No. 12-122

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

BRIEF OF PRODUCT LIABILITY ADVISORY COUNCIL, INC., *AMICUS CURIAE*, IN SUPPORT OF PETITIONER, MCNEIL-PPC, INC.

NANCY J. MARSHALL
(*Counsel of Record*)
nmarshall@dkslaw.com
JOSEPH L. MCREYNOLDS
DEUTSCH, KERRIGAN & STILES, L.L.P.
755 Magazine Street
New Orleans, Louisiana70130
(504) 581-5141

Counsel for Amicus Curiae

QUESTION PRESENTED

Does federal conflict preemption, as held and applied in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), to preempt state-law tort claims against a manufacturer of generic prescription drugs, also apply to preempt state-law failure to warn claims against a manufacturer of "over-the-counter" (OTC) non-prescription drugs, whose labels are governed by mandatory FDA regulations, with no available mechanism to change the drug label unilaterally, without first obtaining FDA approval?

TABLE OF CONTENTS

TABLE OF AUTHORITIES

RULES **Page**

REGULATIONS **Page**

FEDERAL REGISTER **Page**

INTEREST OF THE *AMICUS CURIAE*

Product Liability Advisory Council, Inc. ("PLAC") is a non-profit association with 100 corporate members that represent a broad cross-section of American and international product manufacturers, including manufacturers of prescription and over-the-counter drug medications, such as Bayer Corporation, Eli Lilly and Company, Johnson & Johnson, Merck & Co., Inc., Pfizer, Inc., Teva Pharmaceuticals USA, Inc., and Merck & Co., Inc. (now known as Merck Sharp & Dohme Corp.)[1]

All PLAC members are engaged in commerce in each of the 50 states, as well as commerce among several nations in both hemispheres. All corporate members seek to contribute to the improvement and reform of the law of the United States and elsewhere, with an emphasis on the law governing the liability of manufacturers of products sold in the United States and throughout the world. PLAC's perspective is derived from the experience of a

[1]A list of PLAC's corporate members is attached as Appendix A. Under Rule 37, the parties were given notice on August 16, 2012, ten days before the deadline, of PLAC's intention to file this brief. They have consented to PLAC's brief, and their letters of consent being filed with this brief. In accordance with Rule 37.6, *amicus* states that no counsel for a party involved in this case authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief.

corporate membership that spans a diverse group of industries in various facets of the manufacturing sector.

Since 1983, PLAC has filed over 950 briefs as *amicus curiae* in both state and federal courts, including in this Court, presenting the broad perspective of product manufacturers seeking fairness and balance in the application and development of the law as it affects product liability. Because of its unique ability to provide a broader perspective on federal preemption than perhaps that of the individual parties, and because of its keen interest in ensuring that the federal regulatory environment in which its members operate is rational and consistent, PLAC filed *amicus* briefs in three preemption cases recently decided by this Court,[2] including an *amicus* brief in *Wyeth v. Levine,*555 U.S. 555, 129 S. Ct. 1187 (2009),a case involving federal conflict preemption.

Federal conflict preemption, as applied in *PLIVA Inc. v. Mensing*, 131 S. CT. 2567, 180 L. Ed. 2d 580 (2011) -- and which should also apply in this case --directly implicates the broad national concern of PLAC and its members, many of whom are makers of OTC drugs subject to FDA regulations

[2]*Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000); *United States v. Locke*, 529 U.S. 89, (2000); and *Wyeth v. Levine*, 555 U.S. 555, 129 S. Ct. 1187 (2009).

governing their labels. PLAC and its members have a great interest in achieving uniformity federal law governing preemption of state law claims, where appropriate. This brief is limited to emphasizing the difference between *Wyeth* and *PLIVA* and why PLIVA should control the issue of federal preemption as applied to makers of OTC non-prescription drugs, like the Infants' Tylenol at issue here.

SUMMARY OF THE ARGUMENT

This case presents the third leg of this Court's preemption analysis that began with *Wyeth* and continued with *PLIVA*.

Wyeth held there was no federal conflict preemption between state and federal law because under FDA regulations makers of brand name prescription drugs, under a "changes being effected" (CBE) regulation, have a regulatory mechanism to make unilateral changes to drug labels without first obtaining FDA approval.

PLIVA, on the other hand, held that because makers of generic prescription drugs do not have an equivalent CBE regulation that allowed them to make unilateral changes to their labels, compliance with state tort law governing warnings was not possible, without first obtaining FDA approval.

Under *PLIVA,* compliance with state law is "impossible"—and a state-law claim is preempted -- when federal law prohibits a party from doing independently what state law requires of it; conflict preemption is not dependent on possible actions the FDA might take. *PLIVA, Inc.,* 131 S. Ct. at 2572

Here, because makers of OTC non-prescription drugs are likewise subject to mandatory FDA regulations governing their drug labels, with no corresponding CBE or equivalent regulation permitting unilateral changes without FDA approval, state law claims against OTC manufacturers should likewise be preempted under federal law.

ARGUMENT

As McNeil correctly argues, under the Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. §301 *et seq*. Congress requires FDA approval of all medications, prescription and non-prescription alike, as "safe and effective" before they may be sold in this country. 21 U.S.C. §§ 355(d), 393(b)(2)(B); McNeil Petition, p.2

Approval of brand-name prescription drugs, and the regulation of their labels, is governed by the new drug application (NDA) procedure contained in

21 U.S.C. §355, and corresponding regulations. McNeil Petition, p. 3.

Approval of generic prescription drugs is governed under the abbreviated new drug application (ANDA) procedure found in 21 U.S.C. 355(j).

OTC drugs are not subject to laws governing prescription drugs. Labeling of OTC drugs is governed by federal regulations found at 21 CFR 330, *et seq*.[3] Under those regulations, the FDA employs a monograph procedure for OTC drugs, by which the FDA Commissioner appoints an advisory review panel of qualified experts "to evaluate the safety and effectiveness of OTC drugs, to review OTC drug labeling, and to advise him on the promulgation of monographs establishing conditions under which OTC drugs are generally recognized as safe and effective and not misbranded."21 CFR 330.10(a).

These federal regulations specify precise procedures and standards for publishing a proposed

[3]21 CFR 330.1 states, in pertinent part: "An over-the-counter (OTC) drug listed in this subchapter is generally recognized as safe and effective and is not misbranded if it meets each of the conditions contained in this part and each of the conditions contained in any applicable monograph. Any product which fails to conform to each of the conditions contained in this part and in an applicable monograph is liable to regulatory action."

monograph in the federal register that establishes the "conditions under which a category of OTC drugs or a specific or specific OTC drugs are generally recognized as safe and effective and not misbranded." 21 CFR 330.10(a)(6)(I)-(iv).

After the process for establishing a proposed monograph has been completed,[4] the FDA requires the Commissioner to "publish in the Federal Register a tentative order containing a monograph establishing conditions under which a category of OTC drugs or specific OTC drugs are generally recognized as safe and effective and not misbranded." 21 CFR 330.10(a)(7). The regulations permit a 90-day period for review and comment of a published tentative order, but after that period, any "[n]ew data and information submitted after the time specified in this paragraph but prior to the establishment of a final monograph will be considered as a petition to amend the monograph and will be considered by the Commissioner only after a final monograph has been published in the Federal Register unless the Commissioner finds that

[4]The FDA established the monograph procedure for OTC drugs in 1972. See 37 Fed. Reg. 14,633. The Advisory Review Panel issued its recommendations for a proposed monograph of OTC internal analgesics, which include acetaminophen, the active ingredient in Infants' Tylenol at issue here, in 1977. See 42 Fed. Reg. 35,346, and the codified federal regulation in 21 CFR 343 *et seq*.

good cause has been shown that warrants earlier consideration."21 CFR 330.10(a)(7)(v).

The record and McNeil's petition show that Infants' Tylenol had been operating under a tentative monograph order for years, through and including 2003, when the tragic overdose occurred.[5]

The question is whether federal conflict preemption applies to preempt state law claims, based on inadequate labels, against OTC manufacturers subject to FDA's OTC monograph regulations.

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[5]FDA published its Tentative Final Monograph for internal analgesics and antipyretics, which include acetaminophen, the active ingredient in Infants' Tylenol at issue here, in 1988. It can be found in the Federal Register at 53 Fed. Reg. 46,204. That 1988 monograph order contains the restriction on label dosing information for children under two years of age. The language can be found at 53 Fed. Reg. 46,257, but for the Court's easy reference, is quoted here in relevant part:

> For products containing acetaminophen, aspirin, or sodium salicylate identified in § 343.10(a), (b), and (f). Adults: Oral dosage is 325 to 650 milligrams every 4 hours or 325 to 500 milligrams every 3 hours or 650 to 1,000 milligrams every 6 hours, while symptoms persist, not to exceed 4,000 milligrams in 24 hours, or as directed by a doctor. . . . *Children under 2 years: Consult a doctor. The dosage schedules above are followed by "or as directed by a doctor*." (Emphasis added).

a. Principles of Conflict Preemption

The concept behind conflict, or impossibility, preemption originates from the recognition that a party subject to two legal regimes cannot comply with both when compliance with one renders compliance with the other impossible. When the conflict is between federal and state law, the federal law prevails under the Supremacy Clause of the United States Constitution: "Where state and federal law 'directly conflict,' state law must give way." *PLIVA,* 131 S. Ct. at 2577 citing *Wyeth v. Levine*, 555 U.S. at 587, 129 S. Ct. at 1187 (Thomas, J., concurring). State and federal law conflict where it is "'impossible for a private party to comply with both state and federal requirements.'" *Id.*, quoting *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287, 115 S. Ct. 1483, 131 L. Ed. 2d 385 (1995).

The issue in *Wyeth* was whether the FDA's approval of a warning label on Phenergan, a prescription medication, made it impossible for Wyeth, the drug maker, to comply with Vermont state law that required warnings more specific than the one provided in the FDA approved label. *Wyeth*, 555 U.S. at 560, 129 S. Ct. at 1192.

This Court rejected Wyeth's argument that compliance with state law was impossible, for two reasons. The first reason was the existence of a

specific FDA "changes being effected" (CBE) regulation that "permits a manufacturer to make certain changes to its label before receiving the agency's approval," 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. *"Wyeth*, 555 U.S. at 568, 129 S. Ct. at 1196, citing and quoting 21 CFR §314.105(b) and 21 CFR §314.70(c)(6)(iii)(A). Because the CBE regulation permitted Wyeth unilaterally to strengthen its warning, subject to later FDA approval or rejection, the Court held that Wyeth had not proven that compliance with Vermont law was "impossible."

Second, the Court reasoned that, given the FDA's authority to reject (or rescind) changes made pursuant to the CBE regulation, Wyeth had failed to present "clear evidence that the FDA would not have approved a change to Phenergan's label" (*Id.*, 555 U.S. at 571, 129 S. Ct. at 1198), or would have rejected any different warning pursuant to the CBE regulation, had one been proposed.

This Court reached the opposite conclusion in *PLIVA*, decided in June, 2011. The issue there concerned the preemptive effect of FDA regulations governing the labeling of generic prescription drugs containing metoclopramide, which has a risk of

causing tardive dyskenesia, a severe neurological disorder, among 29% percent of those who take it over several years. Lawsuits in Minnesota and Louisiana sought damages for patients who had developed tardive dyskenesia, alleging that the drug warnings were inadequate under each state's product liability laws. The Eighth and Fifth Circuit Courts of Appeals both held that the state law claims were not preempted. *Mensing v. Wyeth, Inc.*, 588 F. 3d 603 (8th Cir. 2009); *Demahy v. Actavis, Inc.*, 593 F. 3d 428 (5th Cir. 2010).

This Court reversed and held that the state law claims were not preempted because compliance with both federal law and the state product liability law was not possible. Makers of generic prescription drugs are bound by federal law and regulation to use only those warning labels already approved for the brand-name drug; but unlike brand-name manufacturers they do not have the ability under the CBE regulation to change their label pending FDA approval. Because makers of generic prescription drugs could not unilaterally change their labels without violating federal law, this Court held that the state-law claims were preempted.

In reaching this conclusion, the Court deferred to the FDA's interpretation of the CBE and the generic labeling regulations, stating that "the Manufacturers could [not] have used the CBE

process to unilaterally strengthen their warning labels. The agency interprets the CBE regulation to allow 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." *PLIVA, Inc.*, 131 S. Ct. at 2575.

The Court specifically rejected the argument that compliance with state law was not "impossible" because generic manufacturers still had the opportunity to attempt label changes by soliciting FDA assistance in implementing changes to the brand-name label.[6] The Court held that compliance with state law is "impossible" when federal law prohibits a party from doing *independently* what state law requires, and conflict preemption is not dependent on possible actions the FDA might take:

> We can often imagine that a third party or the Federal Government *might* do something that makes it lawful for a private party to accomplish under federal law what state law requires of it. In these cases, it is certainly possible that, had the Manufacturers asked the

[6]The Court also rejected the argument that federal law permitted the generic manufacturers to issue "Dear Doctor" letters directly to treating physicians because such letters "would inaccurately imply a therapeutic difference between the brand and the generic drug and thus could be impermissibly misleading." *PLIVA, Inc.*, 131 S. Ct. at 2576.

> FDA for help, they might have eventually been able to strengthen their warning label. Of course, it is also *possible* that the Manufacturers could have convinced the FDA to reinterpret its regulations in a manner that would have opened the CBE process to them. . . .
>
> If these conjectures suffice to prevent federal and state law from conflicting for Supremacy Clause purposes, it is unclear when, outside of express pre-emption, the Supremacy Clause would have any force. We do not read the Supremacy Clause to permit an approach to pre-emption that renders conflict pre-emption all but meaningless.

PLIVA, Inc., 131 S. Ct. at 2579 (emphasis in original).

In holding that conflict preemption applied – because it was impossible for the manufacturers to comply with both federal and state law – the Court concluded that "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 state duties for pre-

emption purposes." *PLIVA, Inc.*, 131 S. Ct. at 2580-2581.

b. Errors in the state court's analysis and application of federal conflict preemption

With due respect, Louisiana Third Circuit Court of Appeal erred in its analysis and application of the principles of conflict pre-emption articulated in *Wyeth* and *PLIVA*.

The appellate court assumed that the CBE regulation was an available mechanism that would have allowed McNeil to independently change the label of Infants' Tylenol, which is an OTC drug, not a prescription medication. The appellate court cited McNeil's status as a maker of brand-name drugs as the basis for distinguishing *PLIVA*'s analysis and holding. It is true that *PLIVA* distinguished W*yeth* because "the federal regulations [i.e., the CBE regulation] applicable to Wyeth allowed the company, of its own volition, to strengthen its label in compliance with its state tort duty." *PLIVA, Inc.*, 131 S. Ct. at 2581. The difference between the holdings reached in the two cases turned however, not on Wyeth's status as a maker of brand-name drugs, but on Wyeth's ability through the CBE regulation to take independent action to change its label.

The regulatory ability to make unilateral or independent changes to labels is not available to makers of either brand-name or generic OTC drugs. The CBE regulation on which *Wyeth* relied to find that compliance with state law was possible applies only to *prescription* drugs. 21 CFR 314.70(c)(6)(iii). That regulation does not apply to or govern the labeling of OTC drugs, such as Infants' Tylenol.[7] Federal regulations in 21 CFR 201.57 state specifically that "The requirements in this section apply only to prescription drug products described in 201.56(b)(1) and must be implemented according to the schedule specified in 201.56(c) . . . ." Because the lower court thought the distinction turned on the status of the manufacturer, as either brand name or generic drugs, the court reached a result irreconcilable with *PLIVA*.

Regulations governing the labeling of OTC non-prescription drugs contain no procedure equivalent to the CBE regulation applicable to *prescription* drugs that would allow makers of OTC drugs to make any unilateral or independent changes to the label requirements once a tentative order for a monograph has been published in the Federal Register. McNeil, and all other makers of OTC drugs, whether sold under brand names or

[7]Federal regulations governing the labeling of prescription drugs are found in 21 CFR 201.57 *et seq.*

generic labels, thus find themselves in the same regulatory position of generic makers of prescription drugs: They are subject to federal regulations that do not allow for unilateral or independent action that would enable them to comply with state tort law duties, without FDA approval or assistance. It is the absence of equivalent CBE regulations to OTC drugs that makes compliance with state tort law "impossible" for OTC monograph orders.

It is understandable that this Court in *Wyeth* was reluctant to find "impossibility" of compliance when regulatory avenues for effecting label changes unilaterally and independently of FDA action or approval were available but never used or attempted. But when those avenues are absent, as they were in *PLIVA*, and as they are here, possibility of complying with state law becomes impossible, and calls for the application of preemption.

A private party subject to federal law can only do so much. Conflict, or impossibility pre-emption, under federal law, is indeed a demanding defense, *Wyeth*, 555 U.S. at 573, 129 S. Ct. 1187, but as *PLIVA* makes clear, it is not an "impossible" one, and the Supremacy Clause of the U.S. Constitution does not permit "an approach to pre-emption that renders conflict pre-emption all but meaningless." *PLIVA, Inc.*, 131 S. Ct. at 2579.

CONCLUSION

PLAC respectfully requests that the petition of McNeil-PPC, Inc., be granted, and the judgment be summarily reversed, or be vacated and the case remanded, or, alternatively, the case be docketed for full briefing and argument.

Respectfully submitted,

Nancy J. Marshall
Joseph L. McReynolds
Deutsch Kerrigan & Stiles, LLP
755 Magazine Street
New Orleans, LA 70130
504-581-5141

Attorneys for *Amicus Curiae*