Supreme Court of New Jersey

IN RE REGLAN LITIGATION.

Argued April 11, 2016.
|
Decided Aug. 22, 2016.

Justice ALBIN delivered the opinion of the Court.

In 2004, the brand-name manufacturer of Reglan, known generically as metoclopramide, received approval from the Food and Drug Administration (FDA) to publish new label warnings about the dangers of the long-term use of metoclopramide. Plaintiffs are individuals who took metoclopramide, the generic form of Reglan. They claim that defendant generic drug manufacturers of metoclopramide did not timely upgrade their label warnings to match the FDA-approved brand-name labeling. Due to the allegedly inadequate generic drug warnings, plaintiffs took metoclopramide beyond the prescribed period, causing them to develop severe neurological disorders.

Plaintiffs filed failure-to-warn product-liability actions against defendants in state court. Relying on *PLIVA, Inc. v. Mensing,* 564 U.S. 604, 131 S. Ct.

2567, 180 L. Ed. 2d 580 (2011), defendants argue that federal law preempts plaintiffs' state-law claims.

In *Mensing,* the United States Supreme Court explained that, under federal law, generic drug manufacturers are obligated to provide the same warning labels as those provided by the brand-name manufacturer. *Id.* at 612–13, 131 S. Ct. at 2574, 180 L. Ed. 2d at 588–89. On that basis, the Court concluded that federal law preempted state-law tort claims against generic drug manufacturers for failing to give warnings exceeding those on brand-name labels. *Id.* at 618, 131 S. Ct. at 2577–78, 180 L. Ed. 2d at 592. That conclusion followed because generic drug manufacturers could not comply with state law without violating federal law. *Ibid.*

The issue in this case is whether, under *Mensing,* a state-law failure-to-warn claim is preempted when a generic drug manufacturer gives warnings that are outdated and inferior to the manufacturer's brand-name warnings approved by the FDA.

The trial court denied defendants' motions to dismiss plaintiffs' failure-to-warn claims, and similarly denied defendants' motions for summary judgment, finding that federal preemption did not apply because defendant had a duty under state law to provide adequate labeling, and here the labeling did not match the brand-name labeling. The Appellate Division affirmed, holding that plaintiffs' claims are not premised on violations of federal law, but rather

on the failure to give adequate warnings under New Jersey's product-liability law.

We agree with the Appellate Division that plaintiffs' failure-to-warn claims do not put state law and federal law in conflict. Had defendants provided the same labeling as the brand-name manufacturers, as required by federal law, defendants would have enjoyed a safe harbor. Here, however, defendants did not provide the same warning labels that the FDA approved for the brand-name manufacturers. As alleged, defendants' inadequate labeling breached a duty of care under the New Jersey Product Liability Act (PLA), N.J.S.A. 2A:58C–1 to –11. Complying with both federal and state law was not impossible because, unlike in *Mensing,* defendants could have updated their labeling without violating the FDA's sameness requirement. Plaintiffs' claims arise under state law, not by the grace of a federal regulatory scheme. Because plaintiffs' failure-to-warn claims are not preempted by federal law, we affirm the judgment of the Appellate Division.

I.

A.

This case began with the filing of nearly 1000 individual lawsuits against over fifty brand-name and generic manufacturers of metoclopramide. This Court consolidated those individual cases, and the trial court issued a case management order to allow for the filing of a master complaint covering all

plaintiffs.[1] Defendants—PLIVA Inc., Barr Pharmaceuticals, LLC, Barr Laboratories, Inc., Watson Laboratories, Inc., Actavis–Elizabeth LLC, Teva Pharmaceuticals USA, Inc., Mutual Pharmaceutical Company, Inc., and United Research Laboratories, Inc.—are generic drug manufacturers of metoclopramide tablets that did not change their labeling to match the 2004 and 2009 FDA-approved brand-name label warnings.[2] Plaintiffs were prescribed and used metoclopramide tablets after the FDA approved upgraded warnings in 2004. Plaintiffs' claims are premised on defendants' failure to warn of the harmful effects of the long-term use of metoclopramide tablets.

Metoclopramide is a prescription drug used for the treatment of symptomatic, gastro esophageal reflux and for relief of symptoms associated with acute and recurrent diabetic gastro paresis.[3] It is "de-

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[1] "[A] master complaint is an administrative device to manage complex, consolidated cases efficiently and economically." *Cornett v. Johnson & Johnson,* 211 N.J. 362, 370 n. 3, 48 A.3d 1041 (2012) (citing *In re Mercedes–Benz Tele Aid Contract Litig.,* 257 F.R.D. 46, 56 (D.N.J. 2009)). "Although a single complaint is designated the master complaint, each civil action remains distinct for purposes of judgment." *Id.* at 370–71 n. 3, 48 A.3d 1041 (citing *In re Propulsid Prods. Liab. Litig.,* 208 F.R.D. 133, 141 (E.D. La. 2002)).

[2] Plaintiffs allege that defendants failed to comply with a 2009 FDA-approved black-box warning for metoclopramide, but that claim appears to apply only to defendant Watson Laboratories.

[3] Diabetic gastro paresis is a condition in which emptying of food from the stomach is delayed. *Taber's Cyclopedic Medical*

signed to speed the movement of food through the digestive system." *Mensing, supra,* 564 U.S. at 609, 131 S. Ct. at 2572, 180 L. Ed. 2d at 586.

The history of FDA approvals for labeling changes and the accompanying packaging inserts for metoclopramide tablets is not disputed and is set forth in *Mensing* and, in part, in plaintiffs' amended master complaint. In 1980, the brand-name manufacturer of Reglan obtained approval from the FDA to market metoclopramide tablets. *Id.* at 609, 131 S. Ct. at 2572, 180 L. Ed. 2d at 586. Since that time, "warning labels for the drug have been strengthened and clarified several times." *Id.* at 609, 131 S. Ct. at 2572, 180 L. Ed. 2d at 587. In 1985, the FDA approved a label modification, warning that "'[t]ardive dyskinesia ... may develop in patients treated with metoclopramide,' and the drug's package insert added that '[t]herapy longer than 12 weeks has not been evaluated and cannot be recommended.'" *Ibid.* (alterations in original) (quoting *Physician's Desk Reference* 1635–36 (41st ed. 1987)). Tardive dyskinesia is a severe and oftentimes irreversible neurological disorder, *id.* at 609–10, 131 S. Ct. at 2572–73, 180 L. Ed. 2d at 587, which is "marked by slow, rhythmical, stereotyped movements, either generalized or in sin-

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Dictionary 999 (22d ed. 2013). This may cause bloating, abdominal pain, nausea, or vomiting and lead to the worsening of gastroesophageal reflux. *Gastroparesis, Nat'l Inst. of Diabetes & Digestive & Kidney Diseases,* U.S. *Dep't of Health & Hum. Serv..,* https://www.niddk.nih.gov/health-information/health-topics/digestive-diseases/gastroparesis/Pages/facts.aspx.

gle muscle groups," *Taber's Cyclopedic Medical Dictionary* 746 (22d ed. 2013).

In 2004, the then brand-name manufacturer secured the FDA's approval for a labeling change of Reglan tablets. The updated labeling warned in the "Indications and Usage" section that "[t]herapy should not exceed 12 weeks in duration," and in the "Dosage and Administration" section that "[t]herapy with [R]eglan tablets should not exceed 12 weeks in duration." In 2009, the FDA issued "a black box warning—its strongest—which state[d]: 'Treatment with metoclopramide can cause tardive dyskinesia, a serious movement disorder that is often irreversible . . . . Treatment with metoclopramide for longer than 12 weeks should be avoided in all but rare cases.'" *Mensing, supra,* 564 U.S. at 610, 131 S. Ct. at 2573, 180 L. Ed. 2d at 587.

Plaintiffs allege in their complaint that defendant generic manufacturers of metoclopramide tablets, through the early part of 2009, did not update their labeling and packaging inserts to match the FDA-approved warnings until long after those warnings were issued.

Defendant Actavis–Elizabeth asserts that its metoclopramide shipments contained the labeling change as of January 4, 2005—six months after the FDA approved revised warnings. Defendant Teva Pharmaceuticals asserts that its metoclopramide shipments contained the labeling change as of July 28, 2005—one year after the revised warnings. De-

fendants Mutual Pharmaceutical Company and United Research Laboratories assert that their metoclopramide shipments contained that labeling change as of January 31, 2006—one-and-one-half years after the revised warnings. Defendant PLIVA claims that it was not informed of the FDA-approved brand-name-label update through the end of 2008—that is, through the four-and-one-half-year period it continued to manufacture metoclopramide. In December 2008, defendant Watson Laboratories acquired the right from PLIVA to manufacture metoclopramide tablets. Watson received notice from the FDA on November 30, 2009, of the approved brand-name black-box warning. Watson repackaged its metoclopramide with the black-box warning more than ten months later, beginning October 18, 2010.

Plaintiffs claim that as a result of defendants' failure to update the warnings for metoclopramide tablets, they took the drug beyond its prescribed period, causing them to develop tardive dyskinesia or other movement disorders. *See id.* at 609, 131 S. Ct. at 2572, 180 L. Ed. 2d at 586 ("Evidence has accumulated that long-term metoclopramide use can cause tardive dyskinesia, ... [and] [s]tudies have shown that up to 29% of patients who take metoclopramide for several years develop this condition.") (citing *McNeil v. Wyeth,* 462 F.3d 364, 370 n.5 (5th Cir. 2006)). According to plaintiffs, "[d]efendants knew or should have known that the metoclopramide products cause unreasonable, dangerous side-effects," and defendants' failure to give adequate

warnings—the 2004 and 2009 FDA-approved warnings—proximately caused the disorders that have afflicted plaintiffs.[4]

B.

The trial court denied defendants' various motions to dismiss plaintiffs' failure-to-warn claims on federal-preemption grounds.[5] The court maintained that federal law required defendant generic manufacturers of metoclopramide tablets to adopt the brand-name labeling changes approved by the FDA. Thus, the state tort-law duty of generic manufacturers to give adequate warnings about the dangers of

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[4] Based on the representations of defendants in the summary-judgment record, it appears that Watson Laboratories is the only defendant that may have violated the 2009 FDA warnings.

[5] The trial court dismissed a number of plaintiffs' claims that are not relevant to this appeal. A detailed rendition of the procedural history is not necessary for our purposes. Defendants initially filed motions to dismiss on the basis that plaintiffs had "fail[ed] to state a claim upon which relief can be granted," R. 4:6–2(e), and other motions later on the basis that the record as developed entitled them to an entry of summary judgment, R. 4:46–2(c). In a Rule 4:6–2(e) motion, the court reviews the complaint to determine whether the allegations suggest a cause of action, *see Printing Mart–Morristown v. Sharp Elecs. Corp.,* 116 N.J. 739, 746, 563 A.2d 31 (1989) (quoting *Velantzas v. Colgate–Palmolive Co.,* 109 N.J. 189, 192, 536 A.2d 237 (1988)), whereas in a Rule 4:46–2(c) motion, a court reviews the evidence of record "in the light most favorable to the non-moving party" to determine whether the moving party is entitled to judgment as a matter of law. *See Brill v. Guardian Life Ins. Co. of Am.,* 142 N.J. 520, 540, 666 A.2d 146 (1995); *see also* R. 4:46–2(c).

prolonged use of metoclopramide—consistent with brand-name-labeling changes—did not conflict with federal law. The court declined to extend the *Mensing* federal-preemption doctrine to "generic manufacturers of metoclopramide tablets [that] failed to update the labels to be the same as the brand-name label."

Following discovery, defendants moved for summary judgment, claiming that they updated the metoclopramide tablet warnings to conform to those of the brand-name labeling and did so within a reasonable time. The court denied summary judgment, finding that genuine issues of material fact remained concerning whether defendants had timely updated the warnings and whether the prior-used warnings were adequate.

The Appellate Division denied defendants' motion for leave to appeal. Thereafter, we granted defendants leave to appeal and remanded to the Appellate Division for consideration of the merits of defendants' arguments.

C.

In an unpublished opinion, the Appellate Division affirmed the trial court's denial of defendants' motions to dismiss for failure to state a claim and for summary judgment regarding plaintiffs' failure-to-warn actions. The appellate panel found that federal law did not preempt plaintiffs' state-law claims that were premised on defendants' "failure to update

their warnings to conform to changes made to the brand-name warnings." The panel, moreover, held that allowing plaintiffs to proceed with their state-law product-liability claims based on defendants' failure to provide adequate warnings about the dangers of prolonged metoclopramide use would not frustrate federal law. It concluded that preemption did not apply in this case because it was possible for the generic drug manufacturers to comply with both state and federal law. Last, the panel rejected the argument that *Cornett v. Johnson & Johnson,* 211 N.J. 362, 48 A.3d 1041 (2012), supports the dismissal of plaintiffs' failure-to-warn claims. It maintained that *Cornett* barred state-law claims that interfered with the FDA's exclusive authority to enforce federal law. Here, according to the panel, the state-law failure-to-warn claims fall "within a traditional area of state concern and regulation" and are not premised solely on a violation of federal law, quoting *Cornett, supra,* 211 N.J. at 390, 48 A.3d 1041.

We granted defendants' motion for leave to appeal. *In re Reglan Litig.,* 224 N.J. 278, 132 A.3d 422 (2015). We also granted the motion of Amneal Pharmaceuticals, LLC, Par Pharmaceuticals Co., Inc., Sandoz, Inc., and Wes–Ward Pharmaceuticals Corp., which filed a joint brief, to participate as amici curiae.

II.

A.

Defendants contend that plaintiffs' state-law claims are barred by the doctrine of federal preemption and that *Mensing* "marked the end of state-law product liability failure-to-warn claims involving generic drugs." They argue that the source of their duty to update their labeling to conform to the FDA-approved labeling is the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C.A. §§ 301–399f. They claim that, under 21 U.S.C.A. § 337, the federal government, not a private party, is authorized to initiate a suit for noncompliance with the FDCA and state courts cannot impose liability under state law for violations of federal law. Defendants maintain that state law does not require "a generic drug manufacturer to match its labeling to the corresponding brand product." Invoking *Mensing,* defendants insist that "generic drug manufacturers have only a federal duty of 'sameness' and not a duty of 'adequacy.' " According to defendants, "[p]ermitting plaintiffs to proceed on purported state-law claims of 'adequacy' after a brand-name drug's label is revised is tantamount to permitting plaintiffs to enforce the federal duty of 'sameness'" in contravention of federal law. Defendants' overarching premise is that "plaintiffs may not frustrate Congress's purposes and objectives in vesting [the] FDA with exclusive authority to regulate generic drug labeling, under the guise of a state-law claim."

The amici curiae pharmaceutical companies echo defendants' arguments. Their principal position is that the state-law failure-to-warn claims are really "failure-to-timely-update" claims to enforce the federal duty of sameness under the FDCA. They view the Appellate Division and trial court decisions as an end run around federal preemption. They maintain that the FDA, not a jury impaneled in a state court, is in the best position to determine whether a generic drug manufacturer has made a timely labeling change to conform to the brand-name label and to impose sanctions under federal law if it has not.

B.

Plaintiffs contend that their claims sound solely in New Jersey's product-liability law, which required defendants to provide adequate warnings of the dangers of prolonged use of metoclopramide. They assert that their state-law claims are not private enforcement actions of federal law and that their claims promote, rather than frustrate, Congress's objectives under the FDCA. They note that the responsibility of generic drug manufacturers to adhere to the duty of sameness—to provide the same labeling as the brand-name drug—is relevant only because the breach of that duty deprives them of the protection of federal preemption. According to plaintiffs, *Mensing* shields generic drug manufacturers only from state-law claims that seek to impose liability for their failure to provide warnings that go beyond those approved by the FDA for brand-name drugs.

They submit that because federal law required defendants to provide the FDA-approved brand-name warnings, state tort law can impose liability for inadequate warnings that do not meet the federal sameness requirement.

Plaintiffs maintain that defendants' duty to provide adequate warnings for the generic drug under New Jersey's product-liability law runs parallel to their duty to provide the same warnings as the brand-name label. Indeed, plaintiffs argue that state-court lawsuits of this type promote the objectives of the FDCA because the FDA cannot properly monitor the adequacy of label warnings on the thousands of marketed drugs. Plaintiffs' central premise is that "[d]efendants' actions would have given rise to liability even if the FDCA had never been enacted."

Plaintiffs, moreover, posit that defendants' failure to warn of the dangers of the prolonged use of metoclopramide gave them "a competitive advantage in the market because their label misled doctors, pharmacies and consumers into believing that their generic product was safer than the brand[-name drug]."

III.

The primary issue in this case is whether federal law preempts plaintiffs' state-law action. That issue requires that we interpret federal law, and therefore our review is de novo. *St. Peter's Univ. Hosp. v. N.J.*

Bldg. Laborers Statewide Welfare Fund, 431 N.J. Super. 446, 462, 70 A.3d 714 (App. Div.) ("[T]he question of preemption is a legal issue that we review de novo."), *certif. denied,* 216 N.J. 366, 80 A.3d 747 (2013); *see also Farmers Mut. Fire Ins. Co. of Salem v. N.J. Prop.–Liab. Ins. Guar. Ass'n,* 215 N.J. 522, 535, 74 A.3d 860 (2013) ("In construing the meaning of a statute..., our review is de novo[.]").

IV.

The doctrine of federal preemption finds its source in the Supremacy Clause of the United States Constitution. The Supremacy Clause provides that federal law "shall be the supreme Law of the Land," notwithstanding any state law to the contrary. U.S. Const. Art. VI, cl. 2. A state law that conflicts with a federal statute is naturally preempted. *Crosby v. Nat'l Foreign Trade Council,* 530 U.S. 363, 372, 120 S. Ct. 2288, 2294, 147 L. Ed. 2d 352, 361 (2000) (citing *Hines v. Davidowitz,* 312 U.S. 52, 66–67, 61 S. Ct. 399, 85 L. Ed. 581 (1941); *California v. ARC America Corp.,* 490 U.S. 93, 100–01, 109 S. Ct. 1661, 1665, 104 L. Ed. 2d 86, 94–95 (1989); *United States v. Locke,* 529 U.S. 89, 109, 120 S. Ct. 1135, 146 L. Ed. 2d 69 (2000)). When Congress legislates in a field where states have traditionally exercised their "historic police powers," the preemption inquiry begins with the "assumption" that Congress did not intend to supersede a state statute "unless that was [Congress's] clear and manifest purpose." *Medtronic, Inc. v. Lohr,* 518 U.S. 470, 485, 116 S. Ct. 2240,

2250, 135 L. Ed. 2d 700, 715 (1996) (first quoting *Rice v. Santa Fe Elevator Corp.,* 331 U.S. 218, 230, 67 S. Ct. 1146, 1152, 91 L. Ed. 1447, 1459 (1947); and then citing *Hillsborough Cty. v. Automated Med. Labs., Inc.,* 471 U.S. 707, 715, 105 S. Ct. 2371, 2376, 85 L. Ed. 2d 714, 722–23 (1985)).

"Pre-emption may be either express or implied." *Gade v. Nat'l Solid Wastes Mgmt. Ass'n,* 505 U.S. 88, 98, 112 S. Ct. 2374, 2383, 120 L. Ed. 2d 73, 84 (1992). There are two forms of implied preemption—field preemption and conflict preemption. *Ibid.* Field preemption applies "where the scheme of federal regulation is 'so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it.'" *Ibid.* (quoting *Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta,* 458 U.S. 141, 153, 102 S. Ct. 3014, 3022, 73 L. Ed. 2d 664, 675 (1982)). Conflict preemption applies "where 'compliance with both federal and state regulations is a physical impossibility,' " *ibid.* (quoting *Fla. Lime & Avocado Growers, Inc. v. Paul,* 373 U.S. 132, 142–43, 83 S. Ct. 1210, 1217, 10 L. Ed. 2d 248, 257 (1963)), "or where state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress, " *ibid.* (first quoting *Hines, supra,* 312 U.S. at 67, 61 S. Ct. at 404, 85 L. Ed. at 587; and then citing *Felder v. Casey,* 487 U.S. 131, 138, 108 S. Ct. 2302, 101 L. Ed. 2d 123 (1988); *Perez v. Campbell,* 402 U.S. 637, 649, 91 S. Ct. 1704, 29 L. Ed. 2d 233 (1971)). *See also Crosby, supra,* 530 U.S. at 372–73, 120 S. Ct. at 2294, 147 L. Ed. 2d at 361 (noting that

preemption will be found "where it is impossible for a private party to comply with both state and federal law").

Our task here is to determine whether federal law governing the labeling of generic drugs expressly or impliedly preempts a state-law product-liability action alleging that defendants failed to give adequate warnings explaining the dangers and safe use of metoclopramide. We first turn to the federal scheme controlling the approval and labeling of prescription drugs.

V.

A.

In accordance with the Federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. §§ 301–399f, "a manufacturer seeking federal approval to market a new drug must prove that it is safe and effective and that the proposed label is accurate and adequate." *Mensing, supra,* 564 U.S. at 612, 131 S. Ct. at 2574, 180 L. Ed. 2d at 588; *see* 21 U.S.C.A. §§ 355(b)(1)(A), (d). Meeting the FDA's approval requirements for a new drug "involves costly and lengthy clinical testing." *Mensing, supra,* 564 U.S. at 612, 131 S. Ct. at 2574, 180 L. Ed. 2d at 588. The costs related to those rigorous approval requirements are reflected in the price of prescription drugs. *See id.* at 612, 131 S. Ct. at 2574, 180 L. Ed. 2d at 588–89.

In 1984, Congress passed the Drug Price Competition and Patent Term Restoration (Hatch–

Waxman) Act of 1981, Pub. L. No. 98–417, 98 Stat. 1585 (1984). One of the goals of Hatch–Waxman was to make generic drugs more affordable and accessible to the public. *FTC v. Actavis, Inc.,* ——U.S. ——, ——, 133 S. Ct. 2223, 2228, 186 L. Ed. 2d 343, 353–54 (2013). Hatch–Waxman streamlined the process for the FDA's approval of generic drugs. *Ibid.; Mensing, supra,* 564 U.S. at 612–13, 131 S. Ct. at 2574, 180 L. Ed. 2d at 588–89. It allows a generic drug manufacturer to gain FDA approval of a generic drug simply by showing that it is "identical in active ingredients, safety, and efficacy" to a brand-name drug (a reference listed drug) already approved by the FDA. *Mensing, supra,* 564 U.S. at 612 & n. 2, 131 S. Ct. at 2574 & n. 2, 180 L. Ed. 2d at 588 & n. 2. By this expedited process, generic drugs can be developed "inexpensively, without duplicating the clinical trials already performed on the equivalent brand-name drug." *Id.* at 612, 131 S. Ct. at 2574, 180 L. Ed. 2d at 588–89.

In effect, a generic drug manufacturer is able to piggyback on the results of the process that led to FDA approval of both the brand-name drug and the brand-name drug's labeling. "As a result, brand-name and generic drug manufacturers have different federal drug labeling duties." *Id.* at 613, 131 S. Ct. at 2574, 180 L. Ed. 2d at 589. Under the FDCA, "[a] brand-name manufacturer ... is responsible for the accuracy and adequacy of [a drug's] label[ing]," *ibid.,* not only when it files a new drug application, but also when it seeks FDA approval for updated labeling

to inform the public of previously unknown adverse side effects caused by a drug, 21 U.S.C.A. §§ 355(b)(1), (d), (j)(2)(A). On the other hand, a generic drug manufacturer is responsible for ensuring only that its labeling "is the same as the labeling approved for the [brand-name] drug." *Mensing, supra,* 564 U.S. at 612–13, 131 S. Ct. at 2574, 180 L. Ed. 2d at 589 (alteration in original) (quoting 21 U.S.C.A. § 355(j)(2)(A)(v)). Under Hatch–Waxman, a generic drug manufacturer cannot deviate from the labeling used by the brand name drug—the warning label must always be the same. *Ibid.; see also* 21 C.F.R. § 314.150(b)(10).

Because generic labeling must be the same as that of the brand-name drug, "[updated labeling] should be made *at the very earliest time possible.*" U.S. Dep't of Health & Hum. Serv.., Food & Drug Admin., Ctr. for Drug Evaluation & Research, *Guidance for Industry: Revising ANDA Labeling Following Revision of the RLD Labeling* 5 (2000) (emphasis added). Generic manufacturers have been given the means to learn of brand-name-labeling updates. The Office of Generic Drugs in the Office of Pharmaceutical Science, Center for Drug Evaluation and Research, at the FDA has directed generic manufacturers to "routinely monitor the Labeling Review Branch Homepage ... for information on changes in labeling." *Ibid.* The Office of Generic Drugs "[p]lace[s] monthly updates of approved labeling changes" for brand-name drugs with approved generic counterparts "on the Labeling Review Branch

Homepage."[6] *Ibid.* "All approved labeling for [brand-name drugs] is [also] available from Freedom of Information Staff" at the FDA. *Ibid.*

In sum, when a brand-name manufacturer strengthens its labeling to take into account adverse reactions to a medication, federal law requires that the generic drug manufacturer copy the brand-name labeling.[7] Under the sameness doctrine, a generic

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[6] When a labeling revision for a brand-name drug "warrants *immediate* widespread professional notification," a "Dear Doctor letter" is sent to physicians and other health-care professionals by a drug manufacturer or the FDA advising of substantial new warning information. *Ibid.; Mensing, supra,* 564 U.S. at 615, 131 S. Ct. at 2576, 180 L. Ed. 2d at 590; *see* 21 C.F.R. § 200.5.

[7] After a new drug's labeling has been approved, a brand-name manufacturer may seek prior approval from the FDA to update its labeling. 21 C.F.R. § 314.70(b). Alternatively, the brand-name manufacturer may file a "Changes Being Effected" (CBE) supplement with the FDA, 21 C.F.R. § 314.70(c), to make changes to a brand-name drug label to "add or strengthen a contraindication, warning, precaution, or adverse reaction" or to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product." 21 C.F.R. § 314.70(c)(6)(iii)(A), (C). The CBE supplement must be submitted to the FDA thirty days before distribution, but the CBE process does not require FDA approval before changes are made to the label. 21 C.F.R. § 314.70(c).

Unlike brand-name manufacturers, generic manufacturers are not allowed to unilaterally strengthen their labels beyond the brand-name warnings through the CBE process. *Mensing*, *supra*, 564 U.S. at 614, 131 S. Ct. at 2575, 180 L. Ed. 2d at 590. A generic drug manufacturer may only use the CBE process to "change[] its label to match an updated brand-name label or to follow the FDA's instructions." *Ibid.* A generic manufacturer can update its labeling without pre-approval by the FDA after

drug manufacturer may not unilaterally "strengthen a generic drug's warning label" beyond the brand-name labeling, because to do so "would violate the statutes and regulations requiring a generic drug's label to match its brand-name counter-part's." *Mensing, supra,* 564 U.S. at 614, 131 S. Ct. at 2575, 180 L. Ed. 2d at 590 (citing 21 U.S.C.A. § 355(j)(4)(G); 21 C.F.R. §§ 314.94(a)(8)(iii), 314.150(b)(10)).

B.

The United States Supreme Court addressed the preemption doctrine in the context of federal drug labeling requirements in *Mensing* and *Wyeth v. Levine,* 555 U.S. 555, 129 S. Ct. 1187, 173 L. Ed. 2d 51 (2009). In *Mensing, supra,* the United States Supreme Court held that federal law preempted state-law failure-to-warn lawsuits against the defendant generic drug manufacturers, which had provided the same labeling as the brand-name drug. 564 U.S. at 618, 131 S. Ct. at 2577–78, 180 L. Ed. 2d at 592. The plaintiffs in that case alleged that, under state law, the defendants were required "to use a different, stronger label than the label they actually used." *Id.* at 617, 131 S. Ct. at 2577, 180 L. Ed. 2d at 591. The generic label conformed to the brand-name label. *Id.* at 610, 131 S. Ct. at 2573, 180 L. Ed. 2d at 587. The Court concluded that state and federal law were in conflict because it was impossible for the defendants to comply with both laws. *Id.* at 618, 131 S. Ct. at

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issuing the CBE supplement to the FDA. See 21 C.F.R. § 314.70(c)(6)(iii)(A).

2577, 180 L. Ed. 2d at 592. Although the plaintiffs contended that the generic manufacturers had a state-law "duty to attach a safer label to their generic metoclopramide," federal law demanded "that generic drug labels be the same at all times as the corresponding brand-name drug labels." *Id.* at 618, 131 S. Ct. at 2578, 180 L. Ed. 2d at 592. Had the generic manufacturers "independently changed their labels to satisfy their state-law duty, they would have violated federal law." *Ibid.* The Court therefore reasoned that "it was impossible for the Manufacturers to comply with both their state-law duty to change the label and their federal-law duty to keep the label the same." *Ibid.*

Mensing does not directly address the issue before us because, here, defendant generic manufacturers of metoclopramide tablets did not comply with the FDCA requirement that their labeling mimic the brand-name labeling. The question is whether the preemption doctrine is applicable to plaintiffs' failure-to-warn claims when the generic drug manufacturers not only could have given stronger warnings, but also were required to do so under federal law.

Wyeth dealt with a scenario that is relevant to our inquiry. There, the United States Supreme Court held that, even though the FDA had approved Wyeth's labeling of a brand-name prescription drug, federal law did not preempt a state-law tort action against it for giving inadequate warnings about the significant risks of administering its drug. *Wyeth,*

supra, 555 U.S. at 563, 581, 129 S. Ct. at 1193, 1204, 173 L. Ed. 2d at 59, 70. That result followed because in *Wyeth,* unlike in *Mensing,* it was not impossible for the brand-name manufacturer to comply with both federal law and a state-law duty by modifying the drug's labeling. *Id.* at 569, 573, 129 S. Ct. at 1196–97, 1199, 173 L. Ed. 2d at 62, 65.

The Supreme Court in *Wyeth* emphasized that the central premise of the FDCA and FDA regulations is "that the manufacturer bears responsibility for the content of its label at all times [and] is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." *Id.* at 570–71, 129 S. Ct. at 1197–98, 173 L. Ed. 2d at 63; *see also* 21 C.F.R. § 201.80(e) (requiring manufacturer to update label "to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug"). Accordingly, when the risk became apparent to Wyeth that its drug might cause gangrene, "Wyeth had a duty to provide a warning that adequately described that risk, and the [FDCA's] regulation permitted it to provide such a warning before receiving the FDA's approval." *Id.* at 571, 129 S. Ct. at 1198, 173 L. Ed. 2d at 64. Based on the regulatory authorization to issue pre-approval warnings, the Court maintained that it was not "impossible for Wyeth to comply with both federal and state requirements." *Ibid.*

The Court also concluded that, in passing the FDCA, Congress did not intend "to pre-empt common-law tort suits" and that such suits serve "as a complementary form of drug regulation." *Id.* at 578, 129 S. Ct. at 1202, 173 L. Ed. 2d at 68. The Court articulated an overarching federal policy for permitting state-law tort suits by stating:

> The FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge. State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information. Failure-to-warn actions, in particular, lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times.
>
> [*Id.* at 578–79, 129 S. Ct. at 1202, 173 L. Ed. 2d at 68–69 (footnote omitted).]

In light of the Supreme Court's recognition that state tort law may serve as a complementary tool in regulating the warnings on prescription drugs that have potentially dangerous side effects, we next look at this State's product-liability law.

C.

The New Jersey Product Liability Act (PLA), N.J.S.A. 2A:58C–1 to –11, provides that "[a] manufacturer ... of a product shall be liable in a product liability action only if ... the product causing the harm was not reasonably fit, suitable or safe for its intended purpose because it ... failed to contain adequate warnings or instructions." N.J.S.A. 2A:58C–2. In the case of a prescription drug, the PLA defines an adequate warning or instruction as one that a "reasonably prudent person" would give and "that communicates adequate information on the dangers and safe use of the product ... taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician." N.J.S.A. 2A:58C–4. The Legislature recognized the important role of the federal regulatory system over prescription drugs and provided that a warning or instruction approved under the FDCA would enjoy "a rebuttable presumption" of adequacy. *See ibid.*

The PLA is an expression of New Jersey's strong public policy of ensuring that manufacturers attach adequate warnings and instructions to prescription drugs so that consumers, ultimately, will be made aware of the relevant risks, dangers, and precautions in taking such medications. *Cf. Gantes v. Kason Corp.,* 145 N.J. 478, 490, 679 A.2d 106 (1996) ("[T]his State has a strong interest in encouraging the manufacture and distribution of safe products for the public and, conversely, in deterring the manufacture and

distribution of unsafe products within the state."). The Legislature understood, in the case of prescription drugs, that the PLA must coexist with a federal scheme that highly regulates the marketing of such drugs. *See Cornett, supra,* 211 N.J. at 387, 48 A.3d 1041. The PLA is a codification of tort-law principles, where the state has traditionally exercised its historic police powers. *See Medtronic, supra,* 518 U.S. at 485, 116 S. Ct. at 2250, 135 L. Ed. 2d at 715. As such, a failure-to-warn claim under the PLA is not preempted unless Congress has expressed its "clear and manifest purpose" to do so. *Ibid.* (quoting *Rice, supra,* 331 U.S. at 230, 67 S. Ct. at 1152, 91 L. Ed. at 1459).

VI.

A.

Plaintiffs' state-law failure-to-warn claims against defendant generic drug manufacturers are not barred by *Mensing* and are permissible under *Wyeth.*"

The defendant generic manufacturers of metoclopramide in *Mensing* did precisely what the FDCA demanded—they provided the *same* labeling that appeared with the brand name. *See Mensing, supra,* 564 U.S. at 609–10, 618, 131 S. Ct. at 2572–73, 2577–78, 180 L. Ed. 2d at 587, 592. Under Hatch–Waxman, generic manufacturers do not have to replicate the costly and lengthy clinical drug testing and research by brand-name manufacturers. *See id.* at

612, 131 S. Ct. at 2574, 180 L. Ed. 2d at 588–89. In turn, the FDCA also permits the generic manufacturer to rely on the brand-name labeling and forbids them from issuing better or stronger warnings. *See id.* at 614–15, 131 S. Ct. at 2575–76, 180 L. Ed. 2d at 588–89. Federal law preempted the state-law claims in *Mensing* because those claims were premised on a duty of generic manufacturers to give "safer" warnings than the FDA-approved brand-name warnings for metoclopramide. *Id.* at 618, 131 S. Ct. at 2578, 180 L. Ed. 2d at 592. What state law permitted was impossible under federal law. *Ibid.*

The case before us is not like *Mensing*. Here, defendant generic manufacturers of metoclopramide tablets did not conform their labeling to that of the brand-name drug and therefore were in violation of the FDCA's sameness requirement. Had defendants complied with federal law, they would be entitled to the safe-harbor protection afforded by *Mensing*. *See id.* at 613, 131 S. Ct. at 2574–75, 180 L. Ed. 2d at 589. No law prevented defendants from giving the same warnings that appeared on the labeling of the brand-name drug—the warnings that plaintiffs contend the PLA required. Defendants did not have to violate federal law to comply with state law. Unlike *Mensing,* here it was not impossible to comply with both federal and state law.

As a result of the discrepancy between the brand-name and generic labeling of metoclopramide tablets, consumers of Reglan tablets were informed that

"[t]herapy should not exceed 12 weeks in duration," whereas the plaintiff generic consumers were informed only that "[t]herapy longer than 12 weeks has not been evaluated and cannot be recommended."[8] Based on the inadequacy of the generic warnings, plaintiffs allege that they used metoclopramide beyond the prescribed period and therefore developed tardive dyskinesia, a serious neurological disorder.

Under *Wyeth, supra,* plaintiffs' state-law claims are not at odds with the FDCA, but are "a complementary form of drug regulation." 555 U.S. at 578, 129 S. Ct. at 1202, 173 L. Ed. 2d at 68. In keeping with *Wyeth,* each defendant generic drug "manufacturer bears responsibility for the content of its label at all times," and each "had a duty to provide a warning that adequately described that risk, and the [FDCA's] regulation permitted it to provide such a warning." *See id.* at 570–71, 129 S. Ct. at 1197–98, 173 L. Ed. 2d at 63–65.

This case drives home the point made in *Wyeth* that the FDA does not have the resources to monitor the labeling of thousands of drugs after they are marketed, and to the extent that "[s]tate tort suits uncover unknown drug hazards[, they] provide incentives for drug manufacturers to disclose safety

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[8] While the drug labels are initially disseminated to doctors and pharmacists, they, in turn, inform their patients, passing the warnings on to consumers. *See Niemiera v. Schneider,* 114 N.J. 550, 559, 555 A.2d 1112 (1989).

risks promptly." *See id.* at 578–79, 129 S. Ct. at 1202, 173 L. Ed. 2d at 68–69. Thus, state law promotes rather than "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" in passing the FDCA. *See Gade, supra,* 505 U.S. at 98, 112 S. Ct. at 2383, 120 L. Ed. 2d at 84 (first quoting *Hines, supra,* 312 U.S. at 67, 61 S. Ct. at 404, 85 L. Ed. at 587; and then citing *Felder, supra,* 487 U.S. at 138, 108 S. Ct. 2302, 101 L. Ed. 2d 123; *Perez, supra,* 402 U.S. at 649, 91 S. Ct. 1704, 29 L. Ed. 2d 233). Here, plaintiffs' state-law failure-to-warn claims shined a light on the inadequacy of warnings of a drug, which if used for a prolonged period could cause grave harm. The PLA provides a remedy to plaintiffs, if they can prove their claims to a jury, and the pursuit of those claims is not barred by federal law.

B.

Importantly, plaintiffs' state-law claims run parallel to, but are not dependent on, federal law. Plaintiffs could proceed on their failure-to-warn claims under the PLA even if the FDCA and Hatch–Waxman did not exist. From that perspective, the present case is not comparable to *Buckman Co. v. Plaintiffs' Legal Committee,* 531 U.S. 341, 121 S. Ct. 1012, 148 L. Ed. 2d 854 (2001), on which defendants rely.

In *Buckman,* the United States Supreme Court held that the Medical Device Amendments to the FDCA preempted a state-law tort action premised on

a claim that the defendant medical-device manufacturer committed a fraud on the FDA. *Id.* at 348, 121 S. Ct. at 1017, 148 L. Ed. 2d at 861. In that case, the defendant allegedly made fraudulent representations to the FDA to secure approval for the marketing of defective orthopedic bone screws that directly caused injuries to a class of plaintiffs. *Id.* at 343, 121 S. Ct. at 1015, 148 L. Ed. 2d at 858. Preemption applied because "the federal statutory scheme amply empower[ed] the FDA to punish and deter fraud against the Agency," by referring criminal charges, seizing the device, and seeking civil penalties and injunctive relief. *Id.* at 348–49, 121 S. Ct. at 1017–18, 148 L. Ed. 2d at 861–62. The Court concluded that the fraud-on-the-agency claim was not based on traditional state tort law because a "critical element" of those claims was dependent on the Medical Device Amendments. *Id.* at 353, 121 S. Ct. at 1020, 148 L. Ed. 2d at 864.

The Court pointedly distinguished *Buckman* from *Medtronic.* In *Medtronic,* preemption did not apply to state-law negligence claims against a manufacturer for allegedly producing defective pacemakers because those claims did not arise "solely from the violation of FDCA requirements." *Id.* at 352–53, 121 S. Ct. at 1019–20, 148 L. Ed. 2d at 864. The Supreme Court in *Buckman* indicated that "*Medtronic* can be read to allow certain state-law causes of actions that parallel federal safety requirements," *ibid.,* which is precisely what the Court later held in *Wyeth, supra,* 555 U.S. at 581, 129 S. Ct. at 1204, 173 L. Ed. 2d at

70, and what we hold today. The present case is different from *Buckman* because, here, the "critical element" to plaintiffs' claims is not defendants' violation of the FDCA, but defendants' failure to give adequate warnings about the prolonged use of metoclopramide.

Defendants' reliance on *Cornett* is also misplaced. In *Cornett, supra,* we came to the unremarkable conclusion that, under the Medical Device Amendments, federal law preempted state-law tort actions against the defendants premised on a fraud on the FDA. 211 N.J. at 389, 48 A.3d 1041. That result was commanded by *Buckman. Ibid.* We made clear, however, that a failure-to-warn claim alleging that the defendants withheld information from or made misrepresentations to the general public and the medical community about the safe use of the medical device at issue fell "within a traditional area of state concern and regulation." *Id.* at 390, 48 A.3d 1041. That claim could proceed under the Product Liability Act "because fraud on the FDA is not an element of the claim." *Ibid.*

Accordingly, allowing the failure-to-warn claims in the present case to proceed is compatible with the preemption principles articulated in both *Buckman* and *Cornett.*

C.

Our conclusion that plaintiffs' state-law failure-to-warn claims are not preempted by federal law is

supported by *Fulgenzi v. PLIVA, Inc.,* 711 F.3d 578 (6th Cir. 2013), and case law in other jurisdictions. In *Fulgenzi,* like here, PLIVA, a generic manufacturer of metoclopramide, failed to update its labeling to conform to the 2004 FDA-approved brand-name-labeling change. *Id.* at 580. As a result of the inadequate labeling, the plaintiff alleged that she prolonged her use of metoclopramide, which led to her developing tardive dyskinesia. *Ibid.* The plaintiff filed a product-liability failure-to-warn suit under Ohio law, seeking damages. *Id.* at 581–82. The United States Court of Appeals for the Sixth Circuit determined that federal preemption did not bar the state claims. *Id.* at 580. After reviewing *Mensing, Wyeth*, and *Buckman,* the Sixth Circuit concluded that state laws providing damages for inadequate warnings—warnings that did not comply with the federal duty of sameness—did not conflict with the FDCA or Hatch–Waxman. *Id.* at 585–86.

The federal appeals court maintained that the plaintiff's suit was not "*premised* on [a] violation of federal law, but rather on an independent state duty" and that "[t]he federal duty of sameness [was] not 'a critical element' in [the plaintiff's] case." *Id.* at 587 (quoting *Buckman, supra,* 531 U.S. at 353, 121 S. Ct. at 1020, 148 L. Ed. 2d at 864). It reasoned that the adequacy of PLIVA's warnings was not relevant to its duty under federal law and that "[a] jury need not know about the duty of sameness at all to determine whether the warning label used by PLIVA in 2004 and 2006 was inadequate, and whether the

failure to include the updated warning was a proximate cause of [the plaintiff's] injuries." *Ibid.* Last, *Fulgenzi* noted that, at trial, "[t]o avoid *Mensing* preemption, [the plaintiff] must use the language of the 2004 FDA-approved label in her proximate-cause argument, not (or not merely) the fact of the failure to update." *Id.* at 588.[9]

A number of federal and state courts, like the Sixth Circuit in *Fulgenzi,* have found that federal law does not preempt state-law claims arising from the failure of generic drug manufacturers to update labeling to conform to that of the brand name. *See, e.g., In re Fosamax Prods. Liab. Litig.,* 965 F. Supp. 2d 413, 417 (S.D.N.Y. 2013); *Phelps v. Wyeth, Inc.,* 938 F. Supp. 2d 1055, 1063–66 (D. Or. 2013); *Teva Pharms. USA, Inc.*, 158 Cal. Rptr. 3d at 156–61; *Huck v. Wyeth, Inc.,* 850 N.W.2d 353, 364 (Iowa 2014), *cert. denied,* —— U.S. ——, 135 S. Ct. 1699, 191 L. Ed. 2d 695 (2015); *Franzman v. Wyeth, Inc.,* 451 S.W.3d 676, 679 (Mo. Ct. App. 2014).

In contrast, *Morris v. PLIVA, Inc.,* 713 F.3d 774, 777 (5th Cir. 2013) (per curiam), found that *Mensing* preempts failure-to-warn claims against generic manufacturers who have not updated their warnings. There, the United States Court of Appeals for the Fifth Circuit held that a state-law claim against

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[9] *Fulgenzi* also acknowledged that at trial "[f]ederal standards are also likely to arise in determining the adequacy of PLIVA's warning, since FDA approval and industry practices may be relevant to the state duty of care." *Id.* at 588–89.

the generic manufacturer PLIVA for its failure to adopt the 2004 FDA-approved brand-name-warning label for metoclopramide was "a claim that PLIVA breached a federal labeling obligation [that] sounds exclusively in federal (not state) law, and is preempted." *Ibid.* (citing 21 U.S.C.A. § 337(a); *Buckman, supra,* 531 U.S. at 349 n. 4, 121 S. Ct. at 1018 n. 4, 148 L. Ed. 2d at 862 n. 4). The Fifth Circuit, however, did not give any detailed analysis or reasoning for that conclusion.[10]

We do not find *Morris* persuasive. Instead, we join those courts, such as the Sixth Circuit in *Fulgenzi,* that have concluded that federal preemption does not apply to failure-to-warn claims, such as those in the present case. We reject the notion that a plaintiff can proceed with a state-law failure-to-warn claim against a brand-name drug manufacturer that used FDA-approved warnings, as was true in *Wyeth,* but not against a generic manufacturer that provides warnings that do not even match the FDA-approved brand-name labeling. Congress could not have intended such an absurd result.

VII.

Here, plaintiffs claim that the generic drug manufacturers' inadequate warnings of the dangers of the prolonged use of metoclopramide proximately

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[10] Without citing any authority, the *Morris* court asserted that "[t]ort liability does not arise for failure to attach an inadequate label." *See Morris, supra,* 713 F.3d at 777. The labeling cases cited in this opinion indicate otherwise.

caused neurological disorders, such as tardive dyskinesia. In 2004, with FDA approval, brand-name manufacturers updated their labeling to indicate that the use of metoclopramide "should not exceed 12 weeks in duration." Although generic drug labeling is required to be the same as that of the brand name under federal law, defendant generic manufacturers, apparently, did not update their labeling "at the very earliest time possible" in accordance with the directive of the U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research. *Guidance for Industry: Revising ANDA Labeling Following Revision of the RLD Labeling* 5 (2000). The FDA's Office of Generic Drugs had directed generic manufacturers to "routinely monitor [its] Labeling Review Branch Homepage" for labeling updates that were made monthly on the Homepage. *Ibid.* Generic manufacturers were also advised that information about brand-name labeling changes was available from the FDA's Freedom of Information Staff. *See ibid.*

Some lag time is inevitable before a generic drug manufacturer can conform to the FDA's sameness requirement. For example, the updates on the FDA website appear monthly. *See ibid.* Needless to say, if a generic drug manufacturer is seeking safe-harbor protection under the sameness doctrine, then it must exercise reasonable diligence to learn of updates to the brand-name labeling. If the trial court determines that any defendant updated its labeling "at the very earliest time possible," *ibid.,* the state law

claim would be preempted. Whether preemption applies is a matter of law to be decided by the court, not a jury. *See Fulgenzi, supra,* 711 F.3d at 583.

Despite the easy access to information about brand-name labeling changes and the time-sensitive need to make those changes, defendant generic manufacturers delayed updating their labeling—defendant Actavis–Elizabeth for six months, defendant Teva Pharmaceuticals for one year, defendants Mutual Pharmaceutical Company and United Research Laboratories for one-and-one-half years. Defendant PLIVA did not update its labeling for the four-and-one-half years that it continued to manufacture metoclopramide through 2008. Watson Laboratories did not include the 2009 FDA-approved black-box warning in its metoclopramide shipments until more than ten months after receiving notice of the labeling change.

A violation of the FDCA's sameness requirements is not an element of plaintiffs' claims. Plaintiffs' claims do not "exist solely by virtue of" a federal regulatory scheme. *See Buckman, supra,* 531 U.S. at 353, 121 S. Ct. at 1020, 148 L. Ed. 2d at 864. Their state-law cause of action is not a disguised means of enforcing a federal law or regulation. Rather, plaintiffs are availing themselves of protections long available under this State's product-liability law. States have traditionally exercised their powers to promote the health and welfare of their citizens by regulating the safety of products through state tort

law. Plaintiffs' claims run parallel to the FDCA's sameness requirement for labeling warnings, but they are not based on that requirement. To be sure, to avoid a clash with *Mensing* and Hatch–Waxman, plaintiffs may not contend that defendant generic manufacturers had a duty to provide warnings beyond those that the FDA approved for the brand name.

Under state law, plaintiffs must prove the inadequacy of defendants' labeling of metoclopramide. This State's product-liability law requires defendant generic manufacturers to "communicate[] adequate information on the dangers and safe use of [metoclopramide], taking into account ... knowledge common to[] [a] prescribing physician." *See* N.J.S.A. 2A:58C–4. Plaintiffs therefore must demonstrate that a reasonably prudent generic manufacturer of metoclopramide tablets after July 2004 would have provided a stronger warning than the 1985 warning: "Therapy longer than 12 weeks has not been evaluated and cannot be recommended." In short, plaintiffs must show that defendant generic drug manufacturers had a duty to give a stronger warning than the one provided and that the failure to do so proximately caused their injuries. *See Fulgenzi, supra,* 711 F.3d at 588.

Our charge here is merely to determine whether federal law preempts plaintiffs' claims. We conclude that federal law does not. Whether plaintiffs can prove that defendants breached their state-law duty

to provide adequate warnings and, if so, whether the breach of that duty proximately caused plaintiffs' injuries is a matter for another day.

VIII.

For the reasons expressed, plaintiffs' state-law failure-to-warn claims based on the alleged inadequate labeling of metoclopramide—labeling that did not mimic the brand-name labeling—are not preempted by federal law. We therefore affirm the judgment of the Appellate Division, which upheld the trial court's denial of defendants' motions to dismiss those claims. We remand to the trial court for proceedings consistent with this opinion.

Chief Justice RABNER, Justices LaVECCHIA, FERNANDEZ–VINA and SOLOMON, join in Justice ALBIN's opinion. Justice PATTERSON and Judge CUFF (temporarily assigned) did not participate.