

Nos. 09-993, 09-1039, and 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 CIRCUIT AND FOR THE
FIFTH CIRCUIT

**BRIEF OF THE AMERICAN ASSOCIATION
FOR JUSTICE AS AMICUS CURIAE
SUPPORTING RESPONDENTS**

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INTEREST OF AMICUS CURIAE

The American Association for Justice (“AAJ”), formerly the Association of Trial Lawyers of America, respectfully submits this brief as *amicus curiae* in support of Respondents. This brief is filed with the consent of all parties.¹

AAJ is a voluntary national bar association whose trial lawyer members primarily represent individual plaintiffs in personal injury cases and other civil actions, including products liability cases. Throughout its history, AAJ has advocated in courts, in state legislatures, and in Congress to preserve the fundamental protections afforded by state tort law and to ensure that state tort claims provide injured persons with effective legal recourse and remedies. By bringing such claims on behalf of people injured by pharmaceutical drugs and by testifying before Congress about the Food, Drug, and Cosmetic Act and the need to ensure the safety of pharmaceutical drugs manufactured for the public, AAJ’s members have helped to ensure that the nation’s consumers have access to safe and effective pharmaceuticals.

SUMMARY OF ARGUMENT

The law of preemption has become a continuing tug-of-war between the states and the federal government. Indeed, this tug-of-war is a concerted, targeted, and protracted effort on behalf of the pharmaceutical industry

1. Letters of consent from both parties have been filed with the Clerk of Court. Pursuant to *Rule 37.6*, *amicus* states that no counsel for a party authored any part of this brief, nor did any person or entity other than *amicus*, its members, or its counsel make a monetary contribution to its preparation or submission.

to promote their business interests, namely financial gain, while escaping liability and accountability for their tortious conduct resulting in injury or death to the American people.

Fundamental principles of federalism are at the heart of this case. Following lengthy and spirited debates, the founders of this country established a “compound republic of America,” a system of “two distinct governments.” THE FEDERALIST NO. 51 (James Madison). Under this system, the powers delegated to the federal government are “few and defined,” THE FEDERALIST NO. 45 (James Madison). By contrast, those powers not expressly delegated to the federal government – which are reserved to the states, U.S. CONST. amend. X -- are “numerous and indefinite,” and “extend to all the objects which, in the ordinary course of affairs, concern the lives, liberties, and properties of the people, and the internal order, improvement, and prosperity of the State.” THE FEDERALIST NO. 45 (James Madison). The principles underlying the proper distribution and balance of power between these “two distinct governments” remain as viable today as when they were first articulated over two centuries ago.

In federal preemption cases, particularly those where Congress has “legislated . . . in a field which the States have traditionally occupied,” the presumption is “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.” *Medtronic, Inc. v. Lohr*, 518 U.S. 468, 485 (1996) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947); *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 715 (1985)).

Determining the “purpose of Congress is the ultimate touchstone in every pre-emption case.” Mary J. Davis, *The “New” Presumption Against Preemption*, 61 HASTINGS L.J. 1217, 1220 (2010) (citing *Lohr*, 518 U.S. at 485); *Retail Clerks Int’l Ass’n, Local 1625 v. Schermerhorn*, 375 U.S. 96, 103 (1963)). Fundamental to preemption jurisdiction is the presumption against preemption, which dictates that courts should not presume “that a federal statute was intended to supersede the exercise of the power of the state unless there is a clear manifestation of intention to do so. The exercise of federal supremacy is not lightly to be presumed.” *New York Dep’t of Soc. Servs. v. Dublino*, 413 U.S. 405 (1973) (quoting *Schwartz v. Texas*, 344 U.S. 199, 202-03 (1952)). Issues concerning federalism are implicated the moment the Court “delve[s] into the murky realm of congressional purposes to ascertain whether Congress intended to displace state law.” Robert S. Peck, *A Separation-of-Powers Defense of the “Presumption Against Preemption,”* 84 TUL. L. REV. 1185, 1199 (2010). Once this voyage into congressional intent has begun, it is fathomable that, given the opportunity, courts may overstep the carefully placed boundaries surrounding the spheres of dual sovereignty and preempt state tort law. This ill-advised voyage would improperly enable the federal government to intrude upon a field traditionally reserved for the States. *Id.*

The “presumption against preemption” is essential to the continued protection of state sovereignty and critical to the proper functioning of the procedural and political safeguards of federalism. States have historically maintained tort remedies against pharmaceutical manufacturers who fail to provide adequate warnings when that failure results in an injury. In fact, these state

tort remedies have coexisted with the federal regulation of the pharmaceutical industry for over seventy years. See David A. Kessler & David C. Vladeck, *Health Regulation and Governance: A Critical Examination of the FDA's Efforts to Preempt Failure-To-Warn Claims*, 96 GEO. L.J. 461, 462-63 (2008).

This case presents a claim implicating the health and safety of the citizens of two states, concerns historically within the province of the states. In this case, generic drug companies claim that failure to warn claims are preempted, even though the companies never even attempted to comply with their regulatory duty to ensure that the warnings on their label remained adequate; and even though the label of the drug at issue now contains a much stronger, boxed warning of exactly the adverse effect from which the plaintiffs suffer. Proper analysis thus requires the application of a presumption against preemption, not merely as a procedural nicety, but to fully respect both the historical balance of power between federal and state governments and the precedents of this Court.

Despite multiple amendments to the Food, Drug, and Cosmetic Act of 1962, 21 U.S.C § 301 et seq., Congress has not sought to preempt state tort litigation. Application of the presumption against preemption with the proper historical perspective will lead the Court to conclude—just as it recently held in *Wyeth v. Levine*, 129 S.Ct. 1187 (2009)—that federal law does not preempt failure to warn claims against generic drug companies. Instead, federal regulation and state tort law operate in this area as complementary pieces in an overall system of consumer protection. As such, this Court should affirm the lower courts' rulings, finding no federal preemption.

ARGUMENT

I. Federalism Necessarily Requires a “Presumption Against Preemption”

In its preemption analysis, this Court has “recognized the historic role of state law and paid homage to the role of states in our federal system of government.” Davis, *The “New” Presumption Against Preemption*, 61 HASTINGS L.J. at 1218-19 (citing Caleb Nelson, *Preemption*, 86 VA. L. REV. 225 (2000)). This homage is explicitly stated when the Court references the fundamental principle—“presumption against preemption.” *Id.* at 1219.

The long history of tort litigation in the pharmaceutical industry, particularly regarding the labeling of pharmaceutical drugs, coupled with the fact that Congress has not shown a clear and manifest intent to obliterate the state tort remedies to persons injured by pharmaceutical drugs, gives credence to the argument that this Court should not find federal preemption in this case. Mary J. Davis, *History of Regulation of the Pharmaceutical Industry*, 48 B.C. L. REV. 1089, 1140 (2007) (citing *Witczak v. Pfizer, Inc.*, 377 F.Supp. 2d 726, 728-29 (D. Minn. 2005); *Caraker v. Sandoz Pharm. Corp.*, 172 F.Supp. 2d 1018, 1031-39 (S.D. Ill. 2001)). Certainly, in the context of this matter, where the generic manufacturer shares the regulatory responsibility for including “a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved,” 21 CFR § 201.57(c) (2005), the Court should not find that plaintiffs’ claims arising out of their failure are barred by the manufacturer’s attempt to shield themselves by brand maker’s failure to comply

with this requirement. The ability of injured plaintiffs to bring tort claims directly speaks to the critical necessity of “the States’ traditional ability to protect the health and safety of their citizens[.]” Davis, *History of Regulation*, 48 B.C. L. REV. at 1095. Clearly, it is within the purview of the states to protect their citizens, who like Gladys Mensing and Julie Demahy, suffer from such a severe and irreversible neurological disorder as tardive dyskinesia, when a manufacturer knew that the incidence of injury for long-term users was so high. In fact, relying on *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), the Second Circuit Court of Appeals declared that “[t]he power of the states to govern this field is considerable and undisputed.” *Cipollone*, 505 U.S. at 544 (Blackmun, J., concurring); *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 86 (2d Cir. 2006).

Although the FDA regulatory process and state tort liability scheme “operate independently” of one another, “each provid[es] a significant, yet distinct, layer of consumer protection,” Davis, *History of Regulation*, 48 B.C. L. REV. at 1094 (citations omitted); Margaret Porter, *The Lohr Decision: FDA Perspective and Position*, 52 FOOD & DRUG L.J. 7, 11 (1997), that is essential to the continued well-being of a functioning society. The States’ tort liability scheme works in connection with the FDA’s regulatory purpose. Generally speaking, tort liability serves interests that Congress did not fathom when it created the FDA. Tort liability compensates persons whose injuries occurred because of a pharmaceutical manufacturer’s failure to provide adequate warnings. See generally THOMAS O. MCGARITY, *THE PREEMPTION WAR* 33 (Yale 2008) (arguing “preemption completely eliminates that corrective justice role that common law courts have

played in this country since its founding”). However, tort law and its ability to seek accountability and preventive measures works towards the FDA’s regulatory goals of protecting the health, safety, and general welfare of the people, even in instances where the federal agency fails in those regards. However, as the courts below point out, federal law provides no substitute for the remedy which state failure-to-warn claims have traditionally recognized. Thus, “in this case, the bar to a finding of preemption is set even higher. . . .” *Demahy v. Actavis, Inc.*, 593 F.3d 428, 435 (5th Cir. 2010). The States have the wherewithal and resources to compensate for the FDA’s budgetary constraints and time limitations while providing a system where states are in a position to monitor risks that were unknown at the time of the FDA’s approval. The States are also fully capable of acting quickly when an injury occurs or series of injuries occur. *See generally* MCGARITY, *supra* at 16 (calling Vioxx and the role that the FDA played in approving its safety for production “a profound regulatory failure”).

Viewing the States as independent sovereigns within our federal republic—as the Framers did—it becomes readily apparent that the presumption that state laws—specifically, state tort remedies designed to compensate citizens for personal injuries—are well within the scope of the States’ historic powers. These historic powers emanate directly from the Constitution and are further supported by the Federalist Papers. These “historic powers” may only be preempted when there is a clear and manifest purpose expressed by Congress. Yet, in this matter, petitioners concede that no express preemption exists, but instead argue “that it is impossible to comply with both federal and state law.” *Demahy*, 593 F.3d at

434. However, requests to alter a labeling would not have violated federal or state law.

It stands to reason that tort liability is a field of law traditionally reserved for the States due to the localized impact of personal injury lawsuit on individual states. *See* Gary Schwartz, *Considering the Proper Federal Role in American Tort Law*, 38 ARIZ. L. REV. 917, 922 (1996); Samuel Issacharoff & Catherine M. Sharkey, *Backdoor Federalization*, 53 U.C.L.A. L. REV. 1353, 1384 (2006) (citations omitted). To find federal preemption in this case, this Court would be acting in direct contravention to the constitutional structure that Framers ultimately designed. The fundamental principles of federalism buttress this conclusion.

II. Historical Perspective of Federalism: State Sovereignty is the Rule and Federal Sovereignty is the Exception²

Federalism is critical to this Court's analysis of whether the federal law preempts state tort remedies. As did the Court in *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218 (1947), this Court's analysis here should begin with "the assumption that the historic police powers of the States [a]re not to be superseded by the [f]ederal [government] unless that was the clear and manifest purpose of Congress." *Rice*, 331 U.S. at 230 (citing *Napier v. Atlantic Coast Line R. Co.*, 272 U.S. 605, 611 (1926); *Allen-Bradley Local v. Wisconsin Employment Bd.*, 315 U.S. 740, 749 (1942)); *see generally* *Mintz v. Baldwin*, 289

2. *See* ALEXIS DE TOCQUEVILLE, *DEMOCRACY IN AMERICA* 115 (George Lawrence trans., J.P. Mayer ed., Harper Perennial 1966).

U.S. 346, 350-52 (1933) (recognizing the “presumption against preemption”). The *Rice* Court set forth a principle of significant constitutional dimension, recognizing the necessity of protecting state sovereignty while ensuring that the structural, procedural, and political safeguards³ of federalism remain firmly in place, just as the Framers intended. *Rice*, 331 *U.S.* at 230.

In 1869, this Court addressed “the constitutional scheme of dual sovereigns:

[T]he people of each State compose a State, having its own government, and endowed with all the functions essential to separate and independent existence, . . . [W]ithout the States in union, there could be no such political body as the United States. Not only, therefore, can there be no loss of separate and independent autonomy to the States, through their union under the Constitution, but it may be not unreasonably said that the preservation of the States, and the maintenance of their governments, are as much within the design and care of the Constitution as the preservation

3. “Federal lawmaking was thus consciously held hostage to the ‘political safeguards of federalism,’ to borrow Herbert Wechsler’s famous phrase.” Henry Paul Monaghan, *Supremacy Clause Textualism*, 110 *COLUM. L. REV.* 731 (2010) (quoting Bradford R. Clark, *Federal Lawmaking and the Role of Structure in Constitutional Interpretation*, 96 *CAL. L. REV.* 699, 701 (2008) (quoting 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, 543 (1954)).

of the Union and the maintenance of the National government. The Constitution, in all its provisions, looks to an indestructible Union, composed of indestructible States.

[*Gregory v. Ashcroft*, 501 U.S. 452, 457 (1991) (quoting *Texas v. White*, 7 Wall. 700, 725 (1869) (in turn, quoting *Lane County v. Oregon*, 7 Wall. 71, 76 (1869)) (internal quotation marks omitted)].

The *Gregory* Court recognized this fundamental principle—dual sovereignty—as arising from the axiom that, “under our federal system, the States possess sovereignty concurrent with that of the Federal Government, subject only to limitations imposed by the Supremacy Clause.” *Gregory*, 501 U.S. at 457 (quoting *Tafflin v. Levitt*, 493 U.S. 455, 458 (1990)); see generally ALEXIS DE TOCQUEVILLE, DEMOCRACY IN AMERICA 58 (George Lawrence trans., J.P. Mayer ed., Harper Perennial 1966) (“If there is one country in the world where one can hope to appreciate the true value of the dogma of the sovereignty of the people, study its application to the business of society, and judge both its dangers and its advantages, that country is America.”).

After much debate, the Framers resolved to specifically create a federal government “of limited powers.” *Gregory*, 501 U.S. at 457. The people have never altered that principle. Congress has never altered that principle. No Constitutional Amendment has altered that principle. As a matter of fact, the Tenth Amendment to the Constitution provides that “[t]he powers not delegated to the United States by the constitution, nor prohibited by

it to the states, are reserved to the states, respectively, or to the people.” U.S. CONST. amend. X. In the Federalist Papers, James Madison succinctly stated that “[t]he powers delegated by the proposed Constitution to the federal government, are few and defined.” THE FEDERALIST No. 45 (James Madison). Madison expounding the virtue of a limited federal government, declaring that (1) the powers of the States were to be “numerous and indefinite” and (2) these powers were to “extend to all the objects which, in the ordinary course of affairs, concern the lives, liberties, and properties of the people, and the internal order, improvement, and prosperity of the State.” THE FEDERALIST No. 45 (James Madison). Whereas the powers of the federal government were to be principally exercised on “external objects, as war, peace, negotiation, and foreign commerce; with which last the power of taxation will, for the most part, be connected.” THE FEDERALIST No. 45 (James Madison); *see generally* ALEXIS DE TOCQUEVILLE, DEMOCRACY IN AMERICA 114-17 (George Lawrence trans., J.P. Mayer ed., Harper Perennial 1966) (1835) (explaining that “the attributes of the federal government were carefully defined, and it was declared that everything not contained within that definition returned to the jurisdiction of state governments.”).

“The federalization of tort law finds no support in the annals of early American history.” John C. Toro, *Why Principles of Federalism and Communitarianism Demand That Tort Law be Left up to the States*, 7 GEO. J.L. PUB. POL’Y 655, 658 (2009). As the Framers intended, the field of tort law traditionally has been, almost exclusively, reserved to the States. *Id.* at 658 (quoting Robert M. Ackerman, *Tort Law and Federalism: Whatever Happened to Devolution?*, 14 YALE L. & POL’Y

REV. 429, 430 (1996)). In careful precision, the Framers created a republic where the States would govern the majority of fields, including tort litigation. The purpose was to ensure the active participation of the people at a local level. *Id.* at 658; *see generally* THE FEDERALIST No. 45 (James Madison).

This federalist structure envisioned by the Framers was deliberately designed to preserve numerous advantages given to the people, but also to “ensure the protection of ‘our fundamental liberties.’ ” *Atascadero State Hosp. v. Scanlon*, 473 U.S. 234, 242 (1985) (citing *Garcia v. San Antonio Metro. Transit Auth.*, 469 U.S. 528, 572 (1985) (Powell, J., dissenting) (internal quotation marks omitted); *see also Wyeth v. Levine*, 129 S.Ct. 1187, 1205 (2009)(Thomas, J., concurring) (expounding the notion that a “federalist structure of joint sovereigns preserves to the people numerous advantages,’ such as ‘a decentralized government that will be more sensitive to the diverse needs of a heterogeneous society’ and ‘increase[d] opportunity for citizen involvement in democratic processes[.]’ ”). This “constitutionally mandated balance of power,” *Atascadero*, 473 U.S. at 242, was designed to “reduce the risk of tyranny and abuse” from the States or the federal government. *Gregory*, 501 U.S. at 458; *see* Erwin Chemerinsky, *Empowering States When It Matters: A Different Approach to Preemption*, 69 BROOK. L. REV. 1313, 1325 (2004) (explaining that “[t]his constitutionally mandated division of authority was adopted by the Framers to ensure protection of our fundamental liberties” (internal quotation marks and citation omitted)).

Alexander Hamilton, in the Federalist Papers, stated that the envisioned federalist structure would be

more competent to a struggle with the attempts of the government to establish a tyranny. But in a confederacy the people, without exaggeration, may be said to be entirely the master of their own fate. Power being almost always the rival of power, the general government will at all times stand ready to check the usurpations of the state governments, and these will have the same disposition towards the general government. The people, by throwing themselves into either scale, will infallibly make it preponderate. If their rights are invaded by either, they can make use of the other as the instrument of redress.

[THE FEDERALIST No. 28 (Alexander Hamilton)].

Similarly, in The Federalist Papers, James Madison addressed the same issue. Stating that “[t]here are [] two considerations particularly applicable to the federal system of America, which place that system in a very interesting point of view[,]” Madison declared that

First. In a single republic, all the power surrendered by the people is submitted to the administration of a single government; and the usurpations are guarded against by a division of the government into distinct and separate departments. In the compound republic of America, the power surrendered by the people is first divided between two

distinct governments, and then the portion allotted to each subdivided among distinct and separate departments. Hence a *double security* arises to the rights of the people. The different governments will control each other, at the same time that each will be controlled by itself.

Second. It is of great importance in a republic not only to guard the society against the oppression of its rulers, but to guard one part of the society against the injustice of the other part. Different interests necessarily exist in different classes of citizens. If a majority be united by a common interest, the rights of the minority will be insecure. . . .

[THE FEDERALIST NO. 51 (James Madison)].

In order for Madison’s “double security” to be effective, the balance of power between the States and the federal government must be properly maintained. *Gregory*, 501 *U.S.* at 459. “These twin powers will act as mutual restraints only if both are credible. [Within] the tension between federal and state power lies the promise of liberty.” *Id.* at 459. Nevertheless, as this Court articulated, “[t]he Federal Government holds a decided advantage in this delicate balance: the Supremacy Clause.” *Gregory*, 501 *U.S.* at 460; *see also* U.S. CONST. art. VI, cl. 2. Recognizing that Congress “may impose its will on the States” and “may legislate in areas traditionally regulated by the States,” this Court has stated that this “extraordinary power” is one that “we must assume Congress does not exercise lightly.” *Gregory*, 501 *U.S.* at 460; *see generally* *Wyeth*, 129 *S.Ct.* at 1205.

Recognizing the import of the structural, procedural, and political safeguards of federalism, Justice Brandeis once declared:

To stay experimentation in things social and economic is a grave responsibility. Denial of the right to experiment might be fraught with serious consequences to the Nation. It is one of the happy incidents of the federal system that a single courageous State may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country.

[Samuel Issacharoff & Catherine M. Sharkey, *Backdoor Federalization*, 53 U.C.L.A. L. REV. 1353, 1355 (2006) (quoting *New State Ice Co. v. Liebemann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting)].

The deliberate design of dual sovereigns described above necessarily leads to two conclusions: (1) that the “States retain a substantial sovereign authority,” *Wyeth*, 129 S.Ct. at 1205-06 (citations omitted); see *Tafflin*, 493 U.S. at 458, and (2) that the “tacit postulates” of the Constitution described by Chief Justice Burger and Justice Rehnquist are “as much engrained in the fabric of the documents as its express provisions.” *Nevada v. Hall*, 440 U.S. 410, 433 (1979) (Rehnquist, J., dissenting) (noting that without the “tacit postulates . . . the Constitution is denied force and often meaning”); see generally LAURENCE H. TRIBE, CONSTITUTIONAL CHOICES 50 (1985).

III. Constitutional Perspective: the Supremacy Clause, Preemption, and Separation of Powers

Succinctly stated, the Supremacy Clause is “the provision at the epicenter of the constitutional structure” envisioned by the Framers. Henry Paul Monaghan, *Supremacy Clause Textualism*, 110 COLUM. L. REV. 731 (2010) (quoting Bradford R. Clark, *Federal Lawmaking and the Role of Structure in Constitutional Interpretation*, 96 CAL. L. REV. 699, 724 (2008)). Of particular note, during the debates at the Constitutional Convention, the Framers contemplated, but ultimately rejected, a “stronger version of the Supremacy Clause under which the National Legislature would have been [e]mpowered . . . to negative all laws passed by the several States, contravening in the opinion of the National Legislature the article of Union.” Alan Untereiner, *The Defense of Preemption: A View From the Trenches*, 84 TUL. L. REV. 1257, 1258 (2010) (internal quotation marks and citation omitted) (citing James Madison, Notes on the Constitutional Convention (May 29, 1787), in 1 *The Records of the Federal Convention of 1787*, at 21 (Max Farrand ed., 1911)).

As it exists today, the Supremacy Clause “must operate only in accordance with its terms,” if the task of maintaining the “delicate balance of power mandated by the Constitution” is to be achieved. *Wyeth*, 129 S.Ct. at 1206 (Thomas, J., concurring). The language of the clause provides:

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, anything in the constitution or laws of any state to the contrary notwithstanding.

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

Entrenched within the Supremacy Clause is the basic presumption that state laws are *not* to be preempted. This Court has explained that this presumption arises from the recognition that “ ‘States are independent sovereigns in our federal system, [and courts] have long presumed that Congress does not cavalierly [preempt] state-law causes of actions.’ ” Peck, “*Presumption Against Preemption*,” 84 TUL. L. REV. at 1195 (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996); see generally *Cal. Fed. Sav. & Loan Ass’n v. Guerra*, 479 U.S. 272, 281 (1987)). This fundamental presumption is often justified by maxims of federalism. See generally *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 166-67 (1989); *Tafflin*, 493 U.S. at 458. As Professor Caleb Nelson adeptly explains, the Framers created the preemption mechanism for where there is an actual conflict, not a speculative or potential conflict. Nelson, *Preemption*, 86 VA. L. REV. at 259-61. “Under the Supremacy Clause, then, the test for preemption is simple: Courts are required to disregard state law if, but only if, it contradicts a rule validly established by federal law.” *Id.*

As illustrated by this Court’s preemption jurisprudence, see *Wyeth v. Levine*, 129 S.Ct. 1187 (2009), the implementation of preemption depends upon congressional intent; therefore, because of this reliance, “a freewheeling inquiry that ends up supplying [the] *missing* legislative intent implicates separation of powers.” Peck,

“Presumption Against Preemption,” 84 TUL. L. REV. at 1197; *see also Wyeth*, 129 S.Ct. at 1217 (Thomas, J., concurring) (explaining that “freewheeling, extratextual, and broad evaluations of the purposes and objectives embodied within federal law . . . lead[] to decisions giving improperly broad pre-emptive effect to judicially manufactured policies, rather than to the statutory text enacted by Congress.”)

The concept of separation of powers is of transcendent importance to our federal republic. In debating the framework for our republic, Thomas Jefferson declared that separation of powers was “the first principle of a good government.” Peck, *“Presumption Against Preemption,”* 84 TUL. L. REV. at 1196 (citing GORDON S. WOOD, *THE CREATION OF THE AMERICAN REPUBLIC 1776-87* 604 (1969); GERHARD CASPER, *SEPARATING POWER: ESSAYS ON THE FOUNDING PERIOD 1* (1997)(“[S]eparation of governmental power along functional lines has been a core concept of American constitutionalism. . .”). The structural dynamic of separation of powers not only “reflects the ‘central judgment of the Framers of the Constitution that, within our political scheme, the separation of governmental powers into three’ distinct branches, *Mistretta v. United States*, 488 U.S. 361, 380 (1989); but it is “essential to the preservation of liberty.” Peck, *“Presumption Against Preemption,”* 84 TUL. L. REV. at 1196.

As James Madison intended, the complicated and intricate design of our federal republic diffuses the “power surrendered by the people . . . among distinct branches, as well as between the federal and the local, to guard against despotism.” *Id.* at 1196 (citing HENRY STEELE COMMAGER, *THE EMPIRE OF REASON: HOW EUROPE IMAGINED AND AMERICA REALIZED THE ENLIGHTENMENT* 194 (1977)).

The presumption against federal preemption “comports with the fundamental principles of federalism articulated by the Supreme Court: By declining to infer preemption in the face of congressional ambiguity, the Court is not interposing a judicial barrier to Congress’s will in order to protect state sovereignty . . . but is instead furthering the spirit of [its federalism decisions] by requiring that decisions restricting state sovereignty be made in a deliberate manner by Congress, through the explicit exercise of its lawmaking power to that end.” Peck, “*Presumption Against Preemption*,” 84 TUL. L. REV. at 1195 (citing LAURENCE H. TRIBE, *AMERICAN CONSTITUTIONAL LAW* 480 (2d ed. 1988)).

It is not an unreasonably extreme notion that the “courts would violate the principle of federalism by abrogating a state’s power to protect its citizens’ health and safety absent a clear congressional expression to abrogate that power.” *Id.* at 1196 (citing Richard C. Ausness, *Federal Preemption of State Products Liability Doctrines*, 44 S.C. L. REV. 187, 248 (1993)). Furthermore, without a congressional expression of clear and manifest intent, the utilization of federal preemption forces the Court to step into the role of the Legislative branch; and, thus overstep the bounds that exist between the two spheres of legislative and judicial powers. *Ibid.*

CONCLUSION

For the foregoing reasons, *amicus curiae* the American Association for Justice urges this Court to affirm the judgments of the Eighth Circuit Court of Appeals and the Fifth Circuit Court of Appeals.

Respectfully submitted,

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