No. 09-152

IN THE
Supreme Court of the United States

RUSSELL BRUESEWITZ, *et al.*,

Petitioners,

v.

WYETH, INC., fka WYETH LABORATORIES, *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF OF *AMICI CURIAE* NATIONAL VACCINE INFORMATION CENTER, ITS CO-FOUNDERS AND 24 OTHER ORGANIZATIONS IN SUPPORT OF PETITIONERS

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QUESTION PRESENTED

Section 22(b)(1) of the National Childhood Vaccine Injury Act of 1986 (Act) precludes liability for certain 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: does Section 22(b)(1) preclude all vaccine design-defect claims even if the vaccine's side effects were avoidable?

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STATEMENT OF INTEREST OF *AMICI CURIAE*

Amici are the parent advocates who helped draft the Act, §§ 300aa-1 *et seq*, and twenty five organizations. They respectfully submit this brief in support of Petitioners. It is a matter of national importance that the judiciary interprets and applies the Act as Congress intended.[1] A list of *amici* is available at Exhibit A.

Amicus curiae the National Vaccine Information Center (NVIC), founded in 1982 by parents whose children were injured or died following DPT vaccination, is widely recognized as the oldest, largest and most effective non-profit national organization advocating for the institution of vaccine safety and informed consent protections in U.S. public health programs. NVIC has assisted thousands of individuals who have suffered serious health problems, hospitalizations, injuries and deaths following vaccination. It promotes scientific research to evaluate vaccine safety and defends the ethical principle of informed consent for medical interventions, including vaccination, which carry a risk of injury or death.

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[1] No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than the *amicus curiae*, or its counsel, made a monetary contribution intended to fund its preparation or submission. The parties have consented to the filing of this brief and such consents have been lodged with the Clerk.

Amici curiae Jeffrey Schwartz, Barbara Loe Fisher and Kathi Williams, former members of Dissatisfied Parents Together (DPT) and co-founders of NVIC, were the leading parent advocates in negotiating and drafting the Act. From 1973-79, Mr. Schwartz was Environmental Counsel for the House of Representatives Health and Environment Subcommittee of the Energy and Commerce Committee, the Subcommittee and Committee that drafted the Act. Ms. Fisher is President and Ms. Williams is Vice-President of NVIC.

Amici curiae the International Medical Council on Vaccination, the Center for Personal Rights, the New Jersey Coalition for Vaccination Choice and the New York Alliance for Vaccination Choice advocate for the right to free and informed vaccination choices.

Amicus curiae the National Gulf War Resource Center promotes the health and welfare of U.S. military veterans and their families and focuses on environmental toxins and the safety of vaccines. *Amicus curiae* Veterans for Common Sense advocates for veterans. It focuses on public health and safety for Gulf War veterans, and in particular on vaccine safety.

Amici curiae the Elizabeth Birt Center for Autism Law and Advocacy, Autism One, Generation Rescue, the Autism Trust USA, the *Autism File* magazine, the *Age of Autism* daily web newspaper, the *Schafer Autism Report*, the National Autism

Association (NAA), the Autism Action Network, and Talk About Curing Autism (TACA) are organizations that serve individuals and families affected by autism and other neurological disorders.

Amici curiae The Coalition for Safe Minds (Sensible Action for Ending Mercury-Induced Neurological Disorders), NoMercury, the Coalition for Mercury-Free Drugs and the Alan D. Clark, M.D. Memorial Research Foundation are organizations which investigate and raise awareness about the risks of exposure to mercury from medical products, including mercury in vaccines.

Amicus curiae Truth About Gardasil provides information and assistance to families about the human papillomavirus vaccine. *Amicus curiae* the Pandemic Response Project seeks to reform emergency health laws to allow citizens to make free and informed decisions.

Amicus curiae the National Economic and Social Rights Initiative promotes a human rights vision for the United States that ensures dignity and access to the basic resources needed for human development and civic participation, including healthcare. *Amicus curiae* Citizens for Health advocates citizens' rights to make natural health choices.

SUMMARY OF ARGUMENT

Hannah Bruesewitz was a healthy infant until she received a diphtheria, tetanus and pertussis (DPT) vaccine in 1995. Soon after vaccination, she suffered catastrophic injuries and now endures a lifelong residual seizure disorder. Her condition requires extraordinary care and financial resources. Hannah's family sought compensation under the Act but the compensation program denied her recovery. She then proceeded to trial court to argue that the DPT vaccine she received was defectively designed and that her injuries should have been avoided through use of a known, safer alternative. The court granted summary judgment against her, deciding that Section 22(b)(1) of the Act preempted all vaccine design defect claims. The Third Circuit affirmed the federal district court's decision to grant summary judgment. Fourteen years after Hannah's injury, she has yet to find justice.

The primary purpose of the Act is to compensate children. The Act created a compensation system as an alternative to the tort system, not a substitute.

Parents of vaccine-injured children stood up for their children's rights in drafting the Act and do so now in asking this Court to reverse the Third Circuit's decision to bar all design defect claims from civil court. The Act is a compromise that has created a compensation system and granted some liability protection to vaccine manufacturers. But that liability protection is not blanket immunity. Section

22 of the Act protects vaccine manufacturers from liability in a civil action "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."

The plain meaning and legislative history of the Act do not support preemption of all design defect claims. Indeed the parent *amici* who helped craft the Act would never have agreed to such preemption.

Unfortunately, the compensation program is not working as Congress intended. The program rejects most petitioners, as it did Hannah. Health and Human Services has failed to maintain and update the presumptions for injury that would allow the system to succeed. Given the compensation system's inadequacy, keeping the courthouse doors open, as Congress intended, is more important than ever.

This Court's precedents, the Act's plain meaning and its legislative history support reversal of the Third Circuit's decision below.

ARGUMENT

I. THE PURPOSE OF THE ACT IS TO COMPENSATE VACCINE-INJURED CHILDREN, NOT TO IMMUNIZE MANUFACTURERS FROM LIABILITY FOR ALL DESIGN DEFECTS.

The House Committee on Energy and Commerce (Committee), which drafted the Act in 1986, created the Vaccine Injury Compensation Program (Compensation Program or vaccine court) as an alternative to the tort litigation system, not its replacement. The tort system was neither compensating the children that vaccines injured nor ensuring a reliable vaccine supply. Tort litigation was costly, time consuming and usually undercompensated or failed to compensate victims. H.R. Rep. No. 99-908, at 6 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6347. The threats of litigation to vaccine manufacturers and grossly insufficient compensation to the vaccine-injured risked the vaccine program itself. *Schafer v. American Cyanamid Co.*, 20 F.3d 1, 2 (1st Cir. 1994) (citations omitted). *See also Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289, 297 (E.D. Pa. 2007). Congress created the Act to generously compensate vaccine victims, to ensure the vaccine supply and improve vaccine safety.

The legislators who drafted the Act understood that this carefully crafted scheme would fail without the support of parents whose children

had already suffered vaccine injuries. As Barbara Loe Fisher recently explained:

> The young parents of vaccine injured children, who came to the table in the early 1980s at the request of congressional staff to fight for the rights of vaccine consumers and the vaccine injured, agreed to work on the Act because of promises made by Congress and the American Academy of Pediatrics (AAP) that the proposed legislation would provide a fair, expedited, non-adversarial, less traumatic, less expensive no-fault compensation alternative to civil litigation. We believed we were participating in the development of a law which would give – in the words of the then AAP Chairman – "simple justice to children."

Statement to the Advisory Commission on Childhood Vaccines (Nov. 18, 2008), (Fisher Statement) http://www.nvic.org/injury-compensation/vaccineinjury.aspx.

These parents, organized initially as Dissatisfied Parents Together (DPT), educated Congress and the public about vaccine injuries and the need for a no-fault compensation system. They worked for nearly five years, through multiple drafts and congressional hearings, to reach a workable

compromise. At first, vaccine manufacturers and physician organizations advocated that an administrative no-fault system be victims' exclusive remedy. But parents insisted on the right to go to court after first filing in the compensation system if it was too slow, provided too little compensation or if victims wished to bring common law claims. The parents also insisted that the Act contain provisions to make vaccines safer, so that fewer children would be harmed in the future. *See generally,* Nitin Shah, *When Injury is Unavoidable: The Vaccine Act's Limited Preemption of Design Defect Claims*, 96 Va. L. Rev. 199 (2010), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1407343n; Division of Health Promotion and Disease Prevention, National Research Council, *Vaccine Supply and Innovation*, 183-92 (National Academies Press, 1985); Harris L. Coulter & Barbara L. Fisher, *A Shot in the Dark* 213-14 (Harcourt Brace Jovanovich, 1985); James Colgrove, *State of Immunity: The Politics of Vaccination in Twentieth-Century America*, 213-17 (University of California Press, 2006). As Dr. Martin H. Smith, AAP's past President wrote, "it became evident that working together with this group [DPT] was well advised and necessary." Martin H. Smith, *National Childhood Vaccine Injury Compensation Act*, 82 Pediatrics 264, 266 (1988).

After long, hard years of negotiation, Congress passed the Act in 1986. The Committee's report (1986 Report) accompanying the Act includes a section-by-section analysis of its provisions. Section 13 of the Act makes clear that the Compensation

Program does not require petitioners to prove that the vaccine was defective or that the injury was avoidable. Rather, vaccine court would presume causation based on certain criteria, such as a temporal relationship between vaccination and symptoms specified in a "Vaccine Injury Table."

The Committee acknowledged the consequences of this presumption, intending to compensate even when the causal relationship was tenuous:

> The Committee…recognizes that the deeming of vaccine-relatedness adopted here may provide compensation to some children whose illness is not, in fact, vaccine-related ….[T]he Committee has chosen to provide compensation to all persons whose injuries meet the requirements of the petition and the Table and whose injuries cannot be demonstrated to be caused by other factors.

H.R. Rep. 99-908 at 8-35, *reprinted in* 1986 U.S.C.C.A.N. at 6349-76.

The Table's purpose was to ensure that the compensation process would remain administrative rather than litigious. If the Vaccine Injury Table contains a particular presumptive vaccine injury, the burden of proof shifts to respondent HHS to demonstrate that the injury was "unrelated to the administration of the vaccine." § 300aa-13(a)(1)(B).

For "off-table" injuries, a claimant must show that the vaccine more likely than not caused the injury. § 300aa-13. The Act also contemplates that the Secretary of HHS should add new vaccine injuries to the Table as new vaccines are mandated. H.R. Rep. 99-908, *reprinted in* 1986 U.S.C.C.A.N. at 6361.

Like in all compromises, no stakeholder in the negotiations got everything it wanted. Parents were forced to accept substantial limitations in the administrative system – mandatory filing, capped damages, no juries and limits on discovery. Manufacturers and physician groups were forced to accept that the administrative system would not be victims' exclusive remedy. And to get the deal done, Congress was forced to pass the Act without funding it. H.R. Rep. No. 100-391(I) (1987) *reprinted in* 1987 U.S.C.C.A.N. 2313-1. As AAP President Dr. Smith wrote in 1988 to his member pediatricians, "[t]his was the best compromise settlement...that could be reached." Smith at 268.

Several statements at the time the Act passed suggest that Congress recognized that victims, who had duly filed in the Compensation Program, could take design defect claims to court under Section 22(b). When presenting the Act to the full House of Representatives for a vote, Rep. Henry Waxman, the Act's chief sponsor, stated that civil claims for "inadequately researched" vaccines would be preserved under Section 22. *National Childhood Vaccine Injury Act of 1986*, 99th Cong. Rec. 30760 (1986) (statement of Rep. Henry A. Waxman). *See also* Henry A. Waxman, *When a Vaccine Injures a*

Child: A No-Fault Way to Compensate, Wash. Post, Oct. 9, 1986, at A27. Rep. Waxman's description of this claim, that a vaccine's design did not take adequate account of avoidable safety risks, would likely be a design defect. *See* Shah at 34.

Furthermore, the Committee explicitly rejected the opportunity to create a broad exemption for all design defect claims when it considered the Act. Proposals were considered by the Committee that would have explicitly preempted all design defect claims, but the final version did not contain those provisions. H.R. Rep. 100-391(I), at 691 (1987), *as reprinted in* 1987 U.S.C.C.A.N. 2313-1, 2313-365. By rejecting language that would have barred all design defect claims, Congress showed its intent to permit courts to decide on a case-by-case which side effects were genuinely "unavoidable." Moreover, the Committee emphasized in its 1987 Report when it authorized funding that it had not decided, as a matter of law, which, if any, vaccines were unavoidably unsafe: "This question is left to the *courts* to determine in accordance with applicable law." *Id.* (emphasis added).

The legislative history suggests that all the stakeholders – Congress, parents, manufacturers and physicians – understood that victims preserved the right to take design defect claims to court. Respondent and its *amici* appear to be trying to achieve through the judiciary what they failed to obtain through Congress.

A. Congress Intended to Streamline Victims' Rights, Not Eliminate Them.

Parent advocates Schwartz, Fisher and Williams did not, and would not, have supported the Act if they thought that executive agencies or federal courts would later interpret it to foreclose access to a civil court remedy for design defect. They argued that because children face compulsory vaccination in order to attend school, their access to justice in the event of injury must be robust and must include design defect claims that manufacturers could have feasibly avoided.

They pointed to past court cases of vaccine design defects to demonstrate the need to preserve this type of claim. They referenced *Griffin v. United States*, in which the U.S. government was held liable because the Division of Biologics Standards of the National Institutes of Health released a batch of Sabin polio vaccine that did not conform to its own regulatory standards (the manufacturer settled), 351 F. Supp. 10 (E.D. Pa. 1972), *aff'd in part, rev'd in part and remanded*, 500 F.2d 1059 (3d Cir. 1974). And they also pointed to four cases in which manufacturers of quadrivalent vaccine (diphtheria, tetanus, pertussis, and poliomyelitis) were held liable because a new preservative activated the pertussis component. *Tinnerhold v. Parke Davis & Co.*, 285 F. Supp. 432 (S.D.N.Y. 1968), *aff'd* 411 F.2d 48 (2d Cir. 1969), *Stromsodt v. Parke Davis & Co.*, 257 F. Supp. 991 (D.N.D. 1966), *aff'd* 411 F.2d 1390 (8th Cir. 1969), *Vincent v. Thompson*, 361 N.Y.S.2d 282 (Sup. Ct. 1974), *rev'd in part*, 377 N.Y.S.2d 118

(App. Div. 2d Dep't 1975), and *Ezagui v. Dow Chemical Corp.*, 598 F.2d 727 (2d Cir. 1979) (finding that plaintiff had introduced enough evidence to go to the jury on the issues of product defect or proximate causation against defendant manufacturer Quadrigen). *See also Vaccine Supply and Innovation* at 86.

The Act and its legislative history simply do not make sense without the understanding that the tort system remains an available alternative for such cases. And Congress' intent to keep the courthouse doors open is even more important today than it was in 1986.

B. The Compensation Program Is Not Working as Congress Intended, Making Recourse to Civil Court More Critical Than Ever.

Although Congress enacted the Act more than twenty years ago, the Compensation Program is not functioning as Congress intended. Already in 1999, Barbara Loe Fisher testified before Congress about why parents of vaccine-injured children were dissatisfied:

> There is bitter disappointment and pervasive unhappiness among parents…with the current structure and administration of the vaccine injury compensation program....[W]hen parents are unable to obtain financial assistance to care for a severely vaccine

> injured children, public faith in the mass vaccination system is further eroded.

Fisher Statement.

Parents of vaccine-injured children perceive vaccine court to be mean-spirited and hostile towards plaintiffs, experts and attorneys. Parents believe that vaccine court has a conflict of interests between protecting the vaccine program and compensating those injured by it. They observe that vaccine court will "protect the reputation of the current vaccine system at all costs – even if it means denying compensation to vaccine victims." *Id.* Vaccine court simply has not fulfilled its mission to compensate vaccine injury victims like Hannah Bruesewitz.

The overwhelming majority of cases in vaccine court today are "off-table," unable to take advantage of presumptive causation and thus require costly and time-consuming causation hearings, are highly adversarial, and end without compensation.[2] The recent Omnibus Autism Proceeding, aggregating almost 5,000 claims of vaccine-induced autism, has no place in the statutory scheme Congress laid out for individual determinations of vaccine injury. *Cedillo v. Secretary of HHS*, 2009 WL 331968 (Fed.

[2] *See* National Vaccine Injury Compensation Program, Statistic Report (May 31, 2010) available at http://www.hrsa.gov/vaccinecompensation/statistics_report.htm showing that as of May 5, 2010, 13,357 petitions have been filed and 2,443 have been compensated, or approximately 18%.

Cl. 2009); *Hazlehurst v. Secretary of HHS*, 2009 WL 332306 (Fed. Cl. 2009); *Snyder v. Secretary of HHS*, 2009 WL 332044 (Fed. Cl. 2009); *see also* Gordon Shemin, Comment, *Mercury Rising: The Omnibus Autism Proceeding and What Families Should Know Before Rushing Out of Vaccine Court*, 58 Am. U. L.Rev. 459, 484-90 (2008).

Furthermore, HHS has not expanded presumptions for recovery, as the 1986 Report recommended. H.R. Rep. 99-908 at 19-20, *reprinted in* 1986 U.S.C.C.A.N. at 6360-61. While the Centers for Disease Control and Prevention now recommend 46 doses of nine new vaccines for children,[3] "no new signs, symptoms or injuries have been added to the Table of Injuries…– except anaphylaxis within four hours for the hepatitis B vaccine." Fisher Statement. In other words, HHS has not updated the Vaccine Injury Table's presumptions to correspond to today's substantially increased vaccine schedule.

Had the Bruesewitz family filed its initial claim one month earlier in 1995, Hannah's residual seizure disorder presumptively would have been

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[3] Department of Health and Human Services, Centers for Disease Control and Prevention, Recommended Immunization Schedule for Persons 0 through 6 Years and 7 Through 18 Years (May 31, 2010) *available at* http://www.cdc.gov/vaccines/recs/schedules/child-schedule.htm#printable, indicating nine new compulsory vaccines added since 1986: hepatitis B, rotavirus, *haemophilus influenzae* type b, pneumococcal, influenza, varicella, hepatitis A, meningococcal, human papillomavirus. Those that existed before 1986 were diphtheria, tetanus, pertussis, measles, mumps, rubella and inactivated poliovirus.

compensated. However, in an administrative sleight of hand, HHS removed this presumption from the Vaccine Injury Table in March, 1995, forcing Hannah Bruesewitz and similar DPT-injured children to prove causation. 60 Fed. Reg. 7678 (Feb. 8, 1995); *see also Andreu v. Secretary of HHS*, 569 F.3d 1367, 1374 (2009). Fourteen years of litigation later, Hannah Bruesewitz has yet to receive one penny in federal compensation for vaccine injury.

By Congress' measure, vaccine court has failed. In its 1986 Report, the Committee wrote:

> The entire [vaccine court] proceeding…is to take place as expeditiously as possible and, in no case, should take more than one year….[W]ithout such quick and certain conclusion of proceedings, the compensation system would work an injustice upon the petitioner.

H.R. Rep. 99-908, at 17, *reprinted in* 1986 U.S.C.C.A.N. at 6358. *See also Compensating Vaccine Injuries: Are Reforms Needed?: Hearing before the House Subcommittee on Criminal Justice, Drug Policy and Human Resources*, 106th Cong. (1999). It was to prevent the sort of injustice that Hannah Bruesewitz has suffered that Congress left petitioners free to reject the Compensation Program's findings "and go on to court." H.R. Rep. 99-908, at 12, *reprinted in* 1986 U.S.C.C.A.N. at 6353.

II. IN *BRUESEWITZ*, THE THIRD CIRCUIT ELIMINATED RIGHTS THAT CONGRESS EXPRESSLY PROTECTED.

While Congress wanted the Compensation Program to divert litigation from the traditional civil tort system, it never bestowed blanket immunity on vaccine manufacturers from all design defect claims. Congress preempted only those tort claims for "unavoidably unsafe" vaccines. Section 22(b)(1) states:

> [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.

§ 300aa-22(b)(1) (emphasis added).

Congress explicitly imported the "unavoidable" language 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 (1965). To read Section 22 as preempting all design defect claims would effectively read the word "unavoidable" out of the statute. As Justices O'Connor and Breyer stated in a concurrence to an earlier case under this Act:

> [t]o the extent possible, we adhere to 'the elementary canon of construction that a statute should be interpreted so as not to render one part inoperative. The construction adopted by the Court of Appeals contravenes this principle.

Shalala v. Whitecotton, 514 U.S. 268, 278 (1995) (O'Connor, J., concurring) (citations omitted).

Furthermore, Congress has subsequently authorized statutes, such as the Pandemic Preparedness Act, 42. U.S.C. § 247d-6d, for epidemic products that explicitly preempt all state laws that otherwise might apply. By contrast, the Act expressly preempts *state* statutes that prohibit civil actions against manufacturers for vaccine-related injuries. 42 U.S.C. § 300aa-22(e). Thus Congress was not silent on preemption of state tort remedies; the Act affirmatively preserved state contract and tort remedies even in cases where states tried to extinguish them on their own.

The plain meaning and legislative history of the Act suggest only one plausible reading of § 22(b)(1): that manufacturers are free from liability for design defects if the injury that a victim suffered was "unavoidable."

This is the conclusion that two Circuit Courts of Appeal have previously reached. The Fourth Circuit in *Abbot v. Am. Cyanimid Co.*, 844 F.2d 1108 (4th Cir. 1988), held that federal law did not foreclose a

plaintiff's defective design claims under Virginia law, even if an adequate warning was present. And the Fifth Circuit similarly found no preemption of state liability law for vaccine manufacturers. *Hurley v. Lederle Labs. Div. of Am. Cyanamid Co.*, 863 F.2d 1173 (5th Cir. 1988). They reasoned that Congress intended for petitioners to be able to determine which vaccine side effects were unavoidable on a case-by-case basis under state common law.

There is nothing in the Act that prohibits vaccine-injured plaintiffs from putting design defect questions before a jury, so long as they meet all other substantive and procedural requirements. And other thresholds remain high in design defect cases, such as the requirements for putting scientific evidence before a jury.[4] But parents of vaccine-injured children believed then, and now, that the tort system provides a critical check to ensure that vaccines on the market are "the safest and most effective vaccines possible." 1986 Report, Part C.

A. The Third Circuit's Decision in *Bruesewitz* Departs From This Court's Precedent on Preemption.

The Court's recent decision in *Wyeth v. Levine*, reaffirming the long-standing presumption against federal preemption, bolsters the conclusion

[4] *See* Shah at 42, citing thimerosal cases in federal and state courts where defendant-manufacturers have succeeded in having courts dismiss plaintiffs' claims under *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993) and *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923) standards of evidence before trial on grounds of scientific implausibility.

that the Third Circuit failed to follow this Court's precedent. 129 S. Ct. 1187, 1194 (2009) (quoting *Medtronic v. Lohr*, 518 U.S. 470, 485 (1996)). Earlier, in *Altria Group v. Good*, the Court explained that

> [this] assumption applies with particular force when Congress has legislated in a field traditionally occupied by the States….Thus, when the text of a preemption clause is susceptible of more than one plausible reading, courts ordinarily accept the reading that disfavors preemption.

129 S. Ct. 538, 543 (2008) (quoting *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005)). Absent explicit language barring design defect claims, the Third Circuit should have allowed Hannah Bruesewitz her day in court.

The Georgia Supreme Court in *American Home Products v. Ferrari* unanimously held that § 22 of the Act does not preempt all design defect claims, but only those side effects that were unavoidable. 284 Ga. 384, 386 (2008). Applying *Bates* to resolve the ambiguity in § 22, the *Ferrari* court opined that "[I]f Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed its intent more clearly." 284 Ga. at 393. The *Ferrari* court looked carefully at Congress' intent, expressed in the Act and in the 1987 amendments to fund the program. It wrote:

> We hesitate to hold that a manufacturer is excused from making changes it knows will improve its product merely because an older, more dangerous version received FDA approval….[To do so] "would 'have the perverse effect of granting complete [tort] immunity from design defect liability to an entire industry'."

284 Ga. at 394 (citations omitted).

To square *Bruesewitz* with the Court's preemption decisions, the Court should find the Act does not imply preemption. The Act permits petitioners to bring design defect claims to court, and manufacturers may then rebut those claims by showing that any injuries from its design were unavoidable.

This Court should reverse the Third Circuit's decision that rewrites the agreement that Congress, parents, manufacturers and physicians painstakingly reached in 1986.

CONCLUSION

For the foregoing reasons, this Court should reverse the judgment below.

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June 1, 2010

EXHIBIT

EXHIBIT A

Age of Autism (www.ageofautism.com)

Alan D. Clark, M.D. Memorial Research Foundation

Autism Action Network (www.autismactioncoalition.org)

Autism File USA (www.autismfile.com)

AutismOne (www.autismone.org)

Autism Trust USA (www.theautismtrust.com)

Center for Personal Rights (www.americanpersonalrights.org)

Citizens for Health (www.citizens.org)

Coalition for Mercury-Free Medicine (http.mercury-freedrugs.org)

The Coalition for Safe Minds (www.safeminds.org)

Elizabeth Birt Center for Autism Law and Advocacy (www.autismone.org, click EBCALA)

Generation Rescue (www.generationrescue.org)
International Medical Council on Vaccination (http.imcv.info)

National Autism Association (www.nationalautismassociation.org)

National Economic and Social Rights Initiative (www.nesri.org)

National Gulf War Resource Center (www.ngwrc.org)

National Vaccine Information Center (www.nvic.org)

New Jersey Coalition for Vaccination Choice (http.njvaccinationchoice.org)

New York Alliance for Vaccination Choice (www.nyavc.com)

NoMercury

Pandemic Response Project (www.pandemicresponseproject.com)

Schafer Autism Report (www.sarnet.org)

Talk About Curing Autism
(www.talkaboutcuringautism.org)

Truth About Gardasil (www.truthaboutgardasil.org)

Veterans for Common Sense
(www.veteransforcommonsense.org)