No. 09-152 FEB 12 2010

In the Supreme Court of the United States

RUSSELL BRUESEWITZ, ROBALEE BRUESEWITZ, PARENTS AND NATURAL GUARDIANS OF HANNAH BRUESEWITZ, A MINOR CHILD AND IN THEIR OWN RIGHT,
Petitioners,

v.

WYETH, INC. F/K/A WYETH LABORATORIES, WYETH-AYERST LABORATORIES, WYETH LEDERLE, WYETH LEDERLE VACCINES AND LEDERLE LABORATORIES,
Respondents.

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

PETITIONERS' SUPPLEMENTAL BRIEF ADDRESSED TO THE BRIEF FOR THE UNITED STATES AS *AMICUS CURIAE* FILED IN *AMERICAN HOME PRODS CORP., D/B/A WYETH, ET AL., V. FERRARI, ET AL.* (08-1120)

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QUESTION PRESENTED

Section 22(b)(1) of the National Childhood Vaccine Injury Act of 1986 ["Vaccine Act" or "the Act"] expressly preempts certain design defect claims against vaccine manufacturers but only "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); A-104.

The Question Presented is

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

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INTRODUCTION

Responding to this Court's request, the Solicitor General has filed a brief on behalf of the United States in *American Home Prods Corp., d/b/a Wyeth, et al., v. Ferrari, et al.*, No. 08-1120. In it, the government agrees with all parties here and petitioners in *Ferrari* that the question of the proper interpretation of Section 22(b)(1) of the Vaccine Act, central to both cases, is of paramount national importance and arises from a direct, mature, and irreconcilable conflict between the decisions of the Georgia Supreme Court and Third Circuit in this case.

Although the Solicitor General's brief was filed in *Ferrari*, the government correctly concludes that ***this*** case provides the better vehicle for resolving the conflict and urges this Court to grant *certiorari* here. Petitioners respectfully ask this Court to take this part of the Solicitor General's advice and grant *certiorari* in this case.

While the government correctly identifies the ***issue*** in dispute, it does not present this Court with a question that will fully resolve it. Instead, it asks the Court to decide only whether Section 22(b)(1) preempts ***some*** design defect claims. This Court need not do so since all parties agree that the provision expressly preempts some design defect claims.

The critical question here, however, is the ***scope*** of the Vaccine Act's displacement of state law: whether, contrary to the Act's plain text, well-established rules of statutory construction, and the decisions of this Court, Section 22(b)(1) broadly preempt ***all*** vaccine

design defect claims, whether a vaccine's side effects were unavoidable or not? Petitioners' question presented properly focuses on Section 22(b)(1)'s preemptive scope, a question that remains of great national import.

Because the government inappropriately conflates the question of whether Section 22(b)(1) expressly preempts some design defect claims and the scope of that preemption, it avoids applying to their resolution the constitutional and statutory construction principles this Court reaffirmed in *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), and *Altria Group, Inc. v. Good*, 129 S. Ct. 538 (2008). Instead, the government construes Section 22(b)(1) without mentioning the presumption against preemption or its mandate that only "clear and manifest" expressions of Congressional intent can overcome it, or the principles that Congressional silence is evidence of intent ***not*** to preempt, and that express preemption clauses should ordinarily be construed narrowly, in a manner that ***disfavors*** preemption.

The Solicitor General's interpretation of Section 22(b)(1) is, therefore, fundamentally at odds with this Court's approach to resolving preemption questions and casts doubt on principles this Court reaffirmed just a year ago. Unless this Court grants *certiorari* here, those doubts will remain. The Solicitor General's brief therefore provides this Court with a cautionary tale and an additional reason to grant *certiorari*: to resolve the conflict over Section 22(b)(1)'s preemptive scope in a manner that preserves this Court's rulings in *Levine* and *Altria* and the essential guidance they provide to lower courts.

STATEMENT OF THE CASE

Petitioners agree with the Solicitor General that this Court should grant *certiorari* but disagree with the government's proposed resolution of the question presented, in part, because it is grounded in incomplete or incorrect factual information.

For example, the Solicitor General describes a unrealistically streamlined procedure in which injured children who received vaccines listed on the Vaccine Injury Table are freed from ordinary evidentiary burdens and "ensur[ed] that compensation is potentially available whenever tort remedies are preempted." Brief of the United States as *Amicus Curiae* ["U.S. Brief"] at 13. That is not the case for children, like Hannah Bruesewitz, whose injuries are ***not*** listed on the Table.[1] Instead, Hannah's family had to prove that her injuries were "caused in fact" by the vaccine she received, a standard far ***higher*** than they would have faced in state court.[2]

The Solicitor General also makes the startling and unsupported assertion that "most vaccines work by introducing ***a harmless substance*** (such as a partial or inactivated ***virus or toxin***) . . ." U.S. Brief at 19 (emphasis supplied). While many vaccines are safe for many people who receive them, no one can responsibly

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[1]In one confusing footnote, the Solicitor General implies that, if an injury is not listed on the Vaccine Injury Table, it is not preempted. *See* U.S. Brief at n.4. Would that that were true.

[2]*See, e.g., Andreu v. Sec'y of HHS,* 569 F.3d 1367, 1382 (Fed. Cir. 2009) ("causation in fact" established for whole-cell DTP vaccine and Hannah's type of injury).

or accurately claim that vaccine antigens, which include viruses and other ***toxins,*** are harmless.[3] Were that the case, Wyeth's whole-cell DTP vaccine would still be on the market, the Vaccine Act would be unnecessary, and Hannah Bruesewitz would be preparing for her prom instead of a lifetime of painful and terrifying seizures.

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[3] *See, e.g., Graham v. Wyeth Labs.*, 906 F.2d 1399, 1403 (10th Cir.), *cert. denied*, 498 U.S. 981 (1990) ("because the whole cell vaccine ***retains its poisonous qualities***, it is neurotoxic and can cause adverse reactions which may be mild or severe") (emphasis supplied).

REASONS FOR GRANTING THE PETITION

I. The Solicitor General and All Parties Agree That a Direct, Mature, and Irreconcilable Conflict Exists Over the Meaning of Section 22(b)(1), a Recurring Question of National Importance, and That This Case Is the Proper Vehicle to Resolve It.

All parties and the Solicitor General agree that *certiorari* is warranted here. In particular, the Solicitor General rightly concludes that "the Georgia court's decision [in *Ferrari*] squarely conflicts with" the Third Circuit's decision here. The government likewise finds the question presented "pressing," posing public health risks and creating unacceptable uncertainty, and that further percolation of the issue in the lower courts will not assist this Court. *See* U.S. Brief at 7, 17. The government therefore concludes that "the issue warrants this Court's review." *Id.* Because of mootness concerns in *Ferrari*, however, the Solicitor General urges this Court to grant the petition in ***this*** case, which presents the same question. *Id.*

While Petitioners do not agree with all of the reasons the Solicitor General advances, Petitioners join the government in asking this Court to grant their petition for writ of *certiorari*.

II. Petitioners Correctly State the Question Presented. The Solicitor General Does Not.

The Solicitor General asks this Court to decide whether Section 22(b)(1) "preempts state law claims against manufacturers based on alleged defects in the design of a vaccine subject to the Act." U.S. Brief at (1). All parties agree, however, that Section 22(b)(1) expressly preempts ***some*** design defect claims but only when it is found that "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." A-104.

In *Altria*, this Court explained that, simply because "a federal law contains an express pre-emption clause, it does not immediately end the inquiry because ***the question of the substance and scope of Congress' displacement of state law still remains*** . . ." 129 S. Ct. at 543 (emphasis supplied). Thus, the question presented here is the ***scope*** of Section 22(b)(1)'s displacement of state law and whether it preempts ***all*** vaccine design defect claims, even when the vaccine's side effects could have been avoided by using a safer alternative vaccine.[4] To answer that question, this Court must use the analytical framework it reaffirmed in *Altria*.

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[4]In fact, the Solicitor General later admits that "the task therefore is to 'identify the domain expressly preempted by'" Section 22(b)(1). U.S. Brief at 8 (quoting *Medtronic v. Lohr*, 518 U.S. 470, 484 (1996)).

> Our inquiry into the scope of a statute's pre-emptive effect is guided by the rule that '[t]he purpose of Congress is the ultimate touchstone' in every pre-emption case' . . . 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.'***[5]

By asking only whether Congress intended any preemption at all, the Solicitor General sidesteps this inquiry. For that reason, the precision of the question presented is critical in this case.

All parties and the government agree that the principal issue here is the scope of Section 22(b)(1)'s preemption of state law; therefore, the question presented should focus on language that delimits its preemptive scope. Because Petitioners' question presented is more precise, clear, and focused than the one offered by the Solicitor General, it merits this Court's review and resolution.

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[5] 129 S. Ct. at 543 (citations omitted) (emphasis supplied); *see Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005).

III. Although Incorrect, the Solicitor General's Proposed Resolution of the Question Presented Highlights Important Additional Reasons Why This Court Should Grant *Certiorari*.

By not mentioning or applying the presumption against preemption, *Levine*'s "clear and manifest" standard for overcoming it, its holding that Congressional silence evinces intent ***not*** to preempt, or *Bates'* rule for narrowly construing express preemption clauses, all of which are applicable here, the Solicitor General interprets Section 22(b)(1) in a manner that is inconsistent with this Court's approach to resolving preemption questions and at odds with each of these principles.[6] Thus, the Solicitor General's interpretation itself provides additional reasons why this Court should grant *certiorari* here: to resolve the conflict here in a manner that reaffirms these principles and preserves this Court's rulings in *Levine* and *Altria*.

For example, the Solicitor General rejects the *Ferrari* court's narrower interpretation of Section 22(b)(1) and its assumption that "if Congress had intended to bar all design defect liability, it could have said so more clearly." U.S. Brief at 9. In interpreting Section 22(b)(1), however, the *Ferrari* court relied squarely upon the presumption against preemption

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[6]By bypassing this Court's recent preemption jurisprudence, the Solicitor General casts doubt upon the administration's ***own*** preemption policy. *See* Memorandum to Heads of Executive Departments and Agencies from Barack Obama, President, May 20, 2009, *available at* http:// www.whitehouse.gov/the_press_office/Presidential-Memorandum-Regarding-Preemption/.

and this Court's recent preemption jurisprudence. *See American Home Prods Corp., d/b/a Wyeth, et al., v. Ferrari, et al.*, 668 S.E.2d 236, 242 (Ga. 2008) (citing *Bates,* 544 U.S. at 449). To hold as the Solicitor General recommends, this Court would have to ignore that presumption too. Moreover, this Court would also have to ignore *Bates*' and *Altria*'s instruction that, under that presumption, where, as here, there are two plausible interpretations of an express preemption clause, the Court must adopt the one that disfavors preemption.[7] Although the government posits "what the best reading of the actual language is," U.S. Brief at 9, it does so without acknowledging or adhering to these bedrock principles for interpreting preemption provisions.

Because the government does not mention the presumption against preemption, the Solicitor General also does not address the "clear and manifest" expression of intent necessary to overcome it. The inconclusive Congressional statements the government supplies, however, do not rise to the level of the "clear and manifest" showing this Court required in *Levine.*

The Solicitor General's reference to Congress' reliance on comment k similarly fails to provide the necessary showing of "clear and manifest" Congressional intent to preempt all vaccine design

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[7] *Altria*, 129 S. Ct. at 543; *Bates,* 544 U.S. at 449. The Solicitor General's attempt to interpret Section 22(b)(1)'s conditional language to apply only to manufacturing defects and labeling, U.S. Brief at 9, would abrogate this rule and is belied by the plain wording of Section 22(b)(1) itself, comment k's own language, and substantial contrary jurisprudence governing comment k. *See, e.g., Amore*, 748 F. Supp. at 854.

defect claims. In fact, it shows the opposite. For example, the Solicitor General relies heavily on the fact that, under RESTATEMENT (SECOND) OF TORTS § 402A, comment k (1965), a source for Section 22(b)(1), the manufacturer of a drug found "unavoidably unsafe" is freed from certain liability for design defects. Petitioners agree. The majority of states, however, embrace the same case-by-case approach for determining when that drug will be considered "unavoidably unsafe" under comment k that the Solicitor General rejects here.[8] In those states, drug manufacturers, including respondents here, routinely bear the burden to prove that their drugs are unavoidably unsafe, that is, that there are no safer alternatives, to demonstrate that their products fall under comment k's protection. *See, e.g., Patten v. Lederle Labs.*, 676 F. Supp. 233, 237 (D. Utah 1987).

The Solicitor General also implies that comment k provides blanket immunity for all prescription drugs. It does not.[9] To the contrary, a blanket exception to strict liability for all prescription drugs was proposed at the American Law Institute meeting where section

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[8] *See, e.g., Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 836 (Neb. 2000) ("the majority of jurisdictions that have adopted comment *k.* apply it on a case-by-case basis, believing that societal interests in ensuring the marketing and development of prescription drugs will be adequately served without the need to resort to a rule of blanket immunity").

[9] *See, e.g., Patten,* 676 F. Supp. at 236; *Toner v. Lederle Labs.*, 732 P.2d 297, 308 (Idaho 1987), *cert. denied,* 485 U.S. 942 (1988).

402A and comment k were adopted, ***but the proposal was rejected.***[10]

This Court cannot rely upon ambiguous legislative statements or incomplete descriptions of source law to find preemption under the "clear and manifest" standard it reaffirmed a year ago.

The Solicitor General's efforts to disregard salient legislative history are also in tension with this Court's other recent jurisprudence. To disregard a 1987 committee report's clear statements of Congress' intent ***not*** to define "unavoidability" as a matter of law,[11] this Court must assume, as the Solicitor General does, that the Act was fully enacted in 1986. It was not.

Even the Third Circuit found that "the compensation program ***and accompanying tort reforms*** [were] ***contingent upon the enactment of***

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[10]38 ALI Proc. 19, 90-98 (1961), *cited in Amore v. G.D. Searle & Co.*, 748 F. Supp. 845, 853-54 (S.D. Fla. 1990).

[11]The report states:

> [T]he codification of Comment (k) of the Restatement (Second) of Torts was not intended to decide as a matter of law the circumstances in which a vaccine should be deemed unavoidably unsafe. The Committee stresses that there should be no misunderstanding that the Act undertook to decide as a matter of law whether vaccines were unavoidably unsafe or not. This question is left to the courts to determine in accordance with applicable law.

H.R. REP. 100-391(I), at 691 (1987), *reprinted in* U.S.C.C.A.N. 2313-1, 2313-365; A-36.

a tax to provide funding for the compensation." A-36 (emphasis supplied). In fact, another court refused to consider passage of the liability limits even as evidence of Congress' intent until the tax was enacted. It explained, "this Act shall only take effect on the effective date of a tax enacted to provide funds for compensation paid under the Act." *Wack v. Lederle Labs.*, 666 F. Supp. 123, 127, n.1 (N.D. Ohio 1987). Without the ***1987*** Congressional vote then, the liability limits respondents seek to invoke here ***would never have gone into effect.***

District of Columbia v. Heller, 128 S. Ct. 2783, 2805 (2008), makes clear that the 1987 Committee Report cannot be discarded in this Court's analysis. Because Congress' 1987 vote to create an excise tax specifically to fund the vaccine program ***and*** to give life to the Act's preemption provisions was contingent upon express assurances that unavoidability under Section 22(b)(1) would be determined on a case-by-case basis, the 1987 legislative history cannot be considered "subsequent" and rejected as such.

Whether this Court gives the 1987 Committee Report full effect or not, however, its existence surely precludes a finding of Congress' "clear and manifest" intent to preempt all vaccine design defect claims.

CONCLUSION

For the reasons stated, this Court should grant the petition for writ of *certiorari*.

Respectfully submitted,

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