannot sell a product, despite the product being FDA-approved for sale. The Supreme Court, and many other courts, have held that so-called "stop selling" claims making such allegations are preempted. Once the FDA has said "yes, you can sell," state law cannot countermand the FDA's in-force decision and say "no."

Plaintiff now claims to be pursuing a manufacturing-defect claim, but she offers no non-recall-related evidence that the alleged defect – which occurred in only one of every 45 products tested (2.2%) – in fact manifested in this case. Neither her treating physician, nor her sole expert witness, points to anything other than the defendant's recall notice as a basis for claiming that the purported defect ever existed in the unit that plaintiff received. Thus, the claimed "manufacturing defect" is inseparable from the recall notice.

Plaintiff also contends that she is now pursuing a "post-sale duty to warn" claim. But once again, the purported inadequate warning is entirely subsumed by the recall. The information she claims should have been provided earlier, but was not, is precisely the information contained in the defendant's recall notice. Thus, the claimed "failure to warn," once again, is in fact an alleged failure to recall. These claims thus fail for the same reasons New Jersey has never recognized failure-to-recall claims in the first place.

II. INTEREST OF *AMICI CURIAE*

Amici curiae are the Product Liability Advisory Council, Inc. ("PLAC") and the Chamber of Commerce of the United States of America ("Chamber").

PLAC is a non-profit professional association of corporate members representing a broad cross-section of American and international product manufacturers.[1] Through PLAC, these companies

[1] A list of current PLAC corporate members is available at https://plac.com/PLAC/Membership/Corporate_Membership.aspx.

seek to contribute to the improvement and the reform of law in the United States and elsewhere, with emphasis on the law governing the liability of product manufacturers and others in the supply chain. PLAC's perspective is derived from the experiences of a corporate membership that spans a diverse group of industries in various facets of the manufacturing sector. In addition, several hundred of the nation's leading product-liability defense attorneys are sustaining (non-voting) members of PLAC. Since 1983, PLAC has filed more than 1,100 briefs as *amicus curiae* in both state and federal courts, including this Court, presenting the broad perspective of product manufacturers seeking fairness and balance in the application and development of the law as it affects product risk management.

The Chamber is the world's largest business federation. It represents approximately 300,000 direct members and indirectly represents the interests of more than three million companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus curiae* briefs in cases, like this one, that raise issues of concern to the nation's business community.

These organizations have members that manufacture, research, produce, and sell prescription drugs and medical devices regulated

by the FDA. They thus have a substantial interest in ensuring the proper relationship between FDA and state-law requirements. Under federal law, the FDA assesses the safety and effectiveness of prescription medical products. Once the FDA approves these products for marketing, states cannot prohibit regulated firms from doing what the FDA has approved. Only the FDA, not the State, can require a recall of an FDA-regulated product.

The common law has long reflected this reality, and has consistently refused to impose liability where, as here, a plaintiff claims that a product should have been recalled before the FDA (or some other governmental entity) has required such an action.[2]

III. LEGAL ARGUMENT

As more thoroughly detailed in Appellant Allergan's brief, the defendant discovered and notified the FDA of a problem with the eye medication Ozurdex®, in June-July 2018 (Da0229; Da0240). Defendant's FDA notice initiated a months-long process, involving more than twenty contacts with the FDA (Da0258 ¶65) that culminated in an FDA recall of several product batches on December 20, 2018 (Da0250; Da0258 ¶¶51-52; Da0255; Da0452 pp. 130-31; Da0479). The FDA's recall was for "product quality" reasons – because the agency determined the problem was "not a safety concern" (Da0250; Da0252). That was because the problem involved release of a tiny silicone particle, and it occurred

[2] No counsel for any party authored this brief in whole or in part and no entity or person, aside from *amici curiae*, their members, and their counsel, made any monetary contribution intended to fund the preparation or submission of this brief.

in only one of every 45 units tested (2.2%) (Da0229; Da0237; Da0240).

The Ozurdex® treatment at issue occurred on November 6, 2018 – after the defendant had notified the FDA of the issue, but before the agency authorized the recall (Da0087). Plaintiff had previously used Ozurdex® without incident several times (Da0087), because she suffered from several serious eye problems that independently could lead to blindness (Da0045; Da0047 pp. 13, 60).

Plaintiff alleged a failure-to-recall claim against Allergan (Da0001 ¶47-49; Da0846 pp. 5-8). The only purported fact (beyond mere timing) that plaintiff's witnesses cited to support her claim that the unit she received was actually one of the 2.2% that shed a silicone particulate was the unit's being from a "recalled lot" (Da0150 p. 102; Da0229; Da0237; Da0452 pp. 50, 54). No other "circumstantial evidence" exists that the claimed defect manifested in the applicator used during plaintiff's treatment. Similarly, plaintiff's treating physician cited only the FDA recall notice to support of his opinion that a silicone particulate caused inflammation that contributed to plaintiff's claimed injury (Da0047, p. 54).

Without the recall, this case would not exist. Plaintiff's brief admits as much. Plaintiff argues that the recall notice "identified" the "defect," Op. Br. at 19, and claims that defendant had "no justification ... to delay issuing a recall." Id. at 28. This is precisely the type of failure-to-recall claim that the common law has long rejected.

Moreover, plaintiff claims that: (1) what she now calls a "post-

sale duty to warn" began on June 21, 2018 – the precise date that the defendant discovered the problem that prompted the recall process – and (2) the "warning" duty required the same information that the FDA received, and that the recall notice later provided. Opp. Br. at 3, 22-23, 35-36, 38. Plaintiff argues that FDA approval was "not need[ed]" to "otherwise issue a product recall." Id. at 5. Plaintiff seeks to distinguish otherwise on-point precedent as "not involv[ing] a recalled product." Id. at 20.[3]

The failure-to-recall claim plaintiff alleged in her complaint does not exist, and no matter what label she now tries to attach to that non-existent claim – it still fails to state a cause of action.

A. THE LAW DOES NOT RECOGNIZE ANY PRODUCT-LIABILITY THEORY GROUNDED IN A DEFENDANT'S ALLEGED FAILURE TO RECALL A PRODUCT BEFORE ANY GOVERNMENT RECALL ORDER.

1. The Common Law Has Long Rejected Failure-To-Recall Claims.

The common law does not impose any duty on a manufacturer to recall its products in the absence of a government order to do so. The law does not require a defendant, such as Allergan, to remove a product from the market entirely, or else face universal liability simply for selling that product. Where consistent with the PLA, New Jersey law follows the Third Restatement in product-liability cases. E.g., Cavanaugh v. Skil Corp., 164 N.J. 1, 4-5 (2000); Myrlak v. Port

[3] Plaintiff's recall-based warning claim also fails because the recall here was not safety related (Da0252). See Asby v. Medtronic, Inc., 673 F. Supp.3d 787, 795 (E.D.N.C. 2023) (warning claim held "implausible" where "the FDA specifically stated in the recall notice that it was not prompted by any reports of injuries or death").

Auth. of New. York & New Jersey, 157 N.J. 84, 103-07 (1999); Mathews v. Univ. Loft Co., 387 N.J. Super. 349, 362 & n.10 (App. Div. 2006). The Third Restatement of Torts addresses recall-related liability. Comprehensively reviewing the law, §11 determined that such liability has never been recognized outside of two limited situations: (1) noncompliance **after** a government recall was **already** declared, or (2) negligently conducting a recall that the defendant voluntarily undertook:

> One engaged in the business of selling or otherwise distributing products is subject to liability for harm to persons or property caused by the seller's failure to recall a product after the time of sale or distribution if:
>
> (a)(1) a **governmental directive** issued pursuant to a statute or administrative regulation **specifically requires the seller or distributor to recall the product**; or
>
> (a)(2) the seller or distributor, **in the absence** of a recall requirement under Subsection (a)(1), **undertakes to recall** the product; and
>
> (b) the seller or distributor fails to act as a reasonable person in recalling the product.

Restatement (Third) of Torts, Products Liability §11 (1998) (emphasis added).

Thus, the Third Restatement's black letter law rejects the purported common-law obligation that plaintiff asserts here: demanding the anticipatory removal of products from the market before **any** recall was ordered or undertaken. Sound reasons support these constraints. An unlimited duty to recall, as plaintiff sought here, would impose "significant burdens" on commerce:

> Duties to recall products impose significant burdens on manufacturers. Many product lines are periodically redesigned so that they become safer over time. If every improvement in product safety were to trigger a common-law duty to recall, manufacturers would face incalculable costs every time they sought to make their product lines better and safer.

Restatement Third §11, comment a. Further, decisions about whether the public as a whole should be deprived of access to otherwise legal products should not be the province of judges and juries in common-law tort litigation:

> [A]n involuntary duty to recall should be imposed on the seller only by a governmental directive issued pursuant to statute or regulation. Issues relating to product recalls are best evaluated by governmental agencies capable of gathering adequate data regarding the ramifications of such undertakings.

Id. "Congress vested the FDA with the authority to monitor and supervise product recalls." Clark v. Actavis Group hf, 567 F. Supp.2d 711, 717 (D.N.J. 2008) (citation omitted).

> Implicit in this authority is the understanding that the FDA possesses the necessary expertise to determine when notice is required, what the [recall] notice should contain, and who the notice should be sent to.... Plaintiffs are essentially asking the Court to perform the tasks traditionally relegated to the FDA.

In re Human Tissue Products Liability Litigation, 488 F. Supp.2d 430, 433 (D.N.J. 2007).

For similar reasons, in State after State, in both common-law and statutory product-liability regimes, and whether the State otherwise follows the Second or Third Restatement, courts have refused

to expand liability by including claims that legal products should not have been sold, but rather should have been recalled.

For instance, in California, the State that invented strict liability, no duty to recall an FDA-regulated product (an over-the-counter medicine) exists unless the FDA has decided to authorize such action:

> We conclude ... as a matter of law, that defendant may not be held liable for failing to withdraw its product from the market.... A few scientific studies had shown [the risk plaintiffs allege] but ... the FDA had determined that further studies were needed to confirm or disprove the association. Pending completion of those studies, the FDA concluded that product warnings were an adequate public safety measure. **Although the FDA's conclusion is not binding on us, we think it deserves serious consideration.**

Ramirez v. Plough, Inc., 863 P.2d 167, 177-78 (Cal. 1993) (citations omitted) (emphasis added).[4]

The New York Court of Appeals similarly rejected a purported "post-sale duty to recall or retrofit a product" in Adams v. Genie Industries, Inc., 929 N.E.2d 380, 385 (N.Y. 2010). Adams involved a lift truck, rather than an FDA-regulated product. The court found "no justification for creating" a duty to recall, since – again as here – "plaintiff merely asserted that [defendant] should have

[4] Cf. Hernandez v. Badger Construction Equipment Co., 34 Cal. Rptr.2d 732, 756-57 (Cal. App. 1994) (allowing retrofit claim without discussing Ramirez's rejection of recall-based claims). Thus, "California recognizes a duty to recall or retrofit if a government agency has ordered a recall or if there was a shift in industry standards." Hamilton v. TBC Corp., 328 F.R.D. 359, 385 (C.D. Cal. 2018). No such facts support liability here.

recalled or retrofitted the [product] for the same reasons that it should not have sold it in the first place[.]" Id. at 386.

Likewise, Illinois law rejects both post-sale warning and recall duties. Jablonski v. Ford Motor Co., 955 N.E.2d 1138, 1160 (Ill. 2011). As to recalls, specifically:

> A duty may be imposed upon a manufacturer by a statute or administrative regulation which mandates the recall of the product.... However, in the absence of such an obligation, or a voluntary undertaking, Illinois has not imposed such a duty on a manufacturer[.]

Id. at 1160 n.1 (citing Third Restatement §11).[5]

Indeed, "virtually every court that has confronted the issue head-on has reached the same conclusion": "'that it is unnecessary and unwise to impose or introduce an additional duty to retrofit or recall a product' separate and apart from those duties to which manufacturers are already subject." Tabieros v. Clark Equipment Co., 944 P.2d 1279, 1298 (Haw. 1997) (quoting Gregory v. Cincinnati, Inc., 538 N.W.2d 325, 333-34 (Mich. 1995)).[6]

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[5] Jablonski also approvingly cited Modelski v. Navistar International Transportation Corp., 707 N.E.2d 239 (Ill. App. 1999), which held:

> The consequences of imposing upon manufacturers an extrastatutory duty to recall ... would be the equivalent of mandating that manufacturers insure that their products will always comply with current safety standards. This we are unwilling to do.

Id. at 247.

[6] Gregory "did not recognize any theory that would impose a postmanufacture duty to ... recall a product." Klein by Klein v. Caterpillar, Inc., 2023 WL 4760707, at *5 (E.D. Mich. July 26, 2023),

The Kentucky Supreme Court reached the same conclusion, rejecting liability "by judicial fiat" for alleged failure to recall products in Ostendorf v. Clark Equipment Co., 122 S.W.3d 530, 534 (Ky. 2003). Product recalls "are properly the province of administrative agencies, as the federal statutes that expressly delegate recall authority to various agencies suggest," and courts should not "arrogate to themselves a power equivalent to that of requiring product recall." Id.

> As Congress has recognized, administrative agencies have the institutional resources to make fully informed assessments of the marginal benefits of recalling a specific product.

Id. at 434-35 (citation and quotation marks omitted).

The Kansas Supreme Court agreed:

> [P]roduct recalls are properly the business of administrative agencies as suggested by the federal statutes that expressly delegate recall authority.... The decision to expand a manufacturer's post sale duty beyond implementing reasonable efforts to warn ... should be left to administrative agencies and the legislature. These institutions are better able to weigh the benefits and costs involved in locating, recalling, and retrofitting products.

Patton v. Hutchinson Wil-Rich Manufacturing Co., 861 P.2d 1299, 1315-16 (Kan. 1993) (citations omitted).[7] Accord Loredo v. Solvay America, Inc., 212 P.3d 614, 632 (Wyo. 2009) (quoting and following Ostendorf);

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aff'd, 2024 WL 1574672 (6th Cir. Apr. 11, 2024).

[7] Patton quoted V. Schwartz, "The Post-Sale Duty to Warn: Two Unfortunate Forks in the Road to a Reasonable Doctrine," 58 N.Y.U.L. Rev. 892, 901 (1983).

Lovick v. Wil-Rich, 588 N.W.2d 688, 696 (Iowa 1999)(affirming that a manufacturer "ha[s] no duty to recall or retrofit" a product).[8]

Other state intermediate appellate courts have also held that failure-to-recall claims would create excessive and unmanageable liability. Perhaps the most thorough is Ford Motor Co. v. Reese, 684 S.E.2d 279 (Ga. App. 2009), cert denied (Ga. Feb. 8, 2010). Reese followed Restatement Third §11 and rejected failure-to-recall claims absent a government-mandated or negligently undertaken voluntary product recall. Id. at 284-85. "Georgia common law does not impose a continuing duty upon manufacturers to recall their products." Id. at 285. Reese also invoked "important public policy concerns" that support leaving recall decisions to administrative agencies. Id.

> Because the cost of locating, recalling, and replacing mass-marketed products can be enormous and will likely be passed on to consumers in the form of higher prices, the recall power should not be exercised without extensive consideration of its economic impact.

Id. (citation and quotation marks omitted). Accord Lance v. Wyeth, 4 A.3d 160, 167 (Pa. Super. 2010) ("this Court is persuaded by the majority of modern jurisdictions that have decided not to impose a common law duty to recall on a manufacturer") (citations omitted)[9];

[8] The only contrary high court authority is a footnote in Izzarelli v. R.J. Reynolds Tobacco Co., 136 A.3d 1232 (Conn. 2016), that a "manufacturer separately may be deemed negligent for failing to recall a product[.]" Id. at 1268 n.8. That brief footnote cited no authority and was tangential to the issues being decided in that case.

[9] Aff'd in part & rev'd in part on other grounds, 85 A.3d 434 (Pa. 2014).

Bragg v. Hi-Ranger, Inc., 462 S.E.2d 321, 331 (S.C. App. 1995) (following the "law adopted by a majority of jurisdictions concerning a manufacturer's duty to recall or retrofit its products"); Morrison v. Kubota Tractor Corp., 891 S.W.2d 422, 429 (Mo. App. 1994) (finding "no such duty absent a state or federal law mandating a recall of the product"), transfer denied (Mo. Feb. 12, 1995); Lynch v. McStome & Lincoln Plaza Associates, 548 A.2d 1276, 1281 (Pa. Super. 1988) (finding no "precedent that imposes such a broad duty on a manufacturer, nor do we think that the imposition of such a duty would be appropriate").

Literally scores of federal courts have made state-law predictions that reject failure-to-recall claims under the laws of many other states. The sheer range of products against which recall claims have been asserted demonstrates how radical a legal change plaintiff's theory would entail, were it to be accepted.[10]

- **Alabama**: Wilhite o/b/o Est. of Wilder v. Medtronic, Inc., 2024 WL 968867, at *6 (N.D. Ala. Mar. 6, 2024) ("no duty to recall under Alabama law") (medical device); Harman v. Taurus International Manufacturing, Inc., 661 F. Supp.3d 1123, 1133 (M.D. Ala. 2023) ("no such duty exists under Alabama law" to "proactively recall[]" a product) (firearm); Harris v. Raymond Corp., 2018 WL 6725329, at *9 (N.D. Ala. Dec. 21, 2018) ("there is no duty to recall") (pallet jack).

- **Alaska**: Nelson v. Original Smith & Wesson Business Entities, 2010 WL 7125186, at *3-4 (D. Alaska May 18, 2010) (following "the weight of jurisdictions that have previously determined

[10] *Amici* have limited this list to no more than three decisions per State and do not include other decisions from the states with on-point high court authority discussed above. Many more decisions reject failure-to-recall claims on facts similar to this case.

that failure to recall ... is not a valid cause of action"), aff'd, 449 F. Appx. 581, 584 (9th Cir. 2011) (firearm).[11]

- **Colorado**: Perau v. Barnett Outdoors, LLC, 2019 WL 2145467, at *2-3 (M.D. Fla. May 15, 2019) (excluding all failure-to-recall evidence) (crossbow) (applying Colorado law).

- **Delaware**: Smith v. Daimlerchrysler Corp., 2002 WL 31814534, at *6 (Del. Super. Nov. 20, 2002) ("There is also no duty under Delaware law to recall defective [products]") (automobile).

- **Florida**: Howey v. Pirelli Tire, LLC, 2017 WL 10978505, at *2 (S.D. Fla. Oct. 31, 2017) (following Wright) (tire); Wright v. Howmedica Osteonics Corp., 2017 WL 4555901, at *4 (M.D. Fla. Oct. 12, 2017) ("find[ing] no Florida case recognizing a cause of action for breach of the duty to recall") (medical device), aff'd, 741 F. Appx. 624 (11th Cir. 2018); Thomas v. Bombardier Recreational Products, Inc., 682 F. Supp.2d 1297, 1302 (M.D. Fla. 2010) ("Florida law does not recognize that a manufacturer has a post-sale duty to recall or retrofit a product") (personal watercraft).

- **Georgia**: Clayton v. Alliance Outdoor Group, Inc., 2021 WL 1947886, at *2 (M.D. Ga. March 30, 2021) ("Georgia law generally does not recognize a cause of action based upon a manufacturer's failure to recall a product") (tree stand); Williamson v. Walmart Stores, Inc., 2015 WL 1565474, at *6 (M.D. Ga. April 8, 2015) (quoting and following Reese, supra) (gas container); Yarbrough v. Actavis Totowa, LLC, 2010 WL 3604674, at *4 (S.D. Ga. Sept. 13, 2010) ("product sellers are not required to issue recalls for defective products") (pre-Reese) (prescription drug).[12]

- **Indiana**: Timm v. Goodyear Dunlop Tires North America Ltd., 309 F. Supp.3d 595, 602 (N.D. Ind. 2018) (finding no "support" for a "claim of negligent recall") (tire); Cincinnati Insurance Companies. v. Hamilton Beach/Proctor-Silex, Inc., 2006 WL 299064, at *3 (N.D. Ind. Feb. 7, 2006) ("no Indiana state law cases indicate the existence of a separate negligent recall cause of action") (citations omitted) (toaster); Tober v. Graco Children's Products, Inc., 2004 WL 1987239, at *9 (S.D. Ind. July 28, 2004) (rejecting "the existence of a separate 'negligent

[11] Cf. Jones v. Bowie Industries, Inc., 282 P.3d 316, 335 n.70 (Alaska 2012) (clarifying that recognizing a post-sale duty to warn does not include any duty to recall).

[12] Cf. Ontario Sewing Machine Co. v. Smith, 572 S.E.2d 533, 535 (Ga. 2002) ("disapprov[ing]" of decision that had allowed a failure-to-recall claim, but not reaching issue).

recall' cause of action"), aff'd, 431 F.3d 572 (7th Cir. 2005) (baby swing).

- **Iowa**: Burke v. Deere & Co., 6 F.3d 497, 510 (8th Cir. 1993) ("we find no independent duty to retrofit or recall under Iowa law") (combine); Doe v. Baxter Healthcare Corp., 2003 WL 27384538, at *5 (S.D. Iowa June 3, 2003) ("no court interpreting Iowa law has recognized a duty to recall"), aff'd, 380 F.3d 399 (8th Cir. 2004) (blood product).

- **Louisiana**: Weams v. FCA US L.L.C., 2019 WL 960159, at *23 (M.D. La. Feb. 27, 2019) ("failure to recall is not a theory of liability under the" exclusive Louisiana product-liability statute) (automobile).

- **Massachusetts**: Ahern v. Sig Sauer, Inc., 2021 WL 5811795, at *4 (D. Mass. Dec. 7, 2021) (plaintiff "cites no legal duty to impose a mandatory recall") (firearm); National Women's Health Network, Inc. v. A.H. Robins Co., 545 F. Supp. 1177, 1181 (D. Mass. 1982) ("[n]o court has ever ordered a notification and recall campaign on the basis of state law") (contraceptive device) ("NWHN").

- **Minnesota**: Kladivo v. Sportsstuff, Inc., 2008 WL 4933951, at *5 (D. Minn. Sept. 2, 2008) ("Minnesota courts have not recognized a cause of action for negligent recall") (inflatable swimming tube); Hammes v. Yamaha Motor Corp., 2006 WL 1195907, at *11 (D. Minn. May 4, 2006) ("this Court declines to impose a separate duty to recall") (motorcycle); Berczyk v. Emerson Tool Co., 291 F. Supp.2d 1004, 1016 (D. Minn. 2003) ("Minnesota would refuse to impose a duty on manufacturers to recall and/or retrofit a defective product because the overwhelming majority of other jurisdictions have rejected such an obligation") (power saw).[13]

- **Mississippi**: Goodwin v. Premier Ford Lincoln Mercury, Inc., 2020 WL 3621317, at *4 n.2 (N.D. Miss. July 2, 2020) ("there is no post-sale duty to warn or recall in Mississippi") (automobile); Clark v. General Motors, 2016 WL 3574408, at *7 (S.D. Miss. June 23, 2016) (same) (automobile); Murray v. General Motors, 2011 WL 52559, at *2 (S.D. Miss. Jan. 7, 2011) (plaintiffs "cannot show that [defendant] breached its duty by not recalling their vehicle"), aff'd, 478 F. Appx. 175 (5th Cir. 2012) (automobile).

[13] Quoting McDaniel v. Bieffe USA, Inc., 35 F. Supp.2d 735, 743 (D. Minn. 1999).

- **Missouri**: Horstmyer v. Black & Decker, (U.S.), Inc., 151 F.3d 765, 774 (8th Cir. 1998) (finding "no indication ... that the Missouri Supreme Court would create a common law duty to recall under these circumstances") (power saw); Smith v. Firestone Tire & Rubber Co., 755 F.2d 129, 135 (8th Cir. 1985) ("Since no duty to recall was established, a fundamental prerequisite to establishing negligence was absent") (tire); Haskell v. PACCAR, Inc., 2021 WL 5407853, at *3 (W.D. Mo. Nov. 18, 2021) ("There is no common law duty to recall under Missouri law absent a mandated recall by a governmental agency.") (citations omitted) (commercial truck).

- **Nebraska**: Anderson v. Nissan Motor Co., 139 F.3d 599, 602 (8th Cir. 1999) ("limiting [Nebraska] products liability law to actions or omissions which occur at the time of manufacture or sale") (forklift); Dubas v. Clark Equipment Co., 532 F. Supp.3d 819, 830 (D. Neb. 2021)("claims asserting post-sale duties to ... recall ... are dismissed") (forklift).

- **New Hampshire**: Bartlett v. Mutual Pharmaceutical Co., 2010 WL 3659789, at *10 (D.N.H. Sept. 14, 2010) ("'almost all of the opinions which have addressed the issue have found that there is no common law duty to recall' products from the market, even if they are unreasonably dangerous") (prescription drug).[14]

- **New Mexico**: Morales v. E.D. Etnyre & Co., 382 F. Supp.2d 1285, 1287 (D.N.M. 2005) (rejecting a "duty to retro-fit or recall"; following Third Restatement §11) (road paving machine).

- **North Dakota**: Eberts v. Kawasaki Motors Corp., 2004 WL 224683, at *2-3 (D.N.D. Feb. 2, 2004) (following Third Restatement §11 and "the overwhelming majority of other jurisdictions [that] have refused to impose a duty on manufacturers to recall ... a defective product") (ATV).

- **Ohio**: Kondash v. Kia Motors America, Inc., 2016 WL 11246421, at *14 (S.D. Ohio June 24, 2016) (given the weight of contrary precedent, "[t]he Court cannot conclude that Ohio law recognizes a duty in negligence to recall") (automobile).

- **Pennsylvania**: Liebig v. MTD Products, Inc., ___ F. Supp.3d ___, 2023 WL 5517557, at *4 n.6 (E.D. Pa. Aug. 25, 2023) ("Pennsylvania law does not recognize a duty to recall or retrofit products") (snow blower); Cleaver v. Honeywell International, LLC, 2022 WL 2442804, at *4 (E.D. Pa. March 31,

[14] Quoting 5 L. Frumer & M. Friedman, Products Liability, §57.01[4], at 57-9 (2010).

2022) ("Under Pennsylvania law, manufacturers and distributors do not have a duty to recall or retrofit products.") (vacuum truck); Talarico v. Skyjack, Inc., 191 F. Supp.3d 394, 401 (M.D. Pa. 2016) (no "independent negligence cause of action exists in Pennsylvania under a duty to recall") (forklift).

- **South Carolina**: Andrews v. CBS Corp., 2015 WL 12831309, at *1 (D.S.C. June 24, 2015) ("there is no-post sale duty to recall or retrofit products"; citing and following Bragg, supra) (asbestos containing products).

- **South Dakota**: Robinson v. Brandtjen & Kluge, Inc., 2006 WL 2796252, at *8 (D.S.D. Sept. 27, 2006) ("[n]othing ... indicates that South Dakota permits a claim based on a manufacturer's duty to recall"; citing Restatement Third §11), aff'd, 500 F.3d 691 (8th Cir. 2007) (printing press).

- **Tennessee**: Spence v. Miles Laboratories, Inc., 810 F. Supp. 952, 959 (E.D. Tenn. 1992) (product-liability statute did not "require manufacturers and suppliers of [their] products to recall and test a product already on the market") (blood product).

- **Texas**: Syrie v. Knoll International, 748 F.2d 304, 311-12 (5th Cir. 1984) ("Texas does not impose on manufacturers the duty ... to recall products") (stool); Gomez v. ALN International, Inc., 2021 WL 3774221, at *8 (S.D. Tex. Mar. 24, 2021) ("there is no general, post-sale, duty to retrofit or recall under Texas law") (medical device); Nester v. Textron, Inc., 2015 WL 9413891, at *13 (W.D. Tex. Dec. 22, 2015) (Texas rejects failure-to-recall claims prior to any actual recall) (utility vehicle).

- **Utah**: Marcovecchio v. Wright Medical Group, Inc., 2019 WL 1406606, at *7 (D. Utah March 28, 2019) ("Plaintiff has alleged only that [defendant] failed to recall the product, which is insufficient to state a claim"; following Restatement Third §11) (medical device); Dowdy v. Coleman Co., 2011 WL 6151432, at *3 (D. Utah Dec. 12, 2011) ("declin[ing] to recognize a post-sale duty to recall or retrofit"; citing Restatement Third §11) (propane heater).

- **Virginia**: Boyer v. Abbott Vascular Inc., 2023 WL 4269764, at *2 (N.D. Cal. June 29, 2023) (predicting that Virginia would follow Restatement §11 and dismissing recall claim; quoting Powell, supra) (catheter) (applying Virginia law); In re General Motors LLC Ignition Switch Litigation, 202 F. Supp.3d 362, 371-72 (S.D.N.Y. 2016) (same) (automobile) (applying Virginia law); Powell v. Diehl Woodworking Machinery, Inc., 198 F. Supp.3d 628, 634 (E.D. Va. 2016) ("Virginia law does not recognize a duty to recall") (ripsaw).

- **Washington**: Bear ex rel. Bloom v. Ford Motor Co., 2007 WL 870344, at *3 (E.D. Wash. Mar. 20, 2007) (failure-to-recall claim does not exist because "the issue of recall is not addressed in the Washington Products Liability Act") (automobile).

- **Wisconsin**: Carlson v. Triton Industries, Inc., 605 F. Supp.3d 1124, 1138 (W.D. Wis. 2022) (rejecting "failure to recall" theory as "much more drastic" than anything Wisconsin law has permitted) (boat).

The overwhelming weight of precedent nationwide thus rejects failure-to-recall claims like this plaintiff pleaded and pursued in the trial court, before attempting to camouflage them on appeal. That a recall occurred later, or was "voluntary," does not matter. Recall-based claims go far beyond ordinary negligence and strict-liability theories. They usurp executive and legislative powers to regulate the public's access to lawful products. New Jersey law, like that of other State, does not permit that result.

2. The New Jersey Product Liability Act Did Not Create Any Failure-To-Recall Claims Not Recognized at Common Law.

Before the New Jersey Product Liability Act ("PLA"), N.J.S.A. 2A:58C-1, *et seq.*, was enacted in 1987, nothing in this State's common law allowed failure-to-recall claims, in either negligence or strict liability. Indeed, the only pre-PLA reference to such possible claims was non-substantive, a two-sentence allusion to a negligence-based recall claim as adequately pleaded in Matter of Cadillac V8-6-4 Class Action, 93 N.J. 412, 430 (1983).[15] Pre-PLA New Jersey law also

[15] Cadillac V8-6-4 solely decided unrelated class certification issues.

rejected any obligation to "retrofit" products or to impose "a continuing duty to protect a purchaser" even "after the sale." Bottignoli v. Ariens Co., 234 N.J. Super. 353, 361 (App. Div. 1989).

The PLA is "a New Jersey tort-reform statute." Sun Chemical Corp. v. Fike Corp., 243 N.J. 319, 332 (2020). It extends to "any claim or action brought by a claimant for harm caused by a product, irrespective of the theory underlying the claim[.]" Sinclair v. Merck & Co., 195 N.J. 51, 62 (2008) (quoting N.J.S.A. 2A:58C-1(b)(3)). The PLA was intended to "rebalanc[e] the law in favor of manufacturers[.]" Kendall v. Hoffman-La Roche, Inc., 209 N.J. 173, 196 (2012) (citations omitted). Through the PLA, "the Legislature intended to limit the liability of manufacturers so as to balance the interests of the public and the individual with a view towards economic reality." Sinclair, 195 N.J. at 62 (citations omitted).

The Supreme Court thus held that, consistent with the Legislature's purpose in enacting the PLA, any attempt to "expand" product liability with novel claims not recognized before the PLA is "best directed to the Legislature," which had enacted the PLA. Id. at 65 (refusing to expand product liability by allowing a no-injury medical-monitoring claim against a prescription-drug manufacturer).

Further, in enacting the PLA, the Legislature specifically intended "to reduce the burden on **manufacturers of FDA-approved products** resulting from products liability litigation," Kendall, 209 N.J. at 194 (emphasis added), and recognized the "importance of the federal regulatory process in relation to the PLA." In re Accutane

Litigation, 235 N.J. 229, 266 (2018).

Therefore, the PLA imposes a statutory presumption that prescription medications such as Ozurdex® that comply with the FDA's requirements are not defective. "[A]bsent deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects, compliance with FDA standards should be virtually dispositive." Perez v. Wyeth Laboratories, Inc., 161 N.J. 1, 25 (1999).

In this case, plaintiff asserts a novel theory of liability that pre-PLA New Jersey common law did not recognize. Moreover, she nowhere claims that the defendant ever violated any FDA requirement. Instead, the crux of her complaint is precisely the opposite: that defendant should **not** have waited for the FDA to authorize the product recall that occurred on December 20, 2018. What plaintiff now claims – without having pleaded it in her complaint or citing anything in the record – to be "deliberate concealment," Op. Br. at 23-24, 43-44, is nothing of the sort. Rather, plaintiff admits that **the same facts she claims were "concealed" were disclosed** in numerous "countries outside the U.S.," id. at 24, that had different, less protracted regulatory schemes for pharmaceutical products. Defendant reported this overseas activity to the FDA (Da0258 ¶70).

The product here – a prescription medicine – and the defendant here, which scrupulously complied with everything the FDA required, are precisely what the PLA was enacted to protect from broad, unprecedented common-law liability theories such as plaintiff's

failure-to-recall claim.[16]

As for the PLA, in terms of post-sale duties, the statute created a limited post-sale duty to warn and went no further. See N.J.S.A. 2A:58C–4 (product manufacturer "shall not be liable" if it "provides an adequate warning or instruction" about "dangers [it] discovers or reasonably should discover after the product leaves its control"). No precedent supports plaintiff's attempt to transform that limited duty into a broad recall obligation by alleging, as a "warning," everything that formed the basis for the FDA's eventual recall. As in Sinclair, such an expansion of liability lies with "the Legislature," not the judiciary. 195 N.J. at 65.

The Trial Division mistakenly relied on Finegold v. General Motors Co., 2021 WL 2810091 (D.N.J. June 30, 2021). See Op. Br. at 24 (quoting opinion). But unlike this case, and similarly to the Third Restatement, Finegold involved a recall that preceded a plaintiff's alleged injuries. 2021 WL 2810091, at *1, 4 ("pointing to a recall for the same defect in ... model years 2015-2017" whereas the vehicle at suit was a "2019" model). Finegold thus in no way supports the claim here, which would impose state common-law liability for failure to recall a drug in advance of any FDA action to that effect.

[16] A product recall does not create any inference of a regulatory violation. E.g., Est. of Benn v. Medtronic, Inc., 2023 WL 3966000, at *4 (D.N.J. June 13, 2023) ("Courts have consistently held that a product recall alone, without more, does not suggest [an FDCA] specification violation.") (collecting cases).

Far more apropos is Leslie v. U.S., 986 F. Supp. 900 (D.N.J. 1997), aff'd mem., 178 F.3d 1279 (3d Cir. 1999). As here, the plaintiff in Leslie asserted a failure-to-recall claim under New Jersey law prior to any governmental recall. Leslie held that a manufacturer's mere intention to recall a product at a future date was not enough to impose PLA liability:

> Plaintiffs have cited no authority, and the Court's research has yielded none, which requires manufacturers of legally distributed [products] to ensure instantaneous removal of their products from the shelves upon an announced intention to discontinue product sales.... Having failed to establish a duty, plaintiffs cannot state a cognizable claim for negligence.

Id. at 913. The "negligent recall" claim in Leslie was thus dismissed. Id.

In any event, Finegold itself defeats plaintiff's position. First, it held that the plaintiff's "failure to recall claim[]," even assuming a post-recall claim could otherwise exist, was "subsumed" by the PLA, since that "Act 'is both expansive and inclusive, encompassing virtually all possible causes of action'" involving product liability. Id. at *4 (quoting Gupta v. Asha Enterprises, L.L.C., 422 N.J. Super. 136, 145 (App. Div. 2011)). Second, Finegold found no authority "delineating a cause of action for failure to recall separate from the [PLA]." 2021 WL 2810091, at *4. As such, dismissal here should be *a fortiori* from Finegold, because plaintiff's liability theories (however denominated) demand a recall before any government action – and that theory has never been recognized in New

Jersey, pre- or post-PLA.

The law is indisputable: (1) failure-to-recall claims have been rejected overwhelmingly nationwide; (2) New Jersey common law never allowed such a claim prior to the 1987 PLA; (3) the PLA was intended to limit product liability for manufacturers generally and FDA-compliant drugmakers specifically; and (4) failure-to-recall claims under the PLA have failed whenever they have demanded product recalls prior to either the government ordering, or the defendant undertaking, such an effort.

B. IF A CLAIM FOR FAILURE TO RECALL AN FDA APPROVED PRODUCT EXISTED UNDER THE COMMON LAW, IT WOULD BE PREEMPTED BY THE FDA'S PRODUCT APPROVAL AND RECALL AUTHORITY.

Even if plaintiff's claim were otherwise viable, federal law would preempt it. A "duty to recall" claim is simply another way of asserting that the defendant should "stop selling" its product. Bartlett, supra, 2010 WL 3659789, at *10.

> [T]here is no common law duty to recall products from the market, even if they are unreasonably dangerous.... [S]trict products liability requires that manufacturers compensate consumers ... not necessarily that they remove such products from the market.

Id. (citations and quotation marks omitted). The question of the viability of the recall/stop selling claim in Bartlett reached the United States Supreme Court in Mutual Pharmaceutical Co. v. Bartlett, 570 U.S. 472 (2013), and the Supreme Court held that such claims were necessarily preempted.

In Bartlett the Supreme Court recognized that common-law "stop-

selling" claims against FDA-approved prescription drugs are inherently preempted, because they conflict with FDA's product approval authority. Initially, Bartlett reaffirmed that "[e]ven in the absence of an express pre-emption provision, the Court has found state law to be impliedly pre-empted where it is impossible for a private party to comply with both state and federal requirements." Id. at 480 (citation and quotation marks omitted).

Bartlett flatly rejected the contention that a drug manufacturer "could escape the impossibility of complying with both its federal- and state-law duties by 'choos[ing] not to make [its FDA-approved drug] at all." 570 U.S. at 488. "[T]his 'stop-selling' rationale [i]s incompatible with our pre-emption jurisprudence." Id. The Bartlett Court explained:

> Our pre-emption cases presume that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability. Indeed, if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption would be all but meaningless.
>
> The incoherence of the stop-selling theory becomes plain when viewed through the lens of our previous cases. In every instance in which the Court has found impossibility pre-emption, the "direct conflict" between federal- and state-law duties could easily have been avoided if the regulated actor had simply ceased acting.

Id. (citation and quotation marks omitted).

Consequently, "the mere fact that a manufacturer may avoid liability by leaving the market does not defeat a claim of impossibility." Id. at 489 n.5. State-law tort litigation, such as

this, that "require[s] a manufacturer to choose between leaving the market and accepting the consequences of its actions," is preempted. Bartlett, 570 U.S. at 491.[17]

Since Bartlett, state-law tort claims that would "require[]" the manufacturer of an FDA-approved drug "to exit the market" have been uniformly preempted, however pleaded. Drager v. PLIVA USA, Inc., 741 F.3d 470, 476 (4th Cir. 2014); accord Hernandez v. Aurobindo Pharma USA, Inc., 582 F. Supp.3d 1192, 1213 (M.D. Fla. 2022). ("any argument that [the defendant] should have stopped selling the drug is unavailing").[18]

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[17] Such litigation conflicts with FDA authority fully as much as a state "statutory mandate" that "directly prohibit[s] the product's sale." Id. at 489 n.5.

[18] Accord Trejo v. Johnson & Johnson, 220 Cal. Rptr.3d 127, 162-63 (Cal. App. 2017) (OTC drug); Yates v. Ortho-Mcneil-Janssen Pharmaceuticals, Inc., 808 F.3d 281, 300 (6th Cir. 2015) ("never start selling" claim); Beaver v. Pfizer, Inc., 2024 WL 234725, at *3 (W.D.N.C. Jan. 22, 2024); GenBioPro, Inc. v. Sorsaia, 2023 WL 5490179, at *8 n.10 (S.D.W. Va. Aug. 24, 2023) (FDA REMS, anti-abortion statute); Bossetti v. Allergan Sales, LLC, 2023 WL 4030681, at *5-6 (S.D. Ohio June 15, 2023); Beaver v. Pfizer, Inc., 2023 WL 2386776, at *3 (W.D.N.C. March 6, 2023), aff'd, 2023 WL 4839368 (4th Cir. July 28, 2023); In re Zantac (Ranitidine) Products Liability Litigation, 548 F. Supp.3d 1225, 1252-53 (S.D. Fla. 2021); Silver v. Bayer Healthcare Pharmaceuticals, Inc., 2021 WL 4472857, at *5 (D.S.C. Sept. 30, 2021); Evans v. Gilead Sciences, Inc., 2020 WL 5189995, at *9-10 (D. Haw. Aug. 31, 2020); Javens v. GE Healthcare, Inc., 2020 WL 2783581, at *6 (Mag. D. Del. May 29, 2020) (claim that defendants should have marketed a different product), adopted, 2020 WL 7051642 (D. Del. June 18, 2020); Drescher v. Bracco Diagnostics, Inc., 2020 WL 1466296, at *5 (D. Ariz. Mar. 26, 2020); Mahnke v. Bayer Corp., 2019 WL 8621437, at *5 (C.D. Cal. Dec. 10, 2019); Trisvan v. Heyman, 305 F. Supp.3d 381, 405 (E.D.N.Y. 2018); Utts v. Bristol-Myers Squibb Co., 251 F. Supp.3d 644, 678 (S.D.N.Y. 2017), aff'd, 919 F.3d 699 (2d Cir. 2019); In re Lipitor Atorvastatin Calcium Marketing, Sales Practices & Products Liability Litigation, 185 F. Supp.3d 761, 771 (D.S.C. 2016); In re Fosamax Products Liability Litigation, 965 F.

Even before Bartlett, the inherent conflict between FDA product-approval authority and state-law failure-to-recall claims demanding removal of FDA-approved products from the market had supported preemption. As early as 1982, a purported Massachusetts state-law claim demanding recall of an FDA-approved product was preempted in NWHN, supra. "No court has ever ordered a notification and recall campaign on the basis of state law." 545 F. Supp. at 1181. The FDA has the sole "discretion" to require recall of a product that it approved. Id. at 1181.

> [E]ven if there were state law authority for a notification and recall campaign, such authority would be preempted by the FDCA for the same reasons that there is no implied right of action.... [A]ny state law which would put these same powers in other hands must be deemed foreclosed.... Since the federal interest in this area is "dominant" and the regulatory scheme is "pervasive," preemption must follow.

Id. (citations omitted).[19]

In Cupek v. Medtronic, Inc., 405 F.3d 421, 424 (6th Cir. 2005), the plaintiffs' proposed failure-to-recall claim "undermine[d] their preemption arguments, because those claims assert that Defendant has duties independent of any obligations ... to comply with applicable federal regulations." Id. at 424-25 (quotation marks omitted). "Any

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Supp.2d 413, 420 (S.D.N.Y. 2013).

[19] Similarly, federal preemption has precluded claims in automotive cases that state law could force recalls of cars and trucks where the federal government has not done so, or to a greater extent. See Cohen v. Subaru of America, Inc., 2022 WL 721307, at *38 (D.N.J. March 10, 2022) (collecting cases).

claim ... that Defendant ... failed to recall a product without first going through the PMA supplement process" was "futile" because it necessarily diverged from the FDA's recall-related requirements. Id. Differing FDCA and state-law recall obligations pertaining to the same FDA-regulated products inherently conflict:

> [F]ederal regulations place a duty on manufactures to inform the FDA of problems, and a duty on the FDA to recall [such products]. Plaintiffs' proposed duties would add to this scheme by requiring the manufacturer to notify patients of potential defects or to pull possibly deficient devices from the market. Therefore, a state action for failure to notify or recall would impose an additional requirement from those prescribed by federal law; such a cause of action is preempted.

Hunsaker v. Surgidev Corp., 818 F. Supp. 744, 754 (M.D. Pa. 1992), aff'd, 5 F.3d 1489 (3d Cir. 1993).[20]

[20] All these cases predate the Supreme Court's 2008 recognition of broad express preemption in pre-market approved medical device cases. See Riegel v. Medtronic, Inc., 552 U.S. 312 (2008). *A fortiori*, post-Riegel medical device cases continue to hold failure-to-recall claims preempted. Sundaramurthy v. Abbott Vascular, Inc., 2023 WL 2311661, at *3 & n.3 (D. Mass. Mar. 1, 2023) (following Cupek); Poozhikala v. Medtronic, Inc., 2022 WL 610276, at *5 n.4 (C.D. Cal. Jan. 31, 2022) (FDCA recall is a voluntary action that state law cannot make mandatory); Bryant v. Thoratec Corp., 343 F. Supp.3d 594, 604-05 (S.D. Miss. 2018) (preempting claims that "Defendants should have sooner issued a recall"; preemption not defeated because "the FDA permits voluntary recalls"); Kubicki v. Medtronic, Inc., 293 F. Supp.3d 129, 185 (D.D.C. 2018) (state-law recall claim that ignored FDA supplementation requirements preempted); Bentzley v. Medtronic, Inc., 827 F. Supp.2d 443, 451-52 (E.D. Pa. 2011) (state-law claim that FDA recall should have included unrecalled products preempted); Franklin v. Medtronic, Inc., 2010 WL 2543579, at *6 (Mag. D. Colo. May 12, 2010), adopted, 2010 WL 2543570 (D. Colo. June 22, 2010) (same as Poozhikala); In re Medtronic, Inc. Sprint Fidelis Leads Products Liability Litigation, 592 F. Supp.2d 1147, 1159 (D. Minn. 2009) ("claims alleging that [defendant] should have recalled the [product] sooner than it did are ... preempted"), aff'd, 623 F.3d 1200 (8th

Preemption of plaintiff's claim that the defendant should have immediately recalled Ozurdex® – without waiting for the FDA to complete its independent review and order the recall – also comports with the PLA, because "[t]he Legislature, by attaching a presumption of adequacy to FDA-approved warnings, 'recognized the preeminent role of federal regulation of drugs and medical devices.'" Accutane, 235 N.J. at 266 (quoting Cornett v. Johnson & Johnson, 211 N.J. 362, 387 (2012)[21]). In this case, plaintiff's failure-to-recall "claim is no more than a challenge to [the FDA's] approval of" this product and is therefore impliedly preempted. Cornett, 211 N.J. at 391.

Plaintiff's argument against preemption, Op. Br. at 29, is largely based on the 1991 Feldman v. Lederle Laboratories, 125 N.J. 117 (1991) decision. But a lot has changed concerning FDCA preemption since then – most notably Bartlett. Feldman accepted, as precluding preemption, **precisely** the sort of "stop selling" claim that the United States Supreme Court later found preempted in Bartlett. "[W]e find no basis for concluding that [defendant] was required to continue marketing [the drug] in [the] forms and packaging [at issue] – or indeed to continue marketing at all." 125 N.J. at 152. See R.F. v. Abbott Laboratories, 162 N.J. 596, 629 (2000) (viewing Feldman as holding "that even if the drug manufacturer could not have provided a warning, it could have suspended production of the drug"). Since

Cir. 2010).

[21] Abrogated on irrelevant grounds by McCarrell v. Hoffmann-La Roche, Inc., 227 N.J. 569 (2017) (choice of law).

Bartlett, the remove-from-the-market rationale Feldman employed to reject preemption is no longer viable.

To the contrary, defendants are "not required to cease acting altogether in order to avoid liability." Bartlett, 570 U.S. at 488. Plaintiff's reliance on Feldman's decades-old preemption argument, directly repudiated by the United States Supreme Court in Bartlett, only further demonstrates that her state-law demand for an anticipatory recall is preempted.

Where "[p]laintiffs' state law claims would directly contradict the FDA's requirements and interfere with the FDA's objectives," such claims under New Jersey law are preempted by reason of that conflict. R.F., 162 N.J. at 627 (2000). Here, the decision when, and how, to recall the defendant's medication "was the FDA's decision; [and] we should not second guess it." Id. 630.

IV. CONCLUSION

For the foregoing reasons, *amici* respectfully request that the Court reverse the ruling below and hold that New Jersey law does not allow failure-to-recall claims in the absence of a prior government recall order.

Alternatively, *amici* respectfully request that the Court hold that any failure-to-recall claim in this case is preempted by the FDCA, as state-law recall duties preceding or exceeding any FDA recall would necessarily prohibit sale of FDA-approved prescription drugs,

and thus conflict with both the FDA's drug approval and recall authority.

Respectfully submitted,

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Dated: May 2, 2024