American Bar Association
www.supremecourtpreview.org

No. 06-1249

IN THE

Supreme Court of the United States

WYETH,

Petitioner,

v.

DIANA LEVINE,

Respondent.

On Writ of Certiorari to the Supreme Court of Vermont

BRIEF OF THE CONSTITUTIONAL ACCOUNTABILITY CENTER AS *AMICUS CURIAE* SUPPORTING RESPONDENT

SEAN H. DONAHUE
DAVID T. GOLDBERG
DONAHUE & GOLDBERG, LLP
2000 L St., NW
Suite 808
Washington, D.C. 20036
(202) 466-2234

DOUGLAS KENDALL
ELIZABETH B. WYDRA
Counsel of Record
CONSTITUTIONAL ACCOUNTABILITY CENTER
1301 Connecticut Ave., NW
Suite 502
Washington, D.C. 20036
(202) 296-6889

Counsel for *Amicus Curiae*

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20002

TABLE OF CONTENTS

TABLE OF AUTHORITIES

TABLE OF AUTHORITIES—Continued

TABLE OF AUTHORITIES—Continued

TABLE OF AUTHORITIES—Continued

INTEREST OF *AMICUS CURIAE* [1]

The 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 safeguards guaranteed by our Constitution.

CAC assists State and local officials in upholding valid and democratically enacted measures and historic common law remedies. Over the last decade, CAC's predecessor organization, Community Rights Counsel, filed *amicus* briefs in preemption cases before this Court in support of many State and local laws. It also has represented scores of governmental and nonprofit organizations in federal and State appellate courts across the country.

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

SUMMARY OF ARGUMENT

This case presents an opportunity for the Court to clarify and reconsider its increasingly complex pre-

---

[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*, its members, or its counsel made a monetary contribution to its preparation or submission.

emption jurisprudence. The Constitutional Accountability Center submits this brief to urge the Court to reconnect the law of federal preemption to its constitutional moorings and thereby rein in—if not wholly jettison—the notion that courts are empowered to invalidate duly enacted State laws on "frustration of purposes" grounds.

Constitutional text and history do not support a general theory of implied obstacle or "frustration of purposes" preemption. In this case, the doctrine of obstacle preemption is particularly misplaced because a provision of the relevant statute regulating drug efficacy—the Federal Food, Drug and Cosmetic Act (FDCA)—specifically limits preemption to "direct and positive" conflicts with federal law. Petitioner Wyeth and its friends nonetheless assert that Respondent Levine's State common law action is preempted because it would "frustrate the purposes of federal law." Pet. Br. 29. Neither the Supremacy Clause nor the FDCA support the logic of this argument.

"Obstacle" preemption, a variant of the Court's implied conflict preemption law, has occasionally been used to preempt State laws where they frustrate the objectives of a federal enactment. However, several members of this Court have recently expressed discomfort with the "potentially boundless (and perhaps inadequately considered) doctrine of implied conflict pre-emption based on frustration of purpose." *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 907 (2000) (Stevens, J., joined by Souter, Thomas, and Ginsburg, JJ., dissenting). Such unease is warranted: a broad obstacle preemption doctrine does not fit easily into the Court's jurisprudence, given that "preemption analysis is not 'a freewheeling

judicial inquiry into whether a state statute is in tension with federal objectives,' but an inquiry into whether the ordinary meanings of state and federal law conflict." *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 459 (2005) (Thomas, J., concurring in the judgment in part and dissenting in part) (quoting *Gade v. Nat'l Solid Wastes Mgmt. Assn.*, 505 U.S. 88, 111 (1992) (Kennedy, J., concurring in part and concurring in the judgment)).

The text and history of the Supremacy Clause support these expressions of skepticism regarding implied obstacle preemption. As scholarship has demonstrated, the Supremacy Clause authorizes displacement of State law only to the extent it directly contradicts a valid federal law. No other provision of the Constitution can support a theory of obstacle preemption either. To the contrary, the text and history of the Constitution express a commitment to the preservation of State authority in traditional areas of local regulation. In addition, because any theory of implied obstacle preemption substitutes "purposes" for "laws," the doctrine improperly circumvents the specific legislative process prescribed by the Constitution. In short, "the modern doctrine of 'obstacle' preemption has no place as a doctrine of constitutional law." Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 304 (2000).

Finally, while *amicus* submits that obstacle preemption has no place in constitutional law generally, the "freewheeling" analysis into congressional purposes it entails is particularly inappropriate here, where Congress expressly limited preemption of State law under the 1962 amendments to the FDCA to instances of "direct and positive" conflicts of law. Pub. L. No. 87-781, § 202, 76 Stat. 780 (1962). Under

both the Constitution and the language of the amended FDCA, then, a State law may be preempted only where it directly contradicts federal law. This framework preserves the Court's "impossibility" variant of implied conflict preemption, which was the type of conflict contemplated by the Framers of the Supremacy Clause, while jettisoning the amorphous theory of "frustration of purposes" or obstacle preemption.

Because Respondent Levine's State common law action does not directly contradict the FDCA, it is not preempted under an impossibility analysis. Accordingly, *amicus* urges the Court to affirm the judgment of the Vermont Supreme Court.

ARGUMENT

I. THE TEXT AND HISTORY OF THE SUPREMACY CLAUSE DO NOT SUPPORT A BROAD THEORY OF IMPLIED OBSTACLE PREEMPTION.

The Supremacy Clause of the U.S. Constitution provides that: "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, para. 2. The Court has applied the Supremacy Clause to preempt State laws that conflict with federal law. *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").

A. The Text Of The Supremacy Clause Makes "Laws," Not "Purposes" Or "Policies," Supreme.

The most basic problem with the doctrine of obstacle preemption is that it fails to heed precisely what it is that Article VI makes "supreme": the "*Laws* of the United States made in Pursuance [of the Constitution]." U.S. CONST. art. VI, para. 2 (emphasis added). Far from authorizing supersession of State law in the name of every federal policy or purpose, Article VI allows displacement of State law only by enacted federal *law*, which requires express agreement among two houses and two democratically-elected branches of government. *See* U.S. CONST. art. I, § 7; *INS v. Chadha*, 462 U.S. 919, 951 (1983) (finding that courts may not give effect to law that did not follow the "single, finely wrought and exhaustively considered, procedures" specified in the Constitution); *see also Thompson v. Thompson*, 484 U.S. 174, 192 (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."); *Bowsher v. Synar*, 478 U.S. 714, 757-759 (1986) (Stevens, J., concurring in the judgment) ("when Congress legislates, when it makes binding policy, it must follow the procedures prescribed in Article I").

The constitutionally mandated lawmaking process not only ensures that important decisions are made deliberately and democratically, but it also contains special federalism safeguards. In particular, 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." THE FEDERALIST No. 62, 408 (James Madison) (B. Wright ed., 1961); *accord* THE FEDERALIST, *supra,* No. 43, 315 (James Madison); *see also Garcia v. San Antonio Metro. Trans. Auth.*, 469 U.S. 528, 551 (1985) ("The significance attached to the States' equal representation in the Senate is underscored by the prohibition of any constitutional amendment divesting a State of equal representation without the State's consent. Art. V"). To permit displacement of State law by judicially imputed policies is to deny States their main "protect[ion] from [federal] overreaching" and circumvent "the principal means chosen by the framers to ensure the role of the States in the federal system." *Garcia*, 469 U.S. at 550-51 & n.11 (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)); *see also id.* at 556 ("the built-in restraints that our system provides through state participation in federal governmental action . . . . ensures that laws that unduly burden the States will not be promulgated."); *see generally* Bradford R. Clark, *Separation of Powers as a Safeguard of Federalism*, 79 TEX. L. REV. 1321, 1328-36 (2001).

B. The Historical Purposes Of The Supremacy Clause Do Not Include Broad And Unpredictable Displacement Of State Laws Based On Judicially Discovered "Purposes" Or "Principles" Of Federal Law.

Historical research demonstrates that the Supremacy Clause was intended by the Framers to serve several fundamental purposes in the Constitution, none of which permits the broad and unpredictable

displacement of State law that modern "obstacle" preemption doctrine claims it effects.

First, the Supremacy Clause ensures that valid treaties and federal statutes would be treated by the States as part and parcel of their own law, and not as the law of a foreign sovereign. *See* Akhil Reed Amar, *Of Sovereignty and Federalism*, 96 YALE L.J. 1425, 1510 (1987); *see also* Lauren K. Robel, *Sovereignty and Democracy: The States' Obligations to Their Citizens Under Federal Statutory Law*, 78 IND. L.J. 543, 559 (2003). This aspect of the Supremacy Clause corrected deficiencies in the Articles of Confederation, which granted law- and treaty-making power to the United States Congress, but failed to make clear that these acts were automatically effective in the States. James Madison, Vices of the Political System of the United States (Apr. 1787), in 9 PAPERS OF JAMES MADISON 345, 352 (Robert A. Rutland & William M.E. Rachal eds., 1975) (noting that in general "the acts of Cong[res]s [under the Articles of Confederation] . . . depen[d] for their execution on the will of the state legislatures").

Second, the Supremacy Clause establishes that federal law is "supreme" and has substantive priority over State law. While it is this aspect of the clause that is often assumed to authorize implied "obstacle" preemption, history belies this interpretation. Rather, the supremacy language addressed a different and narrower problem: the concern that, under the traditional rule of temporal priority, State laws could be deemed to supersede or repeal prior federal enactments. *See* Nelson, *supra* at 250-54. Because this traditional rule of temporal priority had not been expressly modified under the Articles of Confederation, James Madison noted that "'[w]henever a law

of a State happens to be repugnant to an act of Congress,' it 'will be at least questionable' which law should take priority, 'particularly when the latter is of posterior date to the former.'" PAPERS OF JAMES MADISON, *supra* at 352. However, while the Supremacy Clause altered the substance of this conflict of laws rule, making valid federal law supreme over a subsequently enacted State law, it did not affect its domain: both the traditional rule and its constitutional successor "com[e] into play *only* when courts cannot apply both state and federal law, but instead must choose between them." Nelson, *supra* at 251. *See also* Viet D. Dinh, *Reassessing the Law of Preemption*, 88 GEO. L.J. 2085, 2087-88 (2000) (reviewing the enactment history of the Supremacy Clause and describing the clause as a "constitutional choice of law rule that gives federal law precedence over conflicting state law").

Professor Nelson summarizes the meaning of the Supremacy Clause as follows:

> Taken as a whole, the Supremacy Clause says that courts must apply all valid rules of federal law. To the extent that applying state law would keep them from doing so, the Supremacy Clause requires courts to disregard the state rule and follow the federal one. But this is the extent of the preemption it requires. Under the Supremacy Clause, any obligation to disregard state law flows entirely from the obligation to follow federal law.

Id. at 252.[2]

[2] Professor Nelson also argues that the Supremacy Clause has a third purpose: to establish a rule of construction—a *non obstante* clause—that would prohibit courts from reading federal

Petitioner Wyeth and its *amici* offer no explanation of how modern "frustration" preemption, ostensibly pursued under authority of the Supremacy Clause, can be reconciled with the Constitution's text and history. While the Chamber of Commerce's brief in support of Wyeth quotes at length some of the same scholarship discussed in this brief, it isolates the reasoning of the quoted language from its conclusion. *Compare* Chamber Br. 13-14 (quoting at length Professor Nelson's historical analysis of the Supremacy Clause) *with* Nelson, *supra* at 265 (explaining that this historical analysis of the Supremacy Clause demonstrates the "failure of any general doctrine of 'obstacle' preemption"). The Chamber laments what it calls a "misguided assumption that obstacle preemption is somehow less important or entitled to less respect under the Supremacy Clause." Chamber Br. 9. But as the scholarship cited in the Chamber's own brief demonstrates, a proper reading of the Supremacy Clause does not merely render the "frustration prong" a poor relation, it establishes that it has no legitimate place in preemption doctrine. *Compare* Chamber of Commerce Br. 13-14, 18 *with* Nelson,

---

statutes narrowly in order to harmonize them with state laws. Nelson, *supra* at 254-60. Nelson views this *non obstante* clause as evidence against the presumption against preemption that has been applied by this Court. Some members of the Court similarly reject a presumption against preemption. *See, e.g.*, *Engine Mfrs. Ass'n v. S. Coast Air Quality Mgmt. Dist.*, 541 U.S. 246, 256 (2004) (noting that "not all Members of this Court agree" on the "application" of the "presumption against preemption") (internal quotation marks omitted). Because *amicus* believes that the Court may affirm the judgment below without relying upon the presumption against preemption, that question—and this aspect of Professor Nelson's scholarship—is not addressed in this brief.

(concluding that "obstacle preemption has no place as a doctrine of constitutional law").

II. IMPLIED OBSTACLE PREEMPTION UNDERCUTS THE CONSTITUTION'S CAREFULLY CRAFTED ALLOCATION OF FEDERAL-STATE AUTHORITY.

The open-ended, judicially enforced "purpose frustration" theory of preemption embraced by Petitioner and its *amici* is not only contrary to the text and history of the Supremacy Clause, it also risks upsetting the Constitution's carefully crafted federal-state balance of power.

As this Court has long recognized, the enumeration of powers in Article I, reinforced by the Tenth Amendment, make clear the intent to preserve the authority of States, thereby "assur[ing] a decentralized government that will be more sensitive to the diverse needs of a heterogeneous society; increas[ing] opportunity for citizen involvement in democratic processes; [and] allow[ing] for more innovation and experimentation in government." *Gregory v. Ashcroft*, 501 U.S. 452, 458 (1991).[3] Respect for the Constitu-

[3] The United States, arguing in support of broad implied obstacle preemption, ignores these well-established principles of federalism and suggests that the presence of the Supremacy Clause in the Constitution makes it unlikely that federal law would be so "self-negating" as to allow State law to operate in frustration of certain unspoken congressional objectives. U.S. Br. 30. However, robust federalism strengthens our constitutional government. *See, e.g.*, *Younger v. Harris*, 401 U.S. 37, 44 (1971) (explaining that federalism is not "blind deference to 'States Rights'" but is instead based on "the belief that the National Government will fare best if the States and their institutions are left free to perform their separate functions in their separate ways.").

tion's structural safeguards has become even more imperative as Congress has in recent years asserted itself in countless fields that historically have been the primary domain of State law. *See Gonzales v. Raich*, 545 U.S. 1, 17 (2005) (confirming Congress's "power to regulate purely local activities" that substantially affect interstate commerce). Courts should be particularly hesitant to hold that federal policies are "supreme" when the effect is to invalidate State laws on matters of historic State primacy.[4]

A doctrine that substitutes "policies" for "laws" in Article VI—and thereby authorizes judicial displacement of State laws on that basis—is also inconsistent with basic principles of deliberation and democratic accountability expressed in Article I and Article III.

---

[4] Preemption of common law remedies—especially remedies for personal injury—is particularly problematic. There are important historical differences between common law remedies and other forms of state "regulation." Neither the Framers nor the 1962 Congress would have imagined that a statute like this—which provides no alternative remedy—would extinguish a traditional judicial remedy for injured parties. *See Riegel v. Medtronic, Inc.,* 128 S. Ct. 999, 1015 (2008) (MDA's failure to create any federal compensatory remedy "suggests that Congress did not intend broadly to preempt state common-law suits grounded on allegations independent of FDA requirements.") (citing *Silkwood v. Kerr-McGee Corp.,* 464 U.S. 238, 251 (1984)); *Bates v. Dow Agrosciences LLC,* 544 U.S. 431, 449 (2005) ("The long history of tort litigation against manufacturers of poisonous substances adds force to the basic presumption against preemption. If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly."). The Framers, who, after all, constitutionalized a right to *jury trials* in civil cases, had a much greater tolerance for unscientific judgment and nonuniformity than petitioner and its *amici* seem to appreciate. *See* Akhil Reed Amar, THE BILL OF RIGHTS 91-118 (1998).

Although courts have established means of discerning the meaning of laws, there is no similarly reliable method of determining the "policies" of a statute. *See Thompson*, 484 U.S. at 192 (Scalia, J. concurring) ("It is at best dangerous to assume that all the necessary participants in the law-enactment process are acting upon the same unexpressed assumptions. And likewise dangerous to assume that, even with the utmost self-discipline, judges can prevent the implications they see from mirroring the policies they favor"); *see also Riegel*, 128 S. Ct. at 1009 ("It is not our job to speculate upon congressional motives."). Because many federal statutes can be said to embody "countless policies," *Pension Benefit Guar. Corp. v. LTV Corp.*, 496 U.S. 633, 646 (1990), it would be particularly inappropriate to allow a judicial search for ambiguous congressional purposes to trump the longstanding laws of the sovereign States. *See Gregory*, 501 U.S. at 464 (declining "'to give the state-displacing weight of federal law to mere congressional *ambiguity*'") (quoting Laurence H. Tribe, AMERICAN CONSTITUTIONAL LAW § 6-25, 480 (2d ed. 1988)); Kenneth Starr, et al., THE LAW OF PREEMPTION: A REPORT OF THE APPELLATE JUDGES CONFERENCE, 36 (ABA 1991) (criticizing the "purpose inquiry" in preemption cases because "a complex of competing legislative policies can be undermined").

Broad "frustration of purposes" preemption also encourages Congress to delegate the question of preemption to the courts, allowing legislators to avoid the often difficult process of achieving consensus on preemption (as well any political consequences). Indeed, a broad implied preemption doctrine threatens to render the constitutionally prescribed process for enacting laws a "tryout on the road," with implied preemption litigation the "main event." In a regime

where "policies" can have broader preemptive effect than duly enacted statutory text, those who favor controversial and expansive preemption proposals will fight battles over the contents of the legislative history, rather than the text of the enacted statute, thus achieving through the courts what they could not do in the legislature.[5] *Compare Thompson*, 484 U.S. at 192 (Scalia, J., concurring) (noting that "conscientious legislators cannot relish" a situation "where the existence or nonexistence of a private right of action depends upon which of the opposing legislative forces may have guessed right as to the implications the statute will be found to contain") *with* Roderick M. Hills, Jr., *Against Preemption: How Federalism Can Improve the Federal Legislative Process*, 82 N.Y.U. L. REV. 1, 28-29 (2007) (suggesting that some legislators may have little objection to being spared the need to cast a vote on a "politically troublesome" preemption question).

Finally, because States will be uncertain whether local regulatory regimes or causes of action will be preempted by the courts based on an amorphous theory of "obstacle" preemption, State and local innovation—which has been praised since the Founding—will be chilled.

---

[5] Questions of constitutional legitimacy aside, an untethered "obstacle" preemption inquiry serves no practical purpose in the lawmaking process and may, in fact, be corrosive. Congress is fully able to express its intent to preempt State law, as attested by scores of express preemption provisions, and there is no reason to expect that the interests favoring preemption of state tort law—often including well-organized business groups like the *amici* urging *implied* preemption here—suffer from systematic disadvantages in the legislative process. *Cf. United States v. Carolene Products Co.*, 304 U.S. 144, 152 n.4 (1938).

This stark incompatibility with fundamental constitutional principles has contributed to recent concerns expressed by members of the Court about the legitimacy of implied "obstacle" preemption. In a path-marking concurrence in *Gade v. National Solid Wastes Management Association*, Justice Kennedy proposed replacing the broad form of implied obstacle preemption embraced by the majority in that case with one authorizing displacement only of those "state laws which impose prohibitions or obligations which are in direct contradiction to Congress' primary objectives, as conveyed with clarity in the federal legislation." 505 U.S. 88, 111 (1992) (Kennedy, J., concurring in part and concurring in the judgment). In *Geier v. American Honda Motor Co.*, four Justices highlighted the doctrine's "potentially boundless" character and observed that its legitimacy had been "perhaps inadequately considered." 529 U.S. 861, 907 (2000) (Stevens, J., joined by Souter, Thomas, and Ginsburg, JJ., dissenting). As that opinion explained, allowing preemption on "purpose frustration" grounds raises "the risk that federal judges will draw too deeply on malleable and politically unaccountable sources such as regulatory history in finding pre-emption based on frustration of purposes." *Id.* at 908 n.22. More recently, in *Bates v. Dow Agrosciences*, Justice Thomas (joined by Justice Scalia) approvingly noted the "Court's increasing reluctance to expand federal statutes beyond their terms through doctrines of implied pre-emption," 544 U.S. 431, 459 (2005) (Thomas, J., concurring in the judgment in part and dissenting in part), explaining that preemption analysis should be limited to an "inquiry into whether the ordinary meanings of state and federal law conflict.'" *Id.* (quoting *Gade*, 505 U.S. at 110 (Kennedy, J., concurring)).

Amicus urges the Court to take this opportunity to reconsider preemption based on "frustration of purposes" and clarify the limits of implied conflict preemption. Not only is the doctrine unsupported by the text and history of the Supremacy Clause, but it runs counter to the principles and structure of our Constitution.

III. IMPLIED OBSTACLE PREEMPTION IS PARTICULARLY INAPPROPRIATE HERE, BECAUSE CONGRESS LIMITED THE PREEMPTIVE SCOPE OF THE AMENDED FDCA TO "DIRECT AND POSITIVE" CONFLICTS.

Even if the Court were to preserve some variant of implied obstacle preemption, it would be inappropriate to apply it here. The savings clause adopted by Congress as part of the 1962 amendments to the FDCA specifically limits the preemptive scope of the amended statute to "direct and positive" conflicts. Pub. L. No. 87-781, § 202, 76 Stat. 780, 793 (1962).[6] This language demonstrates that, when undertaking to regulate the efficacy of pharmaceuticals through new drug applications, Congress intended to preserve State law unless it directly contradicted the FDCA; in other words, Congress sought to have State law preempted only where it would be impossible to comply with both federal and State law.

---

[6] Section 202 provides:

> Nothing in the amendments made by this Act to the Federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendment and such provision of state law.

Respondent's *amici* have detailed the legislative history and context that demonstrate that Congress intended this "direct and positive" conflict language to limit the preemptive scope of the amended statute. *E.g.*, Br. of Vermont, et al. 34-37 (explaining how § 202 borrowed language from other legislation pending at the same time, which limited preemption to the extent "there is a direct and positive conflict between such provisions so that the two cannot be reconciled or consistently stand together"). Where Congress has expressly limited preemption to cases where there is a "direct and positive" conflict, it is especially inappropriate to preempt State law based on claims of frustration of legislative purposes. *See Cipollone v. Liggett Group, Inc.,* 505 U.S. 504, 517 (1992) (applying "the familiar principle of *expressio unius est exclusio alterius*" and finding that "Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted"), *quoted in Freightliner Corp. v. Myrick*, 514 U.S. 280, 288 (1995) (declining to find express or implied preemption of State law where no contrary federal standard existed).

While the policy objectives underlying the FDCA are surely countless, Congress made one objective clear: it did not want to displace a broad swath of State law under a hazy notion of implied obstacle preemption. Congress expressly preempted State law in other provisions of the Act, as in the Medical Devices Act preemption clause at issue in *Riegel*, but did not choose to do so for the FDCA as a whole. *See Riegel*, 128 S. Ct. at 1009 (noting that "Congress could have applied the [medical devices] pre-emption clause to the entire FDCA . . . but instead wrote a preemption clause that applies only to medical devices"). Accordingly, the doctrine of implied obsta-

cle preemption is just as out of step with the facts of this case as it is with the text and history of the Constitution.

* * *

Without recourse to the vague "frustration of purposes" theory of preemption, Petitioner is left with its argument that Vermont's common law remedy directly and positively conflicts with the FDCA because it is impossible to comply with FDA regulations and state common law duties. As Respondent's brief forcefully demonstrates, "impossibility preemption" does not apply here because Wyeth retained the ability to preclude the "IV push" method of administering Phenergan and the FDA's prior approval of a label that simply warned of the dangers associated with that method is not incompatible with a state law remedy for wrongfully injured persons. Respondent's Br. 31-43; *see also* Br. of Vermont, et al. 6-11 (explaining that federal drug labeling laws have coexisted with state common law damages claims for over 70 years). Because Wyeth has failed to show that it is impossible to comply with Vermont common law and federal drug labeling law, the Court should decline to find preemption.

CONCLUSION

The judgment of the Vermont Supreme Court should be affirmed.

Respectfully submitted,

SEAN H. DONAHUE
DAVID T. GOLDBERG
DONAHUE & GOLDBERG, LLP
2000 L St., NW
Suite 808
Washington, D.C. 20036
(202) 466-2234

DOUGLAS KENDALL
ELIZABETH B. WYDRA
Counsel of Record
CONSTITUTIONAL
ACCOUNTABILITY CENTER
1301 Connecticut Ave., NW
Suite 502
Washington, D.C. 20036
(202) 296-6889

Counsel for *Amicus Curiae*

August 2008