No. _____

IN THE

Supreme Court of the United States

IN RE REGLAN LITIGATION

PLIVA, INC.; BARR PHARMACEUTICALS, LLC;
BARR LABORATORIES, INC.; WATSON LABORATORIES, INC.;
TEVA PHARMACEUTICALS USA, INC.,
Petitioners,

v.

PHYLLIS KOHLES ET AL.,
Respondents.

On Petition for Writ of Certiorari to the Supreme Court of New Jersey

PETITION FOR WRIT OF CERTIORARI

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November 21, 2016

QUESTION PRESENTED

Whether the prohibition on private enforcement of the federal Food, Drug, and Cosmetic Act ("FDCA") precludes state-law tort claims predicated on allegations that a generic drug manufacturer violated the FDCA by failing to implement FDA-approved labeling changes in a manner considered timely under state law.

PARTIES TO THE PROCEEDING

Petitioners, the Defendants-Appellants below, are PLIVA, Inc. ("PLIVA"); Barr Pharmaceuticals, LLC; Barr Laboratories, Inc. (collectively "Barr"); Watson Laboratories, Inc. ("Watson"); and Teva Pharmaceuticals USA, Inc. ("Teva" and with PLIVA, Barr, and Watson, the "Generic Defendants").

Respondents, the Plaintiffs-Appellees below, are individuals who allegedly took metoclopramide, the generic form of the prescription drug Reglan, and who filed individual actions against Petitioners in the state courts of New Jersey. A list of the active individual actions in which Petitioners have been served is produced in the Appendix at 94a-115a. The case below, *In re Reglan Litigation*, is a coordinated proceeding in which all individual plaintiffs were represented by the same liaison counsel for the purpose of deciding the motion addressed in the opinion.

RULE 29.6 DISCLOSURE

Petitioner PLIVA, Inc. is an indirect wholly owned subsidiary of Teva Pharmaceutical Industries Ltd. through the following parent companies: Barr Laboratories, Inc., which in turn is directly owned by Barr Pharmaceuticals, LLC, which in turn is directly owned by Teva which in turn is directly owned by (1) Orvet UK (Majority Shareholder), which in turn is directly owned by Teva Pharmaceuticals Europe B.V., which in turn is directly owned by Teva Pharmaceutical Industries Ltd.; and (2) Teva Pharmaceutical Holdings Coöperatieve U.A. (Minority Shareholder), which in turn is directly owned by IVAX LLC, a direct subsidiary of Teva Pharmaceutical In-

dustries Ltd. No publicly held company other than Teva Pharmaceutical Industries Ltd. directly or indirectly owns 10% or more of the stock of PLIVA.

Petitioner Barr Laboratories, Inc. was wholly owned by Barr Pharmaceuticals, Inc. In December 2008, Barr Pharmaceuticals, Inc. was merged into a wholly owned subsidiary of petitioner Teva, which as set forth above is an indirect wholly owned subsidiary of Teva Pharmaceutical Industries Ltd. After the merger, the surviving company changed its name to Barr Pharmaceuticals, LLC. No publicly held company other than Teva Ltd. directly or indirectly owns 10% or more of the stock of the Barr Petitioners.

Petitioner Watson Laboratories, Inc. is a wholly owned subsidiary of Actavis Holdco US, Inc., which is directly owned by Teva, which as set forth above is an indirect wholly owned subsidiary of Teva Pharmaceutical Industries Ltd. No publicly held company other than Teva Ltd. directly or indirectly owns 10% or more of the stock of Watson Laboratories, Inc.

Petitioner Teva Pharmaceuticals USA, Inc. is an indirect wholly owned subsidiary of Teva Pharmaceutical Industries Ltd. through the following parent companies: (1) Orvet UK (Majority Shareholder), which in turn is directly owned by TEVA Pharmaceuticals Europe B.V., which in turn is directly owned by Teva Pharmaceutical Industries Ltd.; Teva Pharmaceutical Holdings Coöperatieve U.A. (Minority Shareholder), which in turn is directly owned by IVAX LLC, a direct subsidiary of Teva Pharmaceuticals USA, Inc. Teva Pharmaceutical Industries Ltd. is the only publicly traded direct or indirect parent company of Teva Pharmaceuticals USA, Inc., and no

other publicly traded company owns more than ten percent of its stock.

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PETITION FOR A WRIT OF CERTIORARI

Petitioners request a writ of certiorari to review the judgment of the Supreme Court of New Jersey.

OPINIONS BELOW

The decision of the Supreme Court of New Jersey is reported at 226 N.J. 315, 142 A.3d 725, and is reprinted in the Appendix ("App.") at 1a-37a. The New Jersey Appellate Division's unpublished opinion is available at 2014 WL 5840281 and is reprinted in the Appendix at 38a-52a. The New Jersey Superior Court's memorandum of decision denying Petitioners' motion to dismiss based on federal preemption is not officially reported, but the memorandum is reprinted in the Appendix at 76a-93a. The Superior Court also issued orders memorializing its denial of Petitioners' motions for summary judgment, which are reproduced in the Appendix at 53a-55a, based on oral rulings made at a May 3, 2013 hearing, a transcript of which is reproduced in excerpted form at 56a-75a.

JURISDICTION

The Supreme Court of New Jersey issued its decision on August 22, 2016. This Court has jurisdiction under 28 U.S.C. § 1257(a).

PERTINENT CONSTITUTIONAL AND STATUTORY PROVISIONS

The Supremacy Clause provides:

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United

> States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

U.S. CONST. art. VI, cl. 2. The text of 21 U.S.C. § 337 is set forth at 116a-117a.

INTRODUCTION

In 2001, this Court held without dissent that federal law bars private parties from pursuing state-law tort claims that are predicated on alleged violations of the federal Food, Drug, and Cosmetic Act ("FDCA"). In the Court's words, "[t]he FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the [Act]: '[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.'" *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001) (quoting 21 U.S.C. § 337(a)).

Despite *Buckman*'s clarity, lower courts are divided over *Buckman*'s scope—and that division has sharpened considerably in recent years as plaintiffs around the country have advanced novel legal theories designed to evade this Court's preemption rulings in *PLIVA, Inc. v. Mensing,* 564 U.S. 604 (2011), and *Mutual Pharm. Co. v. Bartlett,* 133 S. Ct. 2466 (2013). The decision of the Supreme Court of New Jersey in this case frames the nationwide split of authority in sharp relief: The New Jersey Supreme Court *expressly* departed from federal appellate deci-

sions which have held that federal law preempts the very same novel tort theory that the state supreme court's decision allows plaintiffs to pursue in New Jersey.

Given the open and acknowledged division of authority and its impact on thousands of pending cases that present the same question, this Court should definitively resolve the direct conflict among the state and federal appellate courts over the generic pharmaceutical industry's exposure to private state-law litigation predicated on allegations that generic drug manufacturers violated federal law.

* * *

Like *Mensing* and *Bartlett*, this case arises from "the special, and different, regulation of generic drugs" under the Hatch-Waxman Amendments to the FDCA ("Hatch-Waxman Act"). *Mensing,* 564 U.S. at 626. Among other requirements, the Hatch-Waxman Act requires that generic drug labeling be "the same as" the brand-name drug's label. *Id.* at 612 (quoting 21 U.S.C. § 355(j)(2)(A)(v)). As a result, if the brand-name drug manufacturer alters its labeling, manufacturers of an FDA-approved generic version of that drug must in most cases replicate the FDA-approved changes in their own product labeling.[1] This "duty to update" generic drug labeling is a creature of *federal law* that stems from the "ongoing *federal duty* of sameness" under the FDCA. *Mensing,* 564 U.S. at 614 (emphasis added).

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[1] There is an exception for new language that conveys patent-protected information, but that is not at issue here.

For obvious reasons, there inevitably is some period of delay before generic drug manufacturers can implement the changes following notice of the FDA's approval of a change to the brand-name drug's label. Generic manufacturers first must learn that the FDA has approved the brand manufacturer's changes. Then they must draft, prepare, and produce revised labeling that reflects the changes. They must notify the FDA of the intended changes. And, in most cases, there is lag time before manufacturers are scheduled to ship new batches of product that bear the revised labels—weeks, months, or (in rare cases) years. The FDA is aware of these practical realities, and throughout the thirty-year history of the Hatch-Waxman regime, the Agency consistently has exercised its enforcement discretion by declining to target the inevitable gaps that occur between its approval of branded labeling changes and the subsequent implementation of revised labeling by generic drug companies.

Because the FDA alone has authority to enforce the FDCA, private plaintiffs never previously attempted to premise putative state tort claims on generic manufacturers' alleged violations of the FDCA's sameness requirement. Instead, plaintiffs pursued traditional state-law failure-to-warn and design-defect claims against generic manufacturers whose products allegedly caused them injury. But in *Mensing* (and again in *Bartlett*), this Court held that plaintiffs could not pursue those state-law causes of action because federal law preempts state-law claims targeting generic drug warnings and designs. *Mensing*, 564 U.S. at 624; *Bartlett*, 133 S. Ct. at 2470.

Before the ink dried on *Mensing*, plaintiffs nationwide began advancing a new theory of liability contrived to evade that decision. Today, these so-called "failure-to-update" claims have become the principal line of attack for plaintiffs' lawyers: in literally thousands of cases, plaintiffs now allege that generic companies that did not *instantaneously* update their labeling violated the *federal* sameness requirement and therefore can be held liable under *state* law.

The federal district courts that first considered these "failure-to-update" claims almost universally understood that such claims are a thinly veiled attempt to enforce the FDCA and therefore are preempted under *Buckman* and 21 U.S.C. § 337(a).[2] When the claims eventually reached the appellate courts, the Fifth Circuit understood that *Buckman* bars putative state-law claims predicated on allegations that a generic manufacturer violated the federal duty of sameness by failing to implement labeling changes: "[A] claim that [a generic manufacturer] breached a federal labeling obligation sounds exclusively in federal (not state) law, and is preempted."

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[2] Such claims do not enforce the FDCA directly but do so in the guise of "traditional state-law claims." Yet such claims are tantamount to private enforcement of the FDCA in the same way that the state-law tort claims in *Buckman* amounted to private enforcement of the FDCA: a failure-to-update claim will succeed or fail based on a jury's decision about whether a defendant violated a provision of the FDCA over which Congress granted the FDA enforcement discretion. Such claims "inevitably conflict with the FDA's responsibility to police [FDCA compliance] consistently with the Administration's judgment and objectives." *Buckman*, 531 U.S. at 350.

Morris v. PLIVA, Inc., 713 F.3d 774, 777 (5th Cir. 2013) (citing 21 U.S.C. § 337(a); *Buckman*, 531 U.S. at 349 n.4).

Since then, the Fifth Circuit has twice reaffirmed that holding. *Johnson v. Teva Pharm. USA, Inc.*, 758 F.3d 605, 612 (5th Cir. 2014); *Lashley v. Pfizer, Inc.*, 750 F.3d 470, 475 (5th Cir. 2014). The Sixth Circuit went the other way. *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578, 586 (6th Cir. 2013) (allowing a state-law plaintiff to allege that a generic manufacturer's "failure to update was in violation of its federal duty of sameness"). The Seventh Circuit recently noted the "split in authority as to whether federal law preempts state law failure-to-update claims," though it declined to take a position on the issue. *Wagner v. Teva Pharm. USA, Inc.*, No. 15-2294, 2016 WL 6081381, at *2 (7th Cir. Oct. 18, 2016).

The conflict is not limited to the federal courts. The first state appeals court to consider a failure-to-update claim agreed with the Fifth Circuit and held that such claims are preempted. *See Huck v. Trimark Physicians Grp.,* 834 N.W.2d 82 (Iowa Ct. App. 2013), *vacated sub nom. Huck v. Wyeth, Inc.*, 850 N.W.2d 353 (Iowa 2014). But the Iowa Supreme Court openly departed from that reasoning, reversing the intermediate appellate court and adopting the view set forth in the Sixth Circuit's decision in *Fulgenzi*. *Huck*, 850 N.W.2d at 367-69.

The Supreme Court of New Jersey is now one of several state courts that has followed suit. *See* App. 1a-38a; *see also Franzman v. Wyeth LLC*, 451 S.W.3d 676, 679 (Mo. Ct. App. 2014) (holding a "claim relating to the Generic Defendants' failure to update

their warning labels to reflect the 2004 brand-name label revision … is not pre-empted under *Mensing*"); *In re Reglan/Metoclopramide Litig.*, 81 A.3d 80, 95 (Pa. Super. Ct. 2013) ("[S]tate negligence claims based upon the misbranding of drugs under the federal statute or failure to conform the generic label to the updated RLD label, a form of misbranding, are not foreclosed by *Mensing*."); *Teva Pharm. USA, Inc. v. Superior Court*, 158 Cal. Rptr. 3d 150, 163 (Cal. App. 4th 2013) ("We respectfully believe *Morris v. PLIVA, Inc.* was incorrectly decided.").

As a result of these conflicting decisions, plaintiffs in California, Iowa, New Jersey, Missouri, Pennsylvania, and other states have been allowed to pursue the *same* contrived "failure-to-update claims" that *Morris*, *Lashley*, and *Johnson* held plaintiffs in Louisiana, Mississippi, and Texas cannot pursue—against the *same* defendants (generic drug companies such as Petitioners, who sell their products in all 50 states) with respect to the *same* products (generic drugs approved under the FDCA and distributed nationwide). The stark divide on this important question subjects Petitioners and the entire generic drug industry to conflicting rulings regarding their exposure to high-stakes personal-injury lawsuits, and this Court should resolve the conflict.

On the merits, the decision of the Supreme Court of New Jersey cannot be squared with *Buckman* or with 21 U.S.C. § 337(a). As *Buckman* explained, that statute "leaves no doubt" that the federal government *alone* has authority to "file suit for noncompliance" with the FDCA. 531 U.S. at 349 n.4 (citing § 337(a)); *id.* at 352 ("Congress intended that the

[FDCA] be enforced exclusively by the Federal Government."). State-law tort claims that depend on whether a defendant violated the FDCA "inevitably conflict" with Congress's decision to entrust enforcement discretion exclusively to the FDA. *Id.* at 350. The agency retains that discretion pursuant to a "statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives" through "a variety of enforcement options that allow it to make a measured response" to suspected violations. *Id.* at 349. Tort suits premised on FDCA violations undermine the ability of the FDA to strike the proper balance consistent with its "judgment and objectives." *Id.* at 350.

The court below tried to evade this Court's holding in *Buckman* by asserting that "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." App. 30a. That does nothing to distinguish *Buckman*, in which the plaintiffs likewise attempted to plead their claims as sounding in state common-law fraud—even though in substance their claims sought redress for allegedly fraudulent misrepresentations that violated the FDCA. *Buckman*, 531 U.S. at 346-47.

This Court looked past form to substance and held those claims preempted. The same result should obtain here: As in *Buckman*, the federal regulatory regime is "a critical element in [this] case." *Id.* at 353. Indeed, it is *the* critical element. After all, the putative state-law claims Respondents seek to pursue arise *only* because the FDA approved the brand

manufacturer's new labeling, and *only* because of the federal duty of sameness under the Hatch-Waxman Act. It is the federal duty of sameness—not any state-law tort duty—that identifies the conduct for which Respondents seek to impose liability. In short, without the FDCA and the FDA, there could be no "failure-to-update claim" against Petitioners.

Given the parallels between this case and *Buckman*, it is no surprise that the same policy concerns which animated *Buckman* apply here. As this Court has explained, the FDCA implicates an array of competing policy interests, and § 337(a) reflects Congress's judgment that the FDA alone should balance those interests in making enforcement decisions. *Buckman,* 531 U.S. at 350-51. Just as the FDA has ample authority "to punish and deter fraud" by regulated parties, *id.* at 348, it has ample authority to address alleged regulatory violations by generic manufacturers. In both cases, the FDA uses its authority "to achieve a somewhat delicate balance of statutory objectives." *Id.* Allowing private plaintiffs to seek compensatory and punitive damages outside of the federal structure necessarily undermines the FDA's ability to police the federal scheme in a manner consistent with the balance it has struck.

In sum, the decision of the Supreme Court of New Jersey is irreconcilable with § 337(a) and *Buckman*, widens an entrenched split of authority among the federal and state appellate courts, and implicates significant policy concerns that warrant this Court's review. The petition should be granted.

STATEMENT OF THE CASE

A. Regulatory Background

From the time of its enactment in 1938—and at all times since—the FDCA has provided in clear, unambiguous terms that (except for certain lawsuits brought by state governments) "*all* ... proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a) (emphasis added). In *Buckman*, this Court held that the FDCA's exclusive grant of enforcement authority to the federal government impliedly preempts private lawsuits that are predicated on alleged violations of the statute. "The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance." 531 U.S. at 349 n.4.

Among the many FDCA provisions subject to § 337(a)'s prohibition against private enforcement is the Hatch-Waxman Act, which Congress added to the statute in 1984 in order to expand access to affordable generic drugs by reducing barriers to generic market entry. Those amendments gave rise to the modern generic drug industry—and during the past three decades have reduced pharmaceutical expenditures by trillions of dollars. *See Mensing*, 564 U.S. at 626 ("[I]t is the special, and different, regulation of generic drugs that allowed the generic drug market to expand, bringing more drugs more quickly and cheaply to the public").

The Hatch-Waxman Act achieved its goals because it drew sharp distinctions between branded

and generic drug applicants. Brand companies seeking to market an innovative drug product must submit a New Drug Application ("NDA") that includes clinical trial reports demonstrating the proposed product's safety and efficacy. *Id.* at 614 (citing 21 U.S.C. § 355(b)(1), (d)). Generic companies seeking to market copies of previously approved drugs may file an Abbreviated New Drug Application ("ANDA") that demonstrates the product's chemical and biological equivalence to a previously approved drug (known as the "reference listed drug" or "RLD"). *Id.* (citing 21 U.S.C. § 355(j)(2)(A)). Hatch-Waxman requires ANDA applicants to show that their generic drugs contain the *same* active ingredients, employ the *same* route of administration (e.g., oral or injected), present the *same* dosage form, exhibit the *same* strength, and thus "have the *same* therapeutic effect" as the branded equivalent to which their ANDA refers. 21 U.S.C. § 355(j)(2)(A)(i)-(iv) (emphasis added).

Because "sameness" is the touchstone for generic approval, federal law provides that generic drug labeling—including the warnings and other safety-related information—must in all pertinent respects be "the same as the labeling approved for the [brand-name] drug." *Mensing,* 564 U.S. at 612-13 (quoting 21 U.S.C. § 355(j)(2)(A)(v)). As this Court explained in *Mensing*:

> [B]rand-name and generic drug manufacturers have different federal drug labeling duties. A brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label. A manufactur-

> er seeking generic drug approval, on the other hand, is responsible for ensuring that its warning label is the same as the brand name's.

Id. at 613 (internal citations omitted).

The distinctions between brand and generic responsibilities extend to labeling updates after approval. While NDA holders may in certain circumstances revise their labeling unilaterally (i.e., without prior FDA approval) to "add or strengthen a contraindication, warning, [or] precaution" through the "changes being effected" (or "CBE") procedure, *Mensing,* 564 U.S. at 614 (discussing 21 C.F.R. § 314.70(c)(6)), ANDA applicants may not. Instead, ANDA applicants may use the CBE regulation to make "changes to generic drug labels *only* when a generic drug manufacturer changes its label to match an updated brand-name label or to follow the FDA's instructions." *Id.* (emphasis added).

Neither the FDCA nor the FDA's implementing regulations require generic manufacturers to implement labeling changes within a specified period of time. Instead, the FDA has advised the industry that it would "notify ANDA applicants by facsimile, telephone, and/or letter for any labeling revision approved for the RLD that warrants *immediate* widespread professional notification, such as those changes connected to issuing a *Dear Doctor Letter* or similar significant changes." FDA, Center for Drug Evaluation and Research, *Guidance for Industry: Revising ANDA Labeling Following Revision of the RLD Labeling*, at 5 (May 2000), 2000 WL 34503110, at *2. Outside those circumstances, the FDA histori-

cally has exercised its enforcement discretion with respect to the timing of generic labeling updates on a case-by-case basis.[3]

B. Factual and Procedural Background

1. Metoclopramide

Metoclopramide is approved for the short-term treatment of gastroparesis and the short-term treatment of gastroesophageal reflux disease in adults who fail to respond to conventional therapy. It has a recommended dosing regimen of 10 mg, four times a day, 30 minutes before meals and at bedtime for less than 12 weeks. It is the generic form of brand name Reglan®.

In 1980, the brand-name manufacturer of Reglan obtained approval from the FDA to market metoclopramide tablets. *Mensing*, 564 U.S. at 609. Since that time, "warning labels for the drug have been strengthened and clarified several times." *Id.* In March 1985, the FDA required that the label be "modified to warn that 'tardive 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.'" *Id.* In July 2004, the NDA holder "requested, and the FDA approved, a label change to add that '[t]herapy should not exceed 12 weeks in duration.'" *Id.* In 2009, the FDA issued "a

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[3] The FDA classifies labeling changes by degree of importance as "major changes," "moderate changes," and "minor changes." FDA, Center for Drug Evaluation and Research, *Guidance for Industry: Changes to an Approved NDA or ANDA*, at 24-25 (April 2004), 2004 WL 3199016, at *18-*20.

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.'" *Id.* at 610.

2. Proceedings Below

Respondents allege that they developed tardive dyskinesia, a neurological disorder that causes involuntary repetitive movements, or other movement disorders from their long-term use of metoclopramide. App. 77a.

In November 2010, Respondents filed a Second Amended Complaint against Petitioners and others asserting various state-law theories related to the product's safety as labeled and designed, including negligence, defective design, failure to warn, fraud, breach of express and implied warranties, violation of consumer protection laws, and wrongful death. App. 39a. According to the trial court, Respondents' theories, when "[s]tripped down to the very basics, ... are 'traditional product liability claims for injuries caused by the Generic Defendants' ... failure to provide adequate warning for their products.'" App. 62a (alteration omitted). The Second Amended Complaint sought compensatory and punitive damages, attorneys' fees, and other relief. App. 39a.

Petitioners moved to dismiss the Second Amended Complaint on federal preemption grounds. App. 76a. On May 12, 2012, the Superior Court denied Petitioners' motion to dismiss with respect to claims that the generic manufacturers did not change the

label on their product to match the brand-name's label. App. 92a. The trial court thereafter permitted discovery concerning the dates on which the Petitioners implemented the label changes to incorporate the July 2004 changes to the warnings used by the brand-name manufacturers. App. 41a.

After the completion of discovery on this issue, Petitioners filed motions for summary judgment or to dismiss. Petitioners again argued, among other things, that Respondents' state-law claims for failure to update FDA-approved warnings are preempted by federal law. App. 41a-42a. The Superior Court again denied the motions, reaffirming its earlier ruling that Respondents' claims based on the failure to update warnings to conform to warnings and labels of the brand-name drug are not preempted. App. 42a.

Petitioners filed motions for leave to appeal to the Appellate Division of the Superior Court of New Jersey. App 43a. Those motions were denied. *Id.* Petitioners then filed a motion for leave to appeal with the Supreme Court of New Jersey, which granted the motion and remanded the appeals to the Appellate Division for a decision. *Id.*

On November 12, 2014, the Appellate Division affirmed the trial court, holding that Respondents' claims are not premised on violations of federal law but on the failure to give adequate warnings under New Jersey product-liability law. Relying on the Sixth Circuit's decision in *Fulgenzi*, the Appellate Division concluded that failure-to-warn claims are not preempted by the FDCA if the plaintiffs allege that defendants had a duty under the FDCA to update their labels to conform to the brand-name label.

App. 47a-49a. The appellate court explicitly rejected the holding in *Morris v. PLIVA, Inc.*, 713 F.3d 774 (5th Cir. 2013) and decisions following its reasoning. App. 49a.

Respondents sought further review in the Supreme Court of New Jersey, which granted review and affirmed. The court held that Respondents' "state-law failure-to-warn claims against defendant generic drug manufacturers are not barred by *Mensing* and are permissible under *Wyeth*." App. 25a. Specifically, the court concluded that unlike the preempted state-law claims in *Mensing*, which sought to impose liability for doing "precisely what the FDCA demanded"—namely, providing the same warnings as the brand-name label—Respondents' state-law claims seek to impose liability for violating the FDCA. App. 25a-26a. The New Jersey Supreme Court concluded that this private enforcement of the federal sameness duty under state law does not contradict *Buckman* because the "state-law claims run parallel to, but are not dependent on, federal law." App. 28a. The court suggested that Respondents would be able to proceed on their claims "even if the FDCA and Hatch-Waxman did not exist." *Id.*

The supreme court also concluded that Respondents' claims do not interfere with the purposes and objectives of the FDCA because, according to the court, their claims are "a complementary form of drug regulation." App. 27a (quoting *Wyeth*, 555 U.S. at 578).

REASONS FOR GRANTING THE PETITION

The New Jersey Supreme Court took the wrong side of a pre-existing split when it held that federal law does not preempt Respondents' novel theory of liability. Like thousands of other plaintiffs, Respondents in this case seek to evade this Court's preemption holdings in *Mensing* and *Bartlett* by asserting that Petitioners can be held liable for failing to update revised product labeling when the FDA approved the brand manufacturer's 2004 change to the Reglan label. Yet despite the *state-law* captions Respondents have slapped on their theories, the private action they seek to pursue necessarily hinges on alleged violations of *federal law*—the *federal* duty of sameness, imposed by the *federal* Food, Drug, and Cosmetic Act, in connection with the *federal* generic drug approval process.

The state-court opinions leave no doubt that Respondents' claims turn on Petitioners' violation of the federal requirement of sameness. *See* App. 88a (holding that Respondents may pursue their state-law tort claims "to the extent that generic manufacturers of metoclopramide tablets failed to update the labels to be the same as the brand-name label"); App. 47a (upholding "plaintiffs' claims *based on* the Generic Defendants' failure to update their warnings to conform to changes made to the brand-name warnings") (emphasis added); App. 34a (noting that the trial court must determine whether "any defendant updated its labeling 'at the very earliest time possible'" in order to comply "with the directive of the U.S. Department of Health and Human Services, Food and Drug Administration").

By authorizing state-law claims premised on violations of federal law, the New Jersey Supreme Court deepened an already entrenched split and ignored this Court's instructions in *Buckman*.

I. THE DECISION BELOW IMPLICATES AN ENTRENCHED DIVISION OF AUTHORITY IN THE LOWER COURTS.

The FDCA precludes private plaintiffs from seeking to enforce its provisions: "The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the [Act]: '[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.'" *Buckman*, 531 U.S. at 349 n.4 (quoting 21 U.S.C. § 337(a)). As the Fifth Circuit repeatedly has recognized, "a claim that [a generic manufacturer] breached a federal labeling obligation sounds exclusively in federal (not state) law, and is preempted." *Morris*, 713 F.3d at 777 (citing 21 U.S.C. § 337(a); *Buckman*, 531 U.S. at 349 n.4); *see also Johnson*, 758 F.3d at 610; *Lashley*, 750 F.3d at 472-73. Where the substance of a state-law tort claim is a federal statutory duty, that claim is tantamount to private enforcement and cannot proceed.

The Fifth Circuit's decisions in *Morris*, *Johnson*, and *Lashley* are indistinguishable from this case. As here, the plaintiffs in each of those cases sued manufacturers of generic metoclopramide products under various state-law product-liability theories. *Johnson*, 758 F.3d at 610; *Lashley*, 750 F.3d at 472-73; *Morris*, 713 F.3d at 775-76. As here, the plaintiffs asserted that the generic manufacturers could be held liable

because they violated federal law by failing to update their metoclopramide warnings "to comply with the 2004 FDA-approved label change" to branded Reglan. *Morris*, 713 F.3d at 776; *Lashley*, 750 F.3d at 475 (noting the plaintiffs' claim that "generic manufacturers should be liable for not conforming to the 2004 label change"); *Johnson*, 758 F.3d at 612 (noting a "claim alleging that [the] generic manufacturer … failed to incorporate the 2004 label change into its label" in a reasonable time).

The *only* difference between this case and those cases is the result of the courts' preemption analyses. Whereas the New Jersey Supreme Court's decision *allows* these federal claims to proceed, the Fifth Circuit's decisions in *Morris*, *Lashley*, and *Johnson* held such claims preempted. The federal district courts are no less splintered; those courts likewise reach directly conflicting results in materially identical cases. Many side with the Fifth Circuit and have dismissed failure-to-update claims. As one court has explained:

> The FDA exclusively, not private citizens, has the authority to enforce the FDCA labelling requirement on generic drugs. … [T]he question of whether [a private plaintiff] could use state tort law to effect the same enforcement result to her private benefit is not entirely settled, but most courts that have addressed the issue have decided against allowing it.

Wagner v. Pfizer, Inc., No. 13-497, 2014 WL 3447476, at *4 (W.D. Wis. July 11, 2014), *aff'd sub nom. Wagner v. Teva Pharm. USA, Inc.*, No. 15-2294, 2016 WL 6081381 (7th Cir. Oct. 18, 2016); *see also Garza v.*

Wyeth LLC, No. 12-198, 2015 WL 364286, at *4 (S.D. Tex. Jan. 27, 2015) (holding failure-to-update claims preempted because "it is the duty of sameness—a federal statutory construct—that governs, rather than any alternative state law measure of the adequacy of warnings"); *Abicht v. PLIVA, Inc.*, No. 12-1278, 2013 WL 141724, at *3 (D. Minn. Jan. 9, 2013) ("Where federal law supplies the duty, a state claim to enforce that duty is, in substance if not in form, a cause of action under federal law. And such private actions are not allowed under the FDCA. As such, Plaintiffs' failure-to-update claim fails as a matter of law."); *Bell v. PLIVA, Inc.*, 845 F. Supp. 2d 967, 971 (E.D. Ark. 2012) ("[I]t is clear that PLIVA may still rely on the defense of preemption despite its failure to incorporate the 2004 label change."), *aff'd in part, rev'd in part sub nom. Bell v. Pfizer, Inc.*, 716 F.3d 1087 (8th Cir. 2013); *In re Darvocet, Darvon & Propoxyphene Prod. Liab. Litig.*, No. 11-2226, 2012 WL 718618, at *4 n.8 (E.D. Ky. Mar. 5, 2012) ("*Mensing* would apply to the failure-to-update claims in any event."), *aff'd*, 756 F.3d 917 (6th Cir. 2014); *Gross v. Pfizer, Inc.*, 825 F. Supp. 2d 654, 660 (D. Md. 2011) ("Plaintiff does not claim that the alleged failure of PLIVA to update its label gives rise to any cause of action under Maryland law; nor is the Court aware of any such cause of action."), *aff'd sub nom. Drager v. PLIVA USA, Inc.*, 741 F.3d 470 (4th Cir. 2014).[4]

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[4] *Cf. Willis v. Hospira, Inc.*, No. 13-284, 2014 WL 2795315, at *5 (E.D. Tex. June 3, 2014); *Parris v. Eli Lilly & Co.*, No. 12-572, 2013 WL 5310167, at *3 (E.D. Tenn. Sept. 20, 2013); *Brinkley v. Pfizer, Inc.*, No. 10-274, 2012 WL 1564945, at *5 (W.D.

At the same time, several district courts have sided with the Sixth Circuit by permitting similar claims to proceed. *See, e.g.*, *Woods v. Wyeth, LLC*, No. 13-543, 2016 WL 1719550, at *8 (N.D. Ala. Apr. 29, 2016) (noting that the plaintiff "alleged that the generic defendants could have satisfied both their federal and state law duties by updating their labels to be exactly the same as the brand name labels following the 2004 changes" and that such claims "avoid preemption"); *In re Fosamax Prod. Liab. Litig.*, 965 F. Supp. 2d 413, 417 (S.D.N.Y. 2013) ("'[F]ailure to update' claims against the Generic Defendants are not preempted."); *Neeley v. Wolters Kluwer Health, Inc.*, No. 11-325, 2013 WL 3929059, at *9 (E.D. Mo. July 29, 2013) ("[B]ased upon *Fulgenzi*, the Court does not believe that Plaintiffs' 'parallel claims' are veiled attempts to enforce violations of the FDCA and are not preempted by *Buckman*."); *Phelps v. Wyeth, Inc.*, 938 F. Supp. 2d 1055, 1066 (D. Or. 2013) ("[P]laintiffs' failure to update claim is distinguishable from the claim in *Buckman*, and therefore is not preempted by the FDCA."); *Couick v. Wyeth, Inc.*, No. 09-210, 2012 WL 79670, at *5 (W.D.N.C. Jan. 11, 2012) ("[I]f Defendants' [labels] did not match the brand, there are at least some changes to their [labels] that federal law would allow, or even require, Defendants to make. A state law claim for failure to include such warnings would not be preempted by federal law where the FDA would have permitted, or even required, such chang-

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Mo. Apr. 12, 2012), *aff'd*, 772 F.3d 1133 (8th Cir. 2014); *Guarino v. Wyeth LLC*, 823 F. Supp. 2d 1289, 1292 (M.D. Fla. 2011), *aff'd*, 719 F.3d 1245 (11th Cir. 2013).

es."); *Fisher v. Pelstring*, 817 F. Supp. 2d 791, 805 (D.S.C. 2011) ("[T]his possible deviation in PLIVA's label for generic metoclopramide … is sufficient to conclude the plaintiffs' claims are not entirely preempted.").

Unless this Court provides clarity, this entrenched division in authority threatens to subject thousands of similarly situated parties—both plaintiffs and defendants—to irreconcilable rulings in cases involving scores of different drug products.

The problem will only grow as decisions like the one here lead plaintiffs' lawyers to file suit every time the FDA's website reveals a labeling change that generic companies cannot possibly implement instantaneously. With the widespread adoption of plaintiff-oriented mass proceedings in various state courts—such as California, New Jersey, and Pennsylvania—out-of-state residents have filed and will continue to file product-liability cases against drug manufacturers regardless of where they consumed a defendant's drug product. Literally *thousands* of failure-to-update claims have been consolidated for pretrial decisions in these three states. The opportunities for forum-shopping in the face of this split are boundless. Texas, Mississippi, or Louisiana residents whose claims would be barred under *Morris*, *Lashley*, and *Johnson* inevitably will send their complaints to the welcoming courts of California, New Jersey, or Pennsylvania, which have allowed the very claims the Fifth Circuit repeatedly has found preempted. From the perspective of companies such as Petitioners, who manufacture or market federally regulated generic drug products to consumers in all

50 states, it is hard to overstate the importance of resolving the nationwide split on this question.

II. THE DECISION BELOW CONFLICTS WITH *BUCKMAN*.

On the merits, the New Jersey Supreme Court's decision is indefensible for the same reasons *Buckman* rejected state-law fraud claims predicated on allegations that a regulated party violated its federal duties under the FDCA. In fact, this case is indistinguishable from *Buckman*. In each case, the plaintiffs alleged that a defendant's violation of the FDCA caused the plaintiffs to suffer personal injuries. And in each case, the plaintiffs sought to evade the prohibition against private enforcement of the FDCA by attempting to mask allegations of a federal violation in the guise of a state law claim: In *Buckman*, the plaintiffs asserted that their fraud-on-the-FDA claim was really for a common-law fraud that allegedly led to the plaintiffs' injuries. In this case, Respondents assert that their failure-to-update claim is really for the violation of a state-law tort duty to timely implement FDA-required labeling changes, which likewise allegedly led to their injuries.

Despite the avowed state-law basis for the plaintiffs' common-law fraud claims in *Buckman*, this Court recognized that those claims necessarily relied on the antecedent federal scheme: "[T]he very subject matter of petitioner's statements w[as] dictated by [the FDCA's] provisions," *Buckman*, 531 U.S. at 347-48, so allowing claims predicated on alleged violations of the FDCA in connection with those statements would "inevitably conflict with the FDA's responsibility to police fraud consistently with the

Administration's judgment and objectives." *Id.* at 350. Moreover, the FDA's exclusive purview over the alleged violation stemmed directly from the plain language of § 337(a): "The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance." *Buckman*, 531 U.S. at 349 n.4; *id.* at 352 ("Congress intended that the [FDCA] be enforced exclusively by the Federal Government.") (citing 21 U.S.C. § 337(a)). That *Buckman* requires preemption of state-law failure-to-warn claims was succinctly explained in *Garza*:

> Generic manufacturers' hands are tied by the FDCA in that they must use the same formulation for pharmaceuticals and conform to the name-brand labeling and no more. To measure their compliance with the law, one looks to those federal requirements, the FDA's approvals, and the name-brand manufacturers' actions. None of these issues requires the analysis of a duty to consumers and, in fact, a duty to consumers measured by state law requirements and what a "reasonably prudent person" would do under the same or similar circumstances may well differ from the FDA's regulatory actions. This conflict is resolved through the Supremacy Clause in favor of the federal regulatory scheme.
>
> While [the plaintiff] suggests that a "failure to update" claim is qualitatively different from a state law "failure to warn" claim, the act of "updating" cannot be measured by state law expectations but can only be governed by FDA

> and name-brand manufacturers' actions and the generic manufacturer's duty of sameness.

Garza, 2015 WL 364286, at *2.

The Supreme Court of New Jersey nonetheless tried to evade *Buckman* by asserting that Respondents' "state-law claims run parallel to, but are not dependent on, federal law." App. 28a. But the same argument was rejected in *Buckman*. The *Buckman* plaintiffs likewise characterized their claims as *state common-law fraud claims*; they did not purport to file suit under the FDCA itself. 531 U.S. at 346-47.[5] Allowing a state common-law cause of action that would have permitted an injured plaintiff to recover damages attributable to a defendant's fraud in violation of the FDCA likewise could be said to "run parallel to ... federal law" where federal law—as was true in *Buckman*—bars the submission of fraudulent statements. App. 28a. Yet *Buckman* nevertheless held that the plaintiffs' purported state-law claims were preempted.

It is no response to say that Respondents' state-law claims avoid preemption because "it was not im-

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[5] The Third Circuit decision that this Court reversed in *Buckman* made this clear. *See In re Orthopedic Bone Screw Prods. Liab. Litig.*, 159 F.3d 817, 822 (3d Cir. 1998) ("Count I is thus drafted to track the elements of a common law cause of action for fraudulent misrepresentation: (1) a representation of fact, opinion, intention or law; (2) knowledge of its falsity; (3) an intent to induce reliance; (4) justifiable reliance; (5) resulting injury.") (citing Restatement (Second) of Torts § 525 *et seq.*); *id.* at 826-27 (noting that the plaintiffs' claims in *Buckman* tracked well-known common-law fraud and causation principles reflected in the Restatement (Second) of Torts § 310).

possible to comply with both federal and state law." App. 26a. Again, the exact same thing could have been said in *Buckman*, in which it likewise "was not impossible" for the defendant to tell the truth instead of committing an alleged fraud that caused the plaintiffs' alleged injuries. Just as Petitioners in this case had a federal "duty to provide the same warnings as the brand-name label," App. 13a, the *Buckman* defendant had a federal duty to tell the FDA the truth. There is no principled distinction between this case and *Buckman*.

To avoid any doubt on this point, look no further than the New Jersey Supreme Court's analysis of state-law negligence principles. The court concedes that "federal standards" are relevant to assessing the adequacy of Petitioners' warning labels and determining whether there was a violation of the relevant "duty of care." App. 32a n.9. Moreover, the court concedes that there would be no state-law claim without a violation of the FDCA. App. 3a ("Had defendants provided the same labeling as the brand-name manufacturers, as required by federal law, defendants would have enjoyed a safe harbor."). Conceding that an inquiry into federal standards is a necessary element of Respondents' claim underscores that federal law is "is a critical element in their case," *Buckman*, 531 U.S. at 353, because state-law liability depends on the underlying federal violation. In other words, but for the FDA-approved changes to the branded drug's labeling, but for the FDA's decision to approve those changes, and but for the Hatch-Waxman Act's "sameness" requirement, Respondents would have no basis for seeking to hold

Petitioners liable under this theory. Without these federal requirements, Petitioners would have no duty to add the alternative warning that is the basis of Respondents' claim. That should be the beginning and the end of this case, which seeks to disguise federal claims in state-law garb.

In other contexts, courts routinely hold that *Buckman* and § 337(a) expressly bar private plaintiffs from pursuing ostensibly negligence-based claims predicated on asserted violations of the FDCA. *See, e.g.*, *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1205-06 (8th Cir. 2010) (holding negligence claim premised on failure to comply with the FDCA preempted under § 337(a) and *Buckman*); *Cupek v. Medtronic, Inc.*, 405 F.3d 421, 424 (6th Cir. 2005) (holding negligence *per se* claim premised on "failing to comply with the FDA's conditions of approval" preempted under *Buckman*); *Ramirez v. Medtronic Inc.*, 961 F. Supp. 2d 977, 1000-01 (D. Ariz. 2013) ("[A] claim for negligence that is premised solely on a manufacturer's violation of a federal standard—here the FDCA and MDA—is impliedly preempted. This type of claim presents the exact difficulties that produced implied preemption in *Buckman*."); *Kapps v. Biosense Webster, Inc.*, 813 F. Supp. 2d 1128, 1151-52 (D. Minn. 2011) ("A negligence-per-se claim that is predicated on an alleged violation of the FDCA is, by definition, a claim that would give rise to liability under [state] law only because of the FDCA's enactment. Such a claim is preempted under *Buckman*."); *Leonard v. Medtronic, Inc.*, No. 10-3787, 2011 WL 3652311, at *8 (N.D. Ga. Aug. 19, 2011) ("[P]laintiffs'

claim of negligence per se would not exist prior to the enactment of the FDCA misbranding and adulteration laws because the claim only alleges violation of that law.").

More broadly, other courts likewise have recognized the need to analyze the substance rather than the form of the claim asserted by a plaintiff in determining whether the claim can proceed. *See*, *e.g.*, *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 776-77 (D. Minn. 2009) ("[A] private litigant cannot bring a state-law claim against a defendant when the state-law claim is in substance (even if not in form) a claim for violating the FDCA—that is, when the state claim would not exist if the FDCA did not exist."). Yet these well-established principles have been abandoned when some courts have sought to evade the impact of this Court's preemption decisions in *Mensing* and *Bartlett*.

III. THE DECISION BELOW UNDERMINES FEDERAL POLICY.

It is difficult to overstate the adverse federal policy consequences of allowing these kinds of claims to proceed. As *Buckman* observed, § 337(a) not only vests exclusive authority to police the federal regulatory regime with the FDA but the statutory scheme ensures that the FDA "has at its disposal a variety of enforcement options that allow it to make a measured response to suspected" violations of the statute and implementing regulations. *Buckman*, 531 U.S. at 349. These enforcement tools apply to the FDCA as a whole, not only its anti-fraud provisions. As the federal government forcefully argued in *Buckman*—and as this Court in turn recognized, *see* 531 U.S. at

348-51—private litigation predicated on alleged violations of the FDCA undermines the FDA's broad enforcement discretion because such litigation:

> (1) "permit[s] juries in different States to reach judgments that differ from [the] FDA's" about whether companies violated federal law, and potentially to "impose massive liability, when [the] FDA would not find any misconduct";
>
> (2) "distort[s] the penalty scheme established by the statute" by providing remedies Congress withheld, such as possible punitive damages; and
>
> (3) "interfere[s] with [the] FDA's discretion to decide which of the statutorily prescribed remedies, if any, to pursue" by allowing juries to "substitute their judgments for [the] FDA's as to the appropriate sanction."

Br. for the United States as Amicus Curiae Supporting Petitioner at 23-24, *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) (No. 98-1768), 2000 WL 1364441 (internal quotation marks omitted).

Those consequences are on full display here. The FDA consistently has exercised its enforcement discretion to refrain from targeting the inevitable delays between its approval of revised brand product labeling and the distribution of new labeling by generic companies. Nonetheless, thousands of cases premised on delays in updating generic drug labeling—many, like this one, seeking not only compensatory damages but punitive damages as well—are now pending in state and federal courts across the

country.

If those cases proceed to trial, it is inevitable that juries will reach divergent conclusions. Some state-law juries may conclude that even a single day's delay in implementing updated labeling was too long; others may determine that in various circumstances even a years-long delay was entirely defensible. Scores of cases will involve circumstances in which the FDA determined that a given generic manufacturer's warnings were timely updated under the FDCA but a jury disagrees. In others, juries may issue verdicts calling for massive damage awards—including possible punitive damages—where the FDA has determined that no sanction is appropriate. Suffice it to say, allowing claims predicated on these alleged violations of the FDCA to proceed threatens to "skew" the FDA's "delicate balance of statutory objectives," 531 U.S. at 348, no less than the common-law fraud claims at issue in *Buckman* threatened to undermine the enforcement "flexibility" that Congress granted the FDA to pursue "difficult (and often competing) objectives," *id.* at 349.

There is no legal warrant for allowing a lay jury to second-guess the FDA's exercise of its enforcement discretion by independently assessing the reasonableness of Petitioners' actions—under undefined, ad hoc state-law standards no less—and imposing potentially catastrophic liability when faced with a sympathetic plaintiff. Doing so would upset the balance Congress sought to achieve by placing enforcement discretion in the FDA's hands, and the FDA's hands alone. *See Heckler v. Chaney,* 470 U.S. 821, 835 (1985) ("The [FDCA's] enforcement provisions

thus commit complete discretion to the Secretary to decide how and when they should be exercised.").

IV. THIS COURT HAS JURISDICTION OVER THIS CASE.

This case exhibits those circumstances in which the Court has "treated state-court judgments as final for jurisdictional purposes although there were further proceedings to take place in the state court." *Florida v. Thomas*, 532 U.S. 774, 777 (2001). In *Cox Broad. Corp. v. Cohn*, 420 U.S. 469 (1975), this Court explained that it will take jurisdiction over state-court judgments where reversal of the state court on the federal issue would be preclusive of further litigation and leaving the state-court judgment in place would erode federal policy:

> [T]here are those situations where the federal issue has been finally decided in the state courts with further proceedings pending in which the party seeking review here might prevail on the merits on nonfederal grounds, thus rendering unnecessary review of the federal issue by this Court, and where reversal of the state court on the federal issue would be preclusive of any further litigation on the relevant cause of action rather than merely controlling the nature and character of, or determining the admissibility of evidence in, the state proceedings still to come. In these circumstances, if a refusal immediately to review the state court decision might seriously erode federal policy, the Court has entertained and decided the federal issue, which itself has been finally determined by the state courts for

purposes of the state litigation.

Id. at 482-83. This case meets those criteria. Here, the federal preemption issue has been finally decided by the New Jersey Supreme Court. If Petitioners were to prevail in further proceedings, it would only be on nonfederal grounds because the state courts have conclusively rejected Petitioners' federal-preemption defense. If this Court were to reverse the New Jersey Supreme Court, however, it would preclude any further litigation on Respondents' claims. And leaving the New Jersey Supreme Court's ruling in place would seriously erode federal policy because it would invite state-law causes of action that conflict with federal law.

Indeed, this Court has specifically identified "the power of the state court to proceed in the face of the preemption claim" as "an issue separable from the merits and ripe for review in this Court, particularly 'when postponing review would seriously erode'" the federal policy that underlies the preemption claim. *Id*. at 483 (quoting *Local No. 438 Const. & Gen. Laborers' Union, AFL-CIO v. Curry*, 371 U.S. 542, 550 (1963)). As detailed above, the underlying federal policy is to vest exclusive enforcement discretion of the FDCA to the FDA's expert judgment. State-law tort claims premised on FDCA violations would undermine that policy. *Buckman*, 531 U.S. at 348-49.

Thus, this case resembles the circumstances of *Cox* itself. The state court's judgment "is plainly final on the federal issue and is not subject to further review in the state courts. [Petitioners] will be liable for damages if the elements of the state cause of action are proved." *Cox*, 420 U.S. at 485. Petitioners

could conceivably "prevail at trial on nonfederal grounds, it is true, but if the [New Jersey] court erroneously upheld the [tort claims], there should be no trial at all. Moreover, even if [Petitioners] prevailed at trial and made unnecessary further consideration of the constitutional question, there would remain in effect the unreviewed decision" of the New Jersey Supreme Court undermining the supremacy of federal law. *Id.*

The stark disagreement among the state and federal appellate courts on these important and recurring questions only underscores that this Court's review is needed.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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November 21, 2016

APPENDIX

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.
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> [*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.

Superior Court of New Jersey
Appellate Division

In re REGLAN LITIGATION.

Argued Oct. 15, 2014.

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Decided Nov. 12, 2014.

On appeal from Superior Court of New Jersey, Law Division, Atlantic County, Docket No. L–3865–10.

Before Judges YANNOTTI, FASCIALE and WHIPPLE.

PER CURIAM.

Appellants are the manufacturers of a generic prescription drug called metoclopramide, which is sold under the brand-name Reglan.[1] They appeal, on leave granted, from orders entered by the Law Division on June 13, 2013, which denied their motions to dismiss or for summary judgment on claims relating to the warnings of the risks arising from long-term use of the drug. We affirm.

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[1] Appellants are Actavis Elizabeth, LLC ("Actavis"); Barr Pharmaceuticals, LLC, Barr Laboratories, Inc. (collectively, "Barr"); Mutual Pharmaceutical Company, Inc. ("Mutual"), PLIVA, Inc. ("PLIVA"), Teva Pharmaceuticals USA, Inc. ("Teva"); Watson Laboratories, Inc. ("Watson"), and United Research Laboratories, Inc. ("United"). In this opinion, we refer at times to appellants collectively as the "Generic Defendants."

I.

In November 2010, plaintiffs filed a so-called "Amended Master Long Form Complaint and Jury Demand" against an array of pharmaceutical companies, alleging that they sustained personal injuries as a result of consuming Reglan and/or generic metoclopramide. Among other things, plaintiffs asserted claims of negligent misrepresentation of the risk of physical harm; defective design; failure to warn; breach of express warranties; wrongful death; negligence; fraud; fraudulent concealment; constructive fraud; negligent misrepresentation; negligent infliction of emotional distress; breach of express and implied warranties; violation of consumer protection laws; and wrongful death. They sought compensatory and punitive damages, attorneys' fees and other relief.[2]

The "Generic Defendants" thereafter filed motions pursuant to Rule 4:6–2(e), arguing that the claims against them are preempted by federal law. In support of their motions, they relied upon the Supreme Court's decision in *Pliva, Inc. v. Mensing,* 564 *U.S.* ——, 131 S. Ct. 2567, 2574, 180 L. Ed. 2d 580, 588 (2011). The trial court entered orders dated May 4, 2012, granting the motions in part, and denying the motions in part.

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[2] The long-form complaint was filed pursuant to the trial court's case management order, and it was intended to serve the administrative function of allowing the presentation of certain common claims and issues for the court's consideration.

In an accompanying opinion, the trial court noted that while plaintiffs had asserted various causes of action, their claims were essentially traditional product-liability claims for injuries caused by the manufacturers' failure to provide adequate warnings for the product. The court stated that, as in *Mensing,* the core of plaintiffs' claims is the contention that defendants failed to provide adequate warnings about the risks arising from the long-term use of metoclopramide.

The court noted that *Mensing* was premised "on the notion that as long as generic manufacturers of a product obey the 'sameness' requirement [imposed by federal law] and mimic the brand-name product's labels, then preemption applies and state tort claims cannot be brought against those manufacturers." The court also noted that additional warnings were added to the brand-name product in 2004 and 2009. The court determined the Generic Defendants had not shown that the federal law prevented them from including the additional warnings for their generic metoclopramide tablets.

The court stated that the Generic Defendants had a duty under federal law to adopt the changes to the brand-name warnings. The court wrote:

> [I]f labels belonging to generic manufacturers of tablets did not match the brand-name manufacturers of tablets, then there are [at] least some changes to their labels that federal law would allow, or even require, these defendants

> to make, and state tort law in this situation does not conflict with federal law. Consequently, . . . to the extent that generic manufacturers of metoclopramide tablets failed to update the labels to be the same as the brand-name label, they are excluded from preemption.

The court accordingly decided to dismiss all counts of the complaints against the Generic Defendants, "except for any claims that are made against a generic manufacturer of the tablet that did not change the label on [its] product to match the brand-name's label." The court also decided that the claims against the manufacturers of generic syrup products must be dismissed because these manufacturers could not change their labels since there was no brand-name manufacturer of these products.

The trial court thereafter permitted discovery concerning the dates on which the Generic Defendants implemented the label changes to incorporate the July 2004 changes to the warnings used by the brand-name manufacturers. The discovery revealed that the generic drug manufacturers, other than PLIVA, had submitted applications to the federal Food and Drug Administration (FDA), and were authorized to add the additional warnings to their metoclopramide labels on various dates.

After the completion of discovery on this issue, the Generic Defendants filed motions to dismiss or for summary judgment. They again argued that plaintiffs could not pursue state-law claims for fail-

ure to update warnings to FDA-approved generic drugs because those claims are preempted by federal law. Actavis, Teva, Mutual, and United further argued that the failure-to-update claims failed because they did, in fact, update their warnings to conform to those of the brand-name product and did so within a reasonable time.

PLIVA also argued that it did not change its warnings because it had divested itself of the product in 2008, and was not informed of the approved label change to the brand-name product until 2009, when the FDA sent out notices to all manufacturers of the drug. PLIVA further argued that any duty to update the warnings was a duty imposed by federal law, not state law.

In addition, Watson argued that it purchased the product from PLIVA in 2008, and learned about the changes to the warnings in 2009. Watson maintained that it implemented the change in its warnings in a timely manner.

The trial court denied the motions, for reasons stated on the record on May 3, 2013. The court reaffirmed its earlier ruling that claims based on the failure to update warnings to conform to changes made to the warnings and labels of the brand-name drug are not preempted by federal law. The court also determined that there were genuine issues of material fact as to whether the Generic Defendants changed their warnings in a timely manner and whether the warnings provided were adequate. The

court memorialized its decisions in orders filed on June 13, 2013.

The Generic Defendants thereafter filed motions with this court for leave to appeal pursuant to Rule 2:2–4. We denied the motions. The Generic Defendants then filed motions for leave to appeal with the Supreme Court, which granted the motions and remanded the appeals to this court for disposition.

II.

The Generic Defendants argue that: (1) state law does not provide a cause of action for failure to comply with the federal requirements pertaining to warnings for generic drugs; (2) federal law bars "private enforcement" of FDA requirements; (3) permitting plaintiffs to pursue their claims would frustrate the purposes and objectives of federal law; and (4) plaintiffs lack standing to assert their claims.[3]

In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, known as the Hatch–Waxman Amendments to the Federal Food, Drug and Cosmetics Act ("FDCA"). Pub. L. 98–417, 98 *Stat.* 1585. *See also* 21 U.S.C. § 355(j). Before

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[3] We note that, in their appeals, Generic Defendants do not raise the other arguments they raised in support of their post-discovery motions to dismiss or for summary judgment. For purposes of these appeals, these arguments are deemed to have been waived. *See* N.J. *Div. of Youth & Family Serv.. v. M.C. III,* 201 N.J. 328, 339, 990 A.2d 1097 (2010) (citing *County of Essex v. First Union Nat'l Bank,* 186 N.J. 46, 51, 891 A.2d 600 (2006)).

these amendments were enacted, all drug manufacturers, including generic manufacturers, were required to file a complete new drug application ("NDA") to receive FDA approval to manufacture and distribute the drug. *Mensing, supra,* 564 *U.S.* at ——, 131 S. Ct. at 2574, 180 L. Ed. 2d at 588.

These NDAs often involved "costly and lengthy clinical trials." *Ibid.* The Hatch–Waxman Amendments permitted manufacturers to obtain FDA approval of a generic drug by demonstrating its chemical and biological equivalence to a drug already approved. 21 U.S.C.A. § 355(j)(2)(A). This process has become known as an abbreviated new drug application ("ANDA"). *Ibid. See also Fulgenzi v. PLIVA, Inc.,* 711 F.3d 578, 581 (6th Cir. 2013).

A brand-name manufacturer seeking FDA approval of a new drug must ensure the accuracy and adequacy of the drug's warnings and label. 21 U.S.C. *A.* § 355(a), (b)(1), (d). Furthermore, a manufacturer seeking approval of a generic drug must ensure that its warning label is the same as the label for the equivalent brand-name drug. 21 U.S.C.A. § 355(j)(2)(A)(v); 21 U.S.C.A. § 355(j)(4)(G); 21 C.F.R. § 314.94(a)(8); 21 C.F.R. § 314.127(a)(7). The FDA has interpreted its regulations as imposing upon generic drug manufacturers an ongoing federal duty of "sameness," meaning that their warning labels must always be the same as those of the brand-name drug. *Mensing, supra,* 564 *U.S.* at ——, 131 S. Ct. at 2574–75, 180 L. Ed. 2d at 589.

The FDA first approved metoclopramide in 1980, and the drug was marketed under the name Reglan. *Fulgenzi, supra,* 711 F.3d at 580. Metoclopramide was designed for short-term treatment of gastro esophageal reflux disease and it was available in tablet and syrup form. *Ibid.* Five years after the FDA approved Reglan, generic manufacturers began marketing the drug. *Ibid.*

Evidence thereafter arose indicating that that long-term users of metoclopramide faced a significant risk of developing tardive dyskinesia, a severe neurological disorder. *Ibid.* The original Reglan label stated that "[t]herapy longer than 12 weeks has not been evaluated and cannot be recommended." *Ibid.*

The FDA approved the first Reglan label change in 1985, when the warnings were modified to add the statement, "tardive dyskinesia ... may develop in patients treated with metoclopramide." *Mensing, supra,* 564 *U.S.* at, 131 S. Ct. at 2572180 L. Ed. 2d at 587. The FDA approved a second label change in July 2004, which added the bold-faced statement that "[t]herapy should not exceed 12 weeks in duration." *Ibid.*

In February 2009, the FDA ordered a "black box warning," its strongest label warning, to be placed on Reglan's label. *Ibid.* This warning stated that treatment with metoclopramide could cause tardive dyskinesia, "a serious movement disorder that is often irreversible." *Ibid.* The warning also stated, "Treat-

ment with metoclopramide for longer than 12 weeks should be avoided." *Ibid.*

Mensing involved lawsuits raising state-law claims based on the alleged failure by drug manufacturers to provide adequate warnings for generic metoclopramide. *Id.* at ——, 131 S. Ct. at 2572180 L. Ed. 2d at 586. The plaintiffs in *Mensing* had been prescribed Reglan in 2001 and 2002, respectively, and both had received generic metoclopramide. *Id.* at ——, 131 S. Ct. at 2572180 L. Ed. 2d at 587. The plaintiffs developed tardive dyskinesia. *Ibid.*

They claimed that the manufacturers were liable under state law because, despite "mounting evidence" that the long-term use of metoclopramide carried a risk of tardive dyskinesia, the manufacturers failed to change their labels to adequately warn of that danger. *Ibid.* (quoting *Mensing v. Wyeth, Inc.,* 588 F.3d 603, 605 (8th Cir. 2009)). The Supreme Court held the plaintiffs' state-law claims were preempted by federal law. *Id.* at ——, 131 S. Ct. at 2577180 L. Ed. 2d at 592.

The Court stated that if, as claimed by the plaintiffs, state law required the defendants to use different and stronger warnings, there was a conflict with federal drug regulations which prevented the defendants from independently changing their generic drug-safety labels. *Id.* at ——, 131 S. Ct. at 2576, 180 L. Ed. 2d at 591. The Court held that the state-law claims were preempted because it would be impossible for the manufacturers to comply with both

state and federal requirements. *Id.* at ——, —— U.S. at – —— , 131 S. Ct. at ——180 L. Ed. 2d at 592.

The Court noted that if the manufacturers had independently changed their labels to satisfy their state-law duty, they would have violated federal law. *Id.* at ——, 131 S. Ct. at 2578, 180, L. Ed. 2d at 592. The Court emphasized that federal law "demanded that the generic drug labels be the same at all times as the corresponding brand-name drug labels." *Ibid.*

Here, the trial court correctly determined that *Mensing* did not foreclose plaintiffs from pursuing certain state-law claims based on the alleged failure to provide adequate warnings concerning generic metoclopramide. The court found that plaintiffs were precluded from claiming that the Generic Defendants should have employed "different or stronger" warnings than those approved for Reglan. However, the trial court correctly determined that plaintiffs' claims based on the Generic Defendants' failure to update their warnings to conform to changes made to the brand-name warnings are not preempted by federal law.

The court correctly found that allowing plaintiffs to assert these claims would not frustrate any of the purposes or objectives that Congress sought to achieve in the Hatch–Waxman Amendments to the FDCA. Moreover, plaintiffs are not pursuing state-law claims based on an alleged violation of federal law. They are pursuing state-law products liability claims based on the Generic Defendants' alleged

failure to provide adequate warnings concerning their products. *See* N.J.S.A. 2A:58C–1 to—11. Plaintiffs have standing to assert these claims.

The decision in *Fulgenzi v. PLIVA, Inc., supra,* 711 F.3d 578, supports our conclusion. In that case, the plaintiff asserted a state-law claim against PLIVA based on the alleged failure to adequately warn of the risks of developing tardive dyskinesia from long-term use of generic metoclopramide. *Id.* at 580. The Court of Appeals for the Sixth Circuit held that the claim was not preempted by the FDCA, to the extent the plaintiff was claiming that PLIVA's warnings were inadequate because they did not include the warnings added to the Reglan label in 2004. *Id.* at 584, 588.

The court found that the plaintiff's state-law claim was not preempted because it was not impossible for PLIVA to comply with both the state-law and federal requirements. *Id.* at 584. The court noted that allowing the plaintiff to pursue her state-law claim would not frustrate Congress' purposes and objectives. *Id.* at 586.

In addition, the court rejected the contention that, although styled as a state-law tort claim, the plaintiff was actually pursuing a federal claim to enforce a violation of the FDCA. *Id.* at 586–87. The court pointed out that 21 U.S.C.A. § 337(a) bars private actions premised on violations of the FDCA. *Id.* at 586.

The court determined, however, that the plaintiff's claim was not premised on a violation of the FDCA, but rather on an independent duty imposed by state law. *Ibid.* The court stated that the federal duty of "sameness" was not a "critical element" of the plaintiff's cause of action. *Ibid.* (citing *Buckman Co. v. Plaintiffs' Legal Comm.,* 531 *U.S.* 341, 353, 124 S. Ct. 1012, 1019–20, 148 L. Ed. 2d 854, 864 (2001)).

We note that the Court of Appeals for the Fifth Circuit in *Morris v. PLIVA, Inc.,* 713 F.3d 774, 775 (5th Cir. 2013), affirmed the dismissal of claims against PLIVA for failing to update its warnings to comply with a FDA-approved label change for brand-name metoclopramide. The court stated that the plaintiff had alleged that the warnings that predated 2009 were not adequate. *Id.* at 777.

The court found, however, that there could be no tort liability for "failure to attach an inadequate label." *Ibid.* The court also said that the alleged failure to comply with a federal labeling obligation "sounds exclusively in federal (not state) law and is preempted." *Id.* at 777 (citing 21 U.S.C.A. § 337(a); *Buckman, supra,* 531 *U.S.* at 349 n. 4, 124 S. Ct. at 1018 n.4, 148 L. Ed. 2d at 854 n.4).

We note that other courts have also determined that claims of the sort asserted here against the Generic Defendants are not preempted by federal law. *See, e.g., Huck v. Wyeth,* 850 N.W.2d 353 (Iowa 2014); *Hassett v. Dafoe,* 74 A.3d 202 (Pa. Super. Ct. 2013), *appeal denied,* —— A.3d ——— (2014). Some

courts have followed the Fifth Circuit's reasoning in *Morris*. *See, e.g., Guarino v. Wyeth, LLC,* 719 F.3d 1245 (11th Cir. 2013); *Dietrich v. Actavis, Inc.,* 138 So.3d 1163 (Fla. Dist. Ct. App. 2014).

We are convinced, however, that the reasoning in *Fulgenzi* is more persuasive than that in *Morris*. We therefore conclude that the trial court correctly determined that plaintiff's failure-to-warn claims are not pre-empted.

III.

The Generic Defendants further argue that the decision of our Supreme Court in *Cornett v. Johnson & Johnson,* 211 N.J. 362 (2012), supports dismissal of the failure-to-warn claims against them. In *Cornett,* the decedent's estate and widow asserted various claims arising from the decedent's use of a drug-eluting stent, which allegedly caused his death. *Id.* at 368. The stent was the subject of a "rigorous premarket approval (PMA) process" of the FDA pursuant to Medical Device Amendments to the FDCA. *Id.* at 368, 370 (citations omitted).

The PMA incorporated a finding that the "device is safe and effective, under the conditions of use included on the label and that the label is not false or misleading." *Id.* at 381 (citation omitted). The manufacturer was not permitted to change the label without FDA approval. *Ibid.* (citations omitted).

In addition, under the FDCA, off-label uses of the devices are not illegal per se, and the FDA is pre-

cluded from limiting or interfering with a health care practitioner's prescribing or administration of a "legally marketed device ... within a legitimate health care practitioner-patient relationship." *Id.* at 382 (quoting 21 U.S.C.A. § 396). Congress also provided a "safe harbor" for health-care manufacturers who disseminate certain materials pertaining to the safety, effectiveness and benefits of a use not described in the approved labeling. *Ibid.* (citing 21 U.S.C.A. §§ 360aaa, 306aaa–1).

Among other determinations, the Court in *Cornett* held that the plaintiffs' claim based on the alleged failure to provide adequate warnings regarding the approved use of the product was preempted by federal law because it was "nothing more than a challenge to the adequacy of the information required by the FDA during the PMA process and label approved by the agency." *Id.* at 389. The Court noted that the plaintiffs' failure-to-warn claim was based solely on the contention that the defendants obtained FDA approval of the device by submitting fraudulent representations or withholding material information. *Ibid.* The Court stated that allowing such a claim to proceed would "directly interfere" with the FDA's exclusive authority to enforce the FDCA. *Ibid.* (citing 21 U.S.C.A. § 337(a)).

The Court concluded, however, that the plaintiffs' failure-to-warn claim would not be preempted if it "is based on other allegations of wrong-doing apart from defendants' failure to comply with FDA disclosure

requirements[.]" *Id.* at 390. The Court noted that the plaintiffs were alleging that the defendants had withheld information from the general public and the medical community about the limitations of the device, which were not part of the PMA process. *Ibid.* The Court stated, "Such a claim falls within a traditional area of state concern and regulation because fraud on the FDA is not an element of the claim and it can be proved by evidence other than by evidence of fraud on the FDA." *Ibid.*

We are convinced that *Cornett* does not compel dismissal of plaintiffs' failure-to-warn claims in this case. The claims at issue here do not involve a challenge to the adequacy of information provided to the FDA or the label changes that federal agency approved in 2004 or 2009. In addition, the claims do not involve any allegation of fraud on the FDA. They are grounded in state law and are not based solely upon a federal violation. As in *Cornett,* plaintiffs' claims fall "within a traditional area of state concern and regulation." *Ibid.*

Affirmed.

Superior Court of New Jersey
Law Division, Civil Part
Atlantic County

In re REGLAN LITIGATION.

Applicable to all Cases

Case No. 289

Master Docket No. ATL-L-3865-10

June 13, 2013

ORDER

Carol E. Higbee, P.J. Cv.

THIS MATTER having having been opened to the Court on February 7, 2013 upon Motion by counsel for Defendant Teva Pharmaceuticals USA, Inc. for an Order pursuant to R. 4:46-1 dismissing Plaintiffs' Second Amended Master Long Form Complaint as against Teva Pharmaceuticals USA, Inc., and the Court having reviewed and considered the pleadings, briefing, and submissions of the parties, and having heard the arguments on May 3, 2013;

IT IS on this 13th day of June, 2013, hereby

ORDERED that Teva Pharmaceuticals USA, Inc.'s Motion for Summary Judgment is **DENIED** without prejudice to renewal in individual cases for the reasons stated by the Court on the record on May 3, 2013.

Superior Court of New Jersey
Law Division, Civil Part
Atlantic County

In re REGLAN LITIGATION.

Case No. 289

Master Docket No. ATL-L-3865-10

June 13, 2013

ORDER

Carol E. Higbee, P.J. Cv.

THIS MATTER having having been opened to the Court on February 6, 2013, upon Motion by counsel for Defendants PLIVA, Inc., Barr Pharmaceuticals, LLC, and Barr Laboratories, Inc., for an Order pursuant to R. 4:6-2 dismissing Plaintiffs' Second Amended Master Long Form Complaint, and the Court having reviewed and considered the pleadings, briefing, and submissions of the parties, and having heard the arguments of counsel on May 3, 2013;

IT IS on this 13th day of June, 2013, hereby

ORDERED that Defendants PLIVA, Inc. Barr Pharmaceuticals, LLC, and Barr Laboratories, Inc. is **DENIED** for the reasons stated by the Court on the record on May 3, 2013.

Superior Court of New Jersey
Law Division, Civil Part
Atlantic County

In re REGLAN LITIGATION.

Case No. 289

Master Docket No. ATL-L-3865-10

June 13, 2013

ORDER

Carol E. Higbee, P.J. Cv.

THIS MATTER having having been opened to the Court on February 7, 2013, upon Motion by counsel for Defendant Watson Laboratories, Inc. for an Order pursuant to R. 4:46-1 dismissing Plaintiffs' Second Amended Master Long Form Complaint as against Watson Laboratories, Inc., and the Court having reviewed and considered the pleadings, briefing, and submissions of the parties, and having heard the arguments of counsel on May 3, 2013;

IT IS on this 13th day of June, 2013, hereby

ORDERED that Watson Laboratories, Inc.'s Motion for Summary Judgment is **DENIED** without prejudice to renew in individual cases for the reasons stated by the Court on the record on May 3, 2013.

Superior Court of New Jersey
Law Division, Civil Part
Atlantic County

In re REGLAN LITIGATION.

Case No. 289

[Excerpted] Transcript of Hearing
on Motion and Management Conference
May 3, 2013

BEFORE: The Honorable Carol E. Higbee, P.J. Cv.

[Page 88:23 of Transcript]

(Court in recess. Court in session.)

THE COURT: Okay. I've gotten some additional materials that I've looked at. I really think as far as applications that have been before me, certainly I could be wrong, but this doesn't seem to me to be all that difficult an issue. I think we have to look at the history. The argument of the defense is basically preemption, and that Mensing and federal preemption prevents the plaintiffs from pursuing the generic manufacturers for injuries at really at any time frame no matter what their warning was.

The history of - I'm not old enough that I know the whole history of pharmaceutical litigation, that's for sure. And I'm sure all these people - most of you in the room are more familiar, as many of you spent more time with it than I have and you - but for the

last few years I've been spending most of my time on it, and I have basically looked back through the history. Products liability law, strict liability, I mean, we're only talking a few decades. Negligence has been around forever. But the bottom line is all states for several decades have had some type of product liability actions and have allowed an injured person to sue the manufacturer for inadequate warnings where there's a danger to their product and that product could cause a person injury, basic law, common law, and then subsequently statutes in many states have held that there is a responsibility on the part of that manufacturer to the public, to the consumer, to the person who takes the drug, and they have to provide warnings.

Now, in pharmaceutical litigation that history has gone through some modifications and changes and conditions. And that's because obviously pharmaceuticals are, number one, heavily regulated by the federal government and by the FDA and manufacturers had, you know, strict requirements over the last few decades, and because the prescriptions are written by physicians who are learned intermediaries and most states, although not all, have - require that the viewing of whether a warning is adequate is focused on what's adequate to a physician. So pharmaceutical litigation has not - and drug manufacturers have had a course of case law and statutes and state tort law that's gone along with other product liability law, but it's also had its own niche. And New Jersey and other states - you know, I'm most familiar with New Jersey law, so we go back to Feldman, we go back to other cases that have

held that regardless of the fact that someone complies with the FDA requirements, you can still can be held responsible under tort theories, state tort theories of liability for failure to adequately warn about dangers of a product.

As it appears and as time went on, one of the strongest arguments, and I don't mean strong that it was a good argument, but one of the most aggressively pursued arguments by drug manufacturers was this is preempted by federal law. And understandably, I guess, their argument was, our clients have to - they have to cross their I's, dot their T's, they have to do this, this, this, and this that the federal government requires, that the statutes require, that the regulations require, the FDA is on top of us; we shouldn't, then, be held responsible for injury to people if we've got a warning that was approved by the FDA, and the whole preemption argument became a dominant argument mostly rejected because every state pretty much has allowed continuation of product liability and injured people to recover against pharmaceutical companies.

And at the present ti - even if they comply with FDA - even if they had FDA approval, and I think at the present time the only state that doesn't do that is Michigan which basically has passed a statute that says or has basically has taken the legal position - I can't remember now if it's statute or if it's-

ATTORNEY: A statute.

THE COURT: - it's a statute that says, you know, if it's FDA approved, you can't sue. And so I routinely dismiss Michigan plaintiffs in all the litigation I've

had in front of me because I have to apply the law of the state and frequently that's the law where the plaintiff resides, and if they're Michigan residents - I signed orders the other week dismissing on 20 Michigan cases.

But in every other state that didn't happen. And despite the aggressive argument by the defendants and the constantly repeated argument that this is preempted, that the, you know, we complied with the FDA, we did what we were supposed to do, we can't be responsible, the federal government controls us. And there's cases all over the place on different points on different cases.

But generally speaking, every state still held drug manufacturers responsible for any inadequate warning under different theories. Some are negligent, some are strict liability, some are statute, some are common law, but they all pretty much allowed these issues to go to jury, and that included the federal interpretations of the state law, as well as the state law.

The Buckman case came along, and the Buckman case has been somewhat of a - it certainly added fuel to the fire, and it certainly reinforced the defense position that, hey, you know, you can't sue for fraud on the FDA, you can't sue for misleading the FDA, and therefore - and the FDA approved everything and if we didn't mislead them and they approved it, then, you know, these cases should all be preempted. And Buckman, of course, we all know, was a very a unique fact situation.

Buckman was not a case of an injured person suing a manufacturer at all. It was a case where there was a drug devi - a device, I believe, not a –

ATTORNEY: Device.

THE COURT: - so there was a device, so there's special exemptions for devices, first of all. But second, and more importantly, it was a case where the person had submi - the manufacturer had submitted the device and said it was an exact copy of another or a similar product, and therefore, they - you know, they - first they submitted it and tried to get approval under the - it's a similar product. Or first I think they tried to get study approval, they couldn't get it. Then they applied - then they said, we're going to apply for approval under - they hired an outside company, who's basically a lobbyist or a consulting firm of some sort - I don't know if it was an engineering company or a consulting firm, but it was a separate company - which then rewrote their applications to the FDA and now said this is the equivalent of another device and the FDA said okay.

They then, according to the plaintiff in that case said, you know, they're not using it for what they said they were going to use it for, it's not the same product they said it was going to be, it's a fraud and my client was injured. The manufacturer, I think, was bankrupt. So looking for a deep pocket or any pocket, I guess, and I'm not sure if they were bankrupt, but there was a reason, some reason why they –

ATTORNEY: They - they had settled. I'm not sure –

THE COURT: Did they se - okay.

ATTORNEY: But- but maybe because they were bankrupt, so they settled the case.

THE COURT: Well, whatever it was, the claim - I thought I had read somewhere that the manufacturer didn't have the money to pay for the claim. But at any rate, as a result of that they sued in the way that plaintiffs' lawyers have of creating new causes of action, some of which are admirable and some of which create a lot more problems for them and their clients than - you know, bad facts make bad law, and sometimes - whatever. So that particular case they actually sued this defendant for fraud on the FDA and said, you know, you, when you submitted this application, you consulting company, you created a fraud on the FDA, and we're going to sue you for that. And as a result of that our client was injured.

And the Supreme Court unanimously said no. I think it was unanimous. They said, short opinion, they said, no, we're not going to let you sue for fraud on the FDA when the FDA didn't find it was a fraud, and if we start getting into this where you're suing for enforcing the federal law and you're suing for fraud, we're not going to let you do that, and it's preempted. And if you read Buckman, not just quickly, but maybe the first ten times, and until you look at the history 17 of it, you sort of think it means - it reads like, oh, well, if the FDA is controlling it, everything is preempted, but the courts didn't find that to be the case.

And I have to say that I've gone back and I've taught a couple courses on preemption, nothing long,

nothing - I haven't been asked to teach at Yale yet - I've basically just given some, you know, short two-hour presentations. But if you preemption cases, I sort of devised a game called, "Are you smart enough to be on the Supreme Court?" And then I would ask my audience to vote, and I would give them the Silkwood analysis and the safety belt analysis and say, which way would you vote, because those two particular ones really stretch the - because they found the nuclear regulatory did not preempt, and they found that the safety belt standard that you had to have safety belts by such a date did preempt, which really is a difficult thing to reconcile, I think.

But - and then, of course, at the end I tell everybody, you know, it doesn't matter which way you voted, you're still smart enough to be on the Supreme Court because it four-five and four-five and five-four. So, whichever way you voted you had half the Supreme Court about agreeing with you, so you were right. You know what I -you were just as smart as they were.

So and that's what these preemption cases are. They're always for - they're always close. They're always nasty. I mean, if you want to read people insulting each other, read the preemption cases over the years. They're just incredible. They get rude, they get na - apparently preemption is a really hot issue. I never even - you know, it wasn't anything in my legal career, my 17 years of practice, for the first 10 or 15 years of, you know, being a judge. So I thought it was like a non-issue.

And then when I was walking around telling my colleagues, wait till this Wyeth case comes down,

this is so important, and they're going, what? What's it about? And I said, it's about preemption under - yeah, right. That's real important, you know. They'd walk away from me very quickly because it wasn't important to them. You know, it was- it's only important to people involved in pharmaceutical litigation.

But at any rate, Buckman came down and Buckman, I think, has been misinterpreted sometimes, misconstrued, misused, and - but no - but - and some people have held that it's preemptive, think it's the basis for preemption. But the fact of the matter is, that's not the way the U.S. Supreme Court looks at it and that's not the way most courts have looked at it. And if, in fact, what some people interpret Buckman to mean is what it meant, then there would be no more pharmaceutical litigation because you couldn't do a fraud on the FDA, then you couldn't - you know, you can't mislead the FDA, and if you can't mislead the FDA and you can't, you know, not tell them everything, and if that's not - you know, it becomes such a nitpicking ridiculous thing. And as I said, there's only one state that has really said you can't sue pharmaceutical companies.

So after Buckman we did come down to Wyeth. And before then, it was - preemption arguments were made based on a couple things, but the brands were arguing, that you - they couldn't really use the CBE because of the FDA requirements and the way they were written and they couldn't change their label without FDA approval, and if they did so they risked being misbranded, and they couldn't do it for this reason, and they couldn't do it for that reason,

and it didn't fall under the right definition, and they argued they couldn't send out letters because if they sent out a letter, it would differ from what the label said, which was true. And on that basis, there were a lot of rulings that you can't require somebody to send out a letter that says something different than a label because the FDA says you can't do that.

But in the end, these cases continued because the courts recognized that either their own state statutes, their own state common law, their own state body of law and, in fact, tort law is state law, it's rarely, if ever, a federal law. I mean, it is those few statutes, but generally, state law is tort law, policing the safety of the citizens, you know, from manufacturers, that's state law. So the battle continued.

And then the Wyeth case came down and the U.S. Supreme Court, and again, anybody in the room could be as smart as the court was or at least as smart as some of the judges were because it was split, but the final decision of the U.S. Supreme Court was you can't - the FDA and the fact that they strongly regulate pharmaceutical companies, strongly regulate drug manufacturers, approve all labels, that does not mean that a plaintiff can't sue for injury and recover. And the fact that a jury finds that a warning wasn't adequate, even though the FDA had approved it, is not contrary to federal law.

It's not preempted by federal law because there's a provision in the FDA's requirements that allows for CBE changes being effected, it allows you to change your label when you need to because - and there's a lot of law where the FDA- and a lot of case law and a lot of briefs where the FDA has been say-

ing for years we rely on manufacturers, we can't do this ourselves, we don't have enough people, we don't have enough time. We need to let the manufacturers - if they find out there's a problem with their drug, they have to change the label. They have to warn the public. They have to follow. And the state tort - court rulings and jury findings assist us in that. They don't contradict the federal law. They assist us in doing - protecting the public.

And in Wyeth, that was the issue and the U.S. Supreme Court said absolutely not preempted, at least five of them did, and in fact, you can sue drug manufacturers even if the label is approved and the jury can find that it's not adequate warning and that's perfectly okay. And it's not preempted and they, I think very strongly, emphasized that this is a good thing for the public, it's important for the safety of the public, it's traditional tort law that's been preserved to the states forever, and there is no reason why there is a preemption because drug manufacturers are allowed under FDA regulations to protect the public. They are allowed to change the label, they are allowed to warn, and they should and they have a duty to do that.

We won't get into the fact that the FDA at that point in that - their briefs in that case were arguing on the side of the defense. The Supreme Court said no way. You know, you may say that they're not - that you're not preempting them, but we - you may say that your law preempts them, but we don't feel that way, and that was the decision.

Then comes Mensing. Now, Mensing, of course, is the generics and they come in with a different argu-

ment, again, preemption. And their argument is, well, okay, so the brand names can change their label, they can defend the - they can - they have a responsibility but we can't change our label. We can't. We're not allowed to. We are - have been created by the - by the specific act which was required to make us have the same component products, they've advertised, we're stuck. We're stuck with what we've got and we have benefits from this and disadvantages. One of the benefits is we don't do research, we don't have to create a drug, we just basically copy what the brand manufacturer did when their patent expires, and we can take it and use it. And under the law you're allowed to use it because, you know, it allows for cheaper drugs to be sold. And there is a strong argument that the public has to believe that the generic drug and the brand name drug are the same because at first, of course, there was resistance to that, and I think today, you know, most people, I imagine the majority of people - I don't even know - it's not part of my decision, doesn't matter whether people believe it or not, but I think that certainly the intent of the government that people believe that they're the same, so that you can - hospitals and doctors and patients can have cheaper medications that are the equivalent.

And if you're going to put out the exact same drug, then the FDA says you got to have the exact same warnings, you got have the exact same label. And since you've got to have the exact same label they didn't have the benefit of CBE. They didn't - couldn't go in and change. And the Supreme Court, again very divided, said but ultimately found that

generics – it's impossible for the generics to change their label. They cannot do this. They cannot do what the juries told they should do which is do an adequate warning because even if they want to do an adequate warning - and then, you know, we don't have to get into all the arguments, I'm not going to get into either side, but there were plenty of arguments presented that they should be able to, they could have gone to the FDA, they could have done this, and the Supreme Court basically said no, they're not allowed to change and we're not going to require them to defend the fact that they didn't change when they're not allowed to change. Okay. So there - now we're here.

And the Supreme Court in that case, both the majority and the minority, recognized that this presented a very strange result and a very somewhat unhappy result in the sense that generics were protected but the brands weren't. The patient frequently didn't even know whether they got the generic or the brand, and so the same person taking the same drug could sue the manufacturer if they happened to be given the drug that was the brand namer but they couldn't sue the manufacturer if it was the generic, and both sides recognized that was a problem. But even though it was a problem they just, you know, the majority of the Court felt that it was necessary, that this is - they couldn't resolve that issue. They simply had to say this is the way it is.

And there was a motion before me last year to say that there were all kinds of exceptions to that and that the generics, you know, should be held responsible for not sending out Dear Doctor letters or

should not be responsible for some other kind of communication, should not be responsible for doing a lot of different points. And there's a laundry list that the plaintiffs have established of what they think the generics should have been doing and could have done without preempting but I didn't - I rejected those. I don't think they fit with Mensing. It's not a question of whether I agree with Mensing or not, it's a question of what it says, and what it says is they didn't have an obligation. And, in fact, they couldn't warn because they couldn't send out Dear Doctor letters that conflicted with their label, with the label, the approved label by the FDA. They couldn't do anything without being in violation of the federal law, and therefore, they were held responsible - and - or they were not held responsible, and that is something that I have enforced up to now and continue to enforce and I've already written my decision on that.

What I noted in that decision and which has resulted in these motions is that while they can't change their label from what the FDA approves, they are required to use the FDA-approved label, and they have a duty under state tort law to warn and that's the same duty that all manufacturers have had except that theirs was preempted, so I agree with plaintiff's counsel when he said that on the day before the label change the generics had a duty under state law. They had a responsibility to give an adequate warning. They were not allowed to give the warning because they couldn't change their label until the brands did. But that doesn't prevent the fact that there was a duty, and it was a basic duty in almost every - in every state, under either neg-

ligence or misrepresentation or failure to warn or whatever, strict liability, but there was a - there were theories in every state which would create a duty between the manufacturer of a drug who sells 6 that drug and somebody who gets injured from it.

So now the generics - and I said that I believed, and I still believe and I still find that there is no preemption from providing the - there is no protection from not providing what they were legally allowed to provide. And if by failing to provide what they were legally allowed to provide, they failed to adequately warn, which is a decision a jury makes, then - or probably a decision - I don't know - you could look at it as summary judgment the other way, but I'm not going there right now. The bottom line is if that - once they could legally make a - put in a stronger warning and they don't do it, then a jury could find that they had violated their duty to provide an adequate warning.

Now in the - the argument then was from the generics was, well - and the plaintiffs had argued, I guess, first, well, you know, someone didn't - believe they didn't ever change their warning. So for four years - and I don't think it's an emotional argument, it's a compelling legal argument - for four years they didn't put in the warning that the FDA approved, that the FDA required the brand manufacturers to put in. They did less than the brand manufacturers did. They did less than they were required to do, and they still want to claim that they have preemption for that, that somehow federal law protects them because they weren't allowed to change when they were allowed to change. They not only were allowed

to change, they were required to change. It - to me it's just a no-brainer that that's not what the Supreme Court held. They were holding that if you can't change, okay, you're not responsible. And I will dismiss, if I haven't already, any case up until the label change, whether it's a PLIVA case or a Teva case or a, you know, up until that label change you had no right to change the label and Mensing protects you. So those cases as to the generics are dismissed.

The question is what about after the label change. And the - I think that defense counsel is correct. The focus - it's not for me to decide that you had to change within six months or you had to change within one year or you had to change within ninety days or you had to change within one day. The FDA and the statute, there was no - there is not a standard set forth by them. It doesn't say you have to change your label within forty-five days or you have to change your label within ninety days, there's no specific requirement. But the mere fact that the FDA didn't pull you in and tell you to pull your product off the market, that goes back to the old argument pre-Wyeth that, you know, the FDA approves us. The FDA never did anything here. The FDA doesn't even approve you, but the FDA doesn't stop you or doesn't say, you know, you can't sell the product anymore, you haven't changed your label. Wyeth really definitely said that's not a preemption. I mean, and many, many other cases have said that.

So the bottom line is I don't think it is something that I can do and I'm not going to do and say arbitrarily, if you changed your label within 90 days that

was soon enough, if you change your label within a year that was too long, and I don't think that's where the focus of a trial would be, although it could be presented, I guess, as a defense that we did a reasonable, adequate warning based on what we were allowed to do and what we did do within a time frame, and what exactly the jury will be told about that? In every case we've had there's been some instructions to the jury about the FDA's role and what they could and couldn't do, and reading them regulations or statutes in every case we've tried and they'll be that in these cases, and it will be based on probab - somewhat sensitive to the facts of the case.

So for those people who - to me, the simple part is pre-label change, the cases are dismissed; post-label change where you did not change your label, those cases go to - the summary judgment can't be granted. And I note that even in the ones that we got, under the facts in these cases, there's one where they changed the - there's a - in every case, obviously, they changed the label substantially before the FDA approved, so it's obvious on its face that the CBE was available, you could change it whenever you wanted. You didn't have to have FDA approval. Everybody got the FDA approval substantially after they made the change.

The - and, in fact, in at least one case the CBE application wasn't filed until after the change, and in another case the applications - CBE was filed and then the change was made or at least one they ordered the labels before they filed the CBE. They might have filed it simultaneously –

This is a window of cases because once you've - once your labels on the street changed, then you've done all you can do again as a generic and you're entitled to protections again. They can't say you should have had a better label than that last label because - so the plaintiffs are not going to be able to argue that you should have had a stronger label than what the label was that was approved by the FDA. That's not going to be allowed. And if you did change your label and that was the label that was on the product, then there's no question that those cases are going to be dismissed. So the generics have protection under Mensing up to the date of the label change and post whenever a person buys a drug with a new label on it. That's for sure.

In between is probably going to be fact sensitive and may turn out to be, I think, probably a question for a jury as to whether there was an adequate warning based on what they could and couldn't do, which, as far as I'm concerned, they could change as of that day. Now, can they practically change it that day? Let's wait and see. But I don't think we're going to have a whole lot of cases that occur within one week of the label change or the - maybe we do, but –

ATTORNEY: Three months use.

THE COURT: Huh?

ATTORNEY: I think three months minimum use. I don't think that –

THE COURT: Yeah. I mean, I don't think there's going to be cases where that's even a factor. When you could create a hypothetical situation where you could say, okay, the next day we couldn't do any-

thing. But I'm not - and if you get that case, then bring me a motion for summary judgment and I'll look at it. But to suggest that, you know, that's going to be a major factor in these cases, and it's plaintiff that has to prove, not the defendants. The defendants can't prove who had what label. And generally, a lot of times the plaintiffs in different cases themselves didn't read the label or there's not any sure - if both - if the old label is on the market and the new label is on the market, it's going to be up to plaintiffs to prove that it was inadequate label, so they're going to have to prove that it was the old label that was either purchased or used or - you know, and in some cases they're not going to be able to do that.

So the motion for summary judgment as to all the generics is granted as to pre-, and granted in any case where you can show me that the label change was in effect and, you know, if you can could show that by a certain year your other products were not there or so remote then, you know, those are not going to be very strong cases. We'll have to - you know, but the in- between period, certainly for PLIVA who never changed, I believe that it never changed, for them there is no issue. Anything after that becomes a question of whether they acted - and I think the exact standard is going to be a little different in each case. Some of them it's going to be negligence, were they negligent in failing to change the label. It seems to fit really nicely.

Since I was old enough to practice pre-strict liability, pretty much I was trained in negligence and, you know, so negligence fits, but some states don't have negligence. Some states have products liability

to specific acts. As counsel said, some - most of them talk about what a reasonable manufacturer would do. Even though they're "strict liability," it's still - it's strict liability in the sense that it's as of the date the label is, you know, sent out and manufactured and the product and then it's bought, but - and then whether it's adequate or not is the question.

But reasonableness is usually a jury question and that's probably going to be an element of each question. And there may be a particular question or state where there's some particular thing that might - you know, but we have to deal with that on a case-by-case basis; I'm not going to dismiss cases. And I agree with defense counsel that it's not for me to decide and I'm not going to decide the FDA - as far as the FDA is concerned you had to change your label immediately. That's what the law says. You have to have same label as the brand. Now, does "immediately" mean - what are we going to say about the procedure, the time, the -you know, how it can and can't be done.

And one thing you can tell - I mean, if you want to go to hypotheticals, you go to a hypothetical where, you know, the brand name has to change because all of a sudden they discovered that, you know, if you drink water with a drug it's going to - then you're going to drop dead immediately and the generics are going to take, you know, five years to put that in their label. I mean, this is - there also was some argument that, you know, this wasn't that big a change from the prior label. That goes to adequacy of the label. That's got nothing to do with- but how it's going to play out, if the FDA now had required

you to do a label change that you didn't do, it's something we're going to have to deal with when we get to the trials in these cases, and in preliminary motions as to what can be said and what can't be said and what the jury will be told. And I'm not ruling on all those at this point and we don't have a complete record which we can rule on those. But I think for the basic overall generic motions - and by generic, I mean, motions covering all cases which belong to certain categories, that's my ruling . . . .

Superior Court of New Jersey
Atlantic County

In re REGLAN LITIGATION.

No. 289

May 4, 2012

Memorandum of Decision on Motion Pursuant to Rule 1:6-2(f)

Carol E. Higbee, P.J. Cv.

MOTION: Motion of All Generic Defendants to Dismiss Plaintiffs' Second Amended Master Long Form Complaint

DATE: May 4, 2012

Having carefully reviewed the papers submitted and any response received, I have Ruled on the above Motion as follows:

THIS MATTER comes before the court on generic defendants' collective Motion to dismiss. Plaintiffs filed a timely opposition to the motion, and generic defendants filed a reply. Generic defendants' Motion seeking dismissal of all claims is based on federal preemption and the Supremacy Clause of the United States Constitution pursuant to the United States

Supreme Court's recent decision in *Pliva v. Mensing,* 131 S. Ct. 2567, 180 L. Ed. 2d 580 (2011).

BACKGROUND

This pharmaceutical products liability action arises out of injuries allegedly caused by an anti-emetic prescription drug, metoclopramide, which is commonly used to treat digestive tract problems and is sold under the brand name Reglan. Plaintiffs filed suit against a variety of pharmaceutical entities--brand-name and generic manufacturers--alleged to have designed, manufactured, marketed, or sold metoclopramide. Plaintiffs allege they suffer from, among other things, tardive dyskinesia, a neurological disorder that causes involuntary repetitive movements.

- FDA Regulatory Scheme

All prescription drugs must be approved by the Food and Drug Administration ("FDA") before a company may market or sell them. Brand-name manufacturers must submit a New Drug Application ("NDA") to the FDA that contains extensive information regarding the safety of the drug based on clinical trials that the manufacturer has conducted. 21 U.S.C. §§ 355(a)-(b), (d); *see also* 21 C.F.R. § 201.56. Upon approval of the application, the brand-name manufacturer has the exclusive right to market the drug for a certain period of time, after which other manufacturers may market generic versions of the drug. To gain approval and entry in the market,

generic manufacturers may submit an Abbreviated New Drug Application ("ANDA") to the FDA. The ANDA process removes the need for generic manufacturers to independently conduct clinical trials already completed by brand-name manufacturers as long as the generic drug is essentially the same as the brand-name drug and the generic drug's label is identical in relevant part to the brand-name drug's label. 21 C.F.R. § 314.94(a)(8). The ANDA process was created through the passage of the Drug Price Competition and Patent Term Restoration Act in 1984, a statute that sought to allow the entry of affordable generic drugs into the market. This Act amended the Food, Drug, and Cosmetic Act ("FDCA"), and is known as the "Hatch-Waxman Amendments" to the FDCA. Under Hatch-Waxman, a generic drug manufacturer may produce a drug by showing bioequivalence to a reference-listed drug ("RLD") that is approved by the FDA. 21 U.S.C. §§ 355(j)(2)(A)(i)-(v). The FDA relies upon the brand-name manufacturer's studies to validate the generic product's safety and efficacy. *Mova Pharm. Corp. v. Shalala,* 140 F. 3d 1060, 1063 (D.C. Cir. 1998).

In terms of altering the label of a drug, there are two main ways that a label may be revised. "Major Changes" may be implemented through a prior approval supplement, where the FDA must approve the change that a manufacturer recommends before the change can be implemented. 21 C.F.R. § 314.70(b). "Moderate Changes" may be made through a Changes Being Effected ("CBE") process,

which does not require pre-approval by the FDA. 21 *C.R.* §§ 314.70(c)(6)(iii)(A)-(D). The CBE process allows brand-name drug manufacturers to unilaterally "add or strengthen a contraindication, warning, [or] precaution," or "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)(2006) *see also Wyeth v. Levine* 555 U.S. 555, 568, 129 S. Ct. 1187, 1196, 173 L. Ed. 2d 51, 62 (2009). According to the FDA and as held in *Mensing,* a generic manufacturer may only use the CBE process to "match an updated brand-name label or to follow the FDA's instructions." *Mensing, supra,* 131 S. Ct. at 2575.

- History of Reglan

The FDA first approved metoclopramide in 1980 to treat conditions such as such as acid reflux disease and diabetic gastro paresis. In 1985, generic drug manufacturers began producing metoclopramide. At different times, Wyeth LLC, Schwarz Pharma, Inc., and Alaven Pharmaceutical LLC manufactured and distributed "Reglan," the brand-name form of the drug. From 1989 to 2001, Wyeth manufactured and distributed Reglan in three different forms: tablet, syrup (oral solution), and injectable. Starting in the early 2000s, Wyeth began selling its rights to Reglan to different pharmaceutical companies. Each form of the drug, except the syrup, was sold separately to a different company. In December 2001, Schwarz acquired from Wyeth the

rights to Reglan's brand-name tablets. Since then, Wyeth has neither sold nor distributed any Reglan tablets. Schwarz manufactured and distributed the drug tablets until 2008. Subsequently, in 2008, Alaven acquired the rights to the Reglan tablets, and began manufacturing the drug until 2011. With regards to the injectable form of the drug, Wyeth sold its rights to Reglan injectable to Baxter, Inc., making it the subsequent NDA holder for Reglan injectable. The injectable form of Reglan is excluded from this motion. With regards to the syrup, Wyeth never sold its rights for Reglan syrup after it left the market in 2001-02. Following Wyeth's request, the FDA withdrew approval of the company's NDA for Reglan syrup in October 2002. FDA Notice, Withdrawal of Approval of 16 New Drug Applications and 30 Abbreviated New Drug Applications, 67 Fed. Reg. 63107, 63107 (Oct. 10, 2002). As a result, the metoclopramide syrup was manufactured and distributed by generic companies that received approval under the ANDA process, without a syrup NDA holder present in the market. FDA Notice, Determination That DECADRON Tablets and Nine Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness, 74 Fed. Reg. 22751, 22752 (May 14, 2009).

- Reglan's Label

The warning label for the drug has been amended several times over the years. In 1985, the label accompanying the drug warned that "tardive dyskine-

sia ... 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." In July 2004, the NDA holder of Reglan tablets, Schwarz Pharma, added an FDA-approved label which stated that "[t]herapy should not exceed 12 weeks in duration." *Mensing, supra,* 131 S. Ct. at 2572. This 2004 revision was a change that some generic manufacturers of the tablet did not incorporate into their post-2004 metoclopramide package-inserts. Brand-name Reglan injectables and syrup did not adopt this change, and as a result, neither did the generic manufacturers of metoclopramide injectables and syrup. Later, in 2009, the FDA added a "black box warning" to all forms of the Reglan/metoclopramide drug, which stated that "[t]reatment 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,* 131 S. Ct. at 2573 (citing PHYSICIAN'S DESK REFERENCE 2902 (65th ed. 2011)).

DISCUSSION

I. Legal Standard for a Motion to Dismiss

Pursuant to Rule 4:6-2(e), a defendant may move to strike all or part of a complaint for "failure to state a claim upon which relief can be granted." Such a motion entails scrutiny of the complaint to determine whether any viable cause of actions exists.

"[T]he test for determining the adequacy of a pleading [is] whether a cause of action is 'suggested' by the fact .... At this preliminary stage of the litigation the Court is not concerned with the ability of plaintiffs to prove the allegation contained in the complaint." *Printing Mart-Morristown v. Sharp Electronics Corp.,* 116 N.J. 739, 746 (1989) (quoting *Velantzas v. Colgate-Palmolive Co.,* 109 N.J. 189, 192 (1988)).

II. Preemption

Arguments in this case turn on preemption. The Supremacy clause of the United States Constitution provides that federal law "shall be the supreme Law of the Land ... any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. In *Mensing,* the plaintiffs alleged that their long-term use of generic metoclopramide resulted in tardive dyskinesia and sought remedies under state tort law against the generic manufacturers. It was undisputed that if the plaintiffs' allegations were true, then state tort law "required the manufacturers [of the generic drug] to use a different, safer label." *Mensing, supra,* 131 S. Ct. at 2574. Nevertheless, the Supreme Court pointed out that federal laws as promulgated by the FDA, impose more complex drug labeling requirements than do state tort laws. Ibid. This conflict between federal and state requirements led the Court to find that impossibility preemption exists because it is impos-

sible for generic manufacturers to simultaneously comply with both federal and state laws. *Id.* at 2579.

Specifically, the Court held, "[t]o decide these cases, it is enough to hold that when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those duties for preemption purposes." *Id.* at 2580-8 1. The practical effect of *Mensing's* holding is that generic manufacturers who comply with the FDA requirement that they mimic the brand-name manufacturers' warning labels cannot be held liable under state tort law for failure to warn. As a result, the *Mensing* plaintiffs' state claims were found preempted "because 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." *Id.* at 2578.

In their motion to dismiss, generic defendants argue that *Mensing* is directly on point because it involved the same medication, same injuries, same parties, and same causes of action as the present action. According to defendants, *Mensing* holds that *all* claims under state tort law against them based on an alleged failure to warn theory are preempted because the manufacturers cannot comply with both federal and state law. By contrast, plaintiffs have adopted a rather narrower interpretation of the *Mensing* decision, claiming that the Supreme Court's

ruling only applies to the specific content of the package inserts.

The question before the court is to what extent, if any, do plaintiffs' claims survive the preemption ruling in *Mensing*. The facts of the instant case are largely identical to those in *Mensing*. Here, plaintiffs attempt to espouse a narrow interpretation of *Mensing* by contending that *Mensing* only preempted failure to warn claims involving the adequacy of the warning as provided on the label, and as a result, some of their claims should survive because they do not concern drug labeling.

a. *Effect of 2007 FDAAA Amendments on Preemption Analysis*

While it is true that the Supreme Court in *Mensing* considered federal statutes and regulations that were in place before the 2007 amendments to FDAAA[1] took effect, it is clear that the amendments do not change or eliminate any of those laws or regulations which control this decision. The "sameness" requirement remains in full effect. The generic manufacturers' inability to use the CBE process to unilaterally change their warnings also continues. A generic manufacturer still cannot "independently do under federal law what state law" may require. *Mensing, supra,* 131 S. Ct. at 2579. The new changes in FDAAA do not eliminate or alter the conflict the

[1] The Food and Drug Administration Amendments Act of 2007 was enacted on September 27, 2007. Pub. L. No. 110-85, 121 Stat. 823 (2007).

Supreme Court described in *Mensing*. As a result, claims based on any such duty are preempted post-FDAAA to the same extent as they were pre-FDAAA.

b. *Plaintiffs' Theories of Liability*

Plaintiffs second master long form complaint pleads several causes of action, including but not limited to, defective design, failure to warn, negligence, negligence per se, fraud, misrepresentation and suppression, constructive fraud, breach of express and implied warranties, unfair and deceptive trade practices, and unjust enrichment. Further, plaintiffs allege that in light of published studies the generic defendants knew or should have known that the product created "a high risk of unreasonable harm." Second Am. Compl. ¶367.

Stripped down to the very basics, plaintiffs' claims are "traditional product liability claims for injuries caused by [the Generic Defendants'] ... failure to provide adequate warning for their products." *Kellogg v. Wyeth,* No. 2:07-cv-82, 2012 WL 368658, at *2 (D. Vt. Feb. 3, 2012). Although plaintiffs attempt to distinguish their various theories of liability, the claims are all based on generic manufacturers' alleged failure to provide adequate information or warnings, and thus are preempted under *Mensing*. Like *Mensing,* "at the core of all of Plaintiffs' claims is the basic assertion that [defendants] failed to adequately warn about the association between long-term ingestion of [metoclopramide] and movement disorders." *Mensing v. Wyeth, Inc.,* 562 F. Supp. 2d.

1056, 1058 (D. Minn. 2008); *see also Moretti v. Mut. Pharm. Co.,* No. 10-896, 2012 WL 465867, at *4 (D. Minn. Feb. 13, 2012) ("Despite the different 'labels' given these claims, the essence of these claims is that important safety information as to metoclopramide was not disseminated, or made clear, to the public or the medical community. In other words, Defendants failed to warn of material safety information concerning metoclopramide."). Like *Mensing,* plaintiffs here have also asserted claims of design defect, breach of express and implied warranties, negligence, misrepresentation, and fraud. There are no claims in the plaintiffs' complaint that were not also asserted in *Mensing,* and the court cannot find any meaningful distinction between these two cases. *See generally Demahy v. Actavis,* 650 F. 3d 1045 (5th Cir. 2011) (dismissing as preempted claims of failure-to-warn, design defect, negligence, misrepresentation, and fraud); *Smith v. Wyeth, Inc.,* 657 F. 3d 420 (6th Cir. 2011) (finding claims of products liability, negligence, negligence per se, fraud, fraud by concealment, and breach of express and implied warranties preempted under *Mensing*); *Gaeta v. Perrigo Pharm. Co.,* No. 09-1500, 2012 WL 605678 (9th Cir. Feb. 27, 2012) (affirming the district court's dismissal of plaintiffs design defect, marketing defect, breach of express and implied warranties, negligence, and deceit by concealment claim, based on the *Mensing* decision). In certain prescription drug cases, the design defect claims may differ from failure to warn claims, but not as asserted in these cases.

c. *Exemption from Preemption*

In *Mensing,* the Supreme Court pointed out that "[i]n 2004, the brand-name Reglan manufacturer requested, and the FDA approved, a label change to add that 'therapy should not exceed 12 weeks in duration.'" *Mensing, supra,* 131 S. Ct. at 2572. The passage formerly stated "therapy longer than 12 weeks has not been evaluated and cannot be recommended." *Ibid.* The brand-name manufacturer that requested this change was Schwarz Pharma, which manufactured and marketed Reglan tablets. It appears that some generic manufacturers failed to update their labeling to include this change. *See Fisher v. Pelstring,* 817 F. Supp. 2d 791, 805 n.4 (D.S.C. 2011). *Mensing's* entire premise is based on the notion that as long as generic manufacturers of a product obey the "sameness" requirement and mimic the brand-name product's labels, then preemption applies and state tort claims cannot be brought against those manufacturers. In analyzing Reglan's convoluted history, the court has reached the conclusion that each form of metoclopramide (tablet, syrup, injectable) is a distinct product, and generic manufacturers of each form must follow the brand-name manufacturer's label for that specific form to satisfy the "sameness" requirement.

Here, generic manufacturers of the Reglan tablet have not proven that any federal law prevented them from adding the additional warnings to their generic metoclopramide tablet products. In fact, they

clearly had a duty to adopt the brand-name changes. The court agrees that private enforcement of FDA requirements is foreclosed by 21 U.S.C. § 337(a) ("proceedings for the enforcement, or to restrain violations, of [the Federal Food, Drug, and Cosmetic Act] shall be by and in the name of the United States."). But if labels belonging to generic manufacturers of tablets did not match the brand-name manufacturers of tablets, then there are least some changes to their labels that federal law would allow, or even require, these defendants to make, and state tort law in this situation does not conflict with federal law. Consequently, this absence of "sameness" runs afoul of the preemption ruling in *Mensing,* and the court finds that to the extent that generic manufacturers of metoclopramide tablets failed to update the labels to be the same as the brand-name label, they are excluded from preemption.

d. *Failure-to-Communicate Theory*

Plaintiffs argue that federal law allows generic manufacturers to disseminate truthful, non-misleading information to doctors about the risks associated with their product through means other than labeling, and that therefore it was not "impossible" for the generic defendants to comply with both state and federal requirements. In making these arguments, plaintiffs contend that defendants should have more effectively communicated and disseminated the FDA approved label to the medical community, engaged in risk minimization strategies,

and/or suspended drug sales. For example, plaintiffs raise a failure to communicate theory, which questions defendants' conduct in failing to send out "Dear Doctor letters" or otherwise communicate warnings to the medical community. In support of this argument, plaintiffs primarily rely on *Fisher v. Plestring,* where the court held that generic manufacturers "had avenues available to communicate with physicians about the ... label changes without seeking FDA approval first." 817 F. Supp. 2d at 813.

In *Mensing,* the Court accepted the FDA's interpretation that generic drug manufacturers may not use "Dear Doctor" letters to send additional warnings to physicians because such letters are labeling and "must be 'consistent with and not contrary to [the drug's] approved ... labeling.' " *Mensing, supra,* 131 S. Ct. at 2576 (quoting 21 C.F.R. § 201.100(d)(1)) (alteration and omission in original). By contrast, the court in *Fisher* reasoned that the generic drug manufacturers could have taken *other* avenues to communicate the changes in the warnings without impinging upon the preemption ruling of *Mensing.* As a result, *Fisher* accepted plaintiffs' alternative theory of recovery based on the argument that defendants should have done more when the 2003 and 2004 label changes occurred, such as issue a "Dear Doctor" letter that explained the changes that had occurred.

Under 21 C.F.R. § 202.1(1)(2), labeling is defined to include virtually any type of audio, visual or

printed matter descriptive of a drug and supplied by a manufacturer. Plaintiffs maintain that *Mensing* does not necessarily require preemption of state law causes of action where the duty to warn could have been satisfied through the submission of "Dear Doctor" letters, or other methods of communication, that are consistent with the labels. While this argument has some merit, this court does not find sufficient authority to impose such legal responsibility upon generic manufacturers who have otherwise provided the warnings that they were required to use in the package inserts to independently send out "Dear Doctor" letter emphasizing the changes. Therefore, to the extent that plaintiffs' claims can be read to assert liability against the generic manufacturers solely for failure to highlight changes in the required warnings through dissemination of "Dear Doctor" letter, or other non-promotional materials, these claims are also preempted.

e. *Suspension of Sales*

Plaintiffs have alleged that generic defendants "could simultaneously comply with [their] duties under both state and federal law if [they] stopped selling [their] drug." Pls.' Opp'n Br. 3. Plaintiffs have raised this argument before the Eighth and Sixth Circuits, and both courts have rejected it. *See* Appellant Gladys Mensing's Motion for Leave to File a Supplemental Brief, *Mensing v. Wyeth, Inc.,* No. 08-3850, 2008 WL 5707474, at *4 (8th Cir. Sept. 8, 2011) ("[C]ompanies should have suspended sales of

the drug until such time as an adequate warning was approved by the FDA."), *dismissed by Mensing v. Wyeth, Inc.,* No. 08-3850, 2011 WL 4636653, at * 1 (8th Cir. Sept. 29, 2011); *Smith,* Pls.' Br. 6 ("While the Generic Drug Company Appellees may not have been able to strengthen their warnings without prior FDA approval, no federal statute or regulation prohibited from 'independently' suspending sales of their product out of concern that their labeling lacked adequate warnings."), *dismissed by Smith v. Wyeth,* 657 F. 3d 420 (6th Cir. 2011).

Plaintiffs' "failure to suspend sales" argument is a solution that goes beyond the duties and remedies that have ever been applied in state courts. The duty has always been to prove that the product was defective, not that it should have been withdrawn from the market. Tort law remedies allow compensation but never an order to stop selling the product. The conflict between state and federal law would be much more pronounced if the state courts upheld a decision that an FDA-approved drug should not have been on the market. This "failure to suspend sales" argument was rejected by the Eight Circuit following *Mensing's* remand, and the Sixth Circuit in *Smith.* This court likewise rejects this argument at this time.

CONCLUSION

The Supreme Court in *Mensing,* in signaling that the case spells the end of lawsuits like plaintiffs, suggested that those seeking redress in such cases

must look not to the courts, but to "Congress and the FDA ... to change the laws and regulations if they so desire." *Mensing, supra* 131 S. Ct. at 2582. The alleged failure to warn is clearly the central thrust of plaintiffs' lawsuits here and it underlies every count in the complaint. A generic drug manufacturer may not independently change its warnings, labels, or package-inserts. *Id.* at 2575-76. The court acknowledges that, at least with respect to plaintiffs' failure to warn claims, the disposition of this motion could have turned out differently had plaintiffs' prescriptions been filled with the brand-name drug instead of the generic product. This result is inevitable as voiced in Justice Sotomayor's dissent in *Mensing*. *Id.* at 2592 (Sotomayor, J., dissenting). At this point, precedent constrains this court's decision. Until FDA modifies its regulations, or Congress takes action to amend the statutes, there is no authority to allow claims for "failure to warn" to proceed against generic drug manufacturers that have mimicked the brand-name labeling.

In conclusion, the court will dismiss all counts of the plaintiffs' complaints against the generic manufacturers of the tablets, except for any claims that are made against a generic manufacturer of the tablet that did not change the label on their product to match the brand-name's label. As stated previously, the generic syrup products are distinct from the generic tablet product and the generic syrup manufacturers could not change their label when there was

no brand-name manufacturer.[2] The claims against the generic manufacturers are dismissed.

[2] See decision relating to the motion by Morton Grove and Wockhardt USA, which holds that only the FDA had the power to change the label when there was no NDA holder in the market.

Individual Actions

The case below, *In re Reglan Litigation*, is a coordinated multi-county proceeding to decide the preemption issue common to the following individual actions filed against Petitioners by Respondents. The New Jersey Court website indicates that as of July 2, 2016, there are 663 individual actions filed in the New Jersey state courts. *See Case List*, NEW JERSEY STATE COURTS, http://www.judiciary-.state.nj.us/mass-tort/reglan/case_list.html (last visited Nov. 20, 2016). All Respondents were represented by the same liaison counsel in the appellate proceeding below.

Case No.	Case Name	Date Filed
010437-14	KOHLES V. WYETH INC	9/19/2008
010193-14	SCHUSTER V. WYETH INC	1/8/2010
010168-14	PENO V. WYETH INC	3/8/2010
010322-14	JOHNSON V. WYETH	3/8/2010
010360-14	LOENING V. WYETH INC	3/8/2010
010425-14	CLEIN V. WYETH	3/8/2010
010427-14	MCLAUGHLIN V. WYETH INC	3/8/2010
010428-14	RIKARD V. WYETH INC	3/8/2010
010426-14	WILLEBY V. WYETH INC	3/9/2010
010189-14	LONG V. WYETH INC ETAL	4/5/2010
010169-14	DAVIS V. WYETH INC	4/6/2010
010429-14	MILTON V. WYETH	4/6/2010
010362-14	MOURADIAN V. WYETH INC	4/15/2010
010363-14	KRYSTOF V. WYETH INC	4/15/2010
010431-14	DAVIS V. WYETH INC	4/15/2010
010166-14	BROOME V. WYETH INC	4/16/2010
010187-14	SPURLOCK V. WYETH INC	4/19/2010

010188-14	ASHBY V. WYETH INC	4/19/2010
010663-14	MIDKIFF V. WYETH INCORPORATED	4/21/2010
010186-14	LYNN V. WYETH INC	5/3/2010
010343-14	CONDOURIS RUBY EDNA V. WYETH I	5/3/2010
010585-14	BOLTON V. WYETH INC	5/3/2010
010170-14	CHATFIELD V. WYETH INC	5/4/2010
010361-14	HARRIS V. WYETH INC	5/4/2010
010430-14	ARRUDA V. WYETH INC	5/4/2010
010432-14	HARRISON V. WYETH INC	5/4/2010
010167-14	TURNER V. WYETH	5/6/2010
010419-14	UY V. WYETH	5/14/2010
010195-14	FANNIN V. WYETH LLC	7/22/2010
010424-14	FORD CHERYL V. WYETH LLC	7/28/2010
010171-14	DANZIGER BARBARA V. WYETH INC	8/18/2010
010366-14	KILBURN EULIS V. WYETH INC ET	8/18/2010
010421-14	YOUNG GAIL V. WYETH INC ET AL	8/18/2010
010433-14	CLINE JAMES V. WYETH INC ET AL	8/18/2010
010434-14	DAPO JULIE V. WYETH INC ET AL	8/18/2010
010435-14	GOMEZ CONNIE V. WYETH INC ET A	8/18/2010
010664-14	BELL PARIS DONNA V. WYETH INC	8/18/2010
010173-14	BENTON DONALD R V. PFIZER INC	8/20/2010
010174-14	HARKINS THOMAS V. PFIZER INC E	8/20/2010
010436-14	DOLAN CINDY V. WYETH INC ET AL	8/20/2010
010438-14	COX DOROTHY V. WYETH INC	8/30/2010
010439-14	KILEN JOYCE V. WYETH INC	8/30/2010
010440-14	GUE ORVILLE V. WYETH INC	8/30/2010
010699-14	DORWARD KIMICHIA V. WYETH LLC	9/1/2010
010700-14	CASTIELLO JOHN ET AL V. WYE	9/8/2010
010172-14	MCINTOSH JUDY V. PFIZER INC ET	9/17/2010
010175-14	PIETRZYNK ALEXANDER V PFIZER I	9/17/2010
010176-14	SHUMWAY CHARLES L V. WYETH INC	9/17/2010
010181-14	ANDERSON PAMELA ET AL V. WYETH	10/18/2010
010182-14	WALDRON SHARON V. WYETH LLC E	10/18/2010
010183-14	NEVELS JULIA V. WYETH LLC ET	10/18/2010

010184-14	GOLDBERG LINDA ET AL V. WYETH	10/18/2010
010185-14	FORTNER THELMA V. WYETH LLC E	10/18/2010
010441-14	MARTIN JENNIFER V. WYETH LLC	10/29/2010
010190-14	HEUCKEROTH JOHN ET AL V WYETH	11/3/2010
010192-14	CLARE N WELDEN V. WYETH LLC	11/5/2010
010442-14	BOOKER CHARLES ALLEN V. WYET	11/15/2010
010444-14	LINDA GAY ADAMS V. WYETH LLC	11/18/2010
010194-14	CAROLE DOVI V WYETH LLC	11/22/2010
010443-14	CHAMBERS ROXIE V. WYETH LLC	11/24/2010
010197-14	CHACHERE GEORGE V. WYETH LLC	12/1/2010
010198-14	JAMES E FULLER V. WYETH LLC	12/1/2010
010196-14	SLATER AMY V WYETH LLC ET AL	12/16/2010
010201-14	BARRY P APPELGET V. WYETH LL	12/23/2010
010041-14	RUTH JENNINGS V. WYETH LLC	1/6/2011
010371-14	JENKINS REBECCA V. WYETH LLC E	1/6/2011
010423-14	PETERSON JUANITA V. WYETH LLC	1/6/2011
010445-14	COBB ISOBEL V. WYETH LLC	1/6/2011
010446-14	LITTLE RONALD HAROLD ET AL V.	1/6/2011
010447-14	MCDANIEL ERIC V. WYETH LLC ET	1/6/2011
010042-14	CAROLINE SITKA V. WYETH LLC	1/11/2011
010258-14	CATHERINE MONROE V. WYETH LL	1/11/2011
010259-14	LINDA YUNK-ZIMMERMAN V. WYET	1/11/2011
010260-14	KAMILE DRAKE V. WYETH LLC E	1/11/2011
010483-14	JUDITH ANDERSON V. WYETH LLC	1/11/2011
010043-14	DONNA TILLERY MYHRE V. WYETH	1/14/2011
010286-14	KACKERT SR DAVID W V. WYETH LL	1/14/2011
010044-14	ROBIN BENNETT V. WYETH LLC	1/25/2011
010045-14	FEFFER BEVERLY V. WYETH LLC	1/25/2011
010047-14	MCKELVEY JAMES ET AL V. WYETH	1/25/2011
010250-14	POWERS VIVIAN ET AL V. WYETH	1/25/2011
010287-14	CARMEN DICKERSON V. WYETH LL	1/25/2011
010288-14	PEARL DALTON V. WYETH LLC E	1/25/2011
010375-14	JOYCE FANNING V. WYETH LLC	1/25/2011
010448-14	JANICE CLIFT V. WYETH LLC	1/25/2011

010602-14	RENEE BUERKE V. WYETH LLC E	1/25/2011
010050-14	DAVIS EDNA M V. WYETH LLC	1/26/2011
010052-14	PRICE JR JAY V. WYETH LLC	1/26/2011
010261-14	WILLIAMS BILLIE JO V. WYETH	1/26/2011
010262-14	MURPHY AUDREY V. WYETH LLC	1/26/2011
010420-14	ENGLE JEANNETTE V. WYETH LLC	1/26/2011
010593-14	GERSTLE CHARLENE B V. WYETH L	1/26/2011
010051-14	MITCHELL ALEXANDER V. WYETH	1/31/2011
010449-14	ANGEL ALBANY V. WYETH LLC	1/31/2011
010053-14	VILLA MELANIE V. WYETH LLC	2/3/2011
010293-14	FRYE RONALD J V. WYETH LLC	2/3/2011
010379-14	BASIL DOWNER V. WYETH LLC E	2/3/2011
010380-14	MARSHAL H TAPPRICH V. WYETH	2/3/2011
010381-14	GLADYS P TIPTON V. WYETH LLC	2/3/2011
010382-14	DARAZIO BERNADETTE V. WYETH	2/3/2011
010450-14	SMITH MERRITT M & LUCINDA E V.	2/3/2011
010294-14	BARTHA LORI ET AL V WYETH LLC	2/7/2011
010298-14	LORA E CLARK V. WYETH LLC E	2/7/2011
010378-14	TAFF ALICE M V. WYETH LLC ET A	2/7/2011
010048-14	JETTA BROCK V. WYETH LLC ET	2/9/2011
010054-14	MARY PAULA BACHMAN V. WYETH	2/9/2011
010296-14	PATRICIA MULLINS V. WYETH LL	2/9/2011
010355-14	TAMYRA TROTTER V. WYETH LLC	2/9/2011
010383-14	MINNETTE WALDROP V. WYETH LL	2/9/2011
010384-14	DELPHIA ELDRIDGE V. WYETH LL	2/9/2011
010059-14	PATTON PATTI V. WYETH LLC ET	2/14/2011
010263-14	TYCHELLE HILL V. WYETH LLC	2/16/2011
010264-14	JOSEPH KUEHNE V. WYETH LLC	2/16/2011
010394-14	KENNEDY AMY JOELL V. WYETH LL	2/17/2011
010055-14	LEWIS RAMONA V. WYETH LLC ET	2/18/2011
010058-14	CAUTHEN LOIS V. WYETH LLC ET	2/18/2011
010060-14	SMITH TRACI V. WYETH LLC ET	2/18/2011
010061-14	HOOKS BRIDGETT ET AL V. WYETH	2/18/2011
010062-14	GENET BARBARA V. WYETH LLC	2/18/2011

010063-14	SCHULZ KAY ET AL V. WYETH LLC	2/18/2011
010064-14	BIBBS LAWRENCE ET AL V. WYETH	2/18/2011
010065-14	SPILLERS CLYDE R V. WYETH LLC	2/18/2011
010066-14	RONALD W WAGNER V. WYETH LLC	2/18/2011
010067-14	DEBRA K SKAGGS V. WYETH LLC	2/18/2011
010068-14	KATHRYN S BERRY V. WYETH LLC	2/18/2011
010069-14	MCGAUGHY GLORIA V. WYETH LLC	2/18/2011
010070-14	REGINALD MINOR V. WYETH LLC	2/18/2011
010071-14	CAROLYN A BURTON V. WYETH LL	2/18/2011
010076-14	LENNEA WESIK V. WYETH LLC E	2/18/2011
010279-14	KIRKENDALL DEBORAH ET AL V. W	2/18/2011
010280-14	MILLER DEBRA V. WYETH LLC ET	2/18/2011
010282-14	EMMA CASTILLO V. WYETH LLC	2/18/2011
010283-14	GERALD LANDISI V. WYETH LLC	2/18/2011
010284-14	ROSEMARIE DAVIS V. WYETH LLC	2/18/2011
010290-14	CHERYL TOLAN V. WYETH LLC E	2/18/2011
010291-14	BEAVER DALE ET AL V WYETH LLC	2/18/2011
010292-14	KIMBERLY WILLMS V. WYETH LLC	2/18/2011
010299-14	BETCHLEY GEORGE ET AL V. WYET	2/18/2011
010304-14	PEGGY MINOR V. WYETH LLC ET	2/18/2011
010306-14	WANDA BANKS V. WYETH LLC ET	2/18/2011
010310-14	MIKESELL SHARON K ET AL V. WY	2/18/2011
010311-14	MARTIN JOYCE L ET AL V. WYETH	2/18/2011
010312-14	CHRISTIAN LEESA D V. WYETH LL	2/18/2011
010313-14	KELSEY BARBARA J ET AL V. WYE	2/18/2011
010315-14	GALLAGHER GERALD A ET AL V. W	2/18/2011
010316-14	HENSON EILEEN V. WYETH LLC E	2/18/2011
010317-14	GARCEAU SR JOHN H ET AL V. W	2/18/2011
010357-14	GILLIAM GERALD V. WYETH LLC E	2/18/2011
010373-14	LOPEZ AIDA ET AL V. WYETH LLC	2/18/2011
010374-14	SWARTZ GLORIA M ET AL V. WYET	2/18/2011
010377-14	JAMES DAVID A V. WYETH LLC ET	2/18/2011
010385-14	TIPA DANIELLE V. WYETH LLC ET	2/18/2011
010386-14	WATSON LENA V. WYETH LLC ET A	2/18/2011

010387-14	MILLER CLIFFORD V. WYETH LLC	2/18/2011
010388-14	BARBARA POLLARD MONDEL V. WY	2/18/2011
010389-14	JOANN EMMA BURTON MATTHEWS V.	2/18/2011
010390-14	JESSICA MARSHALL V. WYETH LL	2/18/2011
010391-14	FRANCIS KRAIDMAN V. WYETH LL	2/18/2011
010392-14	KATHRYN RODRIGUEZ V. WYETH L	2/18/2011
010393-14	LITTLE BERTHAN V. WYETH LLC ET	2/18/2011
010395-14	LAKE MAXINE V. WYETH LLC ET	2/18/2011
010452-14	MARGIE JOHNSON V. WYETH LLC	2/18/2011
010454-14	ERWIN SAMUEL ET AL V. WYETH L	2/18/2011
010595-14	CARR JACQUELINE V. WYETH LLC	2/18/2011
010599-14	PITILON ARLENE ET AL V. WYETH	2/18/2011
010607-14	CLINTON HERRIN JR V. WYETH L	2/18/2011
010351-14	MARLEAU MARCIA V. WYETH LLC	2/20/2011
010056-14	SPOON SAMANTHA M ET AL V. WYET	2/22/2011
010057-14	SNYDER PATTI J V WYETH LLC ET	2/22/2011
010074-14	HERRINGTON MARGARET V. WYETH	2/22/2011
010077-14	EDWARD CANTOR V. WYETH LLC	2/22/2011
010300-14	PEASE MICHAEL ET AL V WYETH LL	2/22/2011
010301-14	TOYA BARABAS ET AL V WYETH LLC	2/22/2011
010308-14	GLENDA GAY THOMAS V. WYETH L	2/22/2011
010309-14	KENNETH REBSTOCK V. WYETH LL	2/22/2011
010319-14	THOMAS E FIKE III ET AL V. WYE	2/22/2011
010320-14	PEDUZZI MARK A ET AL V. WYETH	2/22/2011
010321-14	DISHAW DAVID ET AL V WYETH LLC	2/22/2011
010353-14	COLEMAN BENJAMIN ET AL V WYETH	2/22/2011
010359-14	CONNIE BECK V. WYETH LLC ET	2/22/2011
010364-14	JUANITA BELL V. WYETH LLC E	2/22/2011
010367-14	LAWRENCE KING V. WYETH LLC	2/22/2011
010368-14	JOSHUA RAEL V. WYETH LLC ET	2/22/2011
010369-14	AMBER RUSOVICK V. WYETH LLC	2/22/2011
010370-14	DREW LITTLETON V. WYETH LLC	2/22/2011
010372-14	BOBBY WHITE V. WYETH LLC ET	2/22/2011
010396-14	ADAMSON JOHN V. WYETH LLC ET A	2/22/2011

010397-14	OSBORNE HERSEY T ET AL V. WYET	2/22/2011
010453-14	SHARON LOWE V. WYETH LLC ET	2/22/2011
010079-14	BARCZAK LINDA V. WYETH LLC E	2/23/2011
010082-14	HAYES TERRY V. WYETH LLC ET A	2/23/2011
010085-14	GOODING MARSHALL V. WYETH LLC	2/23/2011
010295-14	KLEIN MICHAEL V. WYETH LLC	2/23/2011
010323-14	WILLIAMSON CASSANDRA V WYETH L	2/23/2011
010325-14	AVERY ERMA V WYETH LLC ET AL	2/23/2011
010326-14	NICOSIA JULIE ET AL V. WYETH	2/23/2011
010400-14	KING VANESSA V. WYETH LLC ET A	2/23/2011
010415-14	WYATT REBECCA B V. WYETH LLC	2/23/2011
010072-14	RILEY BARBARA V. WYETH LLC ET	2/24/2011
010073-14	MOORE MAMIE V. WYETH LLC ET	2/24/2011
010075-14	DENSHAM BARBARA V. WYETH LLC	2/24/2011
010078-14	MARLA ALMOS V. WYETH LLC ET	2/24/2011
010092-14	SMITH PETER N ET AL V WYETH LL	2/24/2011
010093-14	GIBSON CYNTHIA LOU V. WYETH LL	2/24/2011
010096-14	MCCAA KEVIN ET AL V WYETH LLC	2/24/2011
010123-14	HALFORD BERTHA V. WYETH LLC ET AL	2/24/2011
010124-14	FITZPATRICK ATAVIA V. WYETH LLC ET AL	2/24/2011
010126-14	JORDAN MARGIE L V. WYETH LLC ET AL	2/24/2011
010127-14	BAECHT HERMAN ET AL V. WYETH LLC ET AL	2/24/2011
010129-14	WILLIAMS MAGNOLIA V. WYETH LLC ET AL	2/24/2011
010131-14	LITAKER PRESTON J V. WYETH LLC ET AL	2/24/2011
010132-14	JONES GERALDINE V. WYETH LLC ET AL	2/24/2011
010133-14	GIDEON THOMAS G ET AL V. WYETH LLC ET A	2/24/2011
010136-14	ALVARADO ANTONIA V. WYETH LLC ET AL	2/24/2011
010141-14	WATKINS PEARL ELLA V. WYETH LLC	2/24/2011

	ET AL	
010143-14	PRETLOW PATRICIA V. WYETH LLC ET AL	2/24/2011
010146-14	DREW SHIRLEY A V. WYETH LLC ET AL	2/24/2011
010148-14	STRACHAN MICHAEL & BETTY V. WYETH LLC	2/24/2011
010149-14	PERRY DANNIE V. WYETH LLC ET AL	2/24/2011
010150-14	VAUGHN MARION V. WYETH LLC ET AL	2/24/2011
010243-14	KLINE DARYL ET AL V WYETH LLC	2/24/2011
010314-14	CHERA SIMPSON V. WYETH LLC	2/24/2011
010324-14	PRICE JANET ET AL V. WYETH LL	2/24/2011
010336-14	GREGG EDWARD ET AL V. WYETH LLC ET AL	2/24/2011
010337-14	GOODSON MARIE V. WYETH LLC ET AL	2/24/2011
010338-14	DODSON MICHAEL G ET AL V. WEYTH LLC ET	2/24/2011
010339-14	PAULDO REYSHAWN V. WYETH LLC ET LA	2/24/2011
010340-14	RIBACK ARNOLD ET AL V. WYETH LLC ET AL	2/24/2011
010344-14	WOODARD VEDA V. WYETH LLC ET AL	2/24/2011
010347-14	PEPITONE BARBARA V. WYETH LLC ET AL	2/24/2011
010349-14	REGIEC JAMES V. WYETH LLC ET AL	2/24/2011
010350-14	LORBER JOYCE V. WYETH LLC ET AL	2/24/2011
010398-14	HUNTER THERESIA V. WYETH LLC	2/24/2011
010399-14	HARN MARY V. WYETH LLC ET AL	2/24/2011
010401-14	SARAH WEBB V. WYETH LLC ETA	2/24/2011
010402-14	GENTHNER CHERYL V WYETH LLC ET	2/24/2011
010460-14	MAXWELL TROY E & BARBARA G V. WYETH LL	2/24/2011
010462-14	BITTNER THERESA V. WYETH LLC ET AL	2/24/2011
010580-14	GOVAN ZENESTER V. WYETH LLC ET LA	2/24/2011

010581-14	BOLDEN WILLIAM ET AL V. WYETH LLC ET AL	2/24/2011
010582-14	WAFER SALLY C V. WYETH LLC ET AL	2/24/2011
010080-14	TEDDY LAMBERT JR V. WYETH LL	2/25/2011
010081-14	SUSAN TEAGUE V. WYETH LLC E	2/25/2011
010083-14	LINDA HOUCK V. WYETH LLC ET	2/25/2011
010084-14	GLENNA MCQUERRY V. WYETH LLC	2/25/2011
010086-14	DANNY REED V. WYETH LLC ETA	2/25/2011
010087-14	LOCKE RITA V WYETH LLC ET AL	2/25/2011
010091-14	ALBINAKIS AMBRIA V. WYETH LLC	2/25/2011
010094-14	DIANA HOGAN V. WYETH LLC ET	2/25/2011
010095-14	DELORES HENDRIX V. WYETH LLC	2/25/2011
010097-14	PATRICIA MUMIE V. WYETH LLC	2/25/2011
010098-14	CATHY COOP V. WYETH LLC ETA	2/25/2011
010099-14	CUSHION TIM V. WYETH LLC ET	2/25/2011
010100-14	SYDNEY POWELL V. WYETH LLC	2/25/2011
010102-14	MOCK LEROY V WYETH LLC ET AL	2/25/2011
010108-14	RONDA LAFFERTY V. WYETH LLC	2/25/2011
010109-14	JULIE HAM V. WYETH LLC ETAL	2/25/2011
010112-14	ROSALYN DONES V. WYETH LLC	2/25/2011
010114-14	RICH JUDY V. WYETH LLC ET AL	2/25/2011
010115-14	CLARKSON JILL V. WYETH LLC ET	2/25/2011
010116-14	SUMIDA JEFF V. WYETH LLC ET AL	2/25/2011
010117-14	KENNELLEY DAVID V. WYETH LLC E	2/25/2011
010118-14	FOWLER CYNTHIA V. WYETH LLC ET AL	2/25/2011
010119-14	GROSSE WILLIAM & BARBARA V. WYETH LLC	2/25/2011
010120-14	HEWLETT LISA V. WYETH LLC ET AL	2/25/2011
010121-14	MANNING THERESA V. WYETH LLC ET AL	2/25/2011
010122-14	KOCH LINDA & CALVIN V. WYETH LLC ET AL	2/25/2011
010125-14	MILLER THERESA V. WYETH LLC ET AL	2/25/2011
010128-14	NISSLEY HEATHER ET AL V. WYETH	2/25/2011

	LLC ET	
010130-14	BUSATH MICHELLE V. WYETH LLC ET AL	2/25/2011
010138-14	ONEAL ROSE MARY V. WYETH LLC ET AL	2/25/2011
010144-14	HAMILTON WILLIAM ET AL V WYETH LLC ET AL	2/25/2011
010145-14	CONNER WEST ET AL V WYETH LLC ET AL	2/25/2011
010151-14	BACOT JULIANA ET AL V. WYETH LLC ET AL	2/25/2011
010155-14	MCMANIS MICHAEL ET AL V. WYETH LLC ET A	2/25/2011
010246-14	GARCIA HELEN V. WYETH LLC	2/25/2011
010247-14	MEDINA JAMES V. WYETH LLC ET AL	2/25/2011
010249-14	KARNES JOHONSON NIKKI V. WYETH LLC ET	2/25/2011
010251-14	ELIZABETH OWENS V. WYETH LLC	2/25/2011
010253-14	WHEAT LINDA V. WYETH LLC ET AL	2/25/2011
010254-14	ELEANOR THOMAS V. WYETH LLC	2/25/2011
010255-14	THELMA WENDT V. WYETH LLC E	2/25/2011
010256-14	GERALD JOHNSON V. WYETH LLC	2/25/2011
010257-14	PAUL REEVES V. WYETH LLC ET	2/25/2011
010265-14	JOSEPHINE NOORDOVER V. WYETH	2/25/2011
010266-14	SIZEMORE MILDRED V. WYETH LLC	2/25/2011
010267-14	DENAULT TOM V. WYETH LLC ET AL	2/25/2011
010274-14	CREIGHTON WALTER ET AL V WYETH	2/25/2011
010275-14	RINCK WILLIAM ET AL V WYETH LL	2/25/2011
010276-14	SUFFRON MISHA V. WYETH LLC ET	2/25/2011
010277-14	RICHARDSON CALVIN ET LA V WYET	2/25/2011
010281-14	CHAMBLIN SANDRA V. WYETH LLC E	2/25/2011
010285-14	HUGHES RAY ET AL V WYETH LLC E	2/25/2011
010289-14	BROCKMAN ELIZABETH V. WYETH LL	2/25/2011
010302-14	PEDRAZA CARMEN V WYETH LLC ET	2/25/2011
010303-14	COBURGER FRANCES V WYETH LLC E	2/25/2011
010305-14	EDWARD SMITH V. WYETH LLC E	2/25/2011

010307-14	MARTIN GLENDA V. WYETH LLC	2/25/2011
010318-14	LUNA ADELA V. WYETH LLC ET AL	2/25/2011
010327-14	PAUL LEO V. WYETH LLC ET AL	2/25/2011
010328-14	ARNOLD JEFFREY V. WYETH LLC ET	2/25/2011
010330-14	TAJUANA LEWIS V. WYETH LLC	2/25/2011
010332-14	KNAACK JEFFREY & JACYLN V. WYE	2/25/2011
010333-14	POWELL GLORIA & RUSSELL V. WYE	2/25/2011
010334-14	KENNEDY DOLLY V. WYETH LLC ET	2/25/2011
010335-14	LILTON EARL V. WYETH LLC ET AL	2/25/2011
010341-14	HANNA RENEE V. WYETH LLC ETALS	2/25/2011
010342-14	HODGES BRENDA V. WYETH LLC ET AL	2/25/2011
010345-14	SCHUMPERT BRANNEN V. WYETH LLC ET AL	2/25/2011
010346-14	MAYER DELORIS & DENNIS V. WYETH LLC ET	2/25/2011
010348-14	PLETZER MELODY ET AL V. WYETH LLC ET A	2/25/2011
010352-14	DUARTE DENISA V. WYETH LLC ET AL	2/25/2011
010354-14	JOSEPHINE DOLLARHIDE V. WYET	2/25/2011
010403-14	RONNIE ROBERTS V. WYETH LLC	2/25/2011
010404-14	LARRY WEST V. WYETH LLC ETA	2/25/2011
010405-14	SUNDAY MICHAEL V WYETH LLC ET	2/25/2011
010406-14	CORBIN ANGELA V. WYETH LLC ET	2/25/2011
010407-14	BRADLEY JUDY V. WYETH LLC ET A	2/25/2011
010408-14	HOOKER WILLEAM E ET AL V WYETH	2/25/2011
010409-14	BULLOCK NELL V. WYETH LLC ET	2/25/2011
010410-14	PABON LIDIA V WYETH LLC ET AL	2/25/2011
010411-14	ROBERTS FLORENCE ET AL V WYETH	2/25/2011
010412-14	COE VIRGINIA V WYETH LLC ET AL	2/25/2011
010414-14	TICE STEPHANIE & KEVIN V. WYET	2/25/2011
010422-14	LINDA TYSON V. WYETH LLC ET	2/25/2011
010455-14	DOUGLAS JOAN V WYETH LLC ET AL	2/25/2011
010458-14	POEPSEL PATRICIA V. WYETH LLC ET AL	2/25/2011

010461-14	WALTON ANNIE V. WYETH LLC ET AL	2/25/2011
010464-14	NEWSOME JOHNNY ET AL V. WYETH LLC ET A	2/25/2011
010466-14	JOHNSON THOMAS ET AL V. WYETH LLC ET A	2/25/2011
010467-14	OLDS DENISE & THOMAS V. WYETH LLC ET AL	2/25/2011
010469-14	SHELTON GAIL & JERRY V. WYETH LLC ET AL	2/25/2011
010470-14	BRENNER PAUL J ET AL V. WYETH LLC ET AL	2/25/2011
010471-14	FEIERBERG LAURIE & MICHAEL V. WYETH LLC	2/25/2011
010472-14	PARKS HAROLD V. WYETH LLC ET AL	2/25/2011
010473-14	HOLLAND SARA H V. WYETH LLC	2/25/2011
010474-14	MCPHERSON KENNETH ET AL V WY-ETH LLC E	2/25/2011
010475-14	WINSCHER LOIS V. WYETH LLC ET AL	2/25/2011
010476-14	KILMER JAMES V. WYETH LLC ET AL	2/25/2011
010478-14	GUIDRY SHERRY V. WYETH LLC ET AL	2/25/2011
010484-14	HARVEY SUSAN V WYETH LLC ET AL	2/25/2011
010485-14	SKIPPER BUSHMAN MARYETTA V. WY	2/25/2011
010486-14	COLYER DOROTHY V WYETH LLC ET	2/25/2011
010487-14	COMER BRIAN V. WYETH LLC ET AL	2/25/2011
010488-14	CASACELI LINDA V WYETH LLC ET	2/25/2011
010489-14	MADDUX KIMBERLY V. WYETH LLC	2/25/2011
010490-14	LOWE BONITA V. WYETH LLC ET AL	2/25/2011
010491-14	BRENDA HERNDON V. WYETH LLC	2/25/2011
010492-14	CHRIS HURLEY V. WYETH LLC E	2/25/2011
010493-14	SMITH CHEYENNE V. WYETH LLC ET	2/25/2011
010494-14	BRENDA JOHNSON V. WYETH LLC	2/25/2011
010495-14	TEEGUARDEN MARY V. WYETH LLC E	2/25/2011
010496-14	SCHWALM CHRISTINE V. WYETH LLC	2/25/2011
010497-14	FANT ROSELLA V WYETH LLC ET AL	2/25/2011
010498-14	GALVAN GABRIELA V WYETH LLC ET	2/25/2011
010499-14	SKAGGS LINDA V. WYETH LLC ET A	2/25/2011

010500-14	VEGA AGOSTO AMELIA V. WYETH LL	2/25/2011
010501-14	CRUZ MERCEDES V WYETH LLC ET A	2/25/2011
010502-14	SCHNEIDER BEVERLY V. WYETH LLC	2/25/2011
010503-14	BACCUS DE VAUGHN RONEL V WYETH	2/25/2011
010504-14	SHAW RAELYN V. WYETH LLC ET AL	2/25/2011
010505-14	SCOTT PATRICIA V. WYETH LLC ET	2/25/2011
010506-14	ROSEN CHARLOTTE V. WYETH LLC E	2/25/2011
010507-14	SHARP DAVID V. WYETH LLC ET AL	2/25/2011
010509-14	SHAFER JAMES V. WYETH LLC ET A	2/25/2011
010510-14	RUIZ ROSADO BENJAMIN V. WYETH	2/25/2011
010511-14	STRONG DEBRA V WYETH LLC ET AL	2/25/2011
010512-14	BULLINER SHELLY V WYETH LLC ET	2/25/2011
010513-14	SEE PATRICIA V. WYETH LLC ET A	2/25/2011
010514-14	BRYANT LAKEISHA V WYETH LLC ET	2/25/2011
010516-14	VAN ZETTIN MILLICENT V. WYETH	2/25/2011
010517-14	STONE MADISEN V WYETH LLC ET A	2/25/2011
010518-14	SALEH ALI V. WYETH LLC ET AL	2/25/2011
010519-14	WHITEHEAD JUNE V WYETH LLC ET	2/25/2011
010520-14	RICHARDS DOROTHY V. WYETH LLC	2/25/2011
010521-14	WALKER SHIRLEY V. WYETH LLC ET	2/25/2011
010522-14	WOOLSEY EDNA V WYETH LLC ET AL	2/25/2011
010523-14	RIVERA SEGARRA LEOVIGILDO V. W	2/25/2011
010524-14	ROBERTS BRENDA V. WYETH LLC ET	2/25/2011
010525-14	WOOLEY DONNA V. WYETH LLC ET A	2/25/2011
010526-14	SOHN STEVEN V WYETH LLC ET AL	2/25/2011
010527-14	KOPIAK EMILY V. WYETH LLC ET A	2/25/2011
010528-14	KELLEY GLADYS V. WYETH LLC ET	2/25/2011
010529-14	WILL MARY V. WYETH LLC ET AL	2/25/2011
010531-14	STOKES ODESTER V WYETH LLC ET	2/25/2011
010532-14	STOVALL TORY V WYETH LLC ET AL	2/25/2011
010533-14	MONTANEZ OQUENDO ARCELIA V WYE	2/25/2011
010534-14	ORTIZ MORALES NEREIDA V. WYETH	2/25/2011
010535-14	MODDELMOG BEVERLY V WYETH LLC	2/25/2011

010536-14	JONES EMILY V. WYETH LLC ET AL	2/25/2011
010537-14	VICKI LANSFORD V. WYETH LLC	2/25/2011
010538-14	ROBY JANET V. WYETH LLC ET AL	2/25/2011
010539-14	VANGORDER TIFFANY V. WYETH LLC	2/25/2011
010540-14	WARD JENNIFER V WYETH LLC ET A	2/25/2011
010541-14	YOKOTA KEVIN V WYETH LLC ET AL	2/25/2011
010542-14	MOJICA BARRETO LILLIAN V WYETH	2/25/2011
010543-14	MONEY JOANN V WYETH LLC ET AL	2/25/2011
010544-14	JONES GLORIA V. WYETH LLC ET A	2/25/2011
010545-14	MOORE BONNIE V WYETH LLC ET AL	2/25/2011
010546-14	GEORGE LAPUMA V. WYETH LLC	2/25/2011
010547-14	MEREDITH LARSON V. WYETH LLC	2/25/2011
010548-14	MORENO PATRICIA V WYETH LLC ET	2/25/2011
010549-14	MOORE BARBARA V WYETH LLC ET A	2/25/2011
010550-14	MARIA LEDEZMA V. WYETH LLC	2/25/2011
010551-14	MIJANEA LESLIE V. WYETH LLC	2/25/2011
010552-14	SWANSON STEPHANIE V. WYETH LLC	2/25/2011
010553-14	SWEICH ANN V. WYETH LLC ET AL	2/25/2011
010554-14	WILLIAMS BETTY V. WYETH LLC ET	2/25/2011
010555-14	JOHN LEWIS V. WYETH LLC ETA	2/25/2011
010557-14	ADELMA LATEANO V. WYETH LLC	2/25/2011
010558-14	WILLIAMS BARBARA V. WYETH LLC	2/25/2011
010559-14	RUSSELL NALLS V. WYETH LLC	2/25/2011
010560-14	ROBERTS MISSY V. WYETH LLC ET	2/25/2011
010561-14	PLOOF CAROL V WYETH LLC ET AL	2/25/2011
010562-14	PERRY SANDRA V. WYETH LLC ET A	2/25/2011
010563-14	RAMSEY ROBERT V WYETH LLC ET A	2/25/2011
010565-14	NELSON JACK V. WYETH LLC ET AL	2/25/2011
010566-14	WILLIAM MOULTON V. WYETH LLC	2/25/2011
010567-14	NEWSOME BARBARA V. WYETH LLC E	2/25/2011
010568-14	NEIL MORRIS V. WYETH LLC ET	2/25/2011
010569-14	NORRIS JUSTIN V. WYETH LLC ET	2/25/2011
010570-14	NIEMEYER MICHELE V. WYETH LLC	2/25/2011
010571-14	NANTZ SAVANNAH V. WYETH LLC ET	2/25/2011

010572-14	PATES SANDRA V. WYETH LLC ET A	2/25/2011
010573-14	WALTON RUBY V WYETH LLC ET AL	2/25/2011
010574-14	WEIL PATRICIA V. WYETH LLC ET	2/25/2011
010575-14	WOOTEN NORMAGENE V WYETH LLC	2/25/2011
010576-14	WASHINGTON KHRISTIE V. WYETH L	2/25/2011
010577-14	RAMEREZ TAMMARI V WYETH LLC ET	2/25/2011
010578-14	ORR WENDIE V. WYETH LLC ET AL	2/25/2011
010579-14	POINDEXTER MELVIN V. WYETH LLC	2/25/2011
010583-14	STEYN ARNOLD V WYETH LLC ET AL	2/25/2011
010588-14	PAUL LELINA V. WYETH LLC ET	2/25/2011
010589-14	STEPHENS KERRY V. WYETH LLC ET	2/25/2011
010590-14	STEPHENS JOAN V. WYETH LLC ET	2/25/2011
010591-14	SURLES MARCIA V. WYETH LLC ET	2/25/2011
010594-14	MICELI SANDRA V WYETH LLC ET A	2/25/2011
010596-14	WILLIAMS JAMES V WYETH LLC ET	2/25/2011
010598-14	WOESTENBURG JONELL V. WYETH LL	2/25/2011
010601-14	WYCHE PIERCE VANESSA V WYETH L	2/25/2011
010603-14	OWENS LUCILLE V WYETH LLC ET A	2/25/2011
010604-14	PANNACHIA DEBBIE V WYETH LLC E	2/25/2011
010605-14	CLYDE TAMMY V WYETH LLC ET AL	2/25/2011
010606-14	LOCKHART CYNTHINA V. WYETH LLC	2/25/2011
010608-14	CORYELL ANTHONY V WYETH LLC ET	2/25/2011
010609-14	CORDER DENNIS V. WYETH LLC ET	2/25/2011
010611-14	LOCKHART SHAWANDA V WYETH LLC	2/25/2011
010613-14	MATTHEWS CHRISSAHWANDA V. WY	2/25/2011
010614-14	MCBRIDE CELESTINE V. WYETH L	2/25/2011
010615-14	MCCALTER SHEILA V. WYETH LLC	2/25/2011
010616-14	MCRAE TINA V. WYETH LLC ET AL	2/25/2011
010617-14	MEECE GLORIA V. WYETH LLC ET A	2/25/2011
010618-14	MESSERSMITH THERESA V. WYETH L	2/25/2011
010619-14	HALL TAMARA V WYETH LLC ET AL	2/25/2011
010620-14	MIDDLETON MELVIN V. WYETH LLC	2/25/2011
010621-14	HAYES MELISSA V WYETH LLC ET	2/25/2011
010622-14	LORI JACKSON V. WYETH LLC E	2/25/2011

010623-14	EULA JENKINS V. WYETH LLC E	2/25/2011
010624-14	JONES ROBERT V. WYETH LLC ET A	2/25/2011
010625-14	DILLINGER DONNA V WYETH LLC ET	2/25/2011
010626-14	SKIPPER MARILYN V. WYETH LLC E	2/25/2011
010627-14	ALDOBORDO RAMON GONZALEZ V WYE	2/25/2011
010628-14	VAUGHN MICHELLE V. WYETH LLC E	2/25/2011
010629-14	VAZQUEZ GLORIA V. WYETH LLC ET	2/25/2011
010630-14	VICTORIN JEAN V. WYETH LLC ET	2/25/2011
010631-14	THOMAS DONNA V. WYETH LLC ET A	2/25/2011
010632-14	DAVIS CARLA V. WYETH LLC	2/25/2011
010633-14	SANCHEZ PETER V. WYETH LLC ET	2/25/2011
010634-14	SINTZ JOANN V. WYETH LLC ET AL	2/25/2011
010635-14	SHULKA CHAD V. WYETH LLC ET AL	2/25/2011
010636-14	BELLEVILLE KATHLEEN V WYETH LL	2/25/2011
010637-14	SCHREURS JEFF V. WYETH LLC ET	2/25/2011
010638-14	BROWN WANDA V WYETH LLC ET AL	2/25/2011
010639-14	BURNETT LYDIA V WYETH LLC ET A	2/25/2011
010640-14	RICHARDSON BUYLENDER V. WYETH	2/25/2011
010641-14	RIOS MARTINEZ FELIX V. WYETH L	2/25/2011
010642-14	RISTAD LYNNE V. WYETH LLC ET A	2/25/2011
010643-14	STACY STEVEN V WYETH LLC ET AL	2/25/2011
010644-14	STEPHENSON LOYCE V WYETH LLC E	2/25/2011
010645-14	SOUTHARD TOMMY V WYETH LLC ET	2/25/2011
010646-14	PARK SHARON V. WYETH LLC ET AL	2/25/2011
010647-14	PLESE MATTHEW V. WYETH LLC ET	2/25/2011
010648-14	GRADEN LEWIS V. WYETH LLC E	2/25/2011
010649-14	PINTAVALLE SUSAN V. WYETH LLC	2/25/2011
010650-14	KATHERINE LEWIS V. WYETH LLC	2/25/2011
010652-14	PETTY MARLEAH V. WYETH LLC ET	2/25/2011
010653-14	REA CYNTHIA V WYETH LLC ET AL	2/25/2011
010654-14	RAMOS VAZQUEZ LUZ V WYETH LLC	2/25/2011
010655-14	OPDYKE THOMAS V. WYETH LLC ET	2/25/2011
010656-14	ORTEGA JACQUELYN V. WYETH LLC	2/25/2011

010657-14	LIVI MURCH V. WYETH LLC ETA	2/25/2011
010658-14	PRIMM SHARON V WYETH LLC ET AL	2/25/2011
010659-14	NEWSOME LINDA V. WYETH LLC ET	2/25/2011
010660-14	NUNN IVY V. WYETH LLC ET AL	2/25/2011
010662-14	TAYLOR LAVERN V. WYETH LLC ET	2/25/2011
010665-14	TERRY JACQUELINE V. WYETH LLC	2/25/2011
010666-14	SMITH SANDRA V. WYETH LLC ET A	2/25/2011
010668-14	VAUGHN JANICE V. WYETH LLC ET	2/25/2011
010669-14	VELASCO VINCENT V. WYETH LLC E	2/25/2011
010670-14	MAIA TORRES V. WYETH LLC ET	2/25/2011
010671-14	LUBOWIEKI SHEILA V. WYETH LLC	2/25/2011
010672-14	LUNDSTROM NOLA V. WYETH LLC	2/25/2011
010673-14	MCCLURE DAVID V. WYETH LLC ET	2/25/2011
010675-14	MCDONALD PATRICIA V. WYETH LLC	2/25/2011
010676-14	MEANS DEBBIE V. WYETH LLC ET A	2/25/2011
010677-14	MEJIA LORENA V. WYETH LLC ET A	2/25/2011
010678-14	MEYER MURENA V. WYETH LLC ET A	2/25/2011
010679-14	HARDEMAN DIANA V WYETH LLC ET	2/25/2011
010680-14	SARGENT GARY V. WYETH LLC ET A	2/25/2011
010681-14	ABRAMS KARLA V WYETH LLC ET AL	2/25/2011
010682-14	KATHY TUCKER V. WYETH LLC E	2/25/2011
010683-14	SIMPSON REBECCA V. WYETH LLC E	2/25/2011
010684-14	SHAPIRO HEATHER V. WYETH LLC E	2/25/2011
010685-14	SEPULVEDA DELGADO ANGEL V. WYE	2/25/2011
010686-14	FRANCESCA WALDROP V. WYETH L	2/25/2011
010687-14	WHEELER MARY V. WYETH LLC ET A	2/25/2011
010688-14	WARRINER HOWARD V. WYETH LLC E	2/25/2011
010689-14	WARHURST STELLA V. WYETH LLC E	2/25/2011
010690-14	WYLIE AKEIA V WYETT LLC ET AL	2/25/2011
010691-14	WINGETT MELISSA V. WYETH LLC E	2/25/2011
010692-14	ZION BIENAIME GLENDA V. WYETH	2/25/2011
010693-14	KILLINGS CAROL V. WYETH LLC ET	2/25/2011
010694-14	KREGER SANDRA V. WYETH LLC ET	2/25/2011
010695-14	LACKEY PRISCILLA V. WYETH LLC	2/25/2011

010696-14	NORTON JAYNEE ET AL V. WYETH	2/25/2011
010697-14	WHITE JEFFERY V WYETH LLC ET A	2/25/2011
010698-14	DAVIS JAMES V WYETH LLC ET AL	2/25/2011
010701-14	GRIMSLEY LATOYA V. WYETH LLC	2/25/2011
010702-14	LATIMER LYNN GUADALIPE V WYETH	2/25/2011
010703-14	JENNIFER JOHNSON V. WYETH LL	2/25/2011
010704-14	FIELDS JACQUELINE V. WYETH LLC	2/25/2011
010706-14	FLINN ROBERTA V WYETH LLC ET A	2/25/2011
010707-14	FRANKLIN BONNIE V WYETH LLC ET	2/25/2011
010708-14	FRIEDLI SHIRLEY V WYETH LLC ET	2/25/2011
010709-14	SMITH BRIDGET V. WYETH LLC ET	2/25/2011
010710-14	HIRALDO PAULA CASTRO V WYETH L	2/25/2011
010711-14	JEAN TURNER V. WYETH LLC ET	2/25/2011
010712-14	BASILISA ALECIA AGOSTO V WYETH	2/25/2011
010713-14	CRISTREL UNDERWOOD V. WYETH	2/25/2011
010714-14	BARRETT CADEN V WYETH LLC ET A	2/25/2011
010715-14	SIMS COURTNEY V. WYETH LLC ET	2/25/2011
010716-14	SELLERS WILLIAM V. WYETH LLC E	2/25/2011
010717-14	TAYLOR EARLINE V. WYETH LLC ET	2/25/2011
010718-14	NICHOLS ERIN V. WYETH LLC ET A	2/25/2011
010720-14	BACAL GRANT V WYETH LLC ET AL	2/25/2011
010101-14	HENSON BETTY V. WYETH LLC	2/28/2011
010103-14	UNDERWOOD ANGALETA V. WYETH	2/28/2011
010104-14	GUILLAME MECCA F V. WYETH LL	2/28/2011
010105-14	FREEBOURN NORBERT E V. WYETH	2/28/2011
010106-14	ACOSTA JENNIE T V. WYETH LLC	2/28/2011
010107-14	BAY ROXANNE L V. WYETH LLC	2/28/2011
010110-14	NAGY CHARLES V. WYETH LLC	2/28/2011
010111-14	ROBERTSON ZOLA V. WYETH LLC	2/28/2011
010113-14	GOSS PATRICIA V. WYETH LLC	2/28/2011
010134-14	LEE VIOLA V. WYETH LLC	2/28/2011
010135-14	DORSEY CLIFFORD V. WYETH LLC	2/28/2011
010137-14	MASSENBERG LETITIA V. WYETH LLC	2/28/2011
010139-14	MCILVEE ROSE C V. WYETH LLC	2/28/2011

010140-14	MEYER MARGARET V. WYETH LLC	2/28/2011
010142-14	MORRIS JR MONROE G V. WYETH LLC	2/28/2011
010147-14	ONEAL KERRI V. WYETH LLC	2/28/2011
010152-14	STEELE EVA V. WYETH LLC	2/28/2011
010244-14	TURNER HAZEL M V. WYETH LLC	2/28/2011
010245-14	LADY SARAH V. WYETH LLC ETAL	2/28/2011
010248-14	EIDSON GLORIA V. WYETH LLC ET AL	2/28/2011
010252-14	ALVAREZ LISA J V. WYETH LLC	2/28/2011
010268-14	HUDSON RAQUEL A V. WYETH LLC	2/28/2011
010269-14	DISHMAN MARIE V. WYETH LLC	2/28/2011
010270-14	THOMAS PATRICIA V. WYETH LLC ET AL	2/28/2011
010271-14	LAVALAIS KHADIJA V. WYETH LLC ET AL	2/28/2011
010272-14	HOLBROOK CECIL V. WYETH LLC ET AL	2/28/2011
010273-14	TENCH KAREN V. WYETH LLC ET AL	2/28/2011
010278-14	KIRK KATHRYN V. WYETH LLC	2/28/2011
010331-14	RICHARDSON KAREN V. WYETH LL	2/28/2011
010376-14	DARLENE COOLLEY V. WYETH LLC	2/28/2011
010413-14	BURKE DAVID V. WYETH LLC	2/28/2011
010451-14	HANSEL DARIN V. WYETH LLC	2/28/2011
010456-14	DYKHUIS PATRICIA V. WYETH LL	2/28/2011
010457-14	SCHWARTZ MICHELLE V. WYETH L	2/28/2011
010459-14	NOLING DEBORAH M V. WYETH LLC	2/28/2011
010463-14	RUSCONI OLGA V. WYETH LLC	2/28/2011
010465-14	TILLETT RICK V. WYETH LLC	2/28/2011
010468-14	PICOT GUNTER PARTICIA V. WYETH LLC	2/28/2011
010477-14	JANNEY ANN V. WYETH LLC ET AL	2/28/2011
010479-14	BOOTH STEVE V. WYETH LLC ET AL	2/28/2011
010515-14	EDEL DIANE V. WYETH LLC	2/28/2011
010584-14	VEGA TERESA V. WYETH LLC	2/28/2011
010586-14	RODRIGUEZ DENELE V. WYETH LLC	2/28/2011
010597-14	WILLIAMS EARNEST V WYETH LLC E	2/28/2011

010153-14	CASE LORETTA V. WYETH LLC ETALS	3/11/2011
010154-14	WEBSTER ANGELA V. WYETH LLC ET AL	3/25/2011
010416-14	ZEMSKY LINDA V. WYETH LLC ET AL	3/25/2011
010417-14	BOWLEY ANNA ET AL V. WYETH LLC ET AL	3/25/2011
010418-14	ELLIOTT DEBORAH ET AL V. WYETH LLC ET A	4/6/2011
010163-14	RAMBO JEAN CAROLYN V. WYETH LLC ET AL	4/29/2011
010180-14	LEDFORD DONALD ET AL V WYETH LLC	4/29/2011
010191-14	CONLEY JR JOHN R V. WYETH LLC ET AL	4/29/2011
010356-14	MULLINS FLOYD ET AL V. WYETH LLC ET AL	4/29/2011
010158-14	MAZZUCA DEANN V. WYETH LLC ET AL	5/2/2011
010159-14	CLEVELAND DONNA M V WYETH LLC ET AL	5/2/2011
010161-14	CAWTHON BARRY V WYETH LLC ET AL	5/5/2011
010162-14	WALKER NATASHA V WYETH LLC ET AL	5/5/2011
010358-14	BUSH SHARON V. WYETH LLC	5/5/2011
010480-14	GREEN FURMAN V WYETH LLC ET AL	5/5/2011
010661-14	CRAIG CATHY V WYETH LLC ET AL	5/5/2011
010156-14	SWOFFORD PATRICIA V. WYETH LLC	5/6/2011
010157-14	GOIN JAMES V. WYETH LLC	5/6/2011
010160-14	WINGET GORDON L V. WYETH LLC	5/6/2011
010164-14	BROADNAX WILLIAM V. WYETH LLC ET LAS	5/16/2011
010481-14	BOSMAN ANNETTE V. WYETH LLC ET AL	5/16/2011
010587-14	REDING GREG V. WYETH LLC	5/26/2011
010719-14	DAVIS HELEN V. WYETH LLC	5/26/2011
010177-14	GLAUSER ANDREA V. WYETH LLC	6/21/2011
010178-14	SHUPPS SANDRA V. WYETH LLC	6/21/2011

010179-14	FELT PATRICIA V. WYETH LLC	6/21/2011
010199-14	JOB TAMMY V. WYETH LLC ET AL	7/28/2011
010202-14	ORTIZ ADOINO JUSTO V. WYETH LLC ETAL	7/28/2011
010203-14	PEREZ SANTIAGO MICHAEL V. WYETH LLC ET	7/28/2011
010204-14	SCHREURS JEFF V. WYETH LLC ETAL	7/28/2011
010205-14	SCZEPANSKI ROBERTA V. WYETH LLC ETAL	7/28/2011
010206-14	NIETEN GREGG V. WYETH LLC ETAL	7/28/2011
010207-14	CARRASCO LOPEZ DOMINGA V. WYETH LLC E	7/28/2011
010208-14	MCNEAL DOTRELL V. WYETH LLC ETAL	7/28/2011
010209-14	HAWKINS GLORIA V. WYETH LLC ETAL	7/28/2011
010210-14	JOHNSON JOEY V. WYETH LLC ETAL	7/28/2011
010211-14	LOGAN ANDREA V. WYETH LLC ETAL	7/28/2011
010212-14	OCONNOR NADINE V. WYETH LLC ET AL	7/28/2011
010213-14	JONES LINDA V. WYETH LLC ETAL	7/28/2011
010214-14	DAVIS MARJORIE V. WYETH LLC ET AL	7/28/2011
010215-14	COHEN RICHARD V. WYETH LLC ET AL	7/28/2011
010216-14	CHISUM SHARON V. WYETH LLC ET AL	7/28/2011
010217-14	BRINCKMAN DIANE V. WYETH LLC ET AL	7/28/2011
010218-14	BEVANS CHERYL V. WYETH LLC ET AL	7/28/2011
010219-14	BUSH CHARLOTTE V. WYETH LLC ET AL	7/28/2011
010221-14	MCBRIDE DENNIS V. WYETH LLC ET AL	7/28/2011
010222-14	BARKLEY ROSE V. WYETH LLC ET AL	7/28/2011
010223-14	ASTALOSH SAM V. WYETH LLC ET AL	7/28/2011
010224-14	AUGUSTIN WANDA V. WYETH LLC ET AL	7/28/2011
010225-14	JENKINS LINDA V. WYETH LLC ET AL	7/28/2011
010226-14	AHLBORN DONNA V. WYETH LLC ET	7/28/2011

	AL	
010227-14	HOLMES EBANY V. WYETH LLC ET AL	7/28/2011
010228-14	AVALOS ALYSSA V. WYETH LLC ET AL	7/28/2011
010229-14	FINLEY REGINA V. WYETH LLC ET AL	7/28/2011
010230-14	ESCALANTE EDWARD V. WYETH LLC ET AL	7/28/2011
010200-14	JOYCE JOHN V. WYETH LLC ETAL	8/3/2011
010232-14	FRANKLIN TERESA V. WYETH LLC ET AL	8/4/2011
010233-14	NORTON JAYNEE V. WYETH LLC ET AL	8/4/2011
010234-14	GRADY MARY V. WYETH LLC ET AL	8/4/2011
010231-14	REYNOLDS GROGAN CARLA A V. WYETH LLC	8/5/2011
010235-14	BERGMAN JACOB V. WYETH LLC ETALS	9/23/2011
010236-14	SMALDONE PAUL V. WYETH LLC ETALS	9/23/2011
010238-14	HACKEBEIL MURIEL V. WYETH LLC ETALS	9/23/2011
010237-14	HAYES TYRAN V. WYETH LLC ETALS	9/28/2011
010239-14	VANDERPOOL ADELINE V. WYETH LLC ETAL	10/11/2011
010240-14	ALGARIN CARMEN V WYETH LLC	10/21/2011
010241-14	SENZARINO AYDEN V. WYETH LLC	11/21/2011
010242-14	LEE WANDA S V. WYETH LLC	11/23/2011
010365-14	CLOUGH GEORGIA A V. WYETH LLC ET AL	12/23/2011
010049-14	WARREN INEZ V. WYETH LLC	1/25/2012
010088-14	BROCKMAN JIMMIE V. WYETH LLC ET AL	2/27/2012
010089-14	ENTWISLE DAVID V. WYETH LLC ET AL	2/27/2012
010090-14	BOYLAN SHERRI V. WYETH LLC ET AL	2/27/2012
010482-14	MARTINEZ LAZARO V. WYETH LLC	5/14/2013

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(a) Except as provided in subsection (b), all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States. Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any proceeding under this section.

(b)

(1) A State may bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations, of section 341, 343(b), 343(c), 343(d), 343(e), 343(f), 343(g), 343(h), 343(i), 343(k), 343(q), or 343(r) of this title if the food that is the subject of the proceedings is located in the State.

(2) No proceeding may be commenced by a State under paragraph (1)—

(A) before 30 days after the State has given notice to the Secretary that the State intends to bring such proceeding,

(B) before 90 days after the State has given notice to the Secretary of such intent if the Secretary has, within such 30 days, commenced an informal or formal enforcement action pertaining to the food which would be the subject of such proceeding, or

(C) if the Secretary is diligently prosecuting a proceeding in court pertaining to such food, has settled such proceeding, or has settled the

informal or formal enforcement action pertaining to such food.

In any court proceeding described in subparagraph (C), a State may intervene as a matter of right.