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 SUPREME COURT OF VERMONT

BRIEF OF *AMICI CURIAE* KENNETH W. STARR AND ERWIN CHEMERINSKY IN SUPPORT OF PETITIONERS URGING REVERSAL

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QUESTION PRESENTED

Section 22(b)(1) of the National Childhood Vaccine Injury Act of 1986 expressly preempts certain design defect claims against vaccine manufacturers "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." 42 U.S.C. § 300aa-22(b)(1).

The Question Presented is:

Whether the Third Circuit erred in holding that, contrary to its plain text and the decisions of this Court and others, Section 22(b)(1) preempts all vaccine design defect claims, whether the vaccine's side effects were unavoidable or not?

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Erwin Chemerinsky, ENHANCING GOVERNMENT (Stanford Univ. Press 2008) 2

Erwin Chemerinsky, CONSTITUTIONAL LAW: PRINCIPLES AND POLICIES (Aspen Law & Business 3d ed. 2006) 2

Erwin Chemerinsky, *Empowering States: The Need to Limit Federal Preemption*, 33 PEPP. L. REV. 69 (2005) 2, 10

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Felix Frankfurter, *Some Reflections on the Reading of Statutes*, 47 COLUM.L.REV. 527 (1947) 8

H.R.Rep. No. 908, 99th Cong., 2d Sess. 4, *reprinted in* 1986 U.S. Code Cong. & Admin. News 6287 18

Joanne Rhoton Galbreath, Annotation, Products Liability: What is an "Unavoidably Unsafe" Product, 70 A.L.R. 4th 16 (1989) 19

Kenneth W. Starr, Patrick E. Higginbotham, Stephanie K. Seymour, William C. Clark, John Criswell & Joe Sneed, THE LAW OF PREEMPTION: A REPORT OF THE APPELLATE JUDGES CONFERENCE (American Bar Association, 1991) 1, 10, 11

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INTEREST OF *AMICI CURIAE*

Amici Kenneth W. Starr and Erwin Chemerinsky are scholars who teach and write about federal preemption of state law, as well as practitioners with extensive experience in the field of preemption.[1]

Kenneth W. Starr is a former Judge of the U.S. Court of Appeals for the District of Columbia (1983-1989) and Solicitor General of the United States (1989-1993). He has served as Dean of the Pepperdine University School of Law and, as of June 2010, will become the fourteenth president of Baylor University. He has written widely on federal preemption issues.[2]

Erwin Chemerinsky is the current and founding dean of the University of California, Irvine School of Law. He has taught at the DePaul College of Law (1980–83), University of Southern California Law School (1983–2004), Duke School of Law (2004–

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[1] This brief has been filed with the written consent of the parties, which is on file with the Clerk of Court. Pursuant to Rule 37.6, *amici* affirm that no counsel for a party authored this brief in whole or in part, nor did any person or entity, other than *amici* or their counsel, make a monetary contribution to the preparation or submission of this brief.

[2] See, e.g., Kenneth W. Starr, Patrick E. Higginbotham, Stephanie K. Seymour, William C. Clark, John Criswell & Joe Sneed, THE LAW OF PREEMPTION: A REPORT OF THE APPELLATE JUDGES CONFERENCE (American Bar Association, 1991); Kenneth W. Starr, Preface to FEDERAL PREEMPTION: STATES' POWERS, NATIONAL Interests (Richard A. Epstein & Michael S. Greve eds., 2007); Kenneth W. Starr, *Reflections on Hines v. Davidowitz: The Future of Obstacle Preemption*, 33 PEPP. L. REV. 1 (2005).

2008), and University of California, Irvine School of Law (2008–present). He has also written at length on the subject of preemption.[3]

SUMMARY OF ARGUMENT

At bottom, this is a case about federalism. This Court has long assumed that "the historic police powers of the States [are] not to be superseded by [federal statute] unless that was the clear and manifest purpose of Congress." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). This starting assumption applies with particular force where Congress has legislated in a field that the states have traditionally occupied.

The principle recognized in *Rice* and its many progeny is necessary to protect state sovereignty and to ensure the proper functioning of the political safeguards of federalism. Requiring evidence of a clear and manifest preemptive purpose provides a political check, by affording notice to the states' representatives in Congress, and it also creates a procedural check, by demanding that state-law-displacing choices satisfy the bicameralism and presentment standards of Article I.

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[3] *See, e.g.*, Erwin Chemerinsky, ENHANCING GOVERNMENT 241-45 (Stanford Univ. Press 2008); Erwin Chemerinsky, CONSTITUTIONAL LAW: PRINCIPLES AND POLICIES (Aspen Law & Business 3d ed. 2006); Erwin Chemerinsky, *Empowering States: The Need to Limit Federal Preemption*, 33 PEPP. L. REV. 69 (2005); Erwin Chemerinsky, *Empowering States: a Rebuttal to Dr. Greve*, 33 PEPP. L. REV. 91 (2005); Erwin Chemerinsky, *Empowering States When It Matters: A Different Approach to Preemption,* 69 BROOK. L. REV. 1313 (2004).

The *Rice* principle in preemption cases is also consistent with a proper conception of the judicial role. It reduces the probability of erroneous judicial displacement of state law without congressional authorization and prevents preemption analysis from becoming a freewheeling, impressionistic judicial inquiry into congressional intent.

The legal requirements for preemption cannot be satisfied in this case. Section 22(b)(1) of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-22(b)(1) (the "Vaccine Act"), does not provide sufficient evidence of a clear and manifest preemptive purpose to bar design defect claims as a categorical matter. Rather, the language of the statute is just as plausibly (if not more plausibly) construed to allow the continued availability of design defect claims based on a plaintiff's showing of a feasible alternative design for a specific vaccine in a particular case. Even if legislative history could satisfy the *Rice* principle, nothing in the history of the Vaccine Act could possibly meet the requirements for preemption here.

The judgment should be reversed.

ARGUMENT

I. PRINCIPLES OF FEDERALISM REQUIRE EVIDENCE OF A CLEAR AND MANIFEST CONGRESSIONAL PURPOSE TO PREEMPT STATE LAW.

A. The *Rice* Principle Is Well Established.

This Court has long cited the need for a strong indication of congressional intent to overcome the usual assumption that "Congress did not intend to displace state law." *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981). The Court first articulated its clear statement rule in *Mintz v. Baldwin*, 289 U.S. 346, 350 (1933) ("The intention [to displace state law] must definitely and clearly appear."). It elaborated in *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218 (1947), that "the historic police powers of the States [are] not to be superseded by [federal statute] unless that was the clear and manifest purpose of Congress." *Id*. at 230. *See also City of Milwaukee v. Illinois*, 451 U.S. 304, 317 (1981) (preemption requires "evidence of a clear and manifest purpose"); *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 146-47 (1963) ("we are not to conclude that Congress legislated the ouster of this California statute . . . in the absence of an unambiguous congressional mandate to that effect").

"In areas of traditional state regulation," the Court "assume[s] that a federal statute has not supplanted state law unless Congress has made such an intention clear and manifest." *Bates v. Dow Agrosciences LLC,* 544 U.S. 431, 449 (2005). A court

has "a duty" to adopt a non-preemptive interpretation despite the presence of a "plausible alternative reading" – even if the "alternative were just as plausible as [the non-preemptive] reading of that text." *Id.*

This Court recently reiterated that it will avoid attributing preemptive force to federal law in cases of statutory ambiguity:

> When addressing questions of express or implied pre-emption, we begin our analysis "with the assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." . . . That assumption applies with particular force when Congress has legislated in a field traditionally occupied by the States . . . Thus, when the text of a pre-emption clause is susceptible of more than one plausible reading, courts ordinarily "accept the reading that disfavors pre-emption."

Altria Group, Inc v. Good, 129 S. Ct. 538, 543 (2008) (citations omitted).

The *Rice* principle applies "[i]n all pre-emption cases, and particularly in those in which Congress has 'legislated . . . in a field which the States have traditionally occupied.'" *Wyeth v. Levine*, 129 S. Ct. 1187, 1194 (2009) (citations omitted). It applies to both the "'question whether Congress intended any pre-emption at all' and to 'questions concerning the

scope of intended invalidation of state law.'" *Engine Mfrs. Ass'n v. S. Coast Air Quality Mgmt. Dist.*, 541 U.S. 246, 260-61 (2004) (citation omitted).

B. The Need For Evidence Of A Clear and Manifest Preemptive Purpose Stems From Important Constitutional Principles.

The *Rice* principle is of constitutional dimension. It arises from the basic axioms of the "system of dual sovereignty between the States and the Federal Government." *Gregory v. Ashcroft,* 501 U.S. 452, 457 (1991). The Framers adopted this "'constitutionally mandated balance of power,'" *Atascadero State Hospital v. Scanlon*, 473 U.S. 234, 242 (1985) (citation omitted), to "reduce the risk of tyranny and abuse from either front," because 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." *Gregory,* 501 U.S. at 458. Furthermore, as the Framers observed, the "compound republic of America" provides "a double security . . . to the rights of the people" because "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." The Federalist No. 51, p. 266 (M. Beloff ed., 2d ed.1987). *See also* Erwin Chemerinsky, *Empowering States When It Matters,* 69 BROOK. L. REV. at 1332 (federalism "is a means to the end of effective government that minimizes the

possibility of tyrannical rules, provides for the related goal of greater accountability, and sets the stage for vigorous experimentation").

Under this federalist system, the states retain substantial sovereign authority, under both the Tenth Amendment and "[t]he tacit postulates" of the constitutional plan, which then-Justice Rehnquist described as "as much ingrained in the fabric of the document as its express provisions." *Nevada v. Hall*, 440 U.S. 410, 433 (1979) (Rehnquist, J., dissenting). "[T]he States possess sovereignty concurrent with that of the Federal Government, subject only to limitations imposed by the Supremacy Clause." *Tafflin v. Levitt,* 493 U.S. 455, 458 (1990). *See also Alden v. Maine,* 527 U.S. 706, 713 (1999); *Printz v. United States,* 521 U.S. 898, 918-22 (1997); *New York v. United States,* 505 U.S. 144, 155-56 (1992).

The need for evidence of a clear and manifest preemptive purpose derives from the nature of federalism. Preemption analysis must include "due regard for the presuppositions of our embracing federal system, including the principle of diffusion of power not as a matter of doctrinaire localism but as a promoter of democracy." *San Diego Building Trades Council v. Garmon*, 359 U.S. 236, 243 (1959).

As this Court explained in *Garcia v. San Antonio Metro. Trans. Auth.*, 469 U.S. 528 (1985), "the States occupy a special and specific position in our constitutional system." *Id.* at 547. Although *Garcia* ended the approach of *National League of Cities v. Usery*, 426 U.S. 833 (1976), which had used principles of federalism as a substantive limit on Congress' commerce power, this Court did not leave

the states bereft of constitutional protection. Instead, this Court substituted procedural checks for the substantive prohibitions of *Usery*. *Garcia* held that state sovereignty is "more properly protected by procedural safeguards inherent in the structure of the federal system than by judicially created limitations on federal power." 469 U.S. at 552.

In order for the "procedural safeguards" of federalism to function, however, Congress must make clear its intent to alter the federal balance and displace state law, particularly in the areas where states have historically exercised their police powers to protect consumers and promote public health, welfare, and safety. "[U]nless Congress conveys its purpose clearly, it will not be deemed to have significantly changed the federal-state balance." *United States v. Bass*, 404 U.S. 336, 349 (1971); *see also Jones v. Rath Packing Co*., 430 U.S. 519, 525 (1977) ("This [*Rice*] assumption provides assurance that 'the federal-state balance' will not be disturbed unintentionally by Congress or unnecessarily by the courts.") (citation omitted); Felix Frankfurter, *Some Reflections on the Reading of Statutes*, 47 COLUM.L.REV. 527, 539-540 (1947).

Requiring evidence of a clear and manifest preemptive purpose provides a political check, by affording notice to the states' representatives in Congress, and it also creates a procedural check, by demanding that state-law-displacing choices satisfy the bicameralism and presentment standards of Article I. *See INS v. Chadha,* 462 U.S. 919, 945-46 (1983) (setting forth the Constitution's Bicameral and Presentment Clauses, Art. I, § 7, cls. 2-3, which "prescribe and define the respective functions of the

Congress and of the Executive in the legislative process"). "The Supremacy Clause thus requires that pre-emptive effect be given only those to federal standards and policies that are set forth in, or necessarily follow from, the statutory text that was produced through the constitutionally required bicameral and presentment procedures." *Wyeth*, 129 S. Ct. at 1207 (Thomas, J., concurring in the judgment).

As this Court recognized in *Gregory v. Ashcroft*, 501 U.S. 452 (1992), according preemptive effect to ambiguous federal statutes would short-circuit the political safeguards of federalism:

> [I]nasmuch as this Court in *Garcia* has left primarily to the political process the protection of the States against intrusive exercises of the Congress' Commerce Clause powers, we must be absolutely certain that Congress intended such exercise. "To give the state-displacing weight of federal law to mere congressional *ambiguity* would evade the very procedure for lawmaking on which *Garcia* relied to protect states' interests."

Id. at 464 (citation omitted). Accordingly, this Court opined that "Congress should make its intention 'clear and manifest' if it intends to pre-empt the historic powers of the States." *Id*. at 461 (quoting *Rice,* 331 U.S. at 230). "'In traditionally sensitive areas, such as legislation affecting the federal balance, the requirement of clear statement assures that the legislature has in fact faced, and intended to

bring into issue, the critical matters involved in the judicial decision.'" *Id*. (quoting *Will v. Michigan Dept. of State Police,* 491 U.S. 58, 65 (1989)). "This plain statement rule is nothing more than an acknowledgment that the States retain substantial sovereign powers under our constitutional scheme, powers with which Congress does not readily interfere." *Id*.

"[B]ecause the States are independent sovereigns in our federal system," this Court has "long presumed that Congress does not cavalierly pre-empt state-law causes of action." *Medtronic v. Lohr,* 518 U.S. 470, 485 (1996); *see also* Kenneth W. Starr, et al., THE LAW OF PREEMPTION at 40-56 (arguing that a "clear intent" requirement for preemption advances the interests of federalism); Erwin Chemerinsky, *Empowering States*, 33 PEPP. L. REV. at 74-75 ("Even as to express preemption, provisions of federal law that expressly preempt state law should be narrowly construed unless Congress has indicated otherwise.").

The need for evidence of a clear and manifest preemptive purpose is but one of several requirements that protect state sovereignty. Thus, this Court has required that Congress clearly state conditions on grants of federal funds to the States, *Arlington Cent. Sch. Dist. Bd. of Educ. v. Murphy*, 548 U.S. 291, 296 (2006); that Congress provide a clear statement of intent when it regulates at the outer limit of its Commerce Clause authority, *Jones v. United States*, 529 U.S. 848, 858 (2000); and that it clearly state any intent to subject states to liability under federal statutes. *Will*, 491 U.S. at 65.

Requiring evidence of a clear and manifest preemptive purpose is also consistent with a proper conception of the judicial role. It reduces the probability of erroneous judicial displacement of state law without congressional authorization by ensuring that preemption analysis does not become "[a] freewheeling judicial inquiry into whether a state statute is in tension with federal objectives." *Gade v. National Solid Wastes Management Assn.,* 505 U.S. 88, 111 (1992) (Kennedy, J., concurring in part and concurring in judgment). *See also Bates*, 544 U.S. at 459 (preemption 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." (Thomas, J., concurring in judgment in part and dissenting in part) (internal quotation marks and citation omitted).

C. The Supremacy Clause Supports The Need For Evidence Of A Clear And Manifest Preemptive Purpose.

Although the Supremacy Clause of Art. VI, cl. 2, means that federal law prevails in the event of any clash between the two concurrent sovereigns of Our Federalism, the Supremacy Clause supports the *Rice* principle in two respects. First, in adopting the Supremacy Clause, the Framers deliberately chose not to vest Congress with untrammeled authority over state law. The Clause was chiefly the product of proposals crafted by James Madison, introduced early in the proceedings at the Constitutional Convention.[4]

[4] *See* Kenneth W. Starr, et al., THE LAW OF PREEMPTION at 5.

Initially, Madison introduced an even stronger clause that would have granted Congress the power "to negative all laws which to [national legislators] shall appear improper."[5] Proponents of the Small State, or New Jersey Plan, rejected this stronger proposed clause due to their mistrust of such a strong federal government.[6] In particular, George Mason warned: "[T]he Danger is that the national [legislature] will swallow up the State Legislatures."[7] Hence, in their consideration of the Supremacy Clause, the Framers elected to retain important limits on the power of the national government.

The Supremacy Clause also supports the *Rice* principle in another respect. Precisely because the Clause represents strong medicine, courts must inquire to satisfy themselves that Congress has actually decided to invoke it. As the Court has observed, the Supremacy Clause gives the Federal Government "a decided advantage in [a] delicate balance" between federal and state authority. *Gregory,* 501 U.S. at 460. "As long as it is acting within the powers granted it under the Constitution, Congress may impose its will on the States" – a prerogative that this Court has described as an "extraordinary power in a federalist system." *Id.* Requiring evidence of a clear and manifest preemptive purpose ensures that courts recognize

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[5] *Id.* at 7 (quoting 1 The Records of the Federal Convention of 1787, at 162 (records of June 8, 1787) (M. Farrand rev. ed., 1966)).

[6] *Id.* at 7-8.

[7] *Id*. at 6 (quoting 1 The Records of the Federal Convention of 1787, at 160 (records of June 7, 1787)).

this "extraordinary power" only when it is proper to do so.

In sum, the *Rice* principle is an important element in the constellation of constitutional doctrines that protect state sovereignty.

II. THE LEGAL REQUIREMENTS OF PREEMPTION CANNOT BE SATISFIED IN THIS CASE.

Section 22(b)(1) of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-22(b)(1) (the "Vaccine Act") provides:

> No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, 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.[8]

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[8] 42 U.S.C. § 300aa-22(b) provides in full:

> (b) Unavoidable adverse side effects; warnings
>
> (1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, 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.

This statutory provision does not meet the legal requirements for preemption of all vaccine design defect claims, whether the vaccine's side effects were unavoidable or not. We reach this conclusion for several reasons.

First, on its face, Section 22(b)(1) does not evidence a clear and manifest purpose to preempt all design defect claims as a categorical matter. An equally plausible (if not more plausible) interpretation is that the inquiry of whether vaccine side effects "were unavoidable" must be made on a case-by-case basis rather than categorically. If a particular plaintiff could show that her injury at issue was avoidable, for example, through the use of a feasible alternative design for a specific vaccine, then she would satisfy the language of the statute, because

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> (2) For purposes of paragraph (1), a vaccine shall be presumed to be ac-companied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] and section 262 of this title (including regulations issued under such provisions) applicable to the vaccine and related to vaccine-related injury or death for which the civil action was brought unless the plaintiff shows—
>
> (A) that the manufacturer engaged in the conduct set forth in sub-paragraph (A) or (B) of section 300aa-23(d)(2) of this title, or
>
> (B) by clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with such Act and section (and regulations issued under such provisions).

she would have demonstrated that the side effects were *not* unavoidable.

If Congress had intended to bar all design defect claims with respect to vaccines, and to allow only manufacturing defect and failure-to-warn claims, it could have written a much simpler statute. As one commentator has observed:

> [The drafters] had a very simple option at their disposal: they could have omitted the words "that were unavoidable" from the provision. The result would have been a statute that shielded vaccine manufacturers from liability in civil actions where "the injury or death resulted from side effects even though the vaccine was properly prepared and was accompanied by proper directions and warnings."[9]

Such alternative language would have preserved manufacturing defect and failure-to-warn liability while precluding claims for defective design where the vaccine was properly prepared. The fact that Congress did not adopt such a straightforward approach indicates that it did not intend to bar all design defect claims categorically.

In *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), this Court used a similar analysis of possible alternative language to support a holding of non-preemption. *See id.* at 448-49 (rejecting an

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[9] Nitin Shah, "Note: When Injury Is Unavoidable: The Vaccine Act's Limited Preemption Of Design Defect Claims," 96 VA. L. REV. 199, 217 (2010).

interpretation that would "read[] . . . words out of the statute.... This amputated version . . . would no doubt have clearly and succinctly commanded the pre-emption of *all* state" tort claims for defective design) (emphasis in original).

Construing the Vaccine Act to bar all design defect claims would introduce the same vice. It would require ignoring part of Section 22(b)(1) – in particular, the clause "that were unavoidable." If the meaning of Section 22(b)(1) were unaffected by the presence or absence of the clause, then that clause would be rendered superfluous, in violation of the "settled rule that a statute must, if possible, be construed in such fashion that every word has some operative effect." *United States v. Nordic Village, Inc.*, 503 U.S. 30, 36 (1992).

Next, the structure of the Vaccine Act militates in favor of an interpretation of Section 22(b)(1) that does not preempt design defect claims categorically. Although the Vaccine Act creates a mandatory national compensation program, the Act contains a savings clause that expressly contemplates the preservation of state law tort claims.[10] It affords claimants three separate chances to exit the administrative compensation program and file suit under state law, including the explicit opportunity to elect "to file a civil action for damages" after receiving

[10] Section 22(a) provides: "Except as provided in subsections (b), (c), and (e) of this section State law shall apply to a civil action brought for damages for a vaccine-related injury or death." 42 U.S.C. § 300aa-22(a).

a judgment from the Vaccine Court.[11] Section 22(b) preserves at least some (and arguably all) manufacturing defect claims, as well as many failure-to-warn claims. Section 23(d)(2) envisions the award of punitive damages against vaccine manufacturers and immunizes them from such damages on a showing of compliance with all material requirements of the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, absent fraud or other criminal misconduct.[12] In short, the structure of the Vaccine Act shows that it is not a statute aimed at categorically ousting state tort law from vaccine-related litigation; to the contrary, the Act clearly envisions the continued availability of state-law claims.

In fact, the only portion of Section 22 that carries the title "Preemption" – Section 22(e) – does not bar state-law tort claims at all. To the contrary: Section 22(e) bars states from establishing new laws that would interfere with claimants' right to sue under state law.[13] Thus, the "preemption" portion of Section 22 facilitates the continued prosecution of claims in state court, rather than restricting them.

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[11] A claimant may reject or appeal the judgment of the Vaccine Court. 42 U.S.C. § 300aa-21(a). Prior to that opportunity, a claimant may opt out 240 days after filing a petition if the special master assigned to the case has not yet reached a decision, or 420 days after filing the petition if the court has failed to enter a judgment. *Id.* § 300aa-21(b).

[12] 42 U.S.C. § 300aa-23(d).

[13] Section 22(e) provides: "No State may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this part."

Even if legislative history could provide evidence of a clear and manifest preemptive purpose, nothing in the history of the Vaccine Act could possibly meet the requirement here. The purpose and summary section of the House Report on the Vaccine Act states that "[v]accine-injured persons . . . [who] reject a judgment and award made under the compensation program . . . may file a civil action for damages relating to a vaccine injury just as he or she may have done prior to the enactment of the legislation."[14] Such language reassured states that Congress was *not* displacing design defect claims as a categorical matter.

The legislative history further indicates that, in discussing Section 22(b), the House Report referred to the principle of Comment k of Section 402A of the Second Restatement of Torts.[15] Comment k exempts from strict liability certain

> [u]navoidably unsafe products. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their

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[14] H.R.Rep. No. 908, 99th Cong., 2d Sess. 4, *reprinted in* 1986 U.S. Code Cong. & Admin. News 6287, 6344-45.

[15] *See* H.R. Rep. No. 99-908, pt. 1, at 25 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6366 ("This provision sets forth the principle contained in Comment k of Section 402A of the Restatement of Torts (Second)"); *see* also H.R. Rep. No. 99-908, pt. 1, at 26, *reprinted in* 1986 U.S.C.C.A.N. at 6367 ("The Committee has set forth Comment K in this bill because it intends that the principle in Comment K regarding 'unavoidably unsafe' products, i.e., those products which in the present state of human skill and knowledge cannot be made safe, apply to the vaccines covered in the bill and that such products not be the subject of liability in the tort system.").

> intended and ordinary use. These are especially common in the field of drugs. . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many . . . drugs, vaccines, and the like. . . .

Restatement (Second) of Torts § 402A cmt. k (1965). Under the majority approach to comment k, a court must make a case-by-case determination of whether a certain side effect is unavoidable. Comment k does not entail a categorical pronouncement that a particular product is unavoidably unsafe in all circumstances. "The longstanding majority approach is to analyze Comment k's applicability on a case-by-case basis."[16]

Because there is insufficient evidence of a clear and manifest preemptive purpose, Section 22(b)(1) cannot be interpreted as preempting design defect claims on a categorical basis. Properly construed, Section 22(b)(1) does not preempt all design defect claims against vaccine manufacturers on a categorical basis, but rather provides that such a manufacturer cannot be held liable for defective design only if it is determined, on a case-by-case

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[16] Nitin Shah, Note, 96 VA. L. REV. at 235; *see also* Joanne Rhoton Galbreath, Annotation, Products Liability: What is an "Unavoidably Unsafe" Product, 70 A.L.R. 4th 16, 41–47 (1989); Am. L. Prods. Liab. 3d § 17:47 (1987) ("Most courts have stated that there is no justification for giving all prescription drug manufacturers blanket immunity from strict liability under Comment k, and that whether a particular drug is unavoidably unsafe should be determined on a case-by-case basis.").

basis, that the particular vaccine was unavoidably unsafe.

CONCLUSION

The judgment below should be reserved.

Respectfully submitted,

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