Nos. 09-993, 09-1039, 09-1501

In The
Supreme Court of the United States

PLIVA, INC., et al.,
Petitioners,
v.
GLADYS MENSING,
Respondent.
ACTAVIS ELIZABETH LLC,
Petitioner,
v.
GLADYS MENSING,
Respondent.
ACTAVIS, INC.,
Petitioner,
v.
JULIE DEMAHY,
Respondent.

On Writs Of Certiorari To The United States Courts Of Appeals For The Eighth And Fifth Circuits

BRIEF OF AMICI CURIAE STATES OF MINNESOTA, LOUISIANA, ALABAMA, ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, HAWAII, IDAHO, ILLINOIS, INDIANA, IOWA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, MISSISSIPPI, MISSOURI, MONTANA, NEBRASKA, NEVADA, NEW HAMPSHIRE, NEW MEXICO, NEW YORK, NORTH CAROLINA, NORTH DAKOTA, OHIO, OKLAHOMA, PENNSYLVANIA, RHODE ISLAND, SOUTH CAROLINA, SOUTH DAKOTA, TENNESSEE, UTAH, VERMONT, WASHINGTON, WEST VIRGINIA, WISCONSIN, WYOMING, AND THE DISTRICT OF COLUMBIA IN SUPPORT OF RESPONDENTS

ALAN I. GILBERT
Solicitor General
Counsel of Record
JOHN S. GARRY
Assistant Attorney General

LORI SWANSON
Attorney General
STATE OF MINNESOTA
445 Minnesota Street, Suite 1100
St. Paul, Minnesota 55101-2128
(651) 757-1450
al.gilbert@state.mn.us

[Additional Counsel Listed On Inside Cover]

COCKLE LAW BRIEF PRINTING CO. (800) 225-6964
OR CALL COLLECT (402) 342-2831

JAMES D. "BUDDY" CALDWELL
Attorney General
STATE OF LOUISIANA

LUTHER STRANGE
Attorney General
STATE OF ALABAMA

JOHN J. BURNS
Attorney General
STATE OF ALASKA

THOMAS C. HORNE
Attorney General
STATE OF ARIZONA

DUSTIN MCDANIEL
Attorney General
STATE OF ARKANSAS

KAMALA D. HARRIS
Attorney General
STATE OF CALIFORNIA

JOHN W. SUTHERS
Attorney General
STATE OF COLORADO

GEORGE JEPSEN
Attorney General
STATE OF CONNECTICUT

JOSEPH R. BIDEN, III
Attorney General
STATE OF DELAWARE

DAVID M. LOUIE
Attorney General
STATE OF HAWAII

LAWRENCE G. WASDEN
Attorney General
STATE OF IDAHO

LISA MADIGAN
Attorney General
STATE OF ILLINOIS

GREGORY F. ZOELLER
Attorney General
STATE OF INDIANA

TOM MILLER
Attorney General
STATE OF IOWA

JACK CONWAY
Attorney General
COMMONWEALTH OF KENTUCKY

WILLIAM J. SCHNEIDER
Attorney General
STATE OF MAINE

DOUGLAS F. GANSLER
Attorney General
STATE OF MARYLAND

MARTHA COAKLEY
Attorney General
COMMONWEALTH OF
MASSACHUSETTS

JIM HOOD
Attorney General
STATE OF MISSISSIPPI

CHRIS KOSTER
Attorney General
STATE OF MISSOURI

STEVE BULLOCK
Attorney General
STATE OF MONTANA

JON BRUNING
Attorney General
STATE OF NEBRASKA

CATHERINE CORTEZ MASTO
Attorney General
STATE OF NEVADA

MICHAEL A. DELANEY
Attorney General
STATE OF NEW HAMPSHIRE

GARY K. KING
Attorney General
STATE OF NEW MEXICO

ERIC T. SCHNEIDERMAN
Attorney General
STATE OF NEW YORK

ROY COOPER
Attorney General
STATE OF NORTH CAROLINA

WAYNE STENEHJEM
Attorney General
STATE OF NORTH DAKOTA

MICHAEL DEWINE
Attorney General
STATE OF OHIO

E. SCOTT PRUITT
Attorney General
STATE OF OKLAHOMA

WILLIAM H. RYAN, JR.
Acting Attorney General
COMMONWEALTH OF PENNSYLVANIA

PETER F. KILMARTIN
Attorney General
STATE OF RHODE ISLAND

ALAN WILSON
Attorney General
STATE OF SOUTH CAROLINA

MARTY J. JACKLEY
Attorney General
STATE OF SOUTH DAKOTA

ROBERT E. COOPER, JR.
Attorney General
STATE OF TENNESSEE

MARK L. SHURTLEFF
Attorney General
STATE OF UTAH

WILLIAM H. SORRELL
Attorney General
STATE OF VERMONT

ROBERT M. MCKENNA
Attorney General
STATE OF WASHINGTON

DARRELL V. MCGRAW, JR.
Attorney General
STATE OF WEST VIRGINIA

J.B. VAN HOLLEN
Attorney General
STATE OF WISCONSIN

BRUCE A. SALZBURG
Attorney General
STATE OF WYOMING

IRVIN B. NATHAN
Acting Attorney General
DISTRICT OF COLUMBIA

TABLE OF CONTENTS

TABLE OF CONTENTS – Continued

TABLE OF CONTENTS – Continued

TABLE OF AUTHORITIES

Page

CASES

TABLE OF AUTHORITIES – Continued

TABLE OF AUTHORITIES – Continued

INTEREST OF THE AMICI CURIAE

The amici states have two principal interests at stake in these consolidated cases. First, as independent sovereigns in our federal system, the states have a strong interest in the Court continuing to apply the doctrine of implied preemption in a way that rarely negates state law. This is the approach the Court recently followed in *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), which held that the Federal Food, Drug, and Cosmetic Act does not impliedly preempt all state tort failure-to-warn claims against brand-name drug manufacturers.

Second, the amici states have a significant public policy interest in the Court reaching the same result here for generic drugs as it did for brand-name drugs in *Levine*. Consumer protection, public health, and state budgets would be undermined if generic drug manufacturers were shielded from all state tort claims of this kind even when they sell drugs knowing that the label does not contain adequate warnings. Implied preemption would: (1) deny injured consumers of generic drugs a remedy; (2) treat similarly-situated consumers differently; (3) eliminate a significant incentive for generic manufacturers to ensure the adequacy of warnings; (4) leave uncompensated damages caused by generic drugs to be borne by state taxpayers who help finance Medicaid and other health-care programs; and (5) be inconsistent with state laws that encourage substitution of generics for brand-name drugs.

In short, the amici states support a constrained application of implied preemption, with the result here that manufacturers are not allowed to sell inadequately labeled generic drugs with impunity.

SUMMARY OF ARGUMENT

In *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), the Court held that the Federal Food, Drug, and Cosmetic Act (FDCA) does not impliedly preempt all state tort failure-to-warn claims against brand-name drug manufacturers. The result should be no different when generic manufacturers are sued, especially since generics are now used to fill 70% of prescriptions. *Levine* stressed that manufacturers bear primary responsibility for drug labeling and that state tort law offers additional protection that is complementary to regulation under the FDCA.

Notwithstanding *Levine*, the generic manufacturers argue that state tort suits are barred in their entirety by implied preemption. They invoke the same theories of impossibility and frustration preemption that failed in *Levine*. Neither of these arguments overcomes the presumption against preemption, which requires a showing that Congress clearly intended to negate state law.

1. Federal law does not make it physically impossible for generic manufacturers to satisfy their state tort duty to adequately warn consumers of serious risks. Although there is disagreement over

the procedures available for generic manufacturers to revise a drug's labeling, it is undisputed that they can request and obtain Food and Drug Administration (FDA) approval to add a new label warning. Moreover, under *Levine*, the burden is on the drug manufacturer to show that the FDA would have prevented compliance with the state-law duty to warn by not permitting a proposed labeling change that would have provided the injured consumer with an adequate warning.

2. The generic manufacturers also have not established that implied frustration preemption bars these state tort suits. Such preemption can be found only if state law frustrates achievement of the purpose of the federal statute. The purpose of the 1984 Hatch-Waxman Amendments to the FDCA is to increase the availability of low-cost generic drugs, but in a safe manner. Achievement of this purpose is not frustrated by a state-law tort duty that requires generic manufacturers to warn consumers of known safety concerns.

a. As shown by *Levine*, the presumption against preemption operates with particular importance and weight in these cases. The Court starts with a strong assumption that Congress did not intend to bar long-standing state-law causes of action which protect consumer health and safety.

b. The absence of an express preemption provision in the FDCA is powerful evidence that Congress did not intend to prohibit all state tort suits of this kind. As evidenced by the FDCA's express preemption

clause for medical devices, Congress can be expected to speak explicitly if it intends to bar tort claims for inadequately labeled generic drugs.

c. The generic manufacturers' overstated assertions of frustration-of-purpose fall well short of showing a clear congressional intent to preempt all state tort claims of the sort asserted here. Avoiding liability in these cases did not require the generic manufacturers to conduct expensive studies and raise their drug prices accordingly. The allegations are simply that published medical literature and existing adverse event reports received by the manufacturers revealed the clear need for a new label warning.

d. Important public policy considerations also weigh against implying frustration preemption in these cases. In particular, implied preemption would deny injured consumers of generic drugs a remedy, one they would have if their prescription had instead been filled with the brand-name drug. It also would result in generic manufacturers having no financial incentive to ensure the adequacy of warnings, even if they know the labeling is inadequate and the brand-name manufacturer has abandoned the market entirely to generics. These and other important public policy considerations further underscore that the Court should not ascribe to Congress an unannounced decision to allow generic manufacturers to sell inadequately labeled drugs with impunity.

———♦———

ARGUMENT

The Court's preemption analysis is "guided by two cornerstones" – congressional intent and the presumption against preemption. *Wyeth v. Levine*, 129 S. Ct. 1187, 1194 (2009). "[T]he purpose of Congress is the ultimate touchstone in every pre-emption case." *Id.* (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)). Congress's purpose in enacting the FDCA was "to bolster consumer protection against harmful products," *Levine*, 129 S. Ct. at 1199, with a recognition that "state-law remedies further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings." *Id*. at 1200.

The FDCA does not contain an express preemption provision for prescription drugs. *Levine*, 129 S. Ct. at 1200. This leaves the generic drug manufacturers to rely on implied conflict preemption, which comes in two forms: impossibility preemption and frustration (or obstacle) preemption. *See, e.g., Pacific Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm'n*, 461 U.S. 190, 203-04 (1983).

The presumption against preemption applies fully to assertions of implied preemption. *Levine*, 129 S. Ct. at 1195 n.3. Moreover, the presumption is especially strong with respect to preserving state law that, as here, is related to health and safety. *See Hillsborough County v. Automated Med. Labs., Inc.,* 471 U.S. 707, 715-20 (1985); *see also Lohr,* 518 U.S. at 475 ("Throughout our history the several States have

exercised their police powers to protect the health and safety of their citizens."); *Altria Group*, *Inc. v. Good*, 129 S. Ct. 538, 543 (2008) (reiterating that the presumption "applies with particular force when Congress has legislated in a field traditionally occupied by the States").

In applying the presumption against preemption, a congressional intent to displace state law will not be found unless it is "clear and manifest." *Levine*, 129 S. Ct. at 1195 (quoting *Lohr*, 518 U.S. at 485 and *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). Overcoming the presumption imposes a "considerable burden" on the advocate of preemption. *De Buono v. NYSA-ILA Med. & Clinical Servs. Fund*, 520 U.S. 806, 814 (1997).

Under these principles, implied preemption of state law is rarely found, particularly in the area of prescription drugs. *Levine*, 129 S. Ct. at 1194-1204. Like their brand-name counterparts, generic manufacturers were not given congressional *carte blanche* to violate state law by selling prescription drugs without adequate warnings.

I. FEDERAL LAW DOES NOT MAKE IT IMPOSSIBLE FOR GENERIC DRUG MANUFACTURERS TO COMPLY WITH THEIR STATE-LAW DUTY TO ADEQUATELY WARN CONSUMERS OF DANGEROUS SIDE EFFECTS.

Impossibility preemption applies only when it is a "physical impossibility" to comply with both the state and federal law. *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963). This occurs when federal law forbids what state law requires or vice versa. *Barnett Bank v. Nelson*, 517 U.S. 25, 31 (1996).

The state tort failure-to-warn suits at issue here are of the same type that *Levine* permits against brand-name manufacturers. 129 S. Ct. at 1190-93. State tort law has long provided that manufacturers of prescription drugs are liable for harm to consumers caused by inadequate warnings of risks of harm. *Restatement (Third) of Torts: Prods. Liab.* § 6 (1998).

"Impossibility pre-emption is a demanding defense" in such cases. *Levine*, 129 S. Ct. at 1199. The generic manufacturers cannot satisfy this heavy burden. As in *Levine*, the manufacturers are not prevented from complying with their state-law duty to warn by the FDCA and its implementing regulations.

A. Federal Law Does Not Forbid Generic Manufacturers From Adding A New Label Warning.

All prescription drug manufacturers, both brand-name and generic, are responsible for ensuring that the labels of their drugs contain adequate warnings. "[T]hrough many amendments to the FDCA and to FDA regulations, it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times." *Levine*, 129 S. Ct. at 1197-98.

Under the FDCA, a drug "shall be deemed to be misbranded" unless "its labeling bears . . . such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users." 21 U.S.C. § 352(f)(2). To implement this prohibition against misbranded drugs, the FDA requires that prescription drug "labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug." 21 C.F.R. § 201.80(e); *see also* 21 C.F.R. § 201.57(c)(6). The Hatch-Waxman Amendments, 21 U.S.C. § 355(j), do not exempt generic drugs from these fundamental consumer-protection requirements.

The parties disagree regarding how the FDCA and its implementing regulations allow generic

manufacturers to warn consumers of potential side effects that surface after FDA approval of the drug and its original labeling. In any event, it is agreed that, at a minimum, a generic manufacturer can inform the FDA when the need for a change in label warnings for its drug becomes apparent. In fact, the federal government states that the FDCA and FDA regulations obligate generic manufacturers to do so. Brief for the United States as Amicus Curiae (Nov. 2010) ("U.S. Cert. Br.") at 11, 15 (stating that "a generic pharmaceutical manufacturer, like a brand-name manufacturer, can (and indeed, must) inform FDA of new information about risks that may require a change in the labeling of its drug" and that the petitioner generic manufacturers "were obligated to provide FDA with information about labeling concerns").

The undisputed manner in which generic manufacturers can notify the FDA of a labeling inadequacy and propose a new label warning is set forth in the FDA's notice promulgating final rules to implement the 1984 Hatch-Waxman Amendments. The notice instructs generic manufacturers as follows:

> If an ANDA applicant [i.e., a generic drug manufacturer] believes new safety information should be added to a product's labeling, it should contact FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised. After approval of an ANDA [a generic drug], if an ANDA holder believes that new safety

> information should be added, it should provide adequate supporting information to FDA, and FDA will determine whether the labeling for the generic and listed [brand-name] drugs should be revised.

57 Fed. Reg. 17,961. For "serious safety concerns" (such as the risk of developing tardive dyskinesia from long-term use of metoclopramide), this procedure results in an FDA "substantive evaluation like that for a [proposed label change using the prior approval supplement (PAS) process] under 21 C.F.R. 314.70." U.S. Cert. Br. 16-17. The FDA gives a high priority to the review of labeling changes that generic manufacturers propose for serious safety concerns. *Id.* at 16. If the FDA approves the proposed change, it requires all manufacturers of the brand-name and generic forms of the drug to revise their label warnings in the same way. *Id.* at 15-16.[1]

It is clear, then, that the FDCA and its implementing regulations allow, if not require, a generic manufacturer to notify the FDA and propose a new label warning when the manufacturer becomes aware of dangerous side effects from the use of its drug. Thus, because generic manufacturers are certainly

[1] The standard used to evaluate such a proposed label change is essentially the same as in the "changes being effected" (CBE) procedure, under which a manufacturer can put a proposed label change in place while FDA approval is pending. Thus, the only practical difference in the two procedures is how quickly the manufacturer can put the change into effect, i.e., either pending or after FDA approval. U.S. Cert. Br. 22-23 n.10.

not prohibited from requesting and obtaining FDA approval to add such a new label warning, federal law does not make it impossible for them to comply with their state-law duty to warn.

B. The Generic Manufacturers Have The Burden To Show That The FDA Would Have Rejected A Proposed Labeling Change.

The generic manufacturers incorrectly argue that any state tort failure-to-warn claim is barred by impossibility preemption because the FDA might have denied a requested labeling change and thereby prevented them from adequately warning consumers. This argument is contrary to *Levine*, which likewise involved a drug manufacturer's failure to seek FDA approval to change an inadequate label. *See Levine*, 129 S. Ct. at 1199 (concluding that, based on the record made at trial, "[w]e . . . cannot credit [the drug manufacturer's] contention that the FDA would have prevented it from adding a stronger warning" to the drug's label). As the proponents of preemption, the generic manufacturers have the burden to show impossibility of compliance with both state and federal law by establishing that the FDA would have rejected a proposed labeling change. *Id.* at 1196-99. "[A]bsent clear evidence that the FDA would not have approved a change to [the drug's] label, [the Court] will not conclude that it was impossible for [the drug

manufacturer] to comply with both federal and state requirements." *Id.* at 1198.[2]

Even if Respondents were assigned the burden of proving that the FDA would have approved a proposed labeling change, it is apparent they could meet that burden given the FDA's subsequent action regarding the label for metoclopramide. In February 2009, the FDA, acting on its own initiative, required manufacturers of metoclopramide to add to the label a warning of the risk of developing tardive dyskinesia from long-term use of the drug. Joint Appendix (JA) at 406, 415, 521, 556. Thus, it is fair to conclude that the FDA would have approved such a label change if it had been proposed earlier by a manufacturer.

Consumers should not, however, be entirely dependent on FDA-initiated action to be warned of dangerous side effects, especially in light of the FDA's limited resources to affirmatively monitor drug safety. *See Levine*, 129 S. Ct. at 1202 & n.11 (recognizing FDA's limited resources). When a generic manufacturer is aware of the need for a change to its label warnings, and yet does nothing to make the change,

[2] Also without merit is any assertion that impossibility preemption applies on the ground that a generic manufacturer could not have changed the drug's label until the FDA approved the proposed change. The tort claims in the instant cases do not seek to hold the manufacturers liable for such an interim period. *See infra* p. 21.

the manufacturer can certainly be held liable under state tort law for the resulting harm to consumers.

II. THE FDCA DOES NOT IMPLIEDLY PREEMPT ALL STATE TORT FAILURE-TO-WARN CLAIMS AGAINST GENERIC DRUG MANUFACTURERS AS PURPORTEDLY FRUSTRATING THE PURPOSE OF THE 1984 HATCH-WAXMAN AMENDMENTS.

Implied frustration-of-purpose preemption can exist only if the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" in enacting a federal statute. *Hines v. Davidowitz,* 312 U.S. 52, 67 (1941). Such preemption does not exist here because the requisite clear and manifest congressional intent to implicitly negate state law on that basis cannot be found. The 1984 Hatch-Waxman Amendments to the FDCA did not sacrifice safety in the interest of lower drug costs. Making low-cost generic drugs available in a safe manner is certainly not frustrated by requiring generic manufacturers to adequately warn of dangerous side effects that are readily apparent to them. Especially in light of the public policy consequences, Congress cannot be deemed to have barred injured consumers from holding generic manufacturers accountable for failing to satisfy this basic requirement of state law.

A. There Is A Strong Presumption Against Preemption.

As *Levine* makes clear, the presumption against preemption is especially critical when evaluating an assertion of implied frustration preemption of state tort claims. 129 S. Ct. at 1195 n.3. The Court stated that in such cases "[w]e rely on the presumption because respect for the States as independent sovereigns in our federal system leads us to assume that Congress does not cavalierly pre-empt state-law causes of action." *Id.* (internal quotations omitted). This prevents implied frustration preemption from being misused to displace too much state law.[3]

Moreover, the presumption is enhanced here because the challenged state tort law relates to the health and safety of victims of inadequately labeled

---

[3] *See Geier v. American Honda Motor Co.*, 529 U.S. 861, 907-08 (2000) (Stevens, Souter, Thomas, Ginsburg, JJ., dissenting) (observing that "the presumption [against preemption] serves as a limiting principle that prevents federal judges from running amok with our potentially boundless (and perhaps inadequately considered) doctrine of implied conflict pre-emption based on frustration of purposes"); *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 459 (2005) (Thomas, J., joined by Scalia, J., concurring in the judgment in part and dissenting in part) (approving "th[e] Court's increasing reluctance to expand federal statutes beyond their terms through doctrines of implied pre-emption"); *Gade v. National Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 111 (1992) (Kennedy, J., concurring in part, concurring in judgment) ("A free wheeling judicial inquiry into whether a state statute is in tension with federal objectives would undercut the principle that it is Congress rather than the courts that pre-empts state law.").

prescription drugs. *See supra* pp. 5-6; *Levine*, 129 S. Ct. at 1195 n.3 (recognizing that enforcement of the state tort law requirement to adequately warn of risks from using prescription drugs is "state regulation of health and safety"); *see also Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001) (acknowledging "the historic primacy of state regulation of matters of health and safety" as distinguished from claims of fraud on a federal agency) (quoting *Lohr*, 518 U.S. at 485).

The strong presumption against preemption precludes dismissal of these suits unless the generic manufacturers show a "clear and manifest" congressional intent, *Levine*, 129 S. Ct. at 1195, to shield them from all state tort claims that are based on failure to adequately warn of dangerous side effects.

B. The Absence Of An Express Preemption Clause Is Compelling Evidence That Congress Did Not Intend To Bar All State Tort Claims.

In its unanimous opinion in *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, the Court stated: "The case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there is between them." 489 U.S. 141, 166-67 (1989) (internal quotation omitted). Such is the case here.

When it enacted the FDCA in 1938, Congress did not include a provision preempting any type of state tort suits, despite "its certain awareness of the prevalence of state tort litigation." *Levine*, 129 S. Ct. at 1199-2000. Congress did add an express preemption clause to the FDCA in 1976, but only for medical devices. 21 U.S.C. § 360k(a); *see also Riegel v. Medtronic, Inc.*, 552 U.S. 312, 327 (2008) (recognizing that the FDCA's express preemption clause was written specifically to apply only to medical devices, and not to include prescription drugs). Congress did not include a preemption provision in the Hatch-Waxman Amendments enacted eight years later in 1984. Nor has Congress subsequently enacted any preemption provision for prescription drugs, despite continued state tort suits against manufacturers of both brand-name and generic drugs. *See, e.g., Foster v. American Home Prods. Corp.*, 29 F.3d 165, 166-67 (4th Cir. 1994).

From this history, the Court concluded in *Levine*: "If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point" such that "[i]ts silence on the issue . . . is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety." 129 S. Ct. at 1200. Consistent with Congress's longstanding decision not to enact a provision preempting state tort suits based on inadequate warning of drug risks, the FDA has "traditionally regarded state law as a complementary form of drug regulation." *Id.* at 1202;

see also Cuomo v. Clearing House Ass'n, LLC, 129 S. Ct. 2710, 2718 (2009) (citing *Levine* to refer to prescription drug regulation as one of "many . . . mixed state/federal regimes in which the Federal Government exercises general oversight while leaving state substantive law in place").

The generic manufacturers minimize the importance of Congress's decision not to enact an express preemption provision for prescription drugs, just as they disregard the presumption against preemption. Under the Court's jurisprudence, however, these two factors act together to set a high bar for establishing implied preemption through an asserted frustration-of-purpose.

C. The 1984 Hatch-Waxman Amendments Do Not Abandon The FDCA's Overarching Purpose Of Protecting Consumers From Harm.

"Congress enacted the FDCA to bolster consumer protection against harmful products." *Levine*, 129 S. Ct. at 1199. Because the 1984 Hatch-Waxman Amendments are part of the FDCA, they must be understood with this broader purpose in mind. *See, e.g., Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 51 (1987) ("On numerous occasions we have noted that '[i]n expounding a statute, we must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law and to its object and

policy.'") (quoting *Kelly v. Robinson*, 479 U.S. 36, 43 (1986) and other cases).

In their single-minded focus on the Hatch-Waxman Amendments' goal of making low-cost generic drugs available, the generic manufacturers give short shrift to Congress's ultimate purpose of protecting consumers. Such isolation of the Hatch-Waxman Amendments from the entirety of the FDCA violates the basic principle that statutes are to be read as a whole.

Reading the Hatch-Waxman Amendments in concert with the rest of the FDCA, their objective is not just to increase the availability of low-cost generic drugs, but to do so in a manner that protects consumer safety. Streamlining the process for initially bringing generic drugs to market does not mean they are to be sold with no regard for whether consumers are properly warned of serious risks.[4]

This view of the goals of the Hatch-Waxman Amendments is supported by the longstanding recognition that "state law offers an additional, and important, layer of consumer protection that complements FDA regulation." *Levine*, 129 S. Ct. at 1202-03.

---

[4] As the Generic Pharmaceutical Association recognizes: "Consumers should be well informed and confident when taking generic drugs." GPhA website, http://www.gphaonline.org/issues/state-consumer-education-efforts (as visited Feb. 11, 2011).

When the Hatch-Waxman Amendments were enacted, state tort suits regarding inadequate warnings had for decades been working in tandem with FDA regulation of drug labeling to protect consumers. These types of state tort "actions, in particular, lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times." *Id.* As noted above, Congress chose not to put an express preemption clause in the Hatch-Waxman Amendments. This left in place the understanding that consumer protection, as aided by state tort suits, remains the FDCA's guiding purpose for prescription drugs in both their brand-name and generic forms.

D. Requiring Generic Manufacturers To Warn Consumers Of Known Risks Does Not Frustrate Hatch-Waxman's Purpose Of Making Generic Drugs Available At A Low Cost, But In A Safe Manner.

Not only do the generic manufacturers incorrectly focus on just one objective of the Hatch-Waxman Amendments – lowering costs – they attempt to show frustration of that isolated objective by overstating what is required of them to avoid liability in these cases. None of the posited obstacles to the goal of keeping generic drugs affordable is persuasive where, as here, generic manufacturers are alleged to have been aware of the inadequacy of the label warnings for their drug but nevertheless took no action to add a new warning.

First, the generic manufacturers were not required to conduct costly clinical trials in order to notify the FDA of the need to change the label warnings for metoclopramide. Respondents allege that the risk of tardive dyskenisa from long-term use of metoclopramide, for which the label did not carry an adequate warning, was or should have been apparent to the generic manufacturers from published medical literature on the drug and adverse event reports they were receiving. JA 402, 417 (*Mensing*); 522, 559-60 (*Demahy*). Nor do FDA regulations require generic manufacturers to conduct new clinical trials in order to propose a labeling change. The FDA requires only "reasonable evidence" for a change in a label warning. 21 C.F.R. §§ 201.80(e), 201.57(c)(6); *see also* 21 C.F.R. § 314.81(b)(2)(i) (requiring a generic manufacturer to annually report to the FDA information "that might affect the safety, effectiveness, or labeling of [its] drug product"); 21 C.F.R. § 314.98(a) (requiring a generic manufacturer to report adverse drug events to the FDA); *Levine*, 129 S. Ct. at 1197 (recognizing that adverse event reports alone can provide a sufficient basis for a manufacturer to propose a new label warning).

Second, the generic manufacturers also miss the mark in suggesting that they would have to inundate the FDA with unneeded and unexamined information to avoid state tort liability. Again, in cases such as these, liability arises from failure to warn of a dangerous side effect that is apparent from published

literature regarding the drug and adverse event reports received by the generic manufacturer itself.[5]

Third, potential liability for failure to warn in such cases is not likely to cause generic manufacturers to pull products off the market. Such action would be an option only if a manufacturer wrongly believed that it could not even propose a new label warning. *See* JA 416 (*Mensing*) (observing that if the generic manufacturers "realized their label was insufficient but did not believe they could even propose a label change, they could have simply stopped selling the product"). In addition, the claims in the instant cases do not seek to hold a generic manufacturer liable for its drug being inadequately labeled during the period the FDA is deciding whether to approve a timely and appropriate label change proposed by the manufacturer. *See supra* p. 12 n.2; *see also Perry v. Novartis Pharma. Corp.*, 456 F. Supp.2d 678, 687 n.12 (E.D. Pa. 2006) (recognizing that "a manufacturer who has sought FDA approval for an additional warning [should not] be held liable for a failure to warn during the pendency of that agency review"); *Levine*, 129 S. Ct. at 1204 ("Although we recognize that some state-law claims might well frustrate the

[5] Nor do state tort suits of this kind obstruct a purpose of federal drug regulation by enmeshing the FDA in litigation, any more than did the suit permitted in *Levine*, where the FDA's records were examined in detail to determine if the FDA would have rejected a proposed change in the drug's labeling. *See Levine*, 129 S. Ct. at 1192-93, 1197-99, 1222-26.

achievement of congressional objectives, this is not such a case.").

Furthermore, the continuous exposure of generic manufacturers to state tort suits since enactment of the Hatch-Waxman Amendments in 1984 has not previously caused them to leave the prescription drug market. *See, e.g., Foster*, 29 F.3d at 166-67. On the contrary, the Generic Pharmaceutical Association reports that the sales and market share of generic manufacturers continue to grow. *See* http://www.gphaonline.org/about-gpha/about-generics/facts (as visited Feb. 11, 2011).

E. Public Policy Considerations Also Support The Conclusion That Congress Did Not Intend To Bar All Such State Tort Claims Against Generic Drug Manufacturers.

In light of the foregoing, congressional intent to bar all tort suits of this kind could be found only if public policy reasonably permitted no other conclusion. To the contrary, it is clear that public policy considerations support this role for state law in the regulation of generic drugs. The adverse public policy consequences of preemption are magnified by the fact that 70% of prescriptions in the United States are now filled with generic drugs, a share that amounts to nearly 2.6 billion prescriptions every year. *See* http://www.gphaonline.org/about-gpha/about-generics/facts (as visited Feb. 11, 2011).

1. Injured consumers should have a remedy.

The FDCA does not provide a remedy for injured consumers because Congress determined that "state rights of action provided appropriate relief for injured consumers." *Levine*, 129 S. Ct. at 1199. Thus, implied frustration preemption would leave consumers who are injured by an inadequately labeled generic drug with no remedy, even in cases where the generic manufacturer takes no action in the face of known safety concerns.

Congress should not be deemed to have implicitly granted generic manufacturers such immunity from state law for selling drugs without adequate warnings. *See Bates,* 544 U.S. at 449 ("If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly."); *Lohr*, 518 U.S. at 487 ("It is, to say the least, 'difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct.'") (quoting *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984)).[6]

---

[6] Moreover, in all but a few states, consumers injured by an inadequately labeled generic drug cannot seek relief against the brand-name manufacturer. As the Eighth Circuit noted, "the overwhelming majority" of courts have concluded that state tort law does not allow consumers of the generic version of a drug to hold the brand-name manufacturer responsible for the inadequacy of label warnings. JA 418-19 (*Mensing*) ("Traditional

(Continued on following page)

2. Similarly-situated consumers should be treated the same.

Implying preemption here would also produce arbitrary and unfair results. Consumers whose prescriptions are filled with the brand-name version of a drug (e.g., Reglan) have a state tort remedy for inadequate label warnings, as held in *Levine*, but consumers whose pharmacists filled their prescriptions with the generic version (e.g., metoclopramide) would be denied a remedy, despite being in precisely the same situation. *See, e.g., McNeil v. Wyeth*, 462 F.3d 364 (5th Cir. 2006) (holding that evidence supporting consumer's inadequate-warning claim against brand-name manufacturer of Reglan precluded summary judgment for manufacturer).

This incongruity is made even worse by the fact that "brand name manufacturers may elect to manufacture and distribute a generic version of their own brand name drug – as Wyeth has done with Reglan – once the brand name drug loses patent protection." *Kellogg v. Wyeth*, 612 F. Supp.2d 437, 441 (D. Vt. 2009). Thus, due to implied preemption, injured consumers using the same drug manufactured by the same company would be treated differently under the law based solely on fortuity.

---

products liability requires a plaintiff to show that she actually consumed the defendant's product.").

3. Generic manufacturers should have incentives to warn consumers.

"The FDA has limited resources to monitor the 11,000 drugs on the market" and lacks the capacity to effectively identify all the warnings that should be added based on the emergence of new risks. *Levine*, 129 S. Ct. at 1202 & n.11. State tort suits help fill this breach because they "provide incentives for drug manufacturers to disclose safety risks promptly." *Id.* at 1202.

Implied preemption would remove these tort-law incentives for generic manufacturers, to the detriment of consumer protection and public health. Generic manufacturers would have little inducement to ensure the adequacy of warnings, even when they have specific knowledge of undisclosed health risks. There would be no financial motive for any generic manufacturer to ever propose a labeling change to the FDA, no matter how obvious the inadequacy of a warning might be to it as the maker of the drug.

Moreover, once the brand-name manufacturer stops marketing the drug, it no longer has any tort-law incentives to ensure the adequacy of warnings for newly emerging risks. Thus, if generic manufacturers were immune from suit, there would be no manufacturer left with these strong incentives to ensure the adequacy of label warnings when a drug is being sold in only its generic form. This would undermine the "central premise" of federal drug regulation that manufacturers are responsible for maintaining

adequate drug labeling "at all times." *Levine*, 129 S. Ct. at 1197-98.

4. Costs should not be shifted to taxpayer funded health-care programs.

In addition to denying consumers the protection of state law, implied preemption would put added pressure on state (and federal) budgets. Not only would a significant incentive for ensuring the safe use of prescription drugs be eliminated, but injuries to consumers would go uncompensated by the wrongdoer. Much of the resulting increase in health-care costs would be borne by state-funded programs.

In particular, the Medicaid program, which provides medical assistance for persons who cannot afford to pay their own medical costs, is funded in significant part by the states. 42 U.S.C. §§ 1396a(a)(2), 1396d(b); *see also Arkansas Dep't of Health & Hum. Servs. v. Ahlborn*, 547 U.S. 268, 275 (2006) (explaining that Medicaid is jointly funded by the state and federal governments). Under Medicaid's third-party liability provisions, states can recoup Medicaid payments from the medical-costs portion of tort judgments and settlements. *Ahlborn*, 547 U.S. at 280-92. Implied preemption would prevent the recoupment of such payments caused by a generic manufacturer's tortious failure to warn.

5. Generic substitution laws should not be undermined.

Most states have laws that encourage pharmacies to substitute generics for brand-name drugs. *See, e.g.,* Minn. Stat. § 151.21 (2010); *see also Inwood Labs., Inc. v. Ives Labs., Inc.*, 456 U.S. 844, 847 n.4 (1982) ("Since the early 1970's, most States have enacted laws allowing pharmacists to substitute generic drugs for brand name drugs under certain conditions."); *FTC v. Warner Chilcott Holdings Co. III, Ltd.*, No. 05-2179, 2007 WL 158746, at *1 (D.D.C. Jan. 22, 2007) ("According to the FTC, almost all states and the District of Columbia encourage generic competition through laws and policies that facilitate pharmacies' substitution of lower-priced [bioequivalent] generic drugs for higher-priced branded drugs.").

The consequences of implied preemption are inconsistent with the favored status that these state laws give to generic drugs. The purpose of these longstanding provisions is to encourage the safe use of lower-priced equivalent drugs – not the use of drugs for which there is no remedy if consumers are injured due to inadequate warnings. The public interest is not served by allowing generic manufacturers to reap the financial benefits of state drug-substitution laws while exempting them from compliance with state tort law that protects consumers.

CONCLUSION

The judgments of the Eighth Circuit Court of Appeals and the Fifth Circuit Court of Appeals should be affirmed.

Respectfully submitted,

LORI SWANSON
Attorney General
STATE OF MINNESOTA

ALAN I. GILBERT
Solicitor General
Counsel of Record
JOHN S. GARRY
Assistant Attorney General
445 Minnesota Street, Suite 1100
St. Paul, Minnesota 55101-2128
(651) 757-1450
al.gilbert@state.mn.us

Dated: March 2, 2011