8/18/2009

Friends,

We are in the process of fine-tuning this amicus brief about the National Childhood Vaccine Injury Act, but the basic structure and content will not change dramatically.

If you would like to sign this amicus brief, please send an email to bruesewitz.amicus@gmail.com with your name, address and phone by FRIDAY, SEPTEMBER 4 at 12:00 noon. We will send you a confirmation email that we have received your email.

Please send this brief to colleague and friends for sign on.
Thanks,
Mary Holland and Todd Rosenbaum, working with the Elizabeth Birt Center for Autism Law and Advocacy (EBCALA)

Amicus Brief to US Supreme Court
Bruesewitz v. Wyeth,
561 F.3d 233 (3rd Cir. 2009)

STATEMENT OF INTEREST OF AMICI CURIAE

[We are parents, doctors, lawyers, teachers, therapists, mentors and friends of vaccine-injured children and are deeply concerned about the future of the National Childhood Vaccine Injury Act. Several of the signatories to this petition participated in negotiations in Congress leading to the National Childhood Vaccine Injury Act (Act) in 1986. We are dismayed at how the Vaccine Injury Compensation Program has evolved since its inception and alarmed that the Third Circuit in *Bruesewitz v. Wyeth* has interpreted the Act to foreclose the right to a civil jury trial when that right is plainly included in the Act. As a community concerned about the safety of vaccines and the care for those who have been, or may be, injured by vaccines, we advocate and educate about vaccine safety and on behalf of vaccine-injured children. Proper interpretation

of the Act is a matter of exceptional national importance; we ask this Court to grant *certiorari* to reverse and remand the Third Circuit's decision.]

SUMMARY OF ARGUMENT

The purpose of the Act was to compensate vaccine-injured children while preserving the national vaccine supply for the general public. In negotiations about the Act, many actors -- Congress, parents, the American Academy of Pediatrics, vaccine manufacturers and others -- agreed on a two-pronged approach. First, they agreed to create a quasi-administrative program, "vaccine court," to afford swift, simple and generous compensation to victims, thus giving petitioners incentives to forego the time, expense and trauma of civil court. And second, they agreed to preserve recourse to traditional tort litigation when vaccine court did not meet the needs of petitioners. The Act contemplates that petitioners may go to civil court when the compensation offered is too little, the court is too slow, or the issue at stake is ill-suited to vaccine court, like a manufacturer's fraud or gross negligence.

It was fundamental to the compromise that the negotiators reached that a civil court remedy would always be available as a default for those who filed in vaccine court first. All parties to the drafting of the Act hoped that the compensation program would suffice, obviating petitioners' need to go to civil court. This hoped-for outcome would speed recovery of damages to petitioners and ease the litigation burden on manufacturers. The compensation program was an incentive to ensure that parents would accept the real risks of vaccination for their infants and children; it manifested the nation's commitment to care for those inadvertently injured by mandatory vaccines.

Unfortunately, the vaccine compensation program has failed – it has served to immunize vaccine manufacturers from liability while denying compensation to legitimate victims. Most cases require costly and time-consuming causation hearings, take years to litigate, are highly adversarial, and end without any compensation at all to petitioners. The most recent Omnibus Autism Proceeding, aggregating almost 5,000 claims of vaccine-induced autism, has no place in the statutory scheme Congress laid out for individualized determinations of vaccine injury. Given the cruel reality of what vaccine court has become, injured children's recourse to civil court is more critical than ever.

This Court should clarify that the plain meaning of the Act preserves access to traditional tort remedies for injured children. Preserving recourse to civil court when the expedited compensation program fails is an essential check and balance Congress contemplated from the start.

Without the right to try a vaccine injury case in civil court, as in Hannah Bruesewitz's case, the vaccine program itself is at risk. When vaccine injuries to innocent infants and families go uncompensated, parents' trust and confidence in the national vaccine program falters. Widespread compliance with the national vaccine program hinges on a just compensation program for vaccine injury. This Court should uphold the check and balance of civil litigation that Congress intended in the Act.

REASONS FOR GRANTING THE WRIT

I. THE PURPOSE OF THE ACT IS TO COMPENSATE VACCINE VICTIMS, NOT TO IMMUNIZE VACCINE MANUFACTURERS.

The House Committee on Energy and Commerce ("Committee"), which drafted the Act in 1986, created the Vaccine Injury Compensation Program ("VICP" or "Compensation Program") as an alternative to the tort litigation system, which at that time 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 at all.[1] The threats of onerous litigation to vaccine manufacturers and grossly insufficient compensation to the vaccine-injured put the vaccine program at grave risk.[2] Congress created NCVIA to ensure the vaccine supply while compensating vaccine victims.

The legislators who drafted the Act understood that it would fail without the support of parents whose children had already suffered vaccine injuries. As Barbara Loe Fisher, signatory, Co-founder and President of the National Vaccine Information Center, explained in a recent statement to the Advisory Commission on Childhood Vaccines:

> 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."[3]

These parents stipulated several conditions for a compromise on the Act: they would not agree to a compensation program if it would bar a lawsuit (1) when the federal vaccine program refused to fully compensate the injured child's lifetime needs; (2) when the evidence showed that a vaccine manufacturer could have made a safer vaccine; or (3) when the manufacturer had engaged in fraud or gross negligence. The parents also insisted that the Act contain provisions to

[1] H.R. Rep. 99-908, 1986 U.S.C.C.A.N. 6344, 6347. [1986 Report]
[2] *Schafer* at 2, *Sykes v. Glaxo-SmithKline* at 297.
[3] Id. at p1 (when printed).

make vaccines safer so that fewer children would be harmed in the future.[4] They fought for a balance to compensate victims, to ensure the safest possible vaccines, and to limit vaccine litigation in order to keep vaccines maximally available.

Fisher and other parents deliberated for four years with congressional staff, AAP representatives, vaccine manufacturers, and the Departments of Health and Human Services ("HHS") and Justice ("DOJ").[5] They did so in good faith, believing that Congress sought to compensate victims and to improve vaccine safety. To ensure victim compensation, § 13 of the Act effectively removed civil litigation's requirement that the victim demonstrate that a vaccine caused the subsequent injury.[6] Rather, vaccine court would presume causation based on certain criteria, such as a temporal relationship between vaccination and specific symptoms.

The Committee's report ("the 1986 Report") accompanying the bill includes a section-by-section analysis of the Act's provisions. Its discussion of § 13 reveals that petitioners were not required to demonstrate that the vaccine was defective or that the injury was avoidable for compensation under the program.[7] The Committee acknowledged the consequences of this presumption, choosing 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.[8]

Those who deliberated over the Act were aware that they needed guidelines to be able to presume that vaccines caused particular injuries. To support these presumptions, Congress created the Vaccine Injury Table, which was

[4] Id. at 1.
[5] Id. at 1.
[6] § 300aa-13(1) (emphasis added).
[7] 1986 Report § 2113 (U.S.C.C.A.N. at 6359).
[8] Id.

> intended to spell out the signs and symptoms associated with [vaccines] … in order to provide a framework to allow for a presumption of causation under the Act. Therefore, the Table was inserted into the law by congressional sponsors to ensure that the compensation process would remain, essentially, administrative rather than litigious.[9]

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."[10] For "off-table" injuries, a claimant must show that the vaccine more likely than not caused the injury.[11]

A. Congress Intended to Expand Victims' Rights, Not Extinguish Them.

Parents would not have supported the Act if they thought that executive agencies or federal courts would later interpret it to extinguish the rights of vaccine-injured children. Their primary objective in negotiating the Act was to compensate innocent children.[12] Fisher says:

> We were assured that, unlike a lawsuit in civil court, the federal compensation system would be based on the *presumption* that a vaccine or combination of vaccines caused the child's injury or death if no other demonstrated cause could be found. The emphasis was on *presumption* and there was recognition that this presumption, in absence of scientific data and certainty, would be in the plaintiff's favor even if that presumption would result in some children being compensated who were not, in fact, vaccine injured. The emphasis on presumption was integral to the integrity of a no-fault, expedited vaccine injury compensation system.[13]

While Congress hoped that "the relative certainty and generosity of the system's awards [would] divert a significant number of potential plaintiffs from litigation" [14] to vaccine court, it did not seek to make the compensation program the exclusive remedy for victims.

[9] Id.
[10] § 200aa-13(a)(1)(B).
[11] § 300aa-13.
[12] Id. at 3.
[13] Id. at 3-4.
[14] 1986 Report at 6345.

C. Vaccine Court Does Not Work as Congress Intended.

Although Congress enacted NCVIA more than twenty years ago, the compensation program is not functioning as Congress intended. More than two-thirds of all petitioners lose, and the process is extremely adversarial. The compensation program, which was initially conceived to compensate those injured by the diphtheria-pertussis-tetanus ("DPT") vaccine, has failed to do even that. Since the 1990s, HHS and DOJ have advanced an agenda opposing the interests of vaccine-injured children. Notably, a past Secretary of HHS used her authority to eliminate almost all on-Table adverse events that created a presumption of causation.[15] This HHS action removed Petitioner Hannah Bruesewitz's DPT-related injury, residual seizure disorder, from the Table as of March 10, 1995, about one month before Hannah's family filed her petition in vaccine court.[16] This sweeping alteration effectively

> turned the administrative compensation process into a highly adversarial, lengthy, expensive, traumatic and unfair imitation of a court trial for vaccine victims and their attorneys. The only difference is that the trial is now conducted in the U.S. Court of Claims in front of one individual who acts as judge and jury.[17]

In addition, HHS used its discretionary authority to redefine what constitutes a permanent vaccine injury to make the category less inclusive and has effectively reduced the pool of attorneys willing to represent vaccine victims by refusing to award interim fees to plaintiffs' attorneys.[18]

Parents of vaccine-injured children perceive vaccine court to be mean-spirited and hostile towards plaintiffs, their families, experts and attorneys:

> [T]here is certainly a sense that parents feel their children are pawns in a political tug of war that compels those in government responsible for administering the compensation program to protect the reputation of the current vaccine system at all costs – even if it

[15] Id.
[16] *Breusewitz v. Wyeth*, Fn. 5.
[17] Fisher at 4.
[18] Id.

> means denying compensation to vaccine victims in order to limit the numbers of children acknowledged by government as having been harmed by vaccines being promoted by government.[19]

The vaccine court simply does not fulfill its mission to compensate legitimate vaccine injury victims. Special masters, who have wide discretion and whose decisions merit deference in higher courts, serve terms of only four years. They do not enjoy the requisite independence to make decisions that have the potential to affect national vaccine policy. DOJ lawyers representing HHS have almost unlimited budgets for expert witnesses and trial preparation. By contrast, the vaccine court generally pays petitioners' lawyers only *after* proceedings are complete, forcing them to fund trial preparation for years, including expert witness fees. This deters lawyers from representing claimants in vaccine court and experts from testifying. In addition, the process does not guarantee discovery, but puts it at the discretion of the special master. The vaccine court's relaxed rules of discovery, evidence and civil procedure – in theory designed to aid petitioners -- often backfire against them, preventing them from discovery and allowing in prejudicial, and marginally relevant, evidence.

In short, vaccine court is not fulfilling its mandate to compensate the victims of vaccine injury. The plain meaning of the Act, the legislative history and the testimony of those who participated in its drafting bear witness to the compromise that the parties did reach: protection of vaccine manufacturers would not be at the expense of vaccine-injured children.

II. IN *BRUESEWITZ*, THE THIRD CIRCUIT WRONGLY EXTINGUISHED RIGHTS THAT CONGRESS GRANTED.

The Third Circuit's decision in *Bruesewitz* takes away victims' opportunity for redress: the right to bring a civil action against vaccine manufacturers. It is a matter of national

[19] Id.

importance that this Court restore the rights Congress granted. Petitioner's case is typical and highlights the importance of granting *certiorari* in this case.

A. The Procedural Rights Congress Granted in the NCVIA Are Even More Pressing Today Than When the Act Passed in 1986.

[The Advisory Committee on Immunization Practice currently recommends 48 doses of 14 vaccines for children before age 6. Most state health departments have mandated these vaccines or may do so in the near future.[20] Yet, there have been no additions of presumptive causal relationships or vaccines themselves to the Vaccination Injury Table [since its creation], though the risk of exposure to adverse events has more than doubled.][21]

B. Congress Intended NCVIA to Safeguard Compensation to Children Injured by Vaccines – not to Carry Out an Experiment in Tort Reform Legislation.

While Congress intended vaccine court to divert litigation from civil court dockets, it never bestowed blanket immunity on vaccine manufacturers. Indeed, the Act's title uses the words "childhood" and "injury," not "vaccine manufacturers" and "immunity." Congress enacted NCVIA to compensate victims as a necessary part of a successful national vaccine program.[22] In the 1986 Report, the Committee elaborated:

[20] Fisher, 4.
[21] Fisher, 4.
[22] *See, e.g., Shalala v. Whitecotton*, 514 U.S. 268, 270 (1995) (NCVIA was intended to streamline compensation for victims by setting up a simple scheme for exhaustion of federal remedies before they could sue in state court); *Brice v. Sec'y of HHS*, 240 F.3d 1367, 1368-1369 (Fed. Cir. 2001) ("Congress established the NCVIP to provide compensation for vaccine-related injuries and deaths"); *Avera v. Sec'y of HHS*, 515 F.3d 1343, 1352 (Fed. Cir. 2008) ("one of the underlying purposes of the Vaccine Act was to ensure that vaccine injury claimants have readily available a competent bar to prosecute their claims"); *see* § 300aa-10.

> The bill establishes a compensation system for those persons injured by routine pediatric vaccines…without requiring the difficult individual determinations of causation of injury and without a demonstration that a manufacturer was negligent or that a vaccine was defective.
>
> While the bill does not prohibit a vaccine-injured person who has completed compensation proceedings from going on to court, the system is intended to lessen the number of lawsuits against manufacturers.[23]

Citing the Committee's 1986 Report, the Federal Circuit described NCVIA's purpose as "[establishing] a compensation program under which awards could be made to vaccine-injured persons 'quickly, easily, and with certainty and generosity.'"[24] While achieving this, Congress did not intend to extinguish petitioners' rights to pursue their claims in the civil system when they were dissatisfied with a vaccine court verdict.

i. Congress Intended Vaccine Court to Resolve Easy Cases; Not To Extinguish the Right To Go Before a Jury in Civil Court.

Although Congress believed that vaccine court would be a more plaintiff-friendly forum than civil court, it did not intend to extinguish recourse to traditional tort litigation. The Act does require that petitioners first bring claims to the vaccine court, but it preserves civil remedies.[25] The 1986 Report states:

> Vaccine-injured persons will now have an appealing *alternative* to the tort system. Accordingly, 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.[26]

[23] 1986 Report at 6353.
[24] H.R. Rep. No. 99-908, 1986 U.S.C.A.N. 6344, 6367, *quoted in Shyface v. Sec'y of HHS*, 165 F.3d 1344, 1351 (Fed. Cir. 1999).
[25] § 300aa-12.
[26] 1986 Report at 2, emphasis added. Check cite in USCANN. See also *Schafer* at 3.

Section 21 of the Act explicitly preserves petitioners' rights to seek traditional tort remedies if they are dissatisfied with the special master's decision or if vaccine court fails to decide the case within eight months after petitioners file a complaint.[27]

ii. Congress Preempted Only Those Tort Claims For "Unavoidably Unsafe" Vaccines.

Congress eliminated one small category of tort claims: in Section 22, it 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. [*italics added*][28]

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."[29] To read Section 22 as preempting all design defect claims would effectively read the word "unavoidable" out of the statute. This would grant unwarranted immunity to vaccine manufacturers.

The Committee explicitly rejected the opportunity to create such a broad exemption when it considered the Act. In fact, there were proposed versions that would have explicitly preempted all design defect claims, but the final version did not contain those provisions.[30] By rejecting language that would have definitively barred all design defect claims, Congress intended to permit design defect claims and to have courts decide on a case-by-case basis which side effects are avoidable. Moreover, the Committee emphasized that in importing the language of comment

[27] § 300aa-21(a).
[28] § 22(b)(1)
[29] R2T § 402A cmt. k.
[30] H.R. Rep. 100-391(I), 100th Cong., 1st Sess. 1987 *reprinted in* U.S. CODE CONG. & ADMIN. NEWS 2313-1 ([R2586a-2588a]. [ADD ACTUAL LANGUAGE]

k, 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."[31]

The plain meaning and legislative history of the Act suggest only one plausible reading of § 22: that manufacturers are free from liability for design defects only when those defects are unavoidable. There is nothing in the Act or its legislative history that prohibits vaccine-injured victims from putting design defect questions before a jury. Indeed, the tort system is the only possible check on manufacturers to ensure that they avoid making products that are less safe than they can make them.

The *Bruesewitz* court's decision to extinguish the right to a civil trial is inconsistent with this Court's precedent on federal preemption. The Court's recent decision in *Wyeth v. Levine*, which reaffirms the long-standing presumption against federal preemption, bolsters this conclusion.[32] 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.[33]

Congress did not express the purpose to extinguish the right to civil court after meeting vaccine court's exhaustion requirement. Absent such language, the Third Circuit should have allowed Petitioner her day in civil court.

American Home Products Corp. v. Ferrari, before this Court on a petition for *certiorari* as well, addresses related questions on preemption under NCVIA. In *Ferrari*, the Georgia Supreme Court unanimously held that § 22 does not preempt all design defect claims, but only those in which the side effects of the vaccine were unavoidable. Applying *Bates* to resolve the

[31] 1987 Budget Report at 691.
[32] 2009 U.S. LEXIS 1774 at 17 (quoting *Medtronic v. Lohr*, 518 U.S. 470, 485 (1996)).
[33] 129 S. Ct. 538, 543 (2008) (quoting *Bates* at 449).

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."[34] The *Ferrari* court reasoned that Congress reasserted its intent when it passed amendments in 1987 to fund and implement the program:

> It is important to note that both at the time of the original enactment and in passing this legislation, the Committee acted with the understanding that tort remedies were and are available. Without this understanding, such provisions of the Act as those allowing rejection of compensation, trifurcation of trial, and limitations of punitive damages would be meaningless.[35]

The Act's language does not make NCVIP an exclusive remedy. To square this case with the Court's recent line of preemption decisions, the Court should find the Act does not imply preemption. Absent a showing that the side effects of the vaccines in question are, in fact, unavoidable, the Act does not bar petitioners from seeking redress for their injuries through traditional civil litigation.

III. ACCESS TO CIVIL COURTS PROTECTS THE VIABILITY OF THE VACCINE PROGRAM.

Allowing petitioners the option of resorting to traditional tort remedies is essential as a check and balance on the fair, efficient operation of the federal remedy. Without it, there is no mechanism to hold the Federal Court of Claims or vaccine manufacturers accountable. Petitioner's lifetime medical costs are about $9 million, yet the Third Circuit demands that she appeal the decision against her in a broken system or walk away. The plain language of the Act and its legislative history show Congress' intent to preserve the right to a civil jury trial. This Court should grant *certiorari* and reverse the Third Circuit's decision in *Bruesewitz*.

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[34] *Ferrari* at 393.
[35] H.R. Rep. 100-391(I), 1987 U.S.C.C.A.N. 2586a-255a. [check cite]

CONCLUSION

For the foregoing reasons, and those stated in the petition, the writ of *certiorari* should be granted, and the judgment below reversed.

Bruesewitz v. Wyeth