

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 COURT
OF APPEALS FOR THE EIGHTH CIRCUIT

**BRIEF OF CONSTITUTIONAL ACCOUNTABILITY
CENTER AS *AMICUS CURIAE* IN SUPPORT OF
RESPONDENTS**

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INTEREST OF *AMICUS CURIAE*¹

Constitutional Accountability Center (CAC) is a think tank, law firm and action center dedicated to fulfilling the progressive promise of our Constitution's text and history. CAC works in our courts, through our government, and with legal scholars to improve understanding of the Constitution and to preserve the rights, freedoms and structural safe-guards guaranteed by our Constitution.

CAC assists state and local officials in upholding valid and democratically enacted measures and historic common law remedies. CAC has filed *amicus* briefs on preemption questions in this Court in *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), and this Term's cases, *Williamson v. Mazda Motor of Am., Inc.*, No. 08-1314 (decided Feb. 23, 2011), and *AT&T v. Concepcion*, No. 09-893 (pending).

CAC seeks to preserve the careful balance of state and federal power established by the Constitution, including its Amendments. CAC thus has a strong interest in this case and the development of preemption law generally.

¹ The parties' letters of consent to the filing of this brief have been filed with the Clerk. Under Rule 37.6 of the Rules of this Court, *amicus* states no counsel for a party 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. No person other than *amicus curiae* or its counsel made a monetary contribution to its preparation or submission.

SUMMARY OF ARGUMENT

The Constitution's Supremacy Clause provides for federal law to trump state law when a state law or remedy directly contradicts a valid federal enactment. The text and history of the Clause support federal preemption when a federal law contains language expressly preempting state law or because it would be impossible to comply with both federal law and the state law or remedy. *See generally* Caleb Nelson, *Preemption*, 86 VA. L. REV. 225 (2000).

The Federal Food, Drug and Cosmetic Act (FDCA) does not expressly preempt state-law tort actions, such as the Respondents' suits alleging that they were injured because Petitioners failed to adequately warn that long-term use of their generic drug metoclopramide could cause severe adverse side effects. Accordingly, in order to assert a preemption claim, the Petitioners argue that it would be impossible for them to comply with federal law and satisfy a state-law tort claim suggesting that their generic drug, approved by the Food and Drug Administration (FDA), was inadequately labeled. Petitioners here, like the petitioners in *Wyeth*, have painted the picture that federal labeling requirements necessarily put them between a rock and a hard place when it comes to state failure-to-warn claims. *E.g.*, *Pliva* Br. 30-46; *Actavis* Br. 18-26. But the reality is 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." U.S. Br. *Amicus*

Curiae 11 (recommending den. of cert.) (hereinafter “U.S. Br. Opp. Cert.”).

As the Court explained in *Wyeth v. Levine*, “the manufacturer bears responsibility for the content of its label at all times.” 129 S. Ct. 1187, 1197-98 (2009). Explaining this concept further, Justice Thomas noted in concurrence that “[i]nitial approval of a label . . . does not represent a finding [by the FDA] that the drug, as labeled, can never be deemed unsafe by later . . . application of state law.” *Id.* at 1210 (Thomas, J., concurring). Because “the FDA’s initial approval of a drug is not a guarantee that the drug’s label will never need to be changed, . . . nothing in the text of the statutory or regulatory scheme necessarily insulates [drug manufacturers] from liability under state law simply because the FDA has approved a particular label.” *Id.* at 1211. As Respondents and the United States have shown, Petitioners’ impossibility preemption claim fails on the merits. *See* Resp’ts Br. at 27-46; U.S. Br. Opp. Cert. at 11-22.

Petitioners’ remaining claim, touted by their *amici*, is one of implied, “frustration of purposes” or “obstacle” preemption. “Obstacle” preemption, a variant of the Court’s implied “conflict preemption” jurisprudence, has occasionally been used to preempt state laws when they frustrate the objectives of a federal enactment. This doctrine, however, has rightfully come under criticism. *See Williamson v. Mazda Motor of Am., Inc.*, 2011 WL 611628 (U.S. S. Ct. Feb. 23, 2011) at *12 (Thomas, J., concurring) (rejecting “purposes-and-objectives pre-emption as inconsistent with the

Constitution”); *Wyeth v. Levine*, 129 S. Ct. 1187, 1211 (2009), (Thomas, J., concurring) (concluding that the “entire body of ‘purposes and objectives’ pre-emption jurisprudence is inherently flawed”); *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 907 (2000) (Stevens, J., joined by Souter, Thomas, and Ginsburg, JJ., dissenting) (noting the “potentially boundless (and perhaps inadequately considered) doctrine of implied conflict pre-emption based on frustration of purposes.”).

To the extent it is ever appropriate to apply implied obstacle preemption, it is not appropriate here. There is nothing in the statutory text of the Hatch-Waxman Amendments, Pub. L. No. 98-417, 98 Stat. 1585, which encouraged the development of low-cost generic drugs, to suggest that the Amendments were intended to override the FDCA’s general preservation of state tort remedies as a complementary form of consumer protection. *See Wyeth*, 129 S. Ct. at 1197, 1199-1200. As this Court noted in *Wyeth*, if Congress wanted to preempt state tort claims based on allegations of inadequate labeling, it could have done so. Given Congress’s 1976 enactment of an express-preemption provision for medical devices and its “certain awareness of the prevalence of state tort litigation,” Congress “surely would have enacted an express preemption provision” for drug-labeling claims if it believed that all “state-law suits posed an obstacle to its objectives.” 129 S. Ct. at 1200.

“[P]re-emption must turn on the text of a federal statute or the regulations it authorizes.” *Williamson*, 2011 WL 611628 at *12 (Thomas, J.,

concurring). Neither the FDCA nor the Hatch-Waxman Amendments to the Act authorize preemption of state failure-to-warn actions brought against manufacturers of generic drugs.

ARGUMENT

I. THE CONSTITUTION'S TEXT AND HISTORY SUPPORT IMPLIED PREEMPTION ONLY WHEN A STATE LAW OR REMEDY DIRECTLY CONFLICTS WITH FEDERAL LAW.

Federal law preempts state laws and remedies pursuant to the Constitution's Supremacy Clause. *E.g.*, *Brown v. Hotel & Restaurant Employees & Bartenders Int'l Union Local 54*, 468 U.S. 491, 501 (1984) (explaining that federal preemption occurs "by direct operation of the Supremacy Clause"). The Supremacy Clause "mapped out America's new legal hierarchy," AKHIL REED AMAR, *AMERICA'S CONSTITUTION: A BIOGRAPHY* 300 (2005), providing:

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

U.S. CONST. art. VI, cl. 2.

The text of the Supremacy Clause makes “supreme” the “*Laws* of the United States made in Pursuance [of the Constitution].” U.S. CONST. art. VI, cl. 2 (emphasis added). This ensures that only those provisions that have gone through the “single, finely wrought and exhaustively considered, procedure[s]” specified in the Constitution will be given effect. *INS v. Chadha*, 462 U.S. 919, 951 (1983); U.S. CONST. art. I, § 7.

The Supremacy Clause thus plays a key role in our federalist system, given that the constitutional procedures for making federal law in a bi-cameral, representative legislature are “the principal means chosen by the Framers to ensure the role of the States in the federal system.” *Garcia v. San Antonio Metro. Trans. Auth.*, 469 U.S. 528, 550-51 & n.11 (1985) (citing, *inter alia*, Herbert Wechsler, *The Political Safeguards of Federalism: The Role of the States in the Composition and Selection of the National Government*, 54 COLUM. L. REV. 543 (1954)). “[T]he built-in restraints that our system provides through state participation in federal governmental action . . . ensure that laws that unduly burden the States will not be promulgated.” *Id.* at 556. Accord THE FEDERALIST No. 62, 408 (James Madison) (B. Wright ed. 1961) (noting that the provision of equal state representation in the Senate in Article I, § 3, represents “a constitutional recognition of the portion of sovereignty remaining in the individual States, and an instrument for preserving that residuary sovereignty”).

Broad, implied purposes or general policy reasons are not “[l]aws,” which, under Article I, require express agreement among two legislative houses and two democratically-elected branches of government. *See Thompson v. Thompson*, 484 U.S. 174, 191 (1988) (Scalia, J., concurring in the judgment) (“An enactment by implication cannot realistically be regarded as the product of the difficult lawmaking process our Constitution has prescribed.”). The Supremacy Clause’s textual specification of “Laws of the United States which shall be made in Pursuance [of the Constitution],” U.S. CONST. art. VI, cl. 2, “thus requires that preemptive effect be given only to those federal standards and policies that are set forth in, or necessarily follow from, the statutory text that was produced through the constitutionally required bicameral and presentment procedures.” *Wyeth*, 129 S. Ct. at 1207 (Thomas, J., concurring), *quoted in Williamson*, at *12 (Thomas, J., concurring).

While the Supremacy Clause affirmed in the text of the Constitution that valid federal law would always trump state law, this strong supremacy rule “comes into play only when courts cannot apply both state law and federal law, but instead must choose between them.” Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 251 (2000). *See also* Viet D. Dinh, *Reassessing the Law of Preemption*, 88 GEO. L.J. 2085, 2087-88 (2000) (describing the Supremacy Clause as a “constitutional choice of law rule . . . that gives federal law precedence over conflicting state law”). In this way, state authority is respected and state and local innovation encouraged, while ensuring

that when the federal government duly acts, its enactments become the law of the land.

**II. NEITHER THE FDCA NOR THE
HATCH-WAXMAN AMENDMENTS
AUTHORIZE PREEMPTION OF STATE
FAILURE-TO-WARN CLAIMS
BROUGHT AGAINST GENERIC DRUG
MANUFACTURERS.**

As explained in the briefs of Respondents and the United States as *amicus curiae*, the statutory scheme at issue here is the Federal Food, Drug and Cosmetics Act (FDCA), as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (Hatch-Waxman Amendments). “Congress enacted the FDCA to bolster consumer protection against harmful products.” *Wyeth*, 129 S. Ct. at 1199.

In addition to federal health and safety regulation, the States have long played an integral role in protecting consumer safety and promoting public health through state tort law. “[S]tate-law remedies further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings.” *Id.* at 1200. As this Court re-affirmed in *Wyeth*, when a federal statute touches on “a field which the States have traditionally occupied,” the Court “start[s] with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.” *Wyeth*, 129 S. Ct. at 1194-95 (quoting *Medtronic, Inc. v.*

Lohr, 518 U.S. 470, 485 (1996), and *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947) (internal quotations omitted)).

Neither the FDCA nor the Hatch-Waxman Amendments contain language expressly preempting state tort claims related to generic drugs. Certainly, Congress has not hesitated to preempt state-law remedies under the FDCA; for example, Congress passed the Medical Device Amendments of 1976, 21 U.S.C. §360c *et seq.*, which contained an express preemption provision for medical devices. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). While “Congress could have applied the pre-emption clause to the entire FDCA,” it declined to do so, and “instead wrote a pre-emption clause that applies only to medical devices.” *Id.* at 327.

Unlike in the medical-devices context, the statutory and regulatory scheme for generic drugs does not conflict with state-law remedies for inadequate labeling, either expressly or impliedly. This Court has already determined in *Wyeth* that state failure-to-warn claims are not preempted for prescription drugs. There is nothing in the FDCA or the Hatch-Waxman Amendments to support a different conclusion here, despite Petitioners’ claims that they have no control over label warnings because generic drug labels must be the same as the relevant brand-name drug label.

While it is true that federal law does require manufacturers of generic drugs to use “labeling . . . [that] is the same as the labeling of the [brand

drug],” 21 C.F.R. 314.94(a)(8)(iii); *see also* U.S. Br. Opp. Cert. at 12-13, it does not absolve them of the responsibility to ensure that their customers are warned of new safety hazards. Quite to the contrary, generic drug manufacturers have a duty to report certain adverse drug experiences to the FDA, 21 C.F.R. § 314.98(a), and annually report “information . . . that might affect the safety, effectiveness, or labeling of the drug product.” 21 C.F.R. § 314.81(b)(2)(i). Moreover, the FDA has explained that if a generic drug manufacturer “believes that new safety information should be added [to a product’s labeling], it should provide adequate supporting information to FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised.” 57 Fed. Reg. 17,950, 17,961. “[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.” U.S. Br. Opp. Cert. at 11.²

As the Court explained in *Wyeth*, “the manufacturer bears responsibility for the content of its label at all times.” 129 S. Ct. at 1197-98. Expanding on this concept, Justice Thomas explained in concurrence that “[i]nitial approval of

² Additionally, generic drug manufacturers may bring relevant information to the attention of the FDA by proposing that the FDA send a “Dear Health Care Professional” letter (“DHCP letter”). By working with the FDA in this manner, generic manufacturers may get information out to doctors without going through the labeling process. *Id.*

a label . . . does not represent a finding [by the FDA] that the drug, as labeled, can never be deemed unsafe by later . . . application of state law.” *Id.* at 1210 (Thomas, J., concurring). Moreover, because “the FDA’s initial approval of a drug is not a guarantee that the drug’s label will never need to be changed, . . . nothing in the text of the statutory or regulatory scheme necessarily insulates [drug manufacturers] from liability under state law simply because the FDA has approved a particular label.” *Id.* at 1211.

Petitioners and their *amici* argue that, even if it is technically possible for generic drug manufacturers to act under the FDCA as well as a system of state-law liability for inadequate labeling, it would frustrate the purposes of the Hatch-Waxman Amendments. *See* Br. of Pliva, Inc. at 47-61; Br. of Apotex, Inc. as *Amicus Curiae* at 27-29. The main objective of the Amendments, they claim, is to bring low-cost generic drugs to the market quickly; to do this, “Congress specifically intended to free up generic manufacturers from the need to conduct costly research studies and clinical trials required of brand-name manufacturers.” Br. of Apotex, Inc. at 28.

This argument exemplifies a basic problem with implied, “frustration of purposes” preemption: “it encourages an overly expansive reading of statutory text.” *Wyeth*, 129 S. Ct. at 1215 (Thomas, J., concurring). The search for broad statutory purposes leads to an assumption “that Congress wanted to pursue those policies ‘at all costs’—even when the text reflects a different balance.” *Id.*

However, as the United States has explained as *amicus curiae*, while Congress undoubtedly intended to speed the availability of low-cost generic drugs, “[t]he Hatch-Waxman Amendments do not pursue the objective of low-cost generic drugs without limitation.” U.S. Br. Opp. Cert. at 20. Indeed, “no legislation pursues its purposes at all costs.” *Dolan v. United States*, 130 S. Ct. 2533, 2547 (2010) (internal quotation marks omitted). Surely, Congress considered both the need for low-cost generic drugs and the need for *safe* drugs in passing the Hatch-Waxman Amendments—given that the entire purpose of the FDCA is to “bolster consumer protection against harmful products,” *Wyeth*, 129 S. Ct. at 1199—and ultimately declined to preempt state-law remedies that may spur adequate product warnings and encourage manufacturers to produce safe and effective drugs.

* * *

In our federalist system of federal powers and retained state authority, it is inevitable that “contests respecting power must arise.” *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1, 205 (1824). Here, there is no contest: the FDCA, as amended by the Hatch-Waxman Amendments, does not directly conflict with state failure-to-warn actions. To the contrary, “state law offers an additional, and important, layer of consumer protection that complements FDA regulation.” *Wyeth*, 129 S. Ct. at 1202. Because the text and history of the Supremacy Clause support displacing state law or remedies only when they actually conflict with

federal law, *amicus* urges the Court to reject Petitioners' preemption arguments.

CONCLUSION

For the foregoing reasons, the decision of the U.S. Court of Appeals for the Eighth Circuit should be affirmed.

Respectfully submitted,

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