No. 08-1120

IN THE
Supreme Court of the United States

AMERICAN HOME PRODUCTS CORP. D/B/A WYETH, ET AL.,
Petitioners,

v.

MARCELO A. FERRARI AND CAROLYN H. FERRARI, INDIVIDUALLY AND AS PARENTS AND NEXT FRIEND OF STEFAN R. FERRARI,
Respondents.

On Petition for a Writ of Certiorari to the Supreme Court of Georgia

BRIEF IN OPPOSITION FOR RESPONDENTS

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QUESTION PRESENTED

Whether the Georgia Supreme Court correctly held that § 22 of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-22, does not preempt all design defect claims against vaccine manufacturers.

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INTRODUCTION

In 1986, Congress enacted the National Childhood Vaccine Injury Act ("NCVIA" or "Act") to compensate children who were the victims of tragic vaccine-related injuries through a no-fault administrative compensation system that provides expeditious recovery to injured children and their families. Congress never intended, however, for the administrative compensation scheme to be an exclusive remedy. Instead, the Act explicitly preserves victims' right to bring a civil lawsuit if they are dissatisfied with the administrative compensation route.

Rather than broadly preempt state tort remedies, Congress carved out a narrow limitation on vaccine manufacturers' civil tort liability under state law in § 22 of the Act. Specifically, § 22(b)(1) provides that "[n]o vaccine manufacturer shall be liable in a civil action 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." 42 U.S.C. § 300aa-22(b)(1) (emphasis added).

After a careful review of the language of § 22, as well as the legislative history, structure, and purposes of the Act, the Georgia Supreme Court correctly held that § 22 precludes state tort liability for a design defect only if the defendant shows that a particular vaccine's side effects are "not avoidable" "by a feasible design alternative" – *i.e.*, "unavoidable." Pet. App. 11. Indeed, Petitioners' contrary view – that § 22 categorically exempts vaccine manufacturers from design defect claims – not only is inconsistent with the plain language of § 22, which covers only vaccines whose side effects are "unavoidable,"

but also would create an enormous loophole by insulating vaccine manufacturers from liability even where the injurious side effects could have been avoided by better product design. The court below therefore ruled that it was premature to conclude that Respondents' design defect claim – which relates to injuries caused by vaccines containing the mercury-based preservative thimerosal – was preempted by the Act. It reversed the trial court's grant of summary judgment to Petitioners and remanded for further proceedings.

This Court should deny certiorari for four reasons. First, this Court lacks jurisdiction over the Georgia Supreme Court's interlocutory order. Despite Petitioners' contention, jurisdiction is not proper under this Court's fourth exception in *Cox Broadcasting Corp. v. Cohn*, 420 U.S. 469 (1975), because two of its three prongs are not met. Specifically, reversal by this Court would not necessarily preclude Respondents' design defect claim, and review by this Court at this juncture is not necessary to vindicate federal policies under the NCVIA.

Second, there is no clear split of authority on the scope of preemption under § 22 of the Act. Only one other decision by a United States court of appeals or the highest court of a state has considered the question. That decision – the Third Circuit's recent decision in *Bruesewitz v. Wyeth Inc.*, 561 F.3d 233 (3d Cir. 2009), *petition for reh'g denied*, No. 07-3794 (May 6, 2009) – disagreed with certain aspects of the analysis of the Georgia Supreme Court below and stated in *dicta* that all design defect claims, even those based on side effects that could have been avoided through feasible design alternatives, are preempted by § 22. However, the *Bruesewitz* court

acknowledged significant doubts about its own conclusion, because of ambiguities in the text and legislative history of the Act that it could not fully resolve. Ultimately, the court's holding rested on a much narrower ground – namely, that the particular vaccine at issue in that case (diphtheria-pertussis-tetanus, or DPT) had already been singled out by Congress in 1986 as falling within the class of vaccines whose side effects were "unavoidable." That narrow holding is consistent with the decision below, which held that preemption should be assessed on a product-specific rather than an industry-wide basis.

Moreover, the interlocutory posture of this case further weakens the claimed split and the need for this Court's intervention at this juncture. All the Georgia Supreme Court ruled, in reversing the trial court's grant of summary judgment, is that it is premature to find that a design defect claim is preempted by the NCVIA because there has been no showing that the vaccine is, in fact, *unavoidably* unsafe. Petitioners, on remand, will still have the right to defend the case on numerous grounds, including that the side effects of vaccines containing thimerosal were, in fact, unavoidable. Moreover, if Respondents were to prevail, and obtain a final judgment, Petitioners would have the ability to seek this Court's review of the preemption issue then. At that point, this Court would have the benefit of not only further percolation in the lower courts but also a fully developed factual record that will aid the Court's decision.

Third, given the lack of a well-developed split, and the paucity of authority on the issue, certiorari is inappropriate, and further percolation is warranted. Despite Petitioners' assertions about the supposed parade of horribles that will follow if certiorari is

denied, there is no credible evidence to suggest that the lone decision of the Georgia Supreme Court portends a public health crisis and much evidence to suggest the contrary.

Finally, certiorari is unwarranted because the Georgia Supreme Court correctly interpreted the Act. The preemption clause applies to a narrow subset of cases. Not only did the responsible Congressional committee unequivocally state that the Act does not bar *all* design defect claims, but it rejected an amendment that would have created precisely that categorical exemption. Moreover, Congress explicitly borrowed the concept of "unavoidable" side effects from comment k to § 402A of the Restatement (Second) of Torts (1965), which courts had long construed to require a product-specific analysis of whether a particular product is actually *incapable* of being any safer. The court below thus correctly held that Respondents' design defect claims were not preempted absent such a showing, which has not been made in this case.

STATEMENT OF THE CASE

The National Childhood Vaccine Injury Act

In the 1980s, Congress became concerned about the unpredictability of compensation for children who have been injured by vaccines, from the perspective of both the children as well as the vaccine manufacturers. After significant debate, Congress enacted the NCVIA, in an effort to foster a comprehensive approach to securing the vaccine supply, promoting future development, and adequately compensating innocent victims.

Among Congress's principal concerns in passing the NCVIA was the need to compensate children who had experienced debilitating vaccine-related injuries.

The Report of the House Committee on Energy and Commerce ("Energy and Commerce Committee"), which had primary responsibility for the bill, expressly noted the problem that too few injured children could receive adequate compensation under the traditional tort system.

> [T]he opportunities for redress and restitution are limited, time-consuming, expensive, and often unanswered. Currently, vaccine-injured persons can seek recovery for their damages only through the civil tort system or through a settlement arrangement with the vaccine manufacturer. Over time, neither approach has proven satisfactory. Lawsuits and settlement negotiations can take months and even years to complete. Transaction costs – including attorneys' fees and court payments – are high. And in the end, no recovery may be available. Yet futures have been destroyed and mounting expenses must be met.

H.R. Rep. No. 99-908, at 6 (1986) ("1986 Report"), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6347.

In addition to compensating victims, Congress also sought to alleviate the uncertainty that vaccine manufacturers had been experiencing in the tort system. To address these twin concerns, Congress created a new, no-fault administrative regime for addressing injuries caused by vaccines.

Under this regime, an injured child and his family must bring a claim, in the first instance, to the so-called Vaccine Court, a division of the Court of Federal Claims. *See* 42 U.S.C. § 300aa-12. The Act requires that a special master of the Court of Federal Claims (i.e., the Vaccine Court) consider the petition in an administrative (rather than an adversarial) setting, make findings of fact and conclusions of

law, and issue a decision within 240 days. *See id.* § 300aa-12(d). If the injury is included on the statute's Vaccine Injury Table, then the burden of proof shifts – the manufacturer must demonstrate, through a preponderance of evidence, that the injury is "unrelated to the administration of the vaccine." *Id.* § 300aa-13(a)(1)(B). After a decision by the special master issues, either party may seek review before the Court of Federal Claims. *See id.* § 300aa-12(e). Thereafter, either party may appeal the decision of the Court of Federal Claims to the Federal Circuit. *See id.* § 300aa-12(f).

Congress made clear its aspiration that the new system would incentivize victims to seek relief in the Vaccine Court, rather than state court, thereby promoting more expeditious compensation for victims and enhancing predictability for manufacturers.

> [T]he speed of the compensation program, the low transaction costs of the system, the no-fault nature of the required findings, and the relative certainty and generosity of the system's awards will divert a significant number of potential plaintiffs from litigation.

1986 Report at 13, *reprinted in* 1986 U.S.C.C.A.N. 6354.

As Congress made clear, however, the new compensation system was conceived as a carrot rather than a stick. The new compensation scheme was not the exclusive remedy available to victims in the Act. Although claimants must *begin* with a petition to the Vaccine Court, § 21 permits victims to take advantage of traditional state tort remedies if either of two conditions is satisfied. First, if a claimant is dissatisfied with the special master's decision – because the special master awarded either no compensation or too

little compensation – he or she may elect to decline the award and file a civil action. *See* 42 U.S.C. § 300aa-21(a). Second, if the special master has failed to render a decision within 240 days, the victim may withdraw his or her petition and proceed to the civil courts. *See id.* § 300aa-21(b)(1), (c). The administrative system created by the NCVIA was designed to be an attractive alternative to, but not a substitute for, the traditional tort system. *See Schafer v. American Cyanamid Co.*, 20 F.3d 1, 3 (1st Cir. 1994) (Breyer, C.J.).

If an injured child and his family do seek resort to traditional state tort remedies, the Act provides for a very limited immunity from liability. The relevant preemption provision in § 22 concerns damages actions for injuries that were "unavoidable." That section 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.

42 U.S.C. § 300aa-22(b)(1).

Apart from the limited immunity created by § 22, the Act makes clear that "State law shall apply to a civil action brought for damages for a vaccine-related injury or death." *Id.* § 300aa-22(a). The Act also prevents states from enacting or enforcing laws that prohibit traditional damages actions against vaccine manufacturers, except when the Act expressly preempts such causes of action. *See id.* § 300aa-22(e).

Although the NCVIA was passed in 1986, Congress understood at that time that one of the Act's core provisions – the no-fault compensation scheme for injured children – would not become effective until subsequent legislation was enacted to create a compensation fund. "The Act as passed did not include a source of payment for such compensation and made the compensation program and accompanying tort reforms contingent on the enactment of a tax to provide funding for the compensation." H.R. Rep. No. 100-391(I), at 690 (1987) ("1987 Budget Report"), *reprinted in* 1987 U.S.C.C.A.N. 2313-1, 2313-364. The following year, Congress enacted amendments to the NCVIA that also provided the funding necessary to make § 22 of the Act effective. *See id.* As with the 1986 bill, the House Energy and Commerce Committee had primary responsibility for the NCVIA amendments. *See id.*

Proceedings Below

In 1998, Respondents' son, Stefan Ferrari, received several vaccines, including the Hepatitis B, Hib, and DTaP vaccines, which Petitioners had designed and manufactured. Those vaccines contained the preservative thimerosal, the primary component of which is a derivative of the toxic metal, mercury. *See* Compl. ¶ 9. In June 1999, the Food and Drug Administration confirmed that "infants who receive Thimerosal-containing vaccines at several visits may be exposed to more mercury than recommended by Federal safety guidelines for total adult mercury exposure." *Id.* ¶ 11. The heart of the Ferraris' claim before the Vaccine Court and, later, in the state courts in Georgia is that the thimerosal-laden vaccines caused severe neurological injuries to Stefan.

In accordance with the Act's requirements, Respondents first submitted a petition to the Vaccine Court. Despite the Act's requirement that the special master render a decision within 240 days, *see* 42 U.S.C. § 300aa-12(d)(3)(A)(ii), the special master did not do so. Consequently, Respondents withdrew their petition pursuant to § 21 of the Act and proceeded to state court in Georgia on behalf of their minor son. They brought several claims against Petitioners, including design defect, fraud and deceit, negligent misrepresentation, and breach of warranty.

On July 5, 2005, the trial court heard oral argument and, in a memorandum dated November 30, 2005, granted Petitioners' motion for summary judgment in part, on the ground that § 22 of the Act preempted Respondents' design defect claim. *See* Pet. App. 40-49. The court also permitted Respondents to amend their complaint on certain other claims, and it allowed discovery to proceed on their manufacturing defect claim. *See id.* at 49-53.

Respondents appealed the trial court's preemption decision to the Georgia Court of Appeals, which reversed on July 5, 2007. *See id.* at 25-31. Relying primarily on the presumption against preemption, a unanimous panel of that court determined that § 22 does not preempt the state-law design defect claim.

In a unanimous decision dated October 6, 2008, the Georgia Supreme Court affirmed the court of appeals' judgment. The court conducted a careful analysis of the text, history, structure, and purposes of the Act and concluded that § 22 does not preempt the state-law design defect claim. *See id.* at 4-18.

First, the court focused on the language of § 22, which immunizes manufacturers from liability only "'if the [vaccine-related] injury or death resulted

from side effects that were unavoidable.'" *Id.* at 10 (quoting 42 U.S.C. § 300aa-22(b)(1)) (alteration in original). The court noted that the language is conditional, making clear that manufacturers are exempt only if the vaccine is "unavoidabl[y]" unsafe. *Id.* at 10-11. The court also noted that Congress explicitly borrowed the "unavoidable" formulation from comment k to § 402A of the Restatement (Second) of Torts, which applies only to "products which, in the present state of human knowledge, are quite incapable of being made safe." Restatement (Second) of Torts § 402A cmt. k. The court observed that a broad reading of the preemption clause – namely, that *all* design defect claims are preempted – would effectively read the word "unavoidable" out of the statute. Pet. App. 11. Accordingly, the court held that § 22 preempts only a narrow subset of design defect claims – i.e., claims for injuries from side effects that are unavoidable in that they could not have been eliminated through better design. *See infra* pp. 28-31.

In addition to the plain language of the statute, the Georgia Supreme Court also looked to the legislative history of the NCVIA. The court noted that in 1987, in considering the amendments that were necessary to make § 22 effective, the Energy and Commerce Committee stated that it was not prejudging whether (or which) vaccines were unavoidably unsafe in adopting the language of comment k. Specifically, the court pointed to language in the 1987 Budget Report in which the Energy and Commerce Committee "stresse[d] 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." 1987 Budget Report at 691 (emphasis added), *reprinted in* 1987 U.S.C.C.A.N. 2313-365. Moreover, the court also noted that "an amendment to the Vaccine Act which would have established 'that a manufacturer's failure to develop [a] safer vaccine was not grounds for liability was rejected by the Committee during its original consideration of the Act.'" Pet. App. 14 (quoting 1987 Budget Report at 691, *reprinted in* 1987 U.S.C.C.A.N. 2313-365) (alteration in original).

Finally, the Georgia Supreme Court found that its analysis of the text and legislative history was "consistent with the structure and purpose of the Vaccine Act as a whole." *Id.* at 15. Because the Act does not make the administrative compensation system an exclusive remedy, the court found that it was important not to "'overstate the degree of uniformity'" intended by Congress. *Id.* (quoting *Bates v. Dow AgroSciences LLC*, 544 U.S. 431, 450 (2005)). The Georgia Supreme Court thus held, based on the text, history, structure, and purposes of the Act, that § 22 does not preempt the Ferraris' state-law design defect claim, absent a showing that the side effects of the vaccines at issue were, in fact, unavoidable.

REASONS FOR DENYING THE PETITION

This Court should deny certiorari for four reasons. First, this Court lacks jurisdiction to review the interlocutory order of the Georgia Supreme Court under the fourth *Cox* exception. Second, no mature split of authority exists on the question presented because the Third Circuit panel's decision in *Bruesewitz v. Wyeth Inc.*, 561 F.3d 233 (3d Cir. 2009), *petition for reh'g denied*, No. 07-3794 (May 6, 2009), is not in square conflict with the decision below. Moreover, the interlocutory posture of this case further weakens any potential split and militates against this Court's intervention at this juncture. Third, Petitioners' claims of vaccine shortages and a health-care crisis are overblown and fail to justify this Court's intervention in the absence of a mature split. Finally, certiorari is unwarranted because the Georgia Supreme Court correctly interpreted the Act.

I. THIS COURT LACKS JURISDICTION TO REVIEW THE DECISION BELOW

Congress's statutory grant of jurisdiction to review the decisions of state courts extends only to "[f]inal judgments or decrees." 28 U.S.C. § 1257(a). This Court has held that it may review a non-final judgment of a state court only in "exceptional situations." *Nike, Inc. v. Kasky*, 539 U.S. 654, 658 (2003) (Stevens, J., concurring) (internal quotation marks omitted). Petitioners claim that this Court has jurisdiction under the fourth exception under *Cox Broadcasting Corp. v. Cohn*, 420 U.S. 469 (1975), which applies where (1) "the federal issue has been finally decided in the state courts with further proceedings pending in which the party seeking review here might prevail on the merits on nonfederal grounds," (2) "reversal of the state court on the federal issue would be preclu-

sive of any further litigation on the relevant cause of action rather than merely controlling the nature and character of, or determining the admissibility of evidence in, the state proceedings still to come," and (3) "refusal immediately to review the state court decision might seriously erode federal policy." *Id.* at 482-83.

Here, however, neither the second nor the third prerequisite under *Cox* is met. First, reversal of the Georgia Supreme Court's decision would not necessarily preclude Respondents' design defect claims altogether. There are at least two ways in which this Court could reverse the decision below. It could decide, as Petitioners urge, that § 22 of the Act preempts *all* design defect claims, whether based on negligence or strict liability. Alternatively, however, it could decide that design defect claims are not preempted to the extent they are predicated on proof of negligence, as opposed to a theory of strict tort liability. *See Bruesewitz*, 561 F.3d at 246-47 (noting ambiguity as to "whether subsection (b) preempts all design defect claims or only strict liability design defect claims"). While a merits opinion adopting the latter approach would reverse the decision below, it would do so without "preclu[ding]" Respondents' design defect claim. *Cox*, 420 U.S. at 482-83.

This Court found that it lacked jurisdiction in an analogous situation in *Nike, Inc. v. Kasky*, *supra*. There, Nike sought review of an interlocutory order of the California Supreme Court refusing to dismiss a false-advertising claim, on the ground that the speech at issue was protected by the First Amendment. This Court dismissed the petition for certiorari as improvidently granted. As Justice Stevens explained in his concurring opinion, the Court lacked

jurisdiction over the case, because, even "if [the Court] were to reverse, [it] might hold that the speech at issue . . . [wa]s subject to suit only if made with actual malice." 539 U.S. at 660 (Stevens, J., concurring). That would not preclude the false-advertising claim altogether, but merely "control[] the nature and character of . . . the state proceedings still to come." *Cox*, 420 U.S. at 482-83. Likewise, here, this Court might hold that injuries caused by defective vaccine design are subject to suit only if the design was negligent, but not based on strict liability. That would not completely preclude Respondents' design defect claim, but merely dictate Respondents' burden of proof. As was the case in *Nike*, because "an opinion on the merits could take any one of a number of different paths," at least one of which would not preclude the underlying cause of action, this Court lacks jurisdiction under the fourth *Cox* exception. 539 U.S. at 656 (Stevens, J., concurring).

The fourth *Cox* exception also does not apply here because "refusal *immediately* to review the state court decision" will not "seriously erode federal policy." *Cox*, 420 U.S. at 483 (emphasis added). This Court created the fourth *Cox* exception to address the limited set of cases where failure to review in a particular case – despite its interlocutory posture – would frustrate this Court's review of an important federal question. *Cf. Nike*, 539 U.S. at 657 (issue was whether First Amendment precluded plaintiffs' particular false-advertising claim). As Petitioners themselves highlight, however, the issue of preemption under § 22 – while not frequently litigated – has been the subject of litigation in a variety of federal courts. *See* Pet. 26-27. This Court is thus likely in a future case to have the ability, if necessary, to review

the question of preemption under § 22 on appeal of a final judgment. Because denial of certiorari in this case will not cause the issue of preemption under § 22 to evade this Court's review, this Court lacks jurisdiction under the fourth *Cox* exception.

II. THERE IS NOT A MATURE DIVISION OF AUTHORITY ON THE QUESTION PRESENTED

A. The Third Circuit's Decision in *Bruesewitz* Does Not Create a Split on the Question Whether § 22 of the Act Preempts All Design Defect Claims Against Vaccine Manufacturers

Besides the Georgia Supreme Court, the only other highest state court or federal circuit court to have addressed the question of preemption under § 22 of the Act is the Third Circuit in *Bruesewitz*.[1] That decision, however, does not create a clear split with the decision below and thus does not warrant this Court's intervention. Although the Third Circuit made statements disagreeing with the decision below and suggesting that design defect claims against *all* vaccine manufacturers were preempted by § 22, the court expressed doubts about its own analysis in that regard. Ultimately, the court's only firm conclusion was that Congress clearly addressed and intended to preempt design defect claims related to the DPT vaccine, on the ground that that vaccine was "un-

[1] Although a handful of other courts have addressed the question whether § 22 of the Act preempts design defect claims, those courts have been federal district courts and state trial or intermediate appellate courts. As Petitioners acknowledge, a purported conflict with non-binding precedents or decisions of lower state courts is not the type of division of authority that this Court traditionally resolves.

avoidably" unsafe. That conclusion has no application to the non-pertussis vaccines involved in this case, which Congress did not specifically address.

Bruesewitz is a highly unusual opinion. The court grappled with whether § 22 preempts design defect claims as to all vaccines, as opposed to those vaccines that are determined by a state court to be unavoidably unsafe, and it stated that the evidence before it suggested that it did. But it admitted that it lacked critical information necessary for its statutory analysis and therefore expressed significant doubts about its analysis at every step.

First, the Third Circuit analyzed the text of § 22, in an effort to "'identify the domain expressly preempted'" by the NCVIA. 561 F.3d at 243 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 484 (1996)). The court found that it was unable to "resolve from statutory text alone the scope of the express preemption provision" of § 22. *Id.* at 245. It concluded that neither the term "unavoidable" nor the "surrounding language" conclusively answers "whether all design defect claims are preempted or whether state courts may determine avoidability on a case-by-case basis." *Id.*

The court then turned to the "legislative history" of the NCVIA in an effort to resolve the perceived ambiguity. *Id.* Here, the court's uncertainty grew deeper. On the one hand, the court noted that the 1986 Report from the Energy and Commerce Committee contained some language that could be read to express an intent to preempt all design defect claims. *Id.* at 247-49.[2] It also acknowledged, on the

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[2] The 1986 Report states: "Vaccine-injured persons will now have an appealing alternative to the tort system. Accordingly,

other hand, that the 1987 Budget Report relied on by the Georgia Supreme Court squarely addressed the issue: "'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.'" *Id.* at 249 (quoting 1987 Budget Report at 691, *reprinted in* 1987 U.S.C.C.A.N. 2313-365). That same report also stated that "'[a]n amendment to establish as part of this compensation system that a manufacturer's failure to develop [a] safer vaccine was not grounds for liability was rejected by the Committee during its original consideration of the Act.'" *Id.* (quoting 1987 Budget Report at 691, *reprinted in* 1987 U.S.C.C.A.N. 2313-365).

The 1987 Budget Report unequivocally supports Respondents' position that Congress did not intend to preempt design defect claims as to all vaccines, even those that could have been made safer. Nonetheless, the *Bruesewitz* court declined to give credit to the clear statement in the 1987 report because it said it lacked certain information that was not provided to it in the parties' briefing.

First, the *Bruesewitz* court expressed confusion as to whether the reference to "the Committee" in the

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if they cannot demonstrate under applicable law either that a vaccine 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." 1986 Report at 26, *reprinted in* 1986 U.S.C.C.A.N. 6367. That statement actually does not support Petitioners' preemption argument, but instead refers to the fact that, under state law, most litigants will often be unable to prove a design defect claim and that the federal compensation scheme is the best alternative.

quoted passages of the 1987 Budget Report referred to the Budget Committee or the Energy and Commerce Committee. *See* 561 F.3d at 250 ("it is unclear whether this refers to the Budget Committee or the Energy and Commerce Committee"). A thorough review of the 1987 report demonstrates, however, that, although the Budget Committee compiled and issued the report, the relevant language was written by the Energy and Commerce Committee, which held hearings on both the original legislation in 1986 and the funding amendments in 1987. In fact, the entirety of Title IV to the 1987 Budget Committee Report (pages 377 to 715) is entitled "Committee on Energy and Commerce." A letter from Rep. John Dingell, the Chairman of the Energy and Commerce Committee, to Rep. William Gray III, the Chairman of the Budget Committee, makes clear that the materials included in that section are "two Committee Prints approved by the Committee on Energy and Commerce for inclusion in the forthcoming reconciliation bill." *See* 1987 Budget Report at 380, *reprinted in* 1987 U.S.C.C.A.N. 2313-200. Had this additional information been brought to the attention of the *Bruesewitz* court, it likely would have materially altered the court's analysis.

Second, the Third Circuit appeared to doubt whether the Energy and Commerce Committee had, in fact, considered and rejected an amendment that would have eliminated liability on the grounds of "a manufacturer's failure to develop [a] safer vaccine." 1987 Budget Report at 691, *reprinted in* 1987 U.S.C.C.A.N. 2313-365; *see Bruesewitz*, 561 F.3d at 250 (stating that "no record is available to confirm" that this amendment was in fact rejected). Again, these doubts appear to be based on the court's un-

certainty as to whether the statements in the 1987 Budget Report – which unequivocally state that such an amendment was rejected – were properly attributable to the Energy and Commerce Committee. Had the 1987 report reflected the Budget Committee's description of an Energy and Commerce Committee markup, the Third Circuit's desire for independent confirmation might have been understandable. As described above, however, the description of the committee's rejection of the amendment is clearly attributable to the Energy and Commerce Committee itself, leaving little room for doubt that the amendment had, in fact, been considered and rejected by that committee just a year earlier.

Finally, the Third Circuit expressed skepticism about the reliability of "subsequent" legislative history. 561 F.3d at 250. Based on the same lack of understanding of the references to "the Committee" in the 1987 Budget Report, the Third Circuit failed to appreciate that the 1987 report did not constitute "subsequent" legislative history at all. Rather, as the 1987 report explains, the enactment of the NCVIA was a multi-year process. Although the Act, including the compensation system and § 22, was originally passed in 1986, those provisions did not become effective until 1987, when Congress passed the amendments to the bill and provided for its funding. *See* 1987 Budget Report at 690 (stating that "[t]he Act . . . made the compensation program and accompanying tort reforms contingent on the enactment of a tax to provide funding for the compensation" and explaining that the 1987 amendments provide that funding), *reprinted in* 1987 U.S.C.C.A.N. 2313-364. The Energy and Commerce Committee considered and oversaw both aspects of the legislation. *See id.*

at 690-91, *reprinted in* 1987 U.S.C.C.A.N. 2313-364 to -365. Given that § 22 did not become effective until the 1987 amendments were passed, and the Energy and Commerce Committee oversaw both bills, the views of that committee expressed in the 1987 Budget Report represent the views of the framers of the Act.

Despite the clear language in the 1987 Budget Report supporting Respondents' position, the Third Circuit "refuse[d] to view the relevant legislative history as containing 'dueling' committee reports." 561 F.3d at 250. That refusal did not reflect a firm conclusion but, rather, reflected the fact that the court did not have a complete understanding of the 1987 report and, in particular, lacked information as to which committee was being described in that report. *See id.* ("*[w]ithout more*, we have no basis to conclude that the [1987] Budget Report is an accurate reflection of what transpired before the Energy and Commerce Committee") (emphasis added).

Given its own professed uncertainty, the *Bruesewitz* court articulated a narrow holding. Specifically, the court held that, "*[e]ven if Congress did not intend to prohibit all design defect claims against vaccine manufacturers*, the legislative history indicates that it intended to preempt the specific claim at issue here" – namely, design defect claims against the manufacturers of DPT vaccines in particular. *See id.* (emphasis added). The court grounded that conclusion in legislative history that the Energy and Commerce Committee had specifically addressed the whole-cell pertussis vaccine as an example of a vaccine whose side effects were unavoidable. *See id.* at 250-51. The committee had noted that, although some efforts to create an acellular pertussis vaccine

were in progress, clinical trials to test such a vaccine would pose significant hurdles. *See id.* at 251.[3] Given that legislative history, the Third Circuit concluded that "Congress weighed the various concerns related to the pertussis vaccine and concluded that DPT manufacturers should be shielded from liability for injuries arising from the whole-cell pertussis vaccine." *Id.*

The *Bruesewitz* court's narrow holding is not in conflict with the decision below. In fact, that holding effectively adopts the product-specific analysis that the Georgia Supreme Court interpreted § 22 to require. Whatever Congress's intent was with respect to the whole-cell pertussis component of the DPT vaccine, Congress did not specifically address vaccines containing thimerosal when it passed the Act, and there is thus no basis to conclude that Congress expressly preempted design defect claims against the manufacturers of thimerosal-containing vaccines.

In sum, the Third Circuit's admitted ambivalence about the statutory text and the import of the legislative history suggests that its more sweeping statements about the scope of § 22 are *dicta* and do not create an actual conflict with the decision below. Further percolation is warranted because there is good reason to believe that future courts – including the Third Circuit itself – will rely on the full legislative history that was not before the *Bruesewitz* court and ultimately limit *Bruesewitz* to its narrow DPT-specific holding. At the very least, further percolation will sharpen the arguments for this Court's con-

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[3] Since 1986, vaccine manufacturers, including Petitioners, have successfully developed a safer acellular pertussis vaccine, which is now administered as part of the DTaP vaccine. The DPT vaccine is no longer used in the United States.

sideration by casting additional light on the meaning of § 22.

B. The Interlocutory Posture of This Case Further Weakens Any Conflict

The interlocutory ruling at issue further weakens any conflict. Not only does this Court lack jurisdiction because of the interlocutory posture of this case, *see supra* Part I, but the interlocutory posture also counsels against this Court's intervention at this early juncture.

In reversing the grant of summary judgment to Petitioners, the Georgia Supreme Court merely held that it was premature, in the absence of a showing that the vaccines' side effects are "unavoidable," to hold that § 22 preempts all liability for design defects. The impact of that decision will depend very heavily on what occurs on remand. There, Petitioners will be able to defend the case on numerous grounds that may result in a final judgment in their favor. For example, Petitioners may demonstrate that the side effects of thimerosal-laden vaccines are, in fact, unavoidable or that there is no causal link between thimerosal and neurological damage, either generally or in the Ferraris' specific case. If so, the import of the Georgia Supreme Court's preemption holding will be severely diminished.

If, alternatively, after further proceedings below, Respondents were to prevail, Petitioners would still have an opportunity to seek this Court's review on the preemption question. At that juncture, it is likely that further percolation will have either eliminated any conflict among the lower courts or further developed that conflict. Moreover, if the Court were to grant certiorari at that stage, the Court would have the benefit of a full evidentiary record and

further legal decisions by the courts below on which to base its decision. Finally, if the Court were to grant certiorari on the issue in an intervening case, Petitioners would not be prejudiced because the Court's holding in that case would be fully applicable to these proceedings.

Even when it has jurisdiction, this Court rarely grants certiorari in an interlocutory posture, and it does so only to resolve an important federal question deserving of urgent review. Here, there is no reason to believe that the Georgia Supreme Court's decision in this case represents the final word on the scope of § 22. Not only will the issue likely remain alive during future stages of litigation in this case, but other cases are likely to present the same legal questions. Consequently, prudential considerations militate strongly in favor of allowing further percolation, especially given the absence of a developed split of authority on the issue presented.

III. THERE IS NO PLAUSIBLE NATIONAL VACCINE CRISIS WARRANTING THIS COURT'S PREMATURE INTERVENTION

Despite a great deal of high-pitched rhetoric, Petitioners have not marshaled any credible evidence to suggest either that there has been a rush to the courthouse by vaccine litigants or that the specter of such a rush will cause a national crisis. Petitioners' suggestion that failure to grant certiorari in this case will jeopardize the availability of essential vaccines in the United States is, to say the least, a vast overstatement.

A. Petitioners Exaggerate the Increase in Vaccine-Related Court Cases

Because of the success of the Act in establishing an attractive administrative mechanism for compensa-

tion of vaccine-related injuries, as Petitioners themselves concede, "[n]o case governed by the Vaccine Act against a vaccine manufacturer has proceeded to trial – much less to verdict – in the two decades since the Vaccine Act became effective." Pet. 20-22. Petitioners nonetheless assert that a single decision in Georgia will create "devastating vaccine shortages," Pet. 19, and assert that "[n]ationwide filings are also bound to spike," Pet. 22. None of the evidence cited by Petitioners actually supports the conclusion that there is an impending crisis.

Petitioners rely in large part on a graph from an article by Geoffrey Evans, which purports to demonstrate a more severe spike in lawsuits than the surge that led to the vaccine crisis in the mid-1980s and ultimately Congressional intervention. *See* Geoffrey Evans, *Update on Vaccine Liability in the United States: Presentation at the National Vaccine Program Office Workshop on Strengthening the Supply of Routinely Recommended Vaccines in the United States, 12 February 2002*, 42 Clinical Infectious Diseases S130, S134 (2006). The recent "spike," however, is nothing more than an illusion created by aggregating data from *four* years into a single bar on the graph. On average, then, the years 2001-04 have seen the filing of fewer than 90 lawsuits per year, far below the levels that Congress faced in the mid-1980s.[4]

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[4] Furthermore, the Evans article appears to be comparing apples and oranges. Although the data for 1979 until 2000 measure the number of lawsuits filed against U.S. manufacturers of two different kinds of DPT vaccines (again, not the vaccine at issue here), the data for 2001-04 measure the filing of "lawsuits alleging the development of autism (or other neurodevelopmental disorders) as a result of vaccines." 42 Clinical Infectious Diseases at S134.

Moreover, the fact that there are some civil suits being brought against vaccine manufacturers does not represent a "crisis" from the standpoint of congressional policy. Indeed, Congress expressly *preserved* the ability of injured children to seek relief in state court. Although vaccine manufacturers, such as Petitioners, lobbied Congress to make the Vaccine Court the *exclusive* remedy for injured children and their families, Congress rejected that approach. The ebb and flow of state-court filings cited by Petitioners thus does not represent a "crisis," but rather the natural workings of the regime that Congress created when it enacted the NCVIA.

B. There Is No Evidence of an Imminent Flood of State-Court Lawsuits by Injured Children

At any rate, beyond the supposed uptick in civil filings cited by the Evans article, there is no reason to believe that there will be an unmanageable flood of new vaccine-related litigation in state courts. First, as demonstrated by the statistics published by the National Vaccine Injury Compensation Program, the number of filings in the Vaccine Court in recent years is well within normal parameters:

National Vaccine Injury Compensation Program
Post-1988 Statistics Report
As of May 1, 2009

Fiscal Year	Non-Autism	Autism	Total
FY 1988	24	0	24
FY 1989	148	0	148
FY 1990	1,492	0	1,492
FY 1991	2,718	0	2,718
FY 1992	189	0	189
FY 1993	140	0	140
FY 1994	107	0	107
FY 1995	180	0	180
FY 1996	84	0	84
FY 1997	104	0	104
FY 1998	120	0	120
FY 1999	410	1	411
FY 2000	162	1	163
FY 2001	194	22	216
FY 2002	187	770	957
FY 2003	155	2,437	2,592
FY 2004	127	1,087	1,214
FY 2005	147	588	735
FY 2006	155	170	325
FY 2007	242	168	410
FY 2008	163	253	416
FY 2009	143	88	231
Total	**7,391**	5,585	**12,976**

U.S. Dep't of Health & Human Services, Health Resources & Services Admin., *Statistics Report* (May 1, 2009), *available at* ftp://ftp.hrsa.gov/vaccinecompensation/StatisticsReport.pdf. Those data dem-

onstrate that, while there was an increase in filings in the Vaccine Court, primarily in 2003 and 2004, there have been similar periods of increased filings over the 20-year history of the Vaccine Court (1990-1991). But, notably, the number of new autism-related claims has plummeted since 2003. Moreover, the decisions by the Georgia courts do not appear to have influenced the number of filings in either the Vaccine Court or the civil courts.

The fact that there are now 4,900 vaccine-autism claimants presently in Vaccine Court does not, contrary to Petitioners' contentions (at 22), presage an impending rush to state courts. The Vaccine Court has successfully achieved Congress's goal of streamlining cases and promoting expeditious settlement of claims. Within just a few years of the Vaccine Court's inception, it had largely succeeded in providing quick remedies and sufficient compensation while drastically reducing attorneys' fees and administrative expenses, all without abrogating the traditional tort system. *See* Denis J. Hauptly & Mary Mason, *The National Childhood Vaccine Injury Act*, 37 Fed. B. News & J. 452 (1990). Indeed, the increase in Vaccine Court filings in 1990-1991, *see supra* p. 26, did not lead to a commensurate increase in civil suits in state court, *see* Pet. 21 (showing an average of 15 cases from 1990-1993).

Despite the success of the Act in avoiding the need for state tort suits, Petitioners hypothesize that the Vaccine Court will reject most of the autism-related claims and that there will be a deluge of new lawsuits in the state courts. But this is sheer speculation. There is no basis to prejudge whether the Vaccine Court will find, in test cases that are currently pending before it, that thimerosal-containing vaccines

cause certain neurological disorders, such as autism. If the Vaccine Court finds causation, the odds of a flood of state-court litigation are extremely low. Even if the Vaccine Court finds no causation, it is highly speculative whether parties will then seek to relitigate that issue in state court or, alternatively, conclude that they have had their "day in court." Ultimately, Petitioners offer no concrete evidence for their alarmist claims that a new rash of vaccine-injury claims is bound to inundate the state courts and threaten the vaccine supply of the United States. It is just as likely that the vaccine-autism cases will successfully be handled by the Vaccine Court, consistent with the success of that court over its 20-year history.

Given the absence of any evidence to support their doomsday predictions, Petitioners, in short, have failed to show that this case presents an issue of such extraordinary importance that it should be decided by this Court in an interlocutory posture and in the absence of a mature and well-developed split of authority.

IV. THE GEORGIA SUPREME COURT CORRECTLY INTERPRETED THE PREEMPTION PROVISION OF THE ACT

Contrary to Petitioners' contentions, certiorari is unwarranted because the Supreme Court of Georgia correctly interpreted § 22 of the Act based on a careful analysis of its text, history, structure, and purposes.

As the Georgia Supreme Court recognized, the language of the Act – which precludes liability 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)

– clearly requires a predicate determination that a particular vaccine's side effects are, in fact, "unavoidable." Were there any doubt left by the language of § 22, the legislative history eliminates it. As discussed above, *see supra* pp. 16-17, the committee overseeing the legislation clearly stated that the question whether a particular vaccine's side effects are unavoidable "is left to the courts to determine in accordance with applicable law." 1987 Budget Report at 691, *reprinted in* 1987 U.S.C.C.A.N. 2313-365. Indeed, the committee rejected "[a]n amendment to establish as part of this compensation system that a manufacturer's failure to develop [a] safer vaccine was not grounds for liability." *Id.* Petitioners are simply wrong that Congress "made the blanket determination that childhood vaccines are 'unavoidably unsafe' and should be categorically exempt from liability." Pet. 30.

This conclusion is further bolstered by the provenance of the language of § 22, which is based on comment k to § 402A of the Restatement (Second) of Torts, which sets forth an exception to strict liability. Both comment k itself and cases interpreting it, make clear that whether a vaccine is "unavoidably" unsafe is a determination that must be made on a product-specific basis. Comment k, by its own terms, covers only those rare products "which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use." Restatement (Second) Torts § 402A cmt. k. Such products – the Pasteur rabies vaccine is cited as an example – are not subject to the strict liability standard otherwise provided for by § 402A. Instead, "[s]uch a product, properly prepared, and accompanied by proper directions and warning, is not defec-

tive, nor is it *unreasonably* dangerous." *Id.* To fall within the scope of comment k, however, a defendant must make a predicate showing that the product is, in fact, "incapable of being made safe."[5]

Congress made clear that, in codifying the principle of comment k in the Act, it understood that immunity from liability would apply only *if* the product was "unavoidabl[y]" unsafe:

> [Section 22(b)] sets forth the principle contained in Comment k of Section 402A of the Restatement of Torts (Second) that a vaccine manufacturer should not be liable for injuries or deaths resulting from unavoidable side effects even

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[5] Judicial interpretations of comment k, both before and after the Act was passed in 1986, make clear that determining whether a product is unavoidably unsafe requires an intensely factual, product-specific determination. *See, e.g., Belle Bonfils Mem'l Blood Bank v. Hansen*, 665 P.2d 118, 123 (Colo. 1983) ("[T]he manufacturer must demonstrate that at the time of the preparation or marketing of the product, the state of the art had not progressed to where the risk was no longer unavoidable, and that the product's benefits could not be achieved by a substitute product or in another manner."); *Feldman v. Lederle Labs.*, 479 A.2d 374, 382-83 (N.J. 1984) ("[W]e see no reason to hold as a matter of law and policy that all prescription drugs that are unsafe are unavoidably so. Drugs, like any other products, may contain defects that could have been avoided by better . . . design."); *Kearl v. Lederle Labs.*, 218 Cal. Rptr. 453, 463-64 (Cal. Ct. App. 1985) (requiring a product-specific showing); *Toner v. Lederle Labs.*, 732 P.2d 297, 306 (Idaho 1987) (same); *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 840 (Neb. 2000) (same); *Bryant v. Hoffmann-La Roche, Inc.*, 585 S.E.2d 723, 726 (Ga. Ct. App. 2003) (acknowledging and embracing majority view that comment k requires product-specific analysis); *see also Weiss v. Fujisawa Pharm. Co.*, Civil Action No. 5:05-527-JMH, 2006 WL 3533072, at *2 (E.D. Ky. Dec. 7, 2006) (collecting cases and indicating overwhelming support for a narrow, product-specific approach).

> [though] the vaccine was properly prepared and accompanied by proper directions and warnings.
>
> 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. . . . [E]ven *if* the defendant manufacturer *may have* made as safe a vaccine as anyone reasonably could expect, a court or jury undoubtedly will find it difficult to rule in favor of the "innocent" manufacturer if the equally "innocent" child has to bear the risk of loss with no other possibility of recompense.

1986 Report at 25-26 (emphases added), *reprinted in* 1986 U.S.C.C.A.N. 6366-67.

Congress's clear intent was to exempt manufacturers from liability only upon a predicate showing that, in fact, they had "made as safe a vaccine as anyone reasonably could expect." *Id.* at 26, *reprinted in* 1986 U.S.C.C.A.N. 6367. It did not categorically exempt liability for all vaccine manufacturers, no matter how poorly the vaccine had been designed. Indeed, such a broad exemption is wholly inconsistent with the structure and purposes of the Act to create an attractive alternative to the traditional tort system, while preserving the right of injured children and their families to seek relief, if they choose, through the traditional tort system.

In sum, this Court lacks jurisdiction to review the decision below. Even if it had jurisdiction, certiorari would be unwarranted because there is no clear split between the decision below and the Third Circuit's

decision in *Bruesewitz*, nor any urgent reason for this Court's review in the absence of such a split. Especially given that the Georgia Supreme Court correctly interpreted § 22 of the Act, this Court's review is not warranted.

CONCLUSION

The petition for a writ of certiorari should be denied.

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