No. 12-

IN THE

Supreme Court of the United States

MCNEIL-PPC, INC.,
Petitioner,

v.

CHRISTINA HOYT HUTTO AND ERIC HUTTO, ET AL.,
Respondents.

On Petition for a Writ of Certiorari to the Louisiana Third Circuit Court of Appeal

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

In *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), this Court held that a state-law claim challenging the adequacy of a generic prescription drug label was preempted, because federal law required the manufacturer to obtain approval from the Food and Drug Administration ("FDA") before making the label change sought by the state-law claim. *Id.* at 2579. In this case, the state-law claim challenged the adequacy of a label for an "over-the-counter" ("OTC") drug, marketed under the FDA's "OTC monograph" regime, which sets forth mandatory labeling requirements and requires FDA approval before a manufacturer can deviate from those requirements. Finding *PLIVA* to be inapplicable because it involved a generic prescription rather than brand-name OTC label, the appellate court affirmed a $1,157,774.40 judgment against petitioner for failing to unilaterally change the label.

The following question is presented:

Whether the preemption rule set forth in *PLIVA* applies to a state-law failure-to-warn claim challenging an OTC drug label, where the label was consistent with the applicable OTC monograph and could not be changed by the manufacturer without prior approval from the FDA.

PARTIES TO THE PROCEEDING

Petitioner is McNeil-PPC, Inc. Respondents are Christina Hoyt Hutto, Eric Hutto, and the Louisiana Patient's Compensation Fund.

RULE 29.6 DISCLOSURE

McNeil-PPC, Inc., is a wholly owned subsidiary of Johnson & Johnson. Johnson & Johnson is a publicly held corporation, and no publicly held corporation owns more than 10% of its stock.

TABLE OF CONTENTS

Page

TABLE OF CONTENTS
(continued)

Page

TABLE OF CONTENTS
(continued)

Page

TABLE OF AUTHORITIES

Page(s)

CASES

TABLE OF AUTHORITIES
(continued)

Page(s)

STATUTES

RULES AND REGULATIONS

TABLE OF AUTHORITIES
(continued)

Page(s)

OTHER AUTHORITIES

PETITION FOR A WRIT OF CERTIORARI

Petitioner McNeil-PPC, Inc., respectfully seeks a writ of certiorari to review the judgment of the Louisiana Third Circuit Court of Appeal in this case.

OPINIONS BELOW

The decision of the Louisiana Third Circuit Court of Appeal is reported at 79 So.3d 1199, and is reprinted in the Appendix hereto ("App.") at 4a-43a. The order of the Supreme Court of Louisiana denying discretionary review is reported at 86 So.3d 628, and is reprinted at App. 1a.

JURISDICTION

The Louisiana Third Circuit Court of Appeal issued its decision on December 7, 2011, App. 4a, and denied a timely application for rehearing on January 18, 2012, App. 2a. The Supreme Court of Louisiana denied petitioner's timely application for a writ of certiorari on April 27, 2012. App. 1a. This Court's jurisdiction is invoked pursuant to 28 U.S.C. § 1257(a).

CONSTITUTIONAL, STATUTORY, AND REGULATORY PROVISIONS INVOLVED

The pertinent constitutional, statutory, and regulatory provisions are set forth at App. 58a-91a.

STATEMENT OF THE CASE

The Louisiana Third Circuit Court of Appeal improperly concluded that plaintiffs' state-law failure-to-warn claims were not preempted by the federal Food Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-399d, and its implementing regulations, even

though petitioner's over-the-counter ("OTC") product was marketed pursuant to the FDA's OTC monograph process, which mandated that petitioner use FDA-approved dosing instructions and product warnings and prevented petitioner from changing its label without prior approval from the FDA. That decision conflicts with *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), where this Court held that implied conflict preemption exists where a "private party [cannot] independently do under federal law what state law requires of it." *Id.* at 2579; *see also Wyeth v. Levine*, 555 U.S. 555, 571 (2009). Because the Court of Appeal's error was plain, this Court should summarily reverse the decision based on *PLIVA*, or grant the petition, vacate the judgment below, and remand the case for further consideration in light of *PLIVA*. Alternatively, the Court should grant plenary review and hold that *PLIVA*'s preemption analysis applies to over-the-counter drugs marketed under the FDA's OTC monograph regime because the labeling for such products is mandated by the applicable monograph, and a manufacturer cannot unilaterally augment a label without violating federal laws on misbranding. *See* 21 U.S.C. §§ 331-334.

A. Statutory and Regulatory Background

Congress requires FDA approval of medications as "safe and effective" before they may be sold in this country. 21 U.S.C. §§ 355(d), 393(b)(2)(B). The process by which a drug is approved varies depending on whether it is a brand-name prescription drug, a generic prescription drug, or a nonprescription OTC drug.

1. The term "prescription drug" includes any drug that "because of its toxicity or other potentiality for harmful effect … is not safe for use except under the supervision of a practitioner licensed by law to administer such drug." 21 U.S.C. § 353(b)(1)(A). To obtain approval for a brand-name prescription drug, the manufacturer must submit a new drug application ("NDA") that contains, among other things, proposed instructions and warnings. 21 U.S.C. § 355. The FDA's new drug approval process includes a procedure by which warning labels are drafted, approved, and required for inclusion in the packaging of drugs. *Id.* The FDA regulates all such labeling, including "all written, printed, or graphic matter" accompanying or marketing the drug. 21 C.F.R. § 1.3(a). An element the FDA considers crucial in determining whether a drug is safe is the labeling used to inform consumers about the proper use and risks of the drug. 50 Fed. Reg. 7,452, 7,470 (Feb. 22, 1985) ("Drug labeling serves as the standard under which FDA determines whether a product is safe and effective."). The FDA refuses approval if the agency determines "that the drug is unsafe for use under the conditions prescribed, recommended, or suggested in its proposed labeling." 21 C.F.R. § 314.125(b)(3).

After approving an NDA, the FDA continues to monitor the drug's safety and must withdraw approval if it later determines that the labeling is inadequate, "false[,] or misleading in any particular." 21 U.S.C. § 355(e). The manufacturer must file a supplemental application if it wishes to change the label, but where the manufacturer seeks to change a label to "add or strengthen a contraindication, warn-

ing, 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," the FDA's "changes being effected" ("CBE") regulation authorizes the manufacturer to change the label unilaterally upon filing its supplemental application, without waiting for FDA approval. 21 C.F.R. §§ 314.70(c)(6)(iii)(A), (C).

2. Generic versions of approved prescription drugs obtain approval through the abbreviated new drug application ("ANDA") process. *See* 21 U.S.C. § 355(j). Rather than submitting independent evidence of safety and efficacy, the manufacturer can gain FDA approval by showing that the generic drug is equivalent to an approved brand-name drug. *See* 21 U.S.C. § 355(j)(2)(A). The equivalence extends to labeling as well, and the generic drug's label must "show that the [safety and efficacy] labeling proposed … is the same as the labeling approved for the [brand name] drug." 21 U.S.C. § 355(j)(2)(A)(v). Because of this duty of "sameness," a generic manufacturer cannot independently change its label (unlike brand-name manufacturers under the CBE regulation). Instead, generic manufacturers must work with the FDA and the brand-name manufacturer to change the label that applies to both the brand-name and generic drugs.

3.a. OTC drugs are those that do not meet the statutory definition of "prescription" drugs and thus do not require a physician's supervision for their use by a consumer. The FDA has adopted an alternative system to the NDA/ANDA process for evaluating whether the hundreds of thousands of over-the-counter drugs available to consumers are safe, effec-

tive, and not misbranded, known as the OTC monograph process. Under the OTC monograph regime, the FDA appoints advisory review panels of qualified experts to evaluate the safety and efficacy of over-the-counter drugs, to review their labeling, and to advise on the promulgation of monographs establishing conditions under which particular categories of over-the-counter drugs can be marketed. 21 C.F.R. § 330.10(a). The FDA publishes proposed and tentative final monographs for public review and comment, and eventually promulgates a final monograph in the form of regulations in the Code of Federal Regulations. *Id.* Those regulations establish conditions under which a category of over-the-counter drugs is recognized as safe and effective and not misbranded. 21 C.F.R. § 330.1 An over-the-counter drug is generally recognized as safe and effective and not misbranded if it meets each condition in the regulations governing such drugs and in any applicable monograph. *Id.* Under the regulations, once a final monograph goes into effect, it is illegal to sell a drug that does not conform to the monograph requirements and any nonconforming drug "is liable to regulatory action." 21 C.F.R. §§ 330.1, 330.10(b).

To promote national consistency in labeling, and to prevent confusion by the public, the regulations for all over-the-counter drugs include *mandatory* labeling requirements. Under the heading "Uses," the product must "contain the labeling describing the 'Indications' that have been established in an applicable [over-the-counter] drug monograph or alternative truthful and nonmisleading statements describing only those indications for use that have been established in an applicable monograph." 21 C.F.R.

§ 330.1(c)(2). "Any other labeling … shall be stated in the exact language where exact language has been established and identified by quotation marks in an applicable OTC drug monograph or by regulation." *Id.* Another regulation provides that the labeling of over-the-counter drugs must be "clear and truthful in all respects and may not be false or misleading in any particular." 21 C.F.R. § 330.10(a)(4)(v). Labeling must state intended uses and results, directions for proper use, warnings against unsafe use, side effects, and adverse reactions "in such terms as to render them likely to be read and understood by the ordinary individual, including individuals of low comprehension, under customary conditions of purchase and use." 21 C.F.R. § 330.10(a)(4)(v). Any deviation from the requirements imposed by the monographs requires FDA approval. 21 C.F.R. § 330.11. Unlike brand-name drugs marketed through the NDA process, there is no CBE regulation allowing manufacturers of OTC monograph drugs to change their labels without FDA approval.

b. In 1988, the FDA published the Tentative Final Monograph for Internal Analgesic, Antipyretic and Antirheumatic Drug Products for Over-the-Counter Human Use (the "monograph")—which governs Tylenol® products.[1] 53 Fed. Reg. 46,204 (Nov. 16, 1988). The FDA monograph's recommended labeling for children over two years of age included weight- and age-based dosing information. For chil-

[1] On April 29, 2009, the FDA published the Final Monograph, Organ-Specific Warnings for Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use. 74 Fed. Reg. 19,385 (Apr. 29, 2009). This final rule became effective on April 29, 2010.

dren under two years of age, the monograph required pediatric drug manufacturers to advise parents to contact their child's doctor before administering the medication. *Id.* at 46,257. The FDA's rationale for not permitting manufacturers to provide dosing information for children under age two was that medical intervention might be necessary for young children, and that parents ought not medicate young children without a doctor's involvement. App. 14a. The monograph was also silent as to any specific warnings about liver damage, a maximum daily dosage, or the specific signs of overdose. *See* 53 Fed. Reg. 46,225-46,260.[2]

B. Factual Background And Procedural History

1. During the time period giving rise to the events in this lawsuit, petitioner manufactured Infants' Tylenol® Concentrated Drops ("Infants' Tylenol®") for use in children under 3 years old. App. 13a. Infants' Tylenol® was administered via an enclosed dropper, and had a concentration of acetaminophen of 160 mg per 1.6 ml. *Id.* By contrast, Children's Tylenol® is labeled for use in children between the ages of 2 and 11 years of age, is administered in teaspoons, and has a concentration of 160 mg per 5 ml (which is equal to 1 teaspoon). *Id.*

Petitioner manufactured Infants' Tylenol® because it was more concentrated than Children's Tylenol® and therefore easier to give to young children

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[2] The final monograph published in 2009 now contains a warning about liver damage. *See* 21 C.F.R. §§ 201.326(a)(1)(iii)-(v).

who may be unable or unwilling to swallow medication in larger amounts. App. 13a. The dropper had markings for 0.4 ml and 0.8 ml, and the label cautioned users: "Use only enclosed dropper to dose this product. Do not use any other dosing device." *Id.* The label also warned: "Do not exceed the recommended dose." *Id.* Petitioner no longer manufacturers the concentrated form of Infants' Tylenol®.

The package for Infants' Tylenol® did not provide dosing information for children under two years of age. App. 13a. Instead, as dictated by the OTC monograph, the label directed parents to "call a doctor" when their child under two years of age was experiencing fever or pain. App. 13a-14a. The label's warnings were all consistent with the FDA's OTC tentative final monograph for analgesic drugs. *See supra* at pp. 6-7.

2. Over the years, petitioner had repeatedly tried to get the FDA to change the OTC monograph to include specific dosing instructions for children under two years of age as well as other warnings, but the FDA consistently declined to do so. C.A. Br. 7. Specifically, petitioner proposed a weight- and age-based dosing schedule for OTC acetaminophen products starting at 4-11 months of age and 12-17 lbs.; sent representatives to numerous FDA advisory committee meetings to discuss labeling issues; and submitted a Citizen's Petition in 1999 requesting that the monograph be amended to expand the age groups for OTC consumer dosing instructions on product labeling. *Id.* Despite petitioner's repeated efforts to obtain approval to place specific dosing instructions and other warnings on the label, the FDA continued to require the label to instruct parents to "call a doc-

tor" for dosing instructions for children under two, and refused to permit more specific dosing information or other warnings on the label. *Id.*

3. Brianna Hutto was born on July 31, 2002, to Respondents Eric and Christina Hutto. App. 7a. Christina and Eric lived with Christina's mother, Theresa Oliver. *Id.* After Brianna's birth, both Christina and Theresa gave Brianna Infants' Tylenol® multiple times to treat colds. C.A. Br. 4. For example, in November 2002, they gave Brianna the proper dose of 0.4 milliliters of Infants' Tylenol® and used the enclosed dropper, after consulting a physician for dosing instructions. *Id.* Also, on January 3, 2003, Christina gave her daughter one dropperful of 0.8 milliliters of Infants' Tylenol®—an appropriate dose. App. 7a.

After administering this correct dose on the morning of January 3, 2003, Christina Hutto took her daughter to the emergency room at Opelousas General Hospital ("OGH"). While waiting for treatment, Christina showed a nurse the bottle of Infants' Tylenol® that she had used that morning. App. 7a.

When it came time to discharge Brianna, an OGH nurse gave Christina written after-care instructions indicating that the appropriate dose was three-quarters of a teaspoon of "Tylenol." App. 7a. An OGH nurse later increased the prescribed dose to one full teaspoon, explaining that the higher dose would be more effective for Brianna, considering her weight. App. 7a-8a.

In prescribing one teaspoon, the hospital staff was referring to the less concentrated Children's Tylenol® used at the hospital. App. 8a. Christina and

her mother Theresa assumed that the discharge instructions referred to Infants' Tylenol®, which was what Christina had given her daughter that morning and had shown to the nurse at the hospital. *Id.*; C.A. Br. 4. No one at OGH specified the type of Tylenol® to be given to Brianna. C.A. Br. 4. A single teaspoon of the more concentrated Infants' Tylenol® was more than four times the recommended dose for a child of Brianna's age and weight. App. 8a.

OGH had a written policy on how to handle patients, like the Huttos, with questions about Tylenol® dosing. OGH's policy required that hospital personnel give patients one of the Tylenol® dosing sheets provided by McNeil. App. 8a. The policy also required the healthcare provider to circle the correct dose on the dosing sheet so the patient would not be confused. OGH violated its own policy by not providing the Huttos with the dosing sheet. *Id.*

After leaving the hospital, Teresa and the Huttos administered a teaspoon dose of Infants' Tylenol® to Brianna three times on January 4 and once on January 5—each one of which was more than four times the recommended dose. App. 9a; C.A. Br. 5. On the evening of Sunday, January 5, after giving Brianna the final dose of Infants' Tylenol®, Eric Hutto noticed that she continued to run a high fever and appeared lethargic. App. 9a. He brought Brianna back to OGH, where it was determined that she had been given an overdose of acetaminophen. *Id.* After unsuccessful efforts to save her (including transfer to different hospitals), Brianna died of liver failure on January 8, 2003. *Id.*

4.a. Brianna's parents, respondents in this action, brought suit against OGH and Brianna's doctor for medical malpractice arising out of the erroneous dosing information provided to them, and against petitioner as the manufacturer of Infants' Tylenol®. App. 9a-10a. OGH subsequently settled the claims against it, paying its statutory share of $100,000 pursuant to La. Rev. Stat. § 40:1299.42. App. 10a. The Louisiana Patient Compensation Fund ("PCF") then intervened to defend the fund from further liability. *Id.* The doctor subsequently was dismissed voluntarily from the suit, and the case proceeded to trial against petitioner and the PCF. *Id.*

b. At trial, petitioner presented the testimony of two different expert witnesses about McNeil's efforts to change the labeling for Infants' Tylenol® and the FDA's unwillingness to do so. Respondents never disputed or in any way contradicted petitioner's evidence about its attempts to convince the FDA to change its labeling instructions. C.A. Br. 7-8.

c. At the close of all the evidence, petitioner raised preemption in a motion for a directed verdict, arguing that respondents' failure-to-warn claims were preempted by federal law. App. 52a-54a. The trial court denied the motion. App. 57a. After a six-day trial, the jury returned a verdict against petitioner and the PCF, and the trial court entered judgment against petitioner for $1,157,774.40 and against the PCF for $421,912.19. App. 10a-11a. Petitioner again raised the preemption issue in a motion for judgment notwithstanding the verdict, App. 48a, which the trial court denied, App. 44a-47a, 50a.

5. Petitioner appealed the case to the Louisiana Third Circuit Court of Appeal, arguing, *inter alia*, that respondents' failure-to-warn claims were preempted by the federal Food Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-399d and its implementing regulations. While the case was on appeal, this Court decided *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), holding that failure-to-warn claims are preempted where a manufacturer cannot "independently do under federal law what state law requires of it." *Id.* at 2579.

In its briefs to the Court of Appeal, petitioner explained that respondents' failure-to-warn claim was preempted under *PLIVA* because the labeling for Infants' Tylenol® was controlled by the FDA's OTC monograph for analgesics and petitioner was powerless to change the label to add dosing instructions or additional warnings unless the FDA approved the changes. C.A. Br. 23-25; C.A. Reply Br. 8-10.

Despite this Court's intervening decision in *PLIVA*, the Court of Appeal affirmed the trial court's verdict. App. 4a-45a. The Court of Appeal found the case to be controlled by *Wyeth v. Levine*, 555 U.S. 555 (2009), where this Court held that state-law failure-to-warn claims against a prescription drug manufacturer were not preempted because the manufacturer could have unilaterally added the warnings required by state law pursuant to the FDA's CBE regulation, and thus the manufacturer had not shown that it was impossible to comply with both federal and state law. The Court of Appeal concluded that because petitioner "did not attempt to have all the warnings the Huttos argue would have prevented Brianna from being overdosed included on its

Infants' Tylenol® label … it did not establish that it was impossible to comply with both federal and state law and failed to show that the Huttos' claims are preempted by federal law." App. 20a. In so holding, the Court of Appeal ignored the crucial fact that, unlike the prescription drug at issue in *Wyeth*, petitioner's product was a nonprescription drug marketed under the FDA's OTC monograph process, and thus petitioner was required to follow the mandatory dosing instructions and warnings prescribed in the OTC monograph and could not unilaterally change its warnings without violating federal law on misbranding. The court also erroneously declined to follow *PLIVA* on the ground that it concerned a generic drug manufacturer, rather than a brand-name drug manufacturer like petitioner. *Id.*

6. Petitioner filed a timely application for rehearing, which the Court of Appeal denied. App. 2a-3a. Petitioner then filed a timely application for a writ of certiorari or review with the Supreme Court of Louisiana, again raising the preemption issue and asserting that the case was controlled by *PLIVA*. On April 27, 2012, the Supreme Court of Louisiana denied the application, with one Justice voting to grant the application. App. 1a.

REASONS FOR GRANTING THE PETITION

I. THIS COURT SHOULD SUMMARILY REVERSE OR GVR THE CASE BECAUSE RESPONDENTS' FAILURE-TO-WARN CLAIMS ARE PLAINLY PREEMPTED UNDER *PLIVA, INC. V. MENSING*

A. Summary Reversal Is Appropriate

As this Court recognized in *PLIVA*, "[t]he question for impossibility [preemption] is whether the private party could independently do under federal law what state law requires of it." 131 S. Ct. 2567, 2579 (2011). "[W]hen 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 state duties for pre-emption purposes." *Id.* at 2581.

PLIVA involved a state-law failure-to-warn claim about a generic prescription drug. Pursuant to federal regulations, the labels for generic drugs are required to use language identical to their brand-name counterparts. 21 U.S.C. § 355(j)(2)(A)(v). The generic manufacturers argued that it would violate the federally required duty of "sameness" to add any warnings that may be required by state law, and thus "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." 131 S. Ct. at 2578. This Court agreed, concluding that the state-law failure-to-warn claims were preempted. *Id.* at 2577-78.

The same analysis applies to the present case, warranting summary reversal of the Court of Ap-

peal. Under the OTC monograph regime, petitioner's label was required to mirror the warnings in the OTC monograph. 21 C.F.R. §§ 330.1, 330.10(b). If petitioner had made unilateral changes to its label, it would have violated the ongoing duty of "sameness" and the drug would have been misbranded. And while there is a process by which manufacturers can seek approval to deviate from the monograph, *see* 21 C.F.R. § 330.11, that regulation—unlike the CBE regulation in *Wyeth*—does not allow a manufacturer to effect the desired change before receiving FDA approval, *see id.*

As in *PLIVA*, there is no CBE regulation in the OTC monograph regime that would have allowed petitioner to change its label without first seeking FDA approval, which is a key distinction from *Wyeth*. Instead, the warnings must at all times comply with the monograph. *See* 21 C.F.R. § 330.10(b). Accordingly, just as with the generic prescription drug in *PLIVA*, where the manufacturers could not add the warning required by state law without violating their federal-law duty to keep the label identical to its brand-name counterpart, the OTC manufacturer here could not add the warnings required by Louisiana state law without violating the FDCA, which makes it illegal to sell a drug that does not conform to the applicable monograph. *See* 21 U.S.C. §§ 331-334.

By failing to recognize that the label for petitioner's OTC drug was required to comply with the applicable monograph, and that, unlike in *Wyeth*, petitioner could not make unilateral changes to the label pursuant to a CBE regulation, *see* 555 U.S. at 568, the Court of Appeal erroneously disregarded the

preemption standard this Court announced in *PLIVA*.

The Court of Appeal also dismissed *PLIVA* on the ground that it "dealt with state law claims against manufacturers of generic drugs, not a brand-name manufacturer like" petitioner. App. 21a. But there is no relevant distinction between manufacturers of generic prescription drugs and brand-name manufacturers of OTC drugs: neither manufacturer can unilaterally add warnings to its label, which is what matters under *PLIVA*. *Wyeth* reached a different result for manufacturers of brand-name prescription drugs precisely because they *can* implement unilateral label changes pursuant to the "changes being effected" regulation. *See Wyeth*, 555 U.S. at 571. Manufacturers (brand-name or not) of drugs marketed under the OTC monograph regime have no such power, and thus labeling claims against them are subject to *PLIVA* preemption, just like labeling claims against manufacturers of generic prescription drugs.

Because there can be no serious doubt that *PLIVA* applies to drugs marketed under an OTC monograph, this Court should reverse the "lower court's demonstrably erroneous application of federal law" by summarily reversing the decision below. *Maryland v. Dyson*, 527 U.S. 465, 467 n.* (1999) (per curiam); *see also Am. Tradition P'ship, Inc. v. Bullock*, 132 S. Ct. 2490, 2490 (2012) (summarily reversing case where Court's prior precedent clearly applied to case).

B. GVR, At A Minimum, Is Warranted

Alternatively, this Court should grant the petition, vacate the judgment below, and remand the case for further consideration in light of *PLIVA*. This Court recently GVR'ed a similar case for consideration in light of *PLIVA*. In *Gaeta v. Perrigo Pharmaceuticals Co.*, 630 F.3d 1225 (9th Cir. 2011), the Ninth Circuit held that a state-law failure-to-warn claim involving a generic OTC ibuprofen drug was not preempted by federal law. *Id.*[3] The manufacturer filed a petition for certiorari, and a few weeks later the Court issued its decision in *PLIVA*, finding preemption. This Court thereafter granted the *Gaeta* petition, vacated the Ninth Circuit's judgment, and remanded the case for reconsideration in light of *PLIVA*. *See L. Perrigo Co. v. Gaeta*, 132 S. Ct. 497 (2011). On remand, the Ninth Circuit found the state-law claims preempted under *PLIVA*.

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[3] While *Gaeta* involved an OTC drug, the drug was marketed pursuant to the ANDA process, rather than pursuant to the OTC monograph process, which raised different questions about the manufacturer's ability to unilaterally change its label. *Compare Gaeta*, 630 F.3d at 1236 (describing NDA/ANDA approval for ibuprofen), *and* 67 Fed. Reg. 54,139, 54,140 (Aug. 21, 2002) (explaining that ibuprofen has been marketed under the NDA process), *with* Div. of Nonprescription Regulation Development, *Regulatory History of Pediatric Acetaminophen Dosing* 3 (Apr. 18, 2011) (explaining that oral, immediate-release acetaminophen was moved from the NDA process to the OTC monograph process in 1972). Nevertheless, the preemption question in both cases is the same: "whether the private party could independently do under federal law what state law requires of it." *PLIVA*, 131 S. Ct. at 2579. Remand for reconsideration in light of *PLIVA* is thus appropriate in both cases.

See Gaeta v. Perrigo Pharms. Co., No. 09-15001, 2012 WL 605678 (Feb. 27, 2012).

The Court should follow the same course here. The fact that the Ninth Circuit's initial opinion in *Gaeta* was issued before this Court issued its decision in *PLIVA*, whereas the Court of Appeal's decision here was issued a few months after *PLIVA*, does not alter the analysis or detract from the need for this Court to remand the case for reconsideration in light of *PLIVA*. *See Robinson v. Story*, 469 U.S. 1081, 1081 (1984) (remanding case for consideration of Supreme Court decision issued three months before the court of appeals' opinion). Indeed, this Court has explained that "[w]here intervening developments, *or recent developments that we have reason to believe the court below did not fully consider*, reveal a reasonable probability that the decision below rests upon a premise that the lower court would reject if given the opportunity for further consideration, and where it appears that such a redetermination may determine the ultimate outcome of the litigation, a GVR order is, we believe, potentially appropriate." *Lawrence v. Chater*, 516 U.S. 163, 167 (1996) (per curiam) (emphasis added); *see also Stutson v. United States*, 516 U.S. 193, 197-98 (1996) (per curiam) (GVR'ing case for consideration of recent case that lower court may not have fully considered); *Youngblood v. West Virginia*, 547 U.S. 867, 875 (2006) (per curiam) (remanding case to state supreme court to reconsider *Brady* line of cases). Accordingly, if this Court does not issue a summary reversal, it should GVR the case so that the Court of Appeal can reconsider *PLIVA*'s application to the case.

II. ALTERNATIVELY, THIS COURT SHOULD GRANT REVIEW AND HOLD THAT FEDERAL LAW PREEMPTS STATE-LAW FAILURE-TO-WARN CLAIMS FOR DRUGS MARKETED PURSUANT TO AN OTC MONOGRAPH

If this Court determines that summary reversal or GVR is not the appropriate course, it should grant the petition for certiorari and hold that federal law preempts state-law failure-to-warn claims for drugs subject to the OTC monograph process.

This result follows directly from *PLIVA*, where the Court explained 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 state duties for pre-emption purposes." 131 S. Ct. at 2581. As the manufacturer of an OTC drug marketed pursuant to the FDA's monograph for analgesics, petitioner was required to follow the monograph's label and warnings. It could not act unilaterally to augment the label for its product, because that would render the drug misbranded and in violation of federal law. *See* 21 U.S.C. §§ 331-334.

And, as in *PLIVA*, a finding of preemption for OTC drugs marketed under the monograph process is entirely consistent with *Wyeth*. In *Wyeth*, the Court found that the manufacturer could unilaterally add a warning without violating federal laws on misbranding by adding the warning pursuant to the CBE regulation (subject, of course, to the FDA later rescinding that change). 555 U.S. at 571. Here, as

in *PLIVA*, the monograph regime does not have a directly applicable CBE provision that would allow a manufacturer unilaterally to add a warning. *Cf. PLIVA*, 131 S. Ct. at 2575-76.

The application of preemption principles in the context of OTC drugs marketed under the FDA's OTC monograph regime is an important question with far-reaching consequences. There are over 300,000 drug products marketed through the OTC process, in 80 different therapeutic classes, *see* FDA, *Drug Applications for Over-the-Counter Drugs* (Apr. 26, 2010),[4] classified into 26 OTC monograph categories, *see* 21 C.F.R. § 330.5. Indeed, "six out of every ten medications bought by consumers are OTC drugs." FDA, *Drug Applications for Over-the-Counter Drugs*. The question of preemption in the context of OTC monograph drugs has been the subject of another petition to this Court, *see McNeil-P.P.C., Inc. v. Valdes*, No. 10-729, *cert. denied*, 131 S. Ct. 1021 (2011) (denying certiorari before this Court's decision in *PLIVA*), and it is bound to recur without this Court's review. This Court has already granted review to resolve questions about the application of the preemption doctrine for brand-name prescription drugs in *Wyeth* and generic prescription drugs in *PLIVA*, and this Court should now grant review to resolve the preemption question for the remaining—and significant—category of drugs: those marketed under the OTC monograph regime.

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[4] *Available at* http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/over-the-counterdrugs/default.htm.

CONCLUSION

This Court should grant the petition for a writ of certiorari and summarily reverse, or vacate the judgment of the Louisiana Third Circuit Court of Appeal and remand the case for further consideration in light of *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011). Alternatively, the Court should grant the petition and set the case for plenary review.

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July 26, 2012