No. 16-684

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

BRIEF IN OPPOSITION

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COUNTERSTATEMENT OF QUESTIONS PRESENTED

The present petition arises out of a state mass tort proceeding in New Jersey, that has involved the claims of more than 600 plaintiffs from virtually every state against numerous manufacturers and distributors of generic metoclopramide ("Generic Defendants"), and that is now on the verge of being formally resolved by settlement agreements among the parties. Generic Defendants filed motions to dismiss or for summary judgment on grounds of federal preemption under this Court's decision in *Pliva, Inc. v. Mensing*, 564 U.S. 604 (2011). After the New Jersey Superior Court denied the motions with respect to claims against Generic Defendants that had not maintained labeling on their generic metoclopramide products that contained the same warning language as the brand-name's label, Petitioners sought leave for an interlocutory appeal of those rulings. Permission for interlocutory review was ultimately granted, and the rulings of the Superior Court were ultimately affirmed, both by the Appellate Division of the Superior Court and also by the Supreme Court of New Jersey.

In light of this procedural history, the questions presented by the petition should be reframed as:

1. Whether this Court has jurisdiction to review the interlocutory decision of the Supreme Court of New Jersey.

2. Whether the Supreme Court of New Jersey correctly ruled that federal law does not pre-empt state tort claims predicated on allegations of injury resulting from drug manufacturers' failure to warn of

the risks of their prescription drug, where federal law authorized the manufacturers to provide a stronger warning without prior action by the United States Food and Drug Administration.

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BRIEF IN OPPOSITION

Respondents Phyllis Kohles, *et al.*, plaintiffs in the underlying litigation, submit this brief in opposition to the Petition for Writ of Certiorari filed by Pliva, Inc.; Barr Pharmaceuticals, LLC; Barr Laboratories, Inc.; Watson Laboratories, Inc.; and Teva Pharmaceutical USA, Inc. For the reasons discussed below, the petition should be denied.

OBJECTION TO JURISDICTION

This Court lacks jurisdiction to review the decision of the Supreme Court of New Jersey. 28 U.S.C. § 1257(a) grants this Court jurisdiction over certain state court "[f]inal judgments or decrees." This petition does not seek review of a final judgment or decree, but rather asks this Court to review an interlocutory decision by a state court.

COUNTERSTATEMENT OF THE CASE

Metoclopramide is a prescription drug approved by the FDA only for short-term treatment (up to twelve weeks) of various gastric disorders. It is the generic equivalent of the brand-name drug, Reglan.

Long-term use of metoclopramide can cause serious neurological disorders, including tardive dyskinesia, a severe, often irreversible neurological condition

resulting in involuntary and uncontrollable repetitive body movements. Symptoms include "grotesque facial grimacing and open-mouthed, uncontrollable tongue movements, tongue thrusting, [and] tongue chewing." *Fisher v. Pelstring*, 817 F. Supp. 2d 791, 802 (D.S.C. 2011). There is no known treatment or cure for tardive dyskinesia.

Nevertheless, because metoclopramide is used to treat chronic gastric conditions, many physicians prescribed it for much longer-term use. To guard against this risk, in July 2004 the FDA approved a request by the manufacturer of Reglan to add a stronger, boldfaced warning at the start of both the "Indications and Usage" and the "Dosage and Administration" sections of the Reglan label. This new language expressly stated: "Therapy should not exceed 12 weeks in duration."[1]

While this language was added to the label for Reglan in July 2004, one of the Generic Defendants, and a petitioner herein—Pliva, Inc.—never added this language to the labeling for its drug, even though federal law permitted it to do so without prior FDA action.[2] Another petitioner, Teva, did not add this

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[1] In February 2009, the FDA went further and ordered manufacturers of metoclopramide to add a "black-box" warning to their labeling. That warning stated that, because of the risk of tardive dyskinesia, "Treatment with metoclopramide for longer than 12 weeks should be avoided in all but rare cases where therapeutic benefit is thought to outweigh the risk of developing tardive dyskinesia." 2009 Reglan Label (Rev. July 2009), at 1, *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/017854s052lbl.pdf.

[2] *See* Letter from Jay P. Lefkowitz, Counsel for Pliva to Clerk, U.S. Supreme Court (Mar. 11, 2011), *Pliva, Inc. v. Mensing*, 564

warning to its approved labeling for a full year. App.6a. A third petitioner, Watson Laboratories, which purchased Pliva's abbreviated new drug application (ANDA) to manufacture metoclopramide in December 2008, did not add this warning to its labeling until October 2010, well over six years after the FDA had approved the warning. App.7a.

Moreover, no manufacturer of metoclopramide took any steps to bring this new warning to the attention of prescribing physicians. They chose not to publish this new warning in the *Physician's Desk Reference*, nor to communicate the new label information to physicians by other means, such as by sending a "Dear Health Care Provider" letter about the change. As a result, many physicians remained unaware of the serious risks associated with long-term metoclopramide use and numerous patients who had been prescribed metoclopramide long-term suffered severe neurological injuries, including tardive dyskinesia. Many have sued for their injuries.

Respondents all used metoclopramide manufactured by one or more of the Petitioners for longer than twelve weeks during the period when Petitioners' products did not carry the July 2004 warning language on their labeling. They allege that their doctors would not have continued to prescribe, and they would not have continued to ingest, metoclopramide if they had been informed of the dangers of long-term use of the drug.

The present petition arises from mass tort proceedings in the Superior Court of New Jersey, in

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U.S. 604 (2011) (Nos. 09-993, 09-1039, 09-1501).

which the claims of more than 600 persons injured by long-term metoclopramide use have been coordinated. *See* App.94a. In order to effectively manage such complex litigation, liaison counsel for all plaintiffs filed a joint Master Long Form Complaint to govern the proceedings.

While these mass tort proceedings were pending, this Court decided *Pliva, Inc. v. Mensing*, 564 U.S. 604 (2011). In *Mensing*, this Court held that state-law failure-to-warn claims against manufacturers of generic drugs based on a state-law duty to provide stronger warnings than those approved by the FDA for the label of the equivalent brand-name drug were pre-empted on grounds of impossibility because of the federal requirement that the labeling on generic drugs must match that for their equivalent Reference Listed Drug ("RLD"), here Reglan. *Id.* at 618-19.

Following *Mensing*, the Generic Defendants moved to dismiss Respondents' Amended Master Long Form Complaint on federal preemption grounds. App.76a. On May 12, 2012, the Superior Court denied Petitioners' motion to dismiss with respect to claims against generic manufacturers that had not changed the label on their product to match the brand-name's label. App.92a. After the completion of discovery concerning the dates on which the Petitioners had implemented the label changes to incorporate the July 2004 changes to the warnings by the brand-name manufacturer, Petitioners filed motions for summary judgment or to dismiss. Petitioners again argued 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 Respondents' failure to warn after 2004 that use of their drug products should not exceed twelve weeks in duration, are not preempted because it was not impossible for Respondents to include such warning in their drug labels after the warning was included in the brand-name drug label in 2004. 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. The Appellate Division concluded that failure-to-warn claims are not preempted by the FDCA if federal law would have permitted the defendants to independently provide, without prior action by the FDA, the warnings that plaintiffs contended was required by state law. App.47a-49a.

The Supreme Court of New Jersey 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 failure to provide warnings that the FDCA permitted. App.25a-26a. The court observed that Respondents would be able to proceed on their claims "even if the FDCA and Hatch-Waxman did not exist." App.28a. The Supreme Court of New Jersey also concluded that Respondents' claims do not interfere with the purposes and objectives of the FDCA because they are "a complementary form of drug regulation." App.27a (quoting *Wyeth v. Levine*, 555 U.S. 555, 578 (2009)).

FDA Regulation of Drug Safety

Under the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), commonly referred to as the Hatch-Waxman Amendments to the federal Food, Drug and Cosmetic Act or FDCA, once a brand-name drug loses patent protection, another company may seek approval for a generic version of that drug through a process known as an abbreviated NDA or ANDA. 21 U.S.C. § 355(j). Generic drugs, like their branded equivalents, are subject to the federal statutory requirement that their labeling carry adequate warnings. 21 U.S.C. § 352(f)(2). In addition, because ANDA approval is based on the RLD, the proposed labeling for the generic drug is subject to a requirement that it be the same as that for the RLD. 21 U.S.C. § 355(j)(2)(A)(v).

Because pre-marketing clinical trials of branded drugs are typically quite small, involving only carefully selected patients taking the drug for limited periods of time, many serious risks associated with a drug are not discovered until the drug has been on the

market for a number of years. Karen E. Lasser, *et al.*, *Timing of New Black Box Warnings and Withdrawals for Prescription Medicines*, 287 JAMA 2215, 2218 (2002) (finding that half of all black box warnings on drugs introduced after 1975 were added after the drug had been on the market for seven or more years). Often, as in this case, risks do not fully emerge until long after generic drugs have entered the market and captured a large percentage of sales.

Because knowledge about a drug's benefits and risks grows over time, especially after a drug has begun to be marketed, the FDA has procedures by which drug manufacturers can make changes to a drug's approved labeling or other changes to an approved application. Drug manufacturers may submit either "Prior Approval Supplements"—which, as the name implies, require FDA approval before the proposed change may be implemented—or "Changes Being Effected" ("CBE") Supplements, under which the proposed change may be implemented before the FDA has acted on the supplemental application. *See* 21 C.F.R. § 314.70(b), (c).

While most changes to a drug's approved labeling must be requested through a Prior Approval Supplement, 21 C.F.R. § 314.70(b), FDA regulations permit a manufacturer to "add or strengthen a contraindication, warning, precaution, or adverse reaction" through a CBE supplement. 21 C.F.R. § 314.70(c).

Generic drug manufacturers are expressly authorized to use both types of supplements, 21 C.F.R. § 314.97; however, they remain subject to the requirement that their labeling be the same as that of the RLD. *Mensing*, 131 S.Ct. at 2575.

Therefore, a generic drug company may invoke the CBE process to make changes to its generic drug's labeling only when it is changing "its label to match an updated brand-name label or to follow the FDA's instructions." *Id.*

Drug companies may also communicate information concerning their drugs to doctors and pharmacists by other means. For instance, they may publish their approved labeling in the *Physician's Desk Reference* and may also issue "Dear Health Care Professional" letters. Nothing in the FDCA or FDA regulations prohibits generic drug companies from communicating in these ways. However, FDA regulations do consider such communications to constitute "labeling;" therefore, such communications must be "consistent with and not contrary to [the drug's] approved . . . labeling." 21 C.F.R. § 201.100(d)(1). A Dear Health Care Professional letter informing doctors of a change to a drug's approved labeling would, almost by definition, be consistent with that labeling.

REASONS FOR DENYING THE WRIT

For numerous reasons, Generic Defendants' petition for a writ of certiorari should be denied. 1) This Court lacks jurisdiction to review the decision of the Supreme Court of New Jersey. 2) Contrary to Petitioners' contention, there is no split in the circuits warranting this Court's intervention. 3) The FDA has expressly rejected Petitioners' interpretation of federal regulatory requirements, as well as its contention that Respondents' claims interfere with the FDA's

enforcement authority, and the FDA's views on these issues are entitled to deference. 4) Moreover, the issues raised in the petition may largely be mooted by a pending global settlement of virtually all remaining products liability suits involving metoclopramide. 5) The interlocutory nature of this appeal, especially in light of the limited record, also makes this case a particularly poor vehicle for considering the questions presented. 6) Finally, this Court has already expressly declined to consider the questions presented in other petitions. For all of these reasons, the petition for a writ of certiorari should be denied.

I. THIS COURT LACKS JURISDICTION TO REVIEW THE INTERLOCUTORY DECISION OF THE NEW JERSEY SUPREME COURT

Section 1257 grants this Court jurisdiction over certain "[f]inal judgments or decrees" of a state court that rest on federal law when the "final" decision is rendered directly by "the highest court of a State," 28 U.S.C. § 1257(a). Section 1257 thereby "establishes a firm final judgment rule," *Jefferson v. City of Tarrant*, 522 U.S. 75, 81 (1997), limiting this Court's "power to intervene in State litigation," and thereby safeguarding the "smooth working of our federal system." *Radio Station WOW, Inc. v. Johnson*, 326 U.S. 120, 124 (1945).

There is no final judgment here. The trial court simply denied the Generic Defendants' motions to dismiss or for summary judgment, thereby allowing Respondents' claims to proceed. Petitioners were only able to obtain review of this ruling by interlocutory appeal. App.43a. The subsequent affirmance of the Superior Court's rulings by both the Appellate Division

and the New Jersey Supreme Court preserved the non-final, interlocutory nature of these proceedings.

Although this Court, in *Cox Broadcasting Corp. v. Cohn*, 420 U.S. 469 (1975), has identified four "exceptional categories" of state-court decisions that can be deemed "'final' on the federal issue despite the ordering of further proceedings in the lower state courts," *Johnson v. California*, 541 U.S. 428, 429-30 (2004) (per curiam), none of those exceptions apply here. In particular, contrary to Petitioners' assertion, Pet.31-33, this is not a situation where a failure to review Petitioners' preemption defense at this time would "seriously erode federal policy" under the fourth category identified in *Cox Broadcasting*. *Id.* at 483. This Court has repeatedly explained that *Cox*'s fourth exception "does not apply" where the party invoking the Court's jurisdiction fails to make a "convincing claim of erosion of federal policy that is not common to all decisions" rejecting similar arguments, lest "'the fourth exception swallow the rule.'" *Johnson v. California*, 541 U.S. 428, 430 (2004) (per curiam) (quoting *Flynt v. Ohio*, 451 U.S. 619, 622 (1981) (per curiam)). There is nothing unique about the preemption issues in this case that make the state court rulings particularly erosive of federal policy or that would preclude effective review of those issues, on a full record, following final resolution of Respondents' claims in state court. This Court therefore lacks jurisdiction under 28 U.S.C. 1257(a).

II. THE DECISION OF THE NEW JERSEY SUPREME COURT DOES NOT "IMPLICATE AN ENTRENCHED DIVISION OF AUTHORITY IN THE LOWER COURTS," AS PETITIONERS ASSERT

The petition asserts that the decision of the Supreme Court of New Jersey in this case "took the wrong side of a pre-existing split" of authority among the federal and state appellate courts on the question whether a state-law failure-to-warn claim based on a generic drug manufacturer's failure to provide a warning that the FDA had approved for its brand-name equivalent was pre-empted. Pet.17. That purported conflict does not exist.

The only federal court of appeals to directly decide the issue whether either *Mensing* or *Buckman* preempts such a state failure-to-warn claim is the Sixth Circuit, which held that a failure-to-warn claim based on a generic drug company's failure to provide a warning that the FDA had already approved was not pre-empted in *Fulgenzi v. Pliva, Inc.*, 711 F.3d 578 (6th Cir. 2013). That court first held that such a claim was not pre-empted on grounds of impossibility under *Mensing*:

> In our case, not only could [the generic drug company defendant] have independently updated its labeling to match that of the branded manufacturer through the CBE process, *see Mensing*, 131 S.Ct. at 2575, but it had a federal duty to do so, 21 C.F.R. § 314.150(b)(10). As a result, compliance with federal and state duties was not just possible; it was required. Impossibility preemption is inappropriate in such a case.

Id. at 584. The court of appeals then rejected the argument that such a claim was pre-empted under *Buckman*:

> Here, Fulgenzi's suit is not even premised on violation of federal law, but rather on an independent state duty. The alleged breach arises from the same act, but the legal basis is different. This is simply not grounds for preemption. The federal duty of sameness is not "a critical element" in Fulgenzi's case.

Id. at 586-87 (quoting *Buckman*, 531 U.S. at 353). Curiously, although it sought and obtained an extension of time to petition this Court, *Pliva, Inc. v. Fulgenzi*, No. 13A122 (U.S. July 30, 2013), Pliva, the generic drug company defendant in *Fulgenzi*—and one of the Petitioners here—decided not to ask this Court to review that decision.

Following *Fulgenzi*, a number of state appellate courts have agreed that such state failure-to-warn claims are not pre-empted. *See*, *e.g.*, *Teva v. Superior Court of Orange Cnty.* (*Pikerie*), 217 Cal. App. 4th 96 (Cal. Ct. App. 2013), *cert. denied*, ___U.S.___, 135 S.Ct. 1152 (2015); *Huck v. Wyeth, Inc.*, 850 N.W.2d 353 (Iowa 2014), *cert. denied sub nom. PLIVA, Inc. v. Huck,* ___U.S.___, 135 S.Ct. 1699 (2015); *In re Reglan/Metoclopramide Litig.*, 81 A.3d 80 (Pa. Super. 2013), *cert. denied sub nom. Teva Pharmaceuticals USA, Inc. v. Bentley*, ___U.S.___, 135 S.Ct. 1892 (2015); *Hassett v. DaFoe, et al.,* 74 A.3d 202 (Pa. Super. 2013), *cert denied sub nom. Teva Pharmaceuticals USA, Inc. v. Hassett,* ___U.S.___, 135 S.Ct. 2310 (2015); *Franzman v. Wyeth, Inc.*, 451 S.W.3d 676 (Mo. Ct. App. 2014).

By contrast, none of the Fifth Circuit decisions identified by Petitioners as in conflict with *Fulgenzi* actually decided this issue. In each of the cases, the court simply found that plaintiff had not adequately raised or pled a state-law failure-to-warn claim based on the generic drug company defendant's failure to provide a warning that the FDA had approved for its RLD. *See Morris v. Pliva, Inc.*, 713 F.3d 774, 777 (5th Cir. 2013) ("no such claim appears in Appellants' live pleading . . . [and] it is logically incoherent to contend that Pliva had a duty to apply the 2004 warning label when Appellants also assert repeatedly that no labels predating 2009 were adequate. Tort liability does not arise for failure to attach an inadequate label."); *Lashley v. Pfizer, Inc.*, 750 F.3d 470, 475 (5th Cir. 2014) (same); *Johnson v. Teva Pharms. USA, Inc.*, 758 F.3d 605, 612 n.1 (5th Cir. 2014) (plaintiff failed to plausibly allege that one-year delay in updating label caused injury when she continued to take drug for four more years); *see also Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1249 n.2 (11th Cir. 2013) ("Guarino does not allege that Teva failed to update its label once the [RLD] strengthened it"); *Wagner v. Teva Pharmaceuticals USA, Inc.*, 840 F.3d 355, 359-60 (7th Cir. 2016) ("In light of the undeveloped record here, we need not answer the open question of preemption of state failure-to-update claims").

Having concluded that the state-law claim was not available to plaintiffs, some of these courts then noted the undisputed proposition that, under 21 U.S.C. § 337(a), plaintiffs could not sue for a violation of the FDCA. *See*, *e.g.*, *Morris*, 713 F.3d at 777 ("a claim that Pliva breached a federal labeling obligation sounds exclusively in federal (not state) law, and is

preempted."). Neither *Fulgenzi*, nor any of the state court decisions that follow it, disagree. *See*, *e.g.*, *Fulgenzi*, 711 F.3d at 586 (pursuant to 21 U.S.C. § 337(a), state-law claims that "'exist solely by virtue of' the [federal] regulatory scheme . . . are preempted") (citing *Buckman*, 531 U.S. at 353).[3]

The purported conflict among state and federal appellate courts identified in the petition is illusory and provides no basis for granting a writ of certiorari.

III. THE FDA HAS REJECTED PETITIONERS' INTERPRETATION OF FEDERAL REGULATORY REQUIREMENTS, AS WELL AS THEIR VIEW THAT RESPONDENTS' CLAIMS INTERFERE WITH THE FDA'S ENFORCEMENT AUTHORITY

The FDA has rejected Petitioners' reading of FDA regulations, as well as their view that Respondents' claims interfere with the FDA's enforcement authority. The FDA's position on these questions is entitled to deference from the courts. *Mensing*, 131 S.Ct. at 2575 ("The FDA's views are controlling unless plainly erroneous or inconsistent with the regulation[s] or there is any other reason to doubt that they reflect the FDA's fair and considered judgment. . . . We defer to the FDA's interpretation of its CBE and generic labeling regulations.") (internal quotation and citation omitted); *id.* at 2576 (deferring to FDA's views of regulations governing Dear Health Care Professional letters).

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[3] The New Jersey Supreme Court observed that the Fifth Circuit "did not give any detailed analysis or reasoning" for equating a failure-to-update claim with a claim for breach of a federal labeling obligation. App.33a.

The petition for a writ of certiorari in the *Pikerie* case, filed by some of the same Petitioners here, raised virtually identical preemption arguments concerning so-called "failure-to-update" claims. In response to a request from this Court, the United States submitted a brief in opposition to the petition for certiorari in *Pikerie*.[4] Brief of the United States as Amicus Curiae (hereinafter "U.S. Amicus Br."), *Teva Pharms. USA, Inc. v. Superior Court of Cal.*, ___U.S.___, 135 S.Ct. 1152 (2014) (No. 13-956), 2014 WL 7169712. That brief expressed the FDA's view that state-law failure-to-warn claims against generic drug companies that had failed to update their labels to match RLD labeling were not pre-empted. In the FDA's view, federal regulations permitted the generic drug company defendant to strengthen its warning to match that of the RLD through the CBE process without prior FDA action, as well as to send Dear Health Care Professional letters alerting prescribing physicians to the new warnings. U.S. Amicus Br., 2014 WL 7169712, at *4-5, *16-17, *20-22. Those agency views are entitled to deference.

The FDA also rejected Petitioners' argument that permitting state failure-to-warn lawsuits where a generic drug company fails to update its labeling to match that of the RLD "would impinge on FDA's enforcement discretion":

> To the contrary, such actions against generic manufacturers who do not promptly update their labeling align with FDA's priorities.

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[4] "The brief filed by the United States represents the views of the FDA." *Mensing*, 131 S.Ct. at 2575 n.3.

> FDA advises generic drug manufacturers to "routinely monitor * * * for information on changes in labeling" and to make appropriate revisions "at the very earliest time possible." *Labeling Guidance* 5. As this Court has explained, FDA "has limited resources to monitor the 11,000 drugs on the market" and, as in *Wyeth*, "[f]ailure-to-warn actions" like that here "lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times." *Wyeth*, 555 U.S. at 578-579.

U.S. Amicus Br., 2014 WL 7169712, at *18.

The *Pikerie* brief expressly noted that Petitioners' reading of *Buckman* cannot be reconciled with this Court's decision in *Wyeth v. Levine*, 555 U.S. 555 (2009): "if [Petitioners'] expansive reading of *Buckman* were correct, *Buckman* presumably would have barred the duty to warn claims in *Wyeth*." U.S. Amicus Br., 2014 WL 7169712, at *17.

The FDA has made clear that it agrees with the decision of the New Jersey Supreme Court in this case. Given the deference due to the agency's views, the FDA's position provides a further reason for denying certiorari.

IV. THE ISSUE PRESENTED MAY LARGELY BE MOOTED BY A PENDING GLOBAL SETTLEMENT OF THE UNDERLYING LITIGATION

As Respondents previously advised the Court, *see* January 23, 2017 letter from counsel for respondents to Clerk of the Court requesting extension of time,

the parties have recently reached a settlement agreement to resolve remaining metoclopramide claims in this case, as well as in similar mass tort proceedings pending in Pennsylvania and California. At a recent hearing, Petitioners' counsel described that agreement to the New Jersey Superior Court as a "binding settlement." *In Re Reglan Metoclopramide Litigation*, No. MID-L-10165-14, Case Management Conf. (N.J. Super. Ct. Feb. 15, 2017). Thus, virtually all claims in this proceeding are likely to be resolved before this Court could take up the merits of the question presented herein.

Respondents cannot represent that, as a result of this settlement agreement, no claims will remain. As in most negotiated resolutions of mass tort litigation, individual plaintiffs do have the option of opting out of the settlement and proceeding with the litigation on their own. Nevertheless, counsel anticipate that few, if any, plaintiffs will avail themselves of this option, rendering the pending petition largely, if perhaps not technically, moot.

More generally, the question of preemption of failure-to-warn claims against manufacturers of generic drugs that fail to update their labeling to add warnings adopted by the brand-name drug will also be rendered largely moot by the pending settlement. The vast majority of cases addressing this issue, including four prior petitions to this Court, *see infra* at 19, have involved metoclopramide. They arose from a highly unusual confluence of circumstances in which one ANDA holder completely ignored its responsibilities to update labeling and the manufacturer of the brand-name equivalent took no actions to alert the medical

community to a significant labeling change. With the settlement of virtually all pending metoclopramide claims, these unusual circumstances are unlikely to often recur. There is therefore considerable doubt whether the issue raised in the petition remains sufficiently significant to merit this Court's attention.

V. OTHER PRUDENTIAL CONSIDERATIONS COUNSEL AGAINST REVIEW

For a number of additional reasons, this case would be a poor vehicle for this Court's consideration of the questions presented, even if this Court deemed those questions worthy of review. To begin with, the interlocutory posture of this case limits the record that would be before the Court if certiorari were granted. For example, while discovery in the Superior Court has documented when each of the Petitioners ultimately implemented the July 2004 label change, there has as of yet been no attempt to correlate that information with the dates of use and products ingested by individual plaintiffs. Nor has a record been developed on the reasonableness of Petitioners' delays in implementing the labeling change. It would be advisable to allow the case to proceed further to develop the factual record appropriate for plenary review.

Moreover, because of the narrow scope of the Superior Court's ruling, and the interlocutory nature of this appeal, the pending petition presents only half of the relevant question to the Court for consideration. A number of other courts have ruled that, even after a generic manufacturer updates its labeling to match that of the brand, it may still be held liable for failure to warn for failing to communicate that new warning the medical community. *See, e.g., Teva v.*

Superior Court (*Pikerie*), 217 Cal. App. 4th 96; *In re Reglan/Metoclopramide Litig.*, 81 A.3d 80. Here, by contrast, the Superior Court dismissed such "failure-to-communicate" claims after the date of a labeling update. App.88a-90a. Respondents retain the right to challenge that portion of the ruling after final judgment. It would be far more sensible for the Court to consider these closely interrelated questions together at such time, rather than in piecemeal fashion in this interlocutory proceeding.

Each of these prudential considerations argues against a grant of certiorari.

VI. THIS COURT HAS ALREADY DECLINED TO CONSIDER THE QUESTION PRESENTED ON MULTIPLE OCCASIONS

Petitioners and their counsel have presented the same question for review by this Court, and alleged the same purported circuit split, in at least four prior petitions for certiorari. *See, e.g.*, Pet. for Certiorari, *Teva v. Superior Court of Orange Cnty.* (*Pikerie*), ___U.S.___, 135 S.Ct. 1152 (2015) (No. 13-956); Pet. for Certiorari, *PLIVA, Inc. v. Huck,* ___U.S.___, 135 S.Ct. 1699 (2015) (No. 14-544); Pet. for Certiorari, *Teva Pharmaceuticals USA, Inc. v. Bentley*, ___U.S.___, 135 S.Ct. 1892 (2015) (No. 14-711); Pet. for Certiorari, *Teva Pharmaceuticals USA, Inc. v. Hassett,* ___U.S.___, 135 S.Ct. 2310 (2015) (No. 14-705). The same issue was also raised by counsel for the plaintiff in the petition filed in *Moretti v. Wyeth, Inc.*, 135 S.Ct. 1398 (2015) (No. 14-6319). This Court decided to deny review of each of these prior petitions. *Id.* Nothing has changed that would warrant a different result here.

CONCLUSION

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

Respectfully submitted,

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