No. 09-152

In the Supreme Court of the United States

RUSSELL BRUESEWITZ, *et al.*,

Petitioners,

v.

WYETH, INC.,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Third Circuit

BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENT

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BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENT[1]

INTEREST OF THE *AMICUS CURIAE*

The Chamber of Commerce of the United States of America (Chamber) is the world's largest business federation. The Chamber represents 300,000 direct members and indirectly represents the interests of more than three million companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus* briefs in cases that raise issues of vital concern to the nation's business community.

This is one such case. The Chamber—which has filed amicus briefs in prior preemption cases, including *Wyeth* v. *Levine*, 129 S. Ct. 1187 (2009), *Altria Group, Inc.* v. *Good*, 129 S. Ct. 538 (2008), *Riegel* v. *Medtronic, Inc.*, 552 U.S. 312 (2008), *Geier* v. *Am. Honda Motor Co.*, 529 U.S. 861 (2000), and *United States* v. *Locke*, 529 U.S. 89 (2000)—is well-situated to address the issue of preemption raised here. Its members, which include manufacturers that depend

[1] Pursuant to Rule 37.6, *amicus* affirms that no counsel for a party authored this brief in whole or in part and that no party, counsel for a party, or any person other than *amicus* and its counsel made a monetary contribution intended to fund the preparation or submission of the brief. The parties have lodged letters with the Clerk expressing their blanket consent to the filing of *amicus* briefs.

on preemption under the National Childhood Vaccine Injury Act of 1986 (Vaccine Act), 42 U.S.C. §§ 300aa-1 *et seq.*—are engaged in commerce in each of the 50 states. The Chamber's membership includes millions of businesses that are subject in varying degrees to a wide range of federal regulatory schemes that expressly preempt state and local laws. As a result, the Chamber is uniquely suited to offer a broader perspective on preemption and keenly interested in ensuring that the regulatory environment in which its members operate is a consistent one.

INTRODUCTION AND SUMMARY OF ARGUMENT

The court of appeals' bottom-line conclusion—that state-law claims challenging the design of covered vaccines are preempted, whether they sound in negligence or in strict liability—undoubtedly is correct, and respondent's brief addresses in detail why. Rather than reprising at length the features of the Vaccine Act's text, structure, and history, all of which support the court of appeals' reading of Section 22(b)'s preemptive scope, we focus on a problematic and more broadly applicable aspect of the decision below: the court's use of a presumption against preemption in the express preemption context, which unnecessarily cluttered its reasoning. We suggest that there is less to the presumption than meets the eye and that there is little basis for applying a presumption against preemption once Congress has expressly stated its intent to preempt state law.

Particularly in the context of express preemption, the presumption against preemption is fundamentally at odds with central principles of preemption law and statutory interpretation. It is difficult to reconcile with the settled understanding that

preemption turns on congressional intent. A presumption that must yield to any indicia of Congress's preemptive purpose—as ascertained through the usual methods of statutory construction—has very limited application. Thus, one unsurprisingly finds that the Court often ignores the presumption or applies it to no discernable effect, suggesting that the presumption is of limited utility as a practical matter. Other courts struggling to apply this Court's jurisprudence have similarly encountered difficulties trying to make sense of the presumption and deciding how much weight to afford it. Because the presumption is logically ungrounded and has been applied in a haphazard fashion, this case presents an excellent opportunity to reexamine the applicability of the presumption and clarify that express preemption provisions should simply be given a fair reading, with a thumb neither on the side favoring preemption nor that disfavoring it.

Petitioners and some of their *amici* assert that the presumption against preemption is justified in order to protect the traditional prerogatives of the States. Pet. Br. 40-41; Br. of the American Association for Justice, *et al.* (AAJ Br.), at 4-8; Br. of Kenneth W. Starr and Erwin Chemerinsky (Starr & Chemerinsky Br.), at 6-13. The threat to federalism they invoke is exaggerated, while the remedy they propose—the presumption against preemption—endangers other constitutional values. When Congress includes an express preemption clause in a statute (as it did in the Vaccine Act), Congress's intent to displace state law is obvious and the only remaining issue is the *extent* of preemption intended. This is an issue of statutory interpretation, and does not implicate our system of federalism. Whatever the force of the view that matters of federal law should

generally be approached with due regard for the States' traditional spheres of responsibility, once Congress has already explicitly stated its intent to preempt state law, the balance that Congress has articulated should not lightly be second-guessed by courts or disrupted by interpretive "presumptions." It is, after all, in the political branches that the Constitution has vested the prerogative of refining the balance between the respective roles of the States and of the Federal government. That is the unmistakable import of the Supremacy Clause, which declares Federal law the "supreme Law of the Land * * * any Thing in the * * * Laws of any State to the Contrary notwithstanding." U.S. CONST. art. VI, cl. 2.

Thus, once Congress has validly enacted a preemption provision pursuant to one of its enumerated powers (and nobody disputes that the Vaccine Act falls squarely within the heartland of the Commerce Clause power), application of a presumption against preemption has no legitimate purpose. When courts adopt crabbed readings of statutory language solely in order to avoid finding preemption, they frustrate Congress's purpose in establishing a uniform federal regulatory regime—a congressional function that takes on additional importance when the alternative to federal regulation is a patchwork of inconsistent state regulation. This very case aptly illustrates how federalism is disserved by the systematic application of a presumption against preemption in express preemption cases. Even one state's choice to impose expansive liability on vaccine manufacturers might well result in the withdrawal of a manufacturer from the national marketplace, thus leading to "the very real possibility of vaccine shortages" nationwide that prompted Congress to enact the Vaccine Act. H.R. REP. No. 99-908, at 7, *reprinted in*

1986 U.S.C.C.A.N. 6344. Allowing individual states to undermine the availability of life-saving products in other states does not advance the cause of federalism a single iota.

Finally, even if a presumption against preemption *ever* had a role to play as a tiebreaker (*e.g.*, when the ordinary tools of statutory construction are in equipoise and the reading disfavoring preemption is truly "*just as plausible*" as the one favoring preemption), that would certainly not be *this* case. See *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005) (emphasis added); Resp. Br. 44. As the court of appeals correctly concluded, Congress's intent to preempt state-law claims relating to the design of covered vaccines is plain on the face of the Vaccine Act's express preemption provision, and is further confirmed by the structure and legislative history of that statute. There is no countervailing reason to believe that Congress would have wanted to preserve the claims asserted by petitioners. Petitioners and their *amici* thus find themselves in the position of asking this Court to adopt a strained reading of Section 22(b) of the Vaccine Act in order to resurrect their barred design-defect claims.[2] This is an easy

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[2] Curiously, petitioners have nothing to say about a supposed presumption against preemption when it comes to interpreting *Section 22(e)*, which preempts state laws that limit individuals from bringing suit against manufacturers when such claims otherwise would not be preempted by *Section 22(b)*. See 42 U.S.C. § 300aa-22(e). Because a "narrow" reading of the preemptive scope of Section 22(b) necessarily implies a "broad" reading of Section 22(e), petitioners' reliance on the presumption is manifestly unprincipled. Petitioners would have this Court apply it as a one-way ratchet—only when it would expand the claims available to plaintiffs under state law.

case—all the more so, once the presumption against preemption has been laid to rest in the express preemption context.

ARGUMENT

The court of appeals began its analysis by declaring that courts must resolve cases like this one by applying a presumption against preemption. See Pet. App. 15a. It concluded that even when viewed through the lens of the presumption against preemption, the Vaccine Act's express preemption provision must be read to bar any state-law claim that seeks recovery for the side effects of a covered vaccine that was "properly prepared and was accompanied by proper directions." 42 U.S.C. § 300aa-22(b)(1). In categorically deeming as "unavoidable" those injuries and deaths resulting from properly manufactured and adequately labeled vaccines, Congress "made it clear" that design-defect claims (whether sounding in negligence or in strict liability) are preempted. See Pet. App. 33a-34a & n.9. Although the court of appeals' (correct) conclusion on this point follows whether or not the presumption against preemption is applied, the Court should take this opportunity to clarify that the presumption should have played no role in the analysis of Section 22(b) of the Vaccine Act.

I. A Presumption Against Preemption Is Not Appropriately Applied In Express Preemption Cases Such As This One.

The application of the presumption against preemption has not been without controversy. In some cases, the Court has applied the doctrine when interpreting express preemption provisions. See, *e.g.*, *Altria Group*, 129 S. Ct. at 543; *Bates*, 544 U.S. at

449; *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 485 (1996); *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 518 (1992). But as recently as the Court's 2008 decision in *Riegel*, the majority held that the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act preempted the plaintiff's state-law claims without even mentioning the presumption against preemption. See 552 U.S. at 330; see also page 10 & nn. 5-6*, infra*. And a number of current members of the Court have explicitly rejected the presumption's applicability in interpreting the scope of express preemption provisions. See, *e.g.*, *Altria Group*, 129 S. Ct. at 558 (Thomas, J., dissenting) ("[T]here is no authority for invoking the presumption against pre-emption in express pre-emption cases."); *Bates*, 544 U.S. at 457 (Thomas, J., concurring in the judgment in part and dissenting in part); *Cipollone*, 505 U.S. at 544 (Scalia, J., concurring in the judgment in part and dissenting in part); see also *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 pre-emption") (internal quotation marks omitted). There is considerable illogic in application of the presumption here.

A. Applying the presumption in the presence of an express preemption provision conflicts with the central, universally acknowledged rule governing preemption cases: "[p]re-emption fundamentally is a question of congressional intent." *English* v. *Gen. Elec. Co.*, 496 U.S. 72, 78-79 (1990).[3] The "task of

[3] See, *e.g.*, *Gade* v. *Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 96 (1992) (plurality opinion); *Cipollone*, 505 U.S. at 545 (Scalia, J., concurring in the judgment in part and dissenting in part); *Allis-Chalmers Corp.* v. *Lueck*, 471 U.S. 202, 208 (1985);

statutory construction must in the first instance focus on the plain wording of the [express preemption] clause, which necessarily contains the best evidence of Congress' pre-emptive intent." *Sprietsma* v. *Mercury Marine*, 537 U.S. 51, 62-63 (2002) (internal quotation marks omitted). Thus, even decisions that have forcefully stated the presumption have gone on to recognize that the Court's "analysis of the scope of [a] statute's pre-emption is guided by [the] oft-repeated comment * * * that '[t]he purpose of Congress is the ultimate touchstone in every pre-emption case.'" *Lohr*, 518 U.S. at 485-486 (quoting *Cipollone*, 505 U.S. at 529 n.27). "As a result, any understanding of the scope of a pre-emptive statute must rest primarily on 'a fair understanding of congressional purpose.'" *Ibid.*; see also *New York State Conference of Blue Cross & Blue Shield*, *Plans* v. *Travelers, Inc.*, 514 U.S. 645, 655 (1995).

When Congress has made its preemptive intent known through "explicit statutory language," the Court's task is "an easy one." *English*, 496 U.S. at 79. The Court's "ultimate task * * * is to determine whether state regulation is consistent with * * * the statute as a whole (*Gade*, 505 U.S. at 98 (plurality opinion)), and Congress's "pre-emptive intent" may be expressed through the "statute's express language or through its structure and purpose" (*Altria Group*, 129 S. Ct. at 543). It is settled that "[i]f the intent of Congress is clear, that is the end of the matter; for the court * * * must give effect to the unambiguously expressed intent of Congress." *FMC Corp.* v. *Holliday*, 498 U.S. 52, 57 (1990) (internal quotation marks omitted). Thus, any presumption against preemption

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Hillsborough County v. *Automated Med. Labs., Inc.*, 471 U.S. 707, 714 (1985).

"dissolves once there is conclusive evidence of intent to pre-empt in the express words of the statute itself." *Cipollone*, 505 U.S. at 545 (Scalia, J., concurring in the judgment in part and dissenting in part). "Under the Supremacy Clause, * * * [the Court's] job is to interpret Congress's decrees of pre-emption neither narrowly nor broadly, but in accordance with their apparent meaning." *Id.* at 544. The judicial task is to "determine which state-law claims [the statute] pre-empts, *without slanting the inquiry* in favor of either the Federal Government or the states." *Bates*, 544 U.S. at 457 (Thomas, J., concurring in the judgment in part and dissenting in part) (emphasis added).

Because it is fundamental that preemption turns on congressional intent—and because the Court conducts an inquiry into preemption by "begin[ning] with the language employed by Congress and the assumption that the ordinary meaning of that language accurately expresses the legislative purpose" (*FMC Corp.*, 498 U.S. at 57 (internal quotation marks omitted))—any presumption regarding preemption must yield to the ordinary tools of statutory construction when Congress has enacted an express preemption provision. This analysis starts with the text of the statute, read (only if necessary) in light of the statute's structure, purpose, regulatory context, and legislative history, and leaves no place for the "unreasonabl[e] interpret[ation of] expressly pre-emptive federal laws in the name of" a supposed presumption against preemption. *Altria Group*, 129 S. Ct. at 558 (Thomas, J., dissenting).

B. In light of the primacy of congressional intent, it is hard to discern what work the presumption actually does in practice. To be sure, there are a fair

number of cases in which the Court has recited the familiar phrases acknowledging the presumption.[4] But there are numerous express preemption decisions—most recently *Riegel*, 552 U.S. 312—in which the Court has "said not a word about 'a presumption against * * * preemption, * * * that was to be applied to construction of the text [of such a provision]." *Cipollone*, 505 U.S. at 546 (Scalia, J., concurring in the judgment in part and dissenting in part).[5] In fact, the Court regularly has "refrained from invoking the presumption in the context of express pre-emption." *Altria Group*, 129 S. Ct. at 556 (Thomas, J., dissenting).[6] This is true both in cases holding state laws not to be preempted,[7] and in those finding them to be preempted.[8] And even when the presumption against

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[4] *E.g.*, *Altria Group*, 129 S. Ct. at 543; *Lohr*, 518 U.S. at 485; *New York State Conference of Blue Cross & Blue Shield Plans*, 514 U.S. at 655; *Cipollone*, 505 U.S. at 518; *English*, 496 U.S. at 79; *Hillsborough County*, 471 U.S. at 715.

[5] Justice Scalia cited *Morales* v. *Trans World Airlines, Inc.*, 504 U.S. 374 (1992) and *Norfolk & W. Ry. Co.* v. *American Train Dispatchers Ass'n*, 499 U.S. 117 (1991).

[6] Justice Thomas cited *Rowe* v. *New Hampshire Motor Transp. Ass'n*, 552 U.S. 364 (2008); *Engine Mfrs. Ass'n*, 541 U.S. 246; *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001); *Locke*, 529 U.S. 89; and *Geier*, 529 U.S. 861. There are many others. *E.g.*, *Freightliner Corp.* v. *Myrick*, 514 U.S. 280 (1995); *Am. Airlines, Inc.* v. *Wolens*, 513 U.S. 219 (1995); *FMC Corp.* v. *Holliday*, 498 U.S. 52 (1990); *La. Pub. Serv. Comm'n* v. *FCC*, 476 U.S. 355 (1986); *Capital Cities Cable, Inc.* v. *Crisp*, 467 U.S. 691 (1984); *Fid. Fed. Sav. & Loan Ass'n* v. *de la Cuesta*, 458 U.S. 141 (1982); *Malone* v. *White Motor Corp.*, 435 U.S. 497 (1978).

[7] See, *e.g.*, *Freightliner Corp.*, *supra*; *La. Public Service Comm'n*, *supra*; *Malone*, *supra*.

[8] See, *e.g.*, *Rowe*, *supra*; *Engine Mfrs. Ass'n.*, *supra*; *Buckman*, *supra*; *Locke*, *supra*; *Geier*, *supra*; *Am. Airlines*, *supra*; *FMC*

preemption is acknowledged, it has been applied by the Court in manner that is far from uniform. Although it has been said to be inapplicable "when the State regulates in an area where there has been a history of significant federal presence" (*Locke*, 529 U.S. at 108), the presumption at other times is said to govern all federal legislation (*Maryland* v. *Louisiana*, 451 U.S. 725, 746 (1981)) or legislation that touches fields where there has been a "historic presence of state law" (*Levine*, 129 S. Ct. at 1194-95 & n.3).

Because the Court's decisions have done little to clarify the question of what it means to interpret an express preemption provision narrowly, and when this must be done, it is unsurprising that confusion and inconsistency dominate other courts' attempts to apply the presumption against preemption. See *Farina* v. *Nokia*, 578 F. Supp. 2d 740, 754-55 (E.D. Pa. 2008) (noting that "Supreme Court precedents have not been consistent" and that "[h]ow this presumption against preemption is to be applied" has varied widely depending on context). The Court's recent 5-4 decision in *Altria Group* is unlikely to dispel this confusion. Although the majority opinion stated in passing that the presumption against preemption applies to express as well as implied preemption analyses, the Court did not explain how that result could be reconciled with *Riegel* or the widely accepted tenet that congressional intent is the ultimate touchstone

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Corp., *supra*; *Capital Cities Cable*, *supra*; *Fid. Fed. Sav.*, *supra.* One study found that the percentage of this Court's cases in which preemption of state common-law tort claims was found actually *increased* following *Cipollone.* Michael S. Greve & Jonathan Klick, *Preemption in the Rehnquist Court: A Preliminary Empirical Assessment*, 14 SUP. CT. ECON. REV. 43, 57 (2006).

of the preemption inquiry. Notwithstanding *Altria*, a few courts since that decision have ignored the presumption in their analyses of express preemption provisions.[9] And even when lower courts do dutifully recite the presumption as an abstract proposition of law, they often decide the case using traditional tools of statutory interpretation without further reference to the presumption in the court's analysis of the statute, or find that the presumption is inapplicable because of the subject matter of the state regulation.[10] All this breeds needless complexity.

In the end, we are not aware of any decision in which the Court found evidence of congressional intent that would have been held sufficient in other contexts, but was rejected because it did not overcome the presumption against preemption. For all of the controversy, the presumption seems to make lit-

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[9] See, *e.g.*, *Chae* v. *SLM Corp.*, 593 F.3d 936, 944 (9th Cir. 2010) (referencing "assumption" of non-preemption only during discussion of conflict preemption); cf. *Zimmerman* v. *Bd. of County Comm'rs*, 218 P.3d 400, 430 (Kan. 2009) ("In *the absence of express preemption* in a federal law, there is a strong presumption that Congress did not intend to displace state law") (emphasis added and internal quotation marks omitted).

[10] *E.g.*, *Colo. Interstate Gas Co.* v. *Wright*, No. 09-4031, 2010 WL 1488934, at *16 (D. Kan. Apr. 13, 2010) (party was not entitled to "claim the benefit of a presumption against preemption" because natural gas transportation was an area "where there has been a history of significant federal presence") (internal quotation marks omitted); *Brown* v. *United Air Lines, Inc.*, 656 F. Supp. 2d 244, 251-52 (D. Mass. 2009) (declining to "imply broad exceptions to the preemption provision" even "for areas of traditional state concern," such as employment law); *Ophir* v. *City of Boston*, 647 F. Supp. 2d 86, 91-92 (D. Mass. 2009) (presumption "not triggered" when state "regulate[d] in an area of significant federal presence [such as] fuel economy").

tle difference to how *this* Court decides express preemption cases. But *other* courts have to struggle with faithfully applying this Court's precedent.[11] It is time to inter the presumption against preemption in this context and to bring to an end the mischief it has occasioned. Express preemption provisions should be analyzed according to the normal tools of statutory interpretation.

II. The Federalism Concerns Asserted By Some Of Petitioners' *Amici* Cannot Justify A Presumption Against Preemption.

The presumption against preemption often is said to rest on "principles of federalism and respect for state sovereignty." *Cipollone*, 505 U.S. at 533 (Blackmun, J., concurring in part and dissenting in part). True to form, some *amici* pick up on this theme, asserting that the presumption is necessary to "protect state sovereignty and to ensure the proper functioning of the political safeguards of federalism." Starr & Chemerinsky Br. 2. This traditionally ad-

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[11] A case in point is *Ferrari* v. *American Home Products Corp.*, 650 S.E.2d 585 (Ga. App. 2007), which took "one part of the [presumption against preemption as articulated in *Bates*] out of its context, and [gave] it broader scope than is appropriate," "so as to make the presumption against preemption irrebuttable." *Am. Home Products Corp.* v. *Ferrari*, 668 S.E.2d 236, 238-39 (Ga. 2008) (internal quotation marks omitted). In fact, the confused application of a presumption against preemption in both the Georgia appellate court and the Georgia Supreme Court in *Ferrari* contributed to those courts' erroneous conclusion that the Vaccine Act preempted design-defect claims only on a case-by-case basis. See Br. for U.S., *Am. Home Products Corp.* v. *Ferrari*, No. 08-1120 (Jan. 29, 2010), at 8, *available at* 2010 WL 342143; Br. for The Chamber of Commerce of the United States of America, *Am. Home Products Corp.* v. *Ferrari*, No. S0761708 (Ga. Mar. 3, 2008), *available at* 2008 WL 4992164.

vanced rationale for the presumption does not, however, stand up to scrutiny. And it certainly does not constitute a legitimate reason for imposing a "clear statement" limitation on the scope of express preemption provisions.

A. Contrary to *amici*'s protestations (*e.g.*, Starr & Chemerinsky Br. 6-11; AAJ Br. 7), no federalism concerns inhere in the operation of express preemption provisions, because preemption of state law is a necessary consequence of the constitutional plan—in particular, the interplay between Congress's legislative powers and the Supremacy Clause. See *New York* v. *United States*, 505 U.S. 144, 156 (1992) ("If a power is delegated to Congress in the Constitution, the Tenth Amendment expressly disclaims any reservation of that power to the States."). Regardless of how "compelling" an interest a State has in preservation of its law, "under the Supremacy Clause, from which our pre-emption doctrine is derived, any state law"—even one "clearly within a State's acknowledged power, which interferes with or is contrary to federal law"—"must yield." *Gade*, 505 U.S. at 108 (internal quotation marks omitted).

Valid federal legislation trumps state law. U.S. CONST. art. VI, cl. 2. The Supremacy Clause's purpose was "to remedy one of the chief defects in the Articles of Confederation by instructing courts to resolve state-federal conflicts in favor of federal law." David Sloss, *Constitutional Remedies for Statutory Violations*, 89 IOWA L. REV. 355, 402 (2004). There is no historical "support * * * for the conclusion that the [F]ramers intended any * * * presumption to be read into [the Supremacy Clause]." Marin R. Scordato, *Federal Preemption of State Tort Claims*, 35 U.C.

DAVIS L. REV. 1, 30 (2001).[12] To the contrary, there is considerable evidence that the Framers would have regarded the Supremacy Clause as *rejecting* "a general presumption that federal law does not contradict state law." Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 293 (2000). In other words, the Supremacy Clause was "designed precisely to eliminate any residual presumption" against implied repeals of state law in the face of contradictory federal law. Jack Goldsmith, *Statutory Foreign Affairs Preemption*, 2000 SUP. CT. REV. 175, 184.

When all is said and done, the issue of constitutional magnitude implicated by the presumption against preemption is not the *vertical* structure of federal-state relations upon which petitioners and their *amici* dwell. After all, "'[t]he relative importance to the State of its own law is not material when there is a conflict with valid federal law, for the

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[12] The Court's earliest Supremacy Clause cases give no indication that any sort of presumption against preemption should govern analysis of the validity of state laws. See, *e.g.*, *Martin* v. *Hunter's Lessee*, 14 U.S. (1 Wheat.) 304, 343-344 (1816) ("the legislatures of the states are, in some respects, under the control of congress, and in every case are, under the constitution, bound by the paramount authority of the United States"); *Ware* v. *Hylton*, 3 U.S. (3 Dall.) 199 (1796) (applying no presumption in case where state criminal law was superseded by treaty). Nor did the Court in these early cases suggest that special treatment was appropriate for state laws involving exercise of the State's traditional police powers. To the contrary, Chief Justice Marshall took pains to explain for the Court that, if a state's laws "come into collision" with federal law by "being contrary to" acts of Congress, it would be immaterial that the laws were passed "in virtue of a power to regulate [the state's] domestic trade and police." *Gibbons* v. *Ogden*, 22 U.S. (9 Wheat.) 1, 210 (1824).

Framers of our Constitution provided that the federal law must prevail.'" *Fid. Fed. Sav. & Loan Ass'n* v. *de la Cuesta*, 458 U.S. 141, 153 (1982) (quoting *Free* v. *Bland*, 369 U.S. 663, 666 (1962)). And "to the extent that other federalism questions remain—the wisdom of national regulation, the balance between regulatory uniformity and policy innovations, etc.—those questions are, by constitutional design, to be *answered by Congress*." Viet D. Dinh, *Reassessing the Law of Preemption*, 88 GEO. L.J. 2085, 2092 (2000) (emphasis added).[13]

Rather, the presumption against preemption aggrandizes the judicial branch over the political branches—a classic *horizontal* clash of authority. Courts depart from the proper judicial role when they apply an interpretive presumption at the expense of concrete indicia of congressional intent. The "systematic[] favor[ing]" of "one result over another" in analyzing preemption questions "risk[s] an illegitimate expansion of the judicial function" by "disrupt[ing] the constitutional division of power between federal and state governments" and by "rewrit[ing] the laws enacted by Congress." Dinh, *supra*, 88 GEO. L.J. at 2092. Respect for the political branches counsels in favor of not placing a judicial thumb on the scales when interpreting the reach of an express preemption provision.

B. Because the Supremacy Clause of the Constitution points in *favor* of, not *against*, preemption,

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[13] Moreover, as a practical matter, "States are among the most influential of interest groups in the federal legislative process," and are therefore eminently well-positioned to raise with Congress their concerns about the preemptive scope of a given statute. Goldsmith, *supra*, 2000 SUP. CT. REV. at 178, 186.

a clear statement rule is not appropriate in the express preemption context. *Amici* therefore are mistaken when they suggest that courts should insist that Congress express a "clear and manifest preemptive purpose" (Starr & Chemerinsky Br. 7) before giving full effect to an express preemption provision. Such a rule would mesh at best uneasily with the clear statement rules that the Court has applied in other contexts.

As Justice Scalia has explained, clear statement rules are designed principally "to ensure that, absent unambiguous evidence of Congress's intent, extraordinary constitutional powers are not invoked, or important constitutional protections eliminated, or seemingly inequitable doctrines applied. *Cipollone*, 505 U.S. at 546-547 (Scalia, J., concurring in the judgment in part and dissenting in part). Such clear statement rules ordinarily are applied to guarantee that Congress actually has focused on achieving a particular result that gives rise to constitutional concern.[14] But there is nothing extraordinary or concerning about express preemption, which is a routine consequence of the constitutional design that does not implicate any genuine federalism concerns.[15]

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[14] *E.g.*, *Kimel* v. *Fla. Bd. of Regents*, 528 U.S. 62, 73 (2000) (Congress's intent to abrogate Eleventh Amendment sovereign immunity must be "unmistakably clear in the language of the statute") (internal quotation marks omitted).

[15] A presumption against preemption in the express preemption context would be conceptually incoherent in yet another respect: namely, it would have to coexist alongside the notion of *implied* preemption, under which federal laws have preemptive effect even "[w]here Congress likely did not focus specifically on the matter," so long as a ruling against preemption would produce an "anomalous result." *Lohr*, 518 U.S. at 504 (Breyer, J.,

The presumption against preemption forces Congress to be *doubly* explicit about drafting legislation that potentially encroaches on traditional areas of state authority. According to the presumption's proponents, it is not enough that Congress be explicit about its *intent* to preempt—by assumption, the fact that Congress has enacted an express preemption provision does not suffice. Under the unworkable approach petitioners' *amici* propose, Congress would be required to go still further, and anticipate every area of potential overlap between the federal and state regulatory regimes. As Justice Scalia explained in a related context, "the result is extraordinary: The statute that says *anything* about pre-emption must say *everything*; and it must do so with great exactitude, as any ambiguity concerning its scope will be read in favor of preserving state power." *Cipollone*, 505 U.S. at 548 (Scalia, J., concurring in the judgment in part and dissenting in part).

Thus, a Congress intent on displacing state law would be left with one of two unpalatable options: (1) it must enumerate and specifically target every conceivable state-law regime subject to preemption,[16] or (2) it must enact a deliberately over-inclusive preemption provision that sweeps so broadly as to deprive courts of the interpretative latitude to find

concurring). When implied preemption is at issue, Congress *by definition* has not clearly spoken to its intent to preempt, yet the Court remains willing to find preemption. This makes it especially odd to impose a clear statement rule when dealing with an express preemption provision.

[16] This would at most be a partial solution. Practically speaking, States would be emboldened to strategically re-characterize their law in order to wedge open a supposed gap in preemptive coverage, notwithstanding Congress's plainly expressed intent to preempt. See Nelson, *supra*, 86 VA. L. REV. at 290-91.

any possible "ambiguity" or alternative "reading that disfavors pre-emption." Cf. *Bates*, 544 U.S. at 449. Neither outcome serves federalism.

* * *

Application of the presumption against preemption in the express preemption context needlessly invites courts to engage in a battle that they should not fight and cannot win. The Constitution entrusts to the political branches the task of allocating regulatory authority between the States and the federal government. Constitutional principle and pragmatism align in this instance and call for the same result: forswearing further reliance on a presumption against preemption that can serve only to distort congressional intent.

III. Section 22(b) Of The Vaccine Act Preempts Petitioners' Design-Defect Claims.

To be clear, the decision below *did* apply the presumption against preemption and concluded that "even in light of the presumption against preemption," there was "clear and manifest" evidence that Congress intended to preempt petitioners' design-defect claims. See Pet. App. 30a. We submit, though, that the same result could have been reached more straightforwardly without the analytical underbrush of the presumption. The appropriate function of the courts in this, as in any other, issue of statutory interpretation, is to identify the *best* (*i.e.*, most plausible) reading of the *actual* statute (see Br. for U.S., *Am. Home Products Corp.* v. *Ferrari*, No. 08-1120 (Jan. 29, 2010), at 9, *available at* 2010 WL 342143)—not to approach the statute with a blue pencil and chide Congress for failing to "speak with the discrimination of an Oxford don." Cf. *Davis* v. *United States*,

512 U.S. 452, 459 (1994) (internal quotation marks omitted).

When employed in the service of gaining a "fair understanding of congressional purpose" (*Lohr*, 518 U.S. at 486-87), the ordinary indicia of legislative intent point in a single direction: that Congress eschewed the case-by-case approach sought by petitioners in favor of a categorical rule deeming "unavoidable" any residual injuries once it has been established that a covered vaccine was properly manufactured and adequately labeled. All state-law claims challenging such injuries are, accordingly, preempted by the Vaccine Act.

A. Section 22(b) of the Vaccine Act provides that "[n]o vaccine manufacturer shall be liable * * * for damages arising from a vaccine-related injury or death * * * if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." In substance, petitioners assert that courts should decide, on a case-by-case basis, whether the side effects in question actually were unavoidable. They contend that the Vaccine Act preempts only claims with respect to injuries or deaths that could not have been prevented by a safer alternative design. Pet. Br. 31.[17]

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[17] Petitioners thus implicitly recognize that Section 22(b) must preempt at least *some* design-defect claims. Section 22(b) would be a dead letter otherwise, since by its terms it permits manufacturing-defect and failure-to-warn claims to proceed. There would be no point to a provision that *also* excluded from its preemptive reach the only remaining category of products liability claims, those alleging a design defect. See generally Restatement (Third) of Torts: Products Liability § 2 ("A product is defective when, at the time of sale or distribution, it contains a

Such a construction cannot be squared with the statutory language. It reads out of the statute the phrase introduced by "even though," and therefore "render[s] superfluous" (*Astoria Fed. Sav. & Loan Ass'n* v. *Solimino*, 501 U.S. 104, 112 (1991)) the very language Congress included in the statute to delimit by contrast *avoidable* causes of vaccine-related injury—namely, those caused by manufacturing defects or improper directions and warnings. Injuries that did *not* result from these avoidable causes were considered by Congress to be "unavoidable" within the meaning of the Vaccine Act and thus compensable, if at all, under the administrative scheme established.

B. The legislative history of Section 22(b) confirms that Congress intended the Vaccine Act to preempt all design-defect claims, regardless of whether the plaintiff could point to a feasible alternative design. The Committee Report on the Vaccine Act makes clear that Section 22(b) was meant to preserve a judicial remedy only for state-law claims alleging defects in the vaccine's manufacture or accompanying labeling, while preempting all design-defect claims.[18]

The Report explains that "if [claimants] cannot demonstrate under applicable law either that a vac-

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manufacturing defect, is defective in *design*, or is defective because of *inadequate instructions or warnings*.") (emphasis added).

[18] As respondent explains, petitioners erroneously place stock on "legislative history" issued *after* the original enactment of the Vaccine Act in connection with its funding. See Resp. Br. 48-51; see also *United States* v. *Price*, 361 U.S. 304, 313 (1960) ("[T]he views of a subsequent Congress form a hazardous basis for inferring the intent of an earlier one.").

cine was improperly prepared or that it was accompanied by improper directions or inadequate warnings [they] should pursue recompense in the compensation system, *not the tort system*." H.R. REP. No. 99-908, at 26 (emphasis added). Congress thus intended to relegate design-defect claims to the administrative compensation system created by the Vaccine Act, as long as the covered vaccine causing injury was properly manufactured and adequately labeled. In making this determination, Congress was guided by the policy of Comment k of Section 402A of the Restatement (Second) of Torts, which the Committee believed was "appropriate and necessary as the policy for civil actions seeking damages in tort" for vaccine-related injures.[19] *Id.* at 26.

Faced with this inconvenient legislative history, petitioners and their *amici* try to explain it away with a superficially appealing syllogism, which at its core is as follows:

- *Major premise*: Congress sought merely to "codify" or "incorporate" Comment k in enact-

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[19] That comment, titled "[u]navoidably unsafe products," states in relevant part:

> There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. * * * Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. * * * The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

ing Section 22(b). Pet. Br. 39; Br. of Mark A. Geistfeld (Geistfeld Br.) at 6.

- *Minor premise*: At the time Section 22(b) was adopted, the prevailing view of courts applying the Restatement's approach to products liability was to conduct a case-by-case analysis of whether the prescription product before the court was "unavoidably unsafe" within the meaning of Comment k. Pet. Br. 30-31 & n.16; Geistfeld Br. 10-12, 19.[20]
- *Conclusion*: Since Congress is presumed to have been aware of the judicial gloss on Comment k, Section 22(b) calls for the determination, on a case-by-case basis, of

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[20] Although not our focus, we note that petitioners' reconstruction of the state of products liability law in 1986 is highly selective. "[W]hile some courts concluded that a case-by-case analysis was necessary to determine whether a prescription drug was unavoidably unsafe, *i.e.*, that it could have been made safer by a better design, others concluded that prescription drug manufacturers were generally not liable for design defect claims." *Militrano ex rel. Militrano* v. *Lederle Labs.*, 769 N.Y.S.2d 839, 844-45 (N.Y. Sup. Ct. 2003) (internal citations omitted); see also Resp. Br. 43-44 & n.25. A not-inconsiderable number of courts had concluded that prescription drugs (such as vaccines) were, as a class, unavoidably unsafe products, and therefore effectively immunized from design-defect liability under Comment k. See David E. Chamberlain, Comment, *The Diminishing Role of Negligence in Manufacturers' Liability for Unavoidably Unsafe Drugs and Cosmetics*, 9 ST. MARY'S L.J. 102, 115 (1977). As even one of petitioners' own *amici* reluctantly recognizes, the "great majority of courts" do in fact invoke "comment k to exempt from strict liability the manufacturers of pharmaceutical projects," presumably on the notion that comment k "define[s]" pharmaceutical products as "unavoidably unsafe." Geistfeld Br. 12 (internal quotation marks omitted).

> whether or not the vaccine in question qualifies as an "[u]navoidably unsafe product."

The major premise of this argument is demonstrably false. Petitioners' assumption to the contrary, Section 22(b) does not merely direct courts to apply Comment k as the *substantive rule of decision* in design-defect claims brought against vaccine manufacturers. Rather, in enacting Section 22(b), Congress intended to articulate the across-the-board legislative judgment that covered vaccines are "unavoidably unsafe" within the meaning of Comment k. See Resp. Br. 40-42. As the Committee Report explains:

> The Committee has set forth Comment K * * * because it intends that the *principle* in Comment K regarding "unavoidably unsafe" products * * * apply to the vaccines covered in the bill and that *such products not be the subject of liability in the tort system.*

H.R. Rep. No. 99-908, at 26 (emphases added).

In other words, what Congress intended in enacting Section 22(b) was to deem *all* covered vaccines to be "unavoidably unsafe" products to which the "principle" of Comment k applied.[21] That "principle"—no liability for properly manufactured and adequately labeled products that are unavoidably unsafe—operates to preclude the availability of design-defect liability for covered vaccines *as a class*. What "un-

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[21] Congress thus viewed covered vaccines as paradigmatic examples of "unavoidably unsafe" products—*i.e.*, those "which in the present state of human skill and knowledge" cannot be made truly "safe," but which nonetheless are of such great social utility that their continued marketing and use are justified. H.R. REP. No. 99-908, at 26.

avoidably unsafe" or Comment k meant to *state courts* in 1986 is a red herring, since "Congress made it clear what *it* intended when it invoked comment k." Pet. App. 34a n.9 (emphasis added); see Resp. Br. 41-42.

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In enacting Section 22(b) of the Vaccine Act, Congress made the judgment that it was necessary to protect vaccine manufacturers from the unpredictability and expense of design-defect claims in the tort system, so as to preserve the continued availability of life-saving vaccines. Congress did not leave it up to the courts to decide on a state-by-state, case-by-case basis whether a given vaccine's design was design because of the existence of a feasible alternative design. All of the usual tools of statutory interpretation—*e.g.*, the plain import of the text, structure, and legislative history of the Vaccine Act—point towards this understanding of Section 22(b). The conclusion that petitioners' design-defect claims are preempted should, accordingly, follow without any additional analytical detours, such as a supposed presumption against preemption.

CONCLUSION

The judgment should be affirmed.

Respectfully submitted.

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