Syllabus

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Timber & Lumber Co.,* 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

Syllabus

BRUESEWITZ ET AL. *v.* WYETH LLC, FKA WYETH, INC., ET AL.

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

No. 09–152. Argued October 12, 2010—Decided February 22, 2011

The National Childhood Vaccine Injury Act of 1986 (NCVIA or Act) created a no-fault compensation program to stabilize a vaccine market adversely affected by an increase in vaccine-related tort litigation and to facilitate compensation to claimants who found pursuing legitimate vaccine-inflicted injuries too costly and difficult. The Act provides that a party alleging a vaccine-related injury may file a petition for compensation in the Court of Federal Claims, naming the Health and Human Services Secretary as the respondent; that the court must resolve the case by a specified deadline; and that the claimant can then decide whether to accept the court's judgment or reject it and seek tort relief from the vaccine manufacturer. Awards are paid out of a fund created by an excise tax on each vaccine dose. As a *quid pro quo,* manufacturers enjoy significant tort-liability protections. Most importantly, the Act eliminates manufacturer liability for a vaccine's unavoidable, adverse side effects.

Hannah Bruesewitz's parents filed a vaccine-injury petition in the Court of Federal Claims, claiming that Hannah became disabled after receiving a diphtheria, tetanus, and pertussis (DTP) vaccine manufactured by Lederle Laboratories (now owned by respondent Wyeth). After that court denied their claim, they elected to reject the unfavorable judgment and filed suit in Pennsylvania state court, alleging, *inter alia,* that the defective design of Lederle's DTP vaccine caused Hannah's disabilities, and that Lederle was subject to strict liability and liability for negligent design under Pennsylvania common law. Wyeth removed the suit to the Federal District Court. It granted Wyeth summary judgment, holding that the relevant Pennsylvania law was preempted by 42 U. S. C. §300aa–22(b)(1), which

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provides that "[n]o 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." The Third Circuit affirmed.

Held: The NCVIA preempts all design-defect claims against vaccine manufacturers brought by plaintiffs seeking compensation for injury or death caused by a vaccine's side effects. Pp. 7–19.

(a) Section 300aa–22(b)(1)'s text suggests that a vaccine's design is not open to question in a tort action. If a manufacturer could be held liable for failure to use a different design, the "even though" clause would do no work. A vaccine side effect could alway*s* have been avoidable by use of a different vaccine not containing the harmful element. The language of the provision thus suggests the design is not subject to question in a tort action. What the statute establishes as a complete defense must be unavoidability (given safe manufacture and warning) with respect to the particular design. This conclusion is supported by the fact that, although products-liability law establishes three grounds for liability—defective manufacture, inadequate directions or warnings, and defective design—the Act mentions only manufacture and warnings. It thus seems that the Act's failure to mention design-defect liability is "by deliberate choice, not inadvertence." *Barnhart* v. *Peabody Coal Co.*, 537 U. S. 149, 168. Pp. 7–8.

(b) Contrary to petitioners' argument, there is no reason to believe that §300aa–22(b)(1)'s term "unavoidable" is a term of art incorporating Restatement (Second) of Torts §402A, Comment *k,* which exempts from strict liability rules "unavoidably unsafe products." "Unavoidable" is hardly a rarely used word, and cases interpreting comment *k* attach special significance only to the term "unavoidably unsafe products," not the word "unavoidable" standing alone. Moreover, reading the phrase "side effects that were unavoidable" to exempt injuries caused by flawed design would require treating "even though" as a coordinating conjunction linking independent ideas when it is a concessive, subordinating conjunction conveying that one clause weakens or qualifies the other. The canon against superfluity does not undermine this Court's interpretation because petitioners' competing interpretation has superfluity problems of its own. Pp. 8–12.

(c) The structure of the NCVIA and of vaccine regulation in general reinforces what §300aa–22(b)(1)'s text suggests. Design defects do not merit a single mention in the Act or in Food and Drug Administration regulations that pervasively regulate the drug manufacturing process. This lack of guidance for design defects, combined with

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the extensive guidance for the two liability grounds specifically mentioned in the Act, strongly suggests that design defects were not mentioned because they are not a basis for liability. The Act's mandates lead to the same conclusion. It provides for federal agency improvement of vaccine design and for federally prescribed compensation, which are other means for achieving the two beneficial effects of design-defect torts—prompting the development of improved designs, and providing compensation for inflicted injuries. The Act's structural *quid pro quo* also leads to the same conclusion. The vaccine manufacturers fund an informal, efficient compensation program for vaccine injuries in exchange for avoiding costly tort litigation and the occasional disproportionate jury verdict. Taxing their product to fund the compensation program, while leaving their liability for design defect virtually unaltered, would hardly coax them back into the market. Pp. 13–16.

561 F. 3d 233, affirmed.

SCALIA, J., delivered the opinion of the Court, in which ROBERTS, C. J., and KENNEDY, THOMAS, BREYER, and ALITO, JJ., joined. BREYER, J., filed a concurring opinion. SOTOMAYOR, J., filed a dissenting opinion, in which GINSBURG, J., joined. KAGAN, J., took no part in the consideration or decision of the case.

SUPREME COURT OF THE UNITED STATES

No. 09–152

RUSSELL BRUESEWITZ, ET AL., PETITIONERS *v.* WYETH LLC, FKA WYETH, INC., FKA WYETH LABORATORIES, ET AL.

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

[February 22, 2011]

JUSTICE SCALIA delivered the opinion of the Court.

We consider whether a preemption provision enacted in the National Childhood Vaccine Injury Act of 1986 (NCVIA)[1] bars state-law design-defect claims against vaccine manufacturers.

I

A

For the last 66 years, vaccines have been subject to the same federal premarket approval process as prescription drugs, and compensation for vaccine-related injuries has been left largely to the States.[2] Under that regime, the elimination of communicable diseases through vaccination became "one of the greatest achievements" of public health in the 20th century.[3] But in the 1970's and 1980's vac-

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[1] 42 U. S. C. §300aa–22(b)(1).

[2] See P. Hutt, R. Merrill, & L. Grossman, Food and Drug Law 912–913, 1458 (3d ed. 2007).

[3] Centers for Disease Control, Achievements in Public Health, 1900–1999: Impact of Vaccines Universally Recommended for Children, 48 Morbidity and Mortality Weekly Report 243, 247 (Apr. 2, 1999).

significant number of parents were already declining vaccination for their children,[10] and concerns about compensation threatened to depress vaccination rates even further.[11] This was a source of concern to public health officials, since vaccines are effective in preventing outbreaks of disease only if a large percentage of the population is vaccinated.[12]

To stabilize the vaccine market and facilitate compensation, Congress enacted the NCVIA in 1986. The Act establishes a no-fault compensation program "designed to work faster and with greater ease than the civil tort system." *Shalala* v. *Whitecotton*, 514 U. S. 268, 269 (1995). A person injured by a vaccine, or his legal guardian, may file a petition for compensation in the United States Court of Federal Claims, naming the Secretary of Health and Human Services as the respondent.[13] A special master then makes an informal adjudication of the petition within (except for two limited exceptions) 240 days.[14] The Court of Federal Claims must review objections to the special master's decision and enter final judgment under a similarly tight statutory deadline.[15] At that point, a claimant has two options: to accept the court's judgment and forgo a traditional tort suit for damages, or to reject the judgment and seek tort relief from the vaccine manufacturer.[16]

Fast, informal adjudication is made possible by the Act's Vaccine Injury Table, which lists the vaccines covered under the Act; describes each vaccine's compensable,

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Lawsuits, and Legal Rights: The Battle over Litigation in American Society 146 (2002).

[10] Mortimer, *supra*, at 906.

[11] See Hagan, 45 Food Drug Cosm. L. J. 477, 479 (1990).

[12] See R. Merrill, Introduction to Epidemiology 65–68 (2010).

[13] See 42 U. S. C. §300aa–11(a)(1).

[14] See §300aa–12(d)(3).

[15] See §300aa–12(e), (g).

[16] See §300aa–21(a).

adverse side effects; and indicates how soon after vaccination those side effects should first manifest themselves.[17] Claimants who show that a listed injury first manifested itself at the appropriate time are prima facie entitled to compensation.[18] No showing of causation is necessary; the Secretary bears the burden of disproving causation.[19] A claimant may also recover for unlisted side effects, and for listed side effects that occur at times other than those specified in the Table, but for those the claimant must prove causation.[20] Unlike in tort suits, claimants under the Act are not required to show that the administered vaccine was defectively manufactured, labeled, or designed.

Successful claimants receive compensation for medical, rehabilitation, counseling, special education, and vocational training expenses; diminished earning capacity; pain and suffering; and $250,000 for vaccine-related deaths.[21] Attorney's fees are provided, not only for successful cases, but even for unsuccessful claims that are not frivolous.[22] These awards are paid out of a fund created by an excise tax on each vaccine dose.[23]

The *quid pro quo* for this, designed to stabilize the vaccine market, was the provision of significant tort-liability protections for vaccine manufacturers. The Act requires claimants to seek relief through the compensation program before filing suit for more than $1,000.[24] Manufacturers are generally immunized from liability for fail-

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[17] See §300aa–14(a); 42 CFR §100.3 (2009) (current Vaccine Injury Table).

[18] See 42 U. S. C. §§300aa–11(c)(1), 300aa–13(a)(1)(A).

[19] See §300aa–13(a)(1)(B).

[20] See §300aa–11(c)(1)(C)(ii).

[21] See §300aa–15(a).

[22] See §300aa–15(e).

[23] See §300aa–15(i)(2); 26 U. S. C. §§4131, 9510.

[24] See 42 U. S. C. §300aa–11(a)(2).

SUPREME COURT OF THE UNITED STATES

No. 09–152

RUSSELL BRUESEWITZ, ET AL., PETITIONERS *v.* WYETH LLC, FKA WYETH, INC., FKA WYETH LABORATORIES, ET AL.

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

[February 22, 2011]

JUSTICE BREYER, concurring.

I join the Court's judgment and opinion. In my view, the Court has the better of the purely textual argument. But the textual question considered alone is a close one. Hence, like the dissent, I would look to other sources, including legislative history, statutory purpose, and the views of the federal administrative agency, here supported by expert medical opinion. Unlike the dissent, however, I believe these other sources reinforce the Court's conclusion.

I

House Committee Report 99–908 contains an "authoritative" account of Congress' intent in drafting the pre-emption clause of the National Childhood Vaccine Injury Act of 1986 (NCVIA or Act). See *Garcia* v. *United States*, 469 U. S. 70, 76 (1984) ("[T]he authoritative source for finding the Legislature's intent lies in the Committee Reports on the bill"). That Report says that, "if" vaccine-injured persons

> "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

manufacturers' product liability while simultaneously augmenting the role of experts in making compensation decisions.

III

The United States, reflecting the views of HHS, urges the Court to read the Act as I and the majority would do. It notes that the compensation program's listed vaccines have survived rigorous administrative safety review. It says that to read the Act as permitting design-defect lawsuits could lead to a recurrence of "exactly the crisis that precipitated the Act," namely withdrawals of vaccines or vaccine manufacturers from the market, "disserv[ing] the Act's central purposes," and hampering the ability of the agency's "expert regulators, in conjunction with the medical community, [to] control the availability and withdrawal of a given vaccine." Brief for United States as *Amicus Curiae* 30, 31.

The United States is supported in this claim by leading public health organizations, including the American Academy of Pediatrics, the American Academy of Family Physicians, the American College of Preventive Medicine, the American Public Health Association, the American Medical Association, the March of Dimes Foundation, the Pediatric Infectious Diseases Society, and 15 other similar organizations. Brief for American Academy of Pediatrics et al. as *Amici Curiae* (hereinafter AAP Brief). The American Academy of Pediatrics has also supported the retention of vaccine manufacturer tort liability (provided that federal law structured state-law liability conditions in ways that would take proper account of federal agency views about safety). Hearings 14–15. But it nonetheless tells us here, in respect to the specific question before us, that the petitioners' interpretation of the Act would undermine its basic purposes by threatening to "halt the future production and development of childhood vaccines

in this country," *i.e.,* by "threaten[ing] a resurgence of the very problems which . . . caused Congress to intervene" by enacting this statute. AAP Brief 24 (internal quotation marks omitted).

I would give significant weight to the views of HHS. The law charges HHS with responsibility for overseeing vaccine production and safety. It is "likely to have a thorough understanding" of the complicated and technical subject matter of immunization policy, and it is comparatively more "qualified to comprehend the likely impact of state requirements." *Geier* v. *American Honda Motor Co., Inc.*, 529 U. S. 861, 883 (2000) (internal quotation marks omitted); see *Medtronic, Inc.* v. *Lohr*, 518 U. S. 470, 506 (1996) (BREYER, J., concurring in part and concurring in judgment) (the agency is in the best position to determine "whether (or the extent to which) state requirements may interfere with federal objectives"). HHS's position is particularly persuasive here because expert public health organizations support its views and the matter concerns a medical and scientific question of great importance: how best to save the lives of children. See *Skidmore* v. *Swift & Co.*, 323 U. S. 134 (1944).

In sum, congressional reports and history, the statute's basic purpose as revealed by that history, and the views of the expert agency along with those of relevant medical and scientific associations, all support the Court's conclusions. I consequently agree with the Court.

SUPREME COURT OF THE UNITED STATES

No. 09–152

RUSSELL BRUESEWITZ, ET AL., PETITIONERS *v.* WYETH LLC, FKA WYETH, INC., FKA WYETH LABORATORIES, ET AL.

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

[February 22, 2011]

JUSTICE SOTOMAYOR, with whom JUSTICE GINSBURG joins, dissenting.

Vaccine manufacturers have long been subject to a legal duty, rooted in basic principles of products liability law, to improve the designs of their vaccines in light of advances in science and technology. Until today, that duty was enforceable through a traditional state-law tort action for defective design. In holding that §22(b)(1) of the National Childhood Vaccine Injury Act of 1986 (Vaccine Act or Act), 42 U. S. C. §300aa–22(b)(1), pre-empts all design defect claims for injuries stemming from vaccines covered under the Act, the Court imposes its own bare policy preference over the considered judgment of Congress. In doing so, the Court excises 13 words from the statutory text, misconstrues the Act's legislative history, and disturbs the careful balance Congress struck between compensating vaccine-injured children and stabilizing the childhood vaccine market. Its decision leaves a regulatory vacuum in which no one ensures that vaccine manufacturers adequately take account of scientific and technological advancements when designing or distributing their products. Because nothing in the text, structure, or legislative history of the Vaccine Act remotely suggests that Congress intended such a result, I respectfully dissent.

because they provide injured persons with significant procedural tools—including, most importantly, civil discovery—that are not available in administrative proceedings under the compensation program. See §§300aa–12(d)(2)(E), (d)(3). Congress thus clearly believed there was still an important function to be played by state tort law.

Instead of eliminating design defect liability entirely, Congress enacted numerous measures to reduce manufacturers' liability exposure, including a limited regulatory compliance presumption of adequate warnings, see §300aa–22(b)(2), elimination of claims based on failure to provide direct warnings to patients, §300aa–22(c), a heightened standard for punitive damages, §300aa–23(d)(2), and, of course, immunity from damages for "unavoidable" side effects, §300aa–22(b)(1). Considered in light of the Vaccine Act as a whole, §22(b)(1)'s exemption from liability for unavoidably unsafe vaccines is just one part of a broader statutory scheme that reflects Congress' careful balance between providing adequate compensation for vaccine-injured children and conferring substantial benefits on vaccine manufacturers to ensure a stable and predictable childhood vaccine supply.

The majority's decision today disturbs that careful balance based on a bare policy preference that it is better "to leave complex epidemiological judgments about vaccine design to the FDA and the National Vaccine Program rather than juries." *Ante*, at 15.[24] To be sure, reasonable minds can disagree about the wisdom of having juries weigh the relative costs and benefits of a particular vaccine design. But whatever the merits of the majority's

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[24] JUSTICE BREYER's separate concurrence is even more explicitly policy driven, reflecting his own preference for the "more expert judgment" of federal agencies over the "less expert" judgment of juries. *Ante*, at 5.

policy preference, the decision to bar all design defect claims against vaccine manufacturers is one that Congress must make, not this Court.[25] By construing §22(b)(1) to

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[25] Respondent notes that there are some 5,000 petitions alleging a causal link between certain vaccines and autism spectrum disorders that are currently pending in an omnibus proceeding in the Court of Federal Claims (Vaccine Court). Brief for Respondent 56–57. According to respondent, a ruling that §22(b)(1) does not pre-empt design defect claims could unleash a "crushing wave" of tort litigation that would bankrupt vaccine manufacturers and deplete vaccine supply. *Id.*, at 28. This concern underlies many of the policy arguments in respondent's brief and appears to underlie the majority and concurring opinions in this case. In the absence of any empirical data, however, the prospect of an onslaught of autism-related tort litigation by claimants denied relief by the Vaccine Court seems wholly speculative. As an initial matter, the special masters in the autism cases have thus far uniformly rejected the alleged causal link between vaccines and autism. See Brief for American Academy of Pediatrics et al. as *Amici Curiae* 20–21, n. 4 (collecting cases). To be sure, those rulings do not necessarily mean that no such causal link exists, cf. Brief for United States as *Amicus Curiae* 29 (noting that injuries have been added to the Vaccine Injury Table for existing vaccines), or that claimants will not ultimately be able to prove such a link in a state tort action, particularly with the added tool of civil discovery. But these rulings do highlight the substantial hurdles to recovery a claimant faces. See *Schafer* v. *American Cyanamid Co.*, 20 F. 3d 1, 5 (CA1 1994) ("[A] petitioner to whom the Vaccine Court gives nothing may see no point in trying to overcome tort law's yet more serious obstacles to recovery"). Trial courts, moreover, have considerable experience in efficiently handling and disposing of meritless products liability claims, and decades of tort litigation (including for design defect) in the prescription-drug context have not led to shortages in prescription drugs. Despite the doomsday predictions of respondent and the various *amici* cited by the concurrence, *ante*, at 6–7, the possibility of a torrent of meritless lawsuits bankrupting manufacturers and causing vaccine shortages seems remote at best. More fundamentally, whatever the merits of these policy arguments, the issue in this case is what Congress has decided, and as to that question, the text, structure, and legislative history compel the conclusion that Congress intended to leave the courthouse doors open for children who have suffered severe injuries from defectively designed vaccines. The majority's policy-driven decision to the contrary usurps Congress' role and deprives such vaccine-injured children of a key remedy that Congress intended them to have.

No. 09-152

IN THE
Supreme Court of the United States

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

v.

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

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

BRIEF AMICI CURIAE OF THE AMERICAN ACADEMY OF PEDIATRICS AND 21 OTHER PHYSICIAN AND PUBLIC HEALTH ORGANIZATIONS IN SUPPORT OF RESPONDENT

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others equally aggrieved away penniless"). The tort system was thus aptly described as a "lottery." *1984 Hearing*, *supra*, at 277 (statement of John E. Lyons, President of Merck Sharp & Dohme).

C. The Vaccine Act Provides Adequate Compensation To Children Injured By Vaccines And Ensures The Stability Of The Vaccine Market And The Nation's Vaccine Supply.

Congress responded to the looming crisis by enacting the Vaccine Act. The overriding goals of the Act were two-fold: (1) to ensure adequate compensation for children injured by vaccines, and (2) to stabilize the vaccine market and safeguard the Nation's vaccine supply. H.R. Rep. No. 99-908, at 7.

Congress addressed both of those goals in part by establishing the National Vaccine Injury Compensation Program ("VICP"), a no-fault alternative compensation system under which children injured by certain vaccines would receive "expeditious and fair" compensation for their injuries. *Id.* at 12. *See* 42 U.S.C. § 300aa-10 *et seq*. Under the VICP, a person seeking compensation for an injury caused by a vaccine covered by the Act must file a petition with the United States Court of Federal Claims, which refers the petition to a "Vaccine Court"—an office within the court of special masters appointed to four-year terms by the court to hear VICP claims. 42 U.S.C. §§ 300aa-11(a)(1)-(2), 300aa-12(c), 300aa-21(a). The Secretary of Health and Human Services is named as a respondent; vaccine manufacturers are not parties to VICP proceedings. *Id.* § 300aa-12(b)(1).

A petitioner is entitled to compensation if he or she has suffered an injury set forth in the "Vaccine Injury Table"—a table of vaccines and the injuries presumed to be caused by those vaccines—unless it can be shown by a preponderance of the evidence that the petitioner's injury was not caused by the vaccine. *Id.* §§ 300aa-11(b), (c), 300aa-13(a)(1), 300aa-14. A petitioner who has not suffered a "Table Injury" may still obtain compensation by proving that his or her injury was in fact caused by a vaccine covered by the Act. *Id.* § 300aa-11(c)(1)(C)(ii). *See Grant* v. *Secretary of HHS*, 956 F.2d 1144, 1147-48 (Fed. Cir. 1992).[4] Payment of compensation is made

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[4] The special masters of the Vaccine Court have developed a proficiency in the complex medical and scientific issues involved in causation claims. Indeed, the Court of Federal Claims has observed that, "instead of being passive recipients of information, such as jurors, special masters are given an active role in determining the facts relevant to Vaccine Act petitions," and that "special masters have the expertise and experience to know the type of information that is most probative of a claim." *Doe* v. *Secretary, HHS,* 76 Fed. Cl. 328, 338-339 (Fed. Cl. 2007).

The expertise of the special masters in evaluating causation claims has been amply demonstrated in a multi-phase Omnibus Autism Proceeding ("OAP") established under the VICP to determine whether there is a causal link between childhood vaccines and autism. Approximately 5,000 cases alleging an association between autism and either vaccines containing the preservative thimerosal, the MMR vaccine (which does not contain thimerosal), or a combination thereof, have been filed with the Vaccine Court. *See* http://www.hrsa.gov/vaccinecompensation. In 2009, special masters in three "test" cases issued voluminous opinions evaluating evidence based on the theory that the MMR vaccine, in combination with vaccines containing thimerosal, causes autism. *See Cedillo* v. *Secretary of HHS*, 2009 WL 331968 (Fed. Cl. Feb. 12, 2009), *aff'd*, 89 Fed. Cl. 158 (2009), *appeal pending*, No. 2010-5004 (Fed. Cir.); *Hazlehurst* v. *Secretary of HHS,* 2009 WL 332306 (Fed. Cl. Feb. 12, 2009),

from a "Vaccine Injury Compensation Trust Fund"—funded by a manufacturers excise tax on those vaccines covered by the Act, *see* 26 U.S.C. §§ 4131, 9510—on a no-fault basis. 42 U.S.C. §§ 300aa-13, 300aa-14, 300aa-15(i). Since 1989, the Vaccine Court has issued more than 2,400 awards totaling over $1.8 billion. *See* National Vaccine Injury Compensation Program, *Statistics Report* (June 7, 2010), *available*

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aff'd, 88 Fed. Cl. 473 (2009), *aff'd*, 604 F.3d 1343 (Fed. Cir. 2010); *Snyder* v. *Secretary of HHS*, 2009 WL 332044 (Fed. Cl. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 706 (2009). All three special masters rejected the proposition that the vaccines in question caused autism. *See id.*

In reaching their decisions, the special masters in each case considered a wealth of scientific evidence. As the special master in *Snyder* observed: "The evidentiary record in this case * * * encompasses, *inter alia*, nearly four weeks of testimony, including that offered in the *Cedillo* and *Hazlehurst* cases; over 900 medical and scientific journal articles; 50 expert reports (including several reports of witnesses who did not testify); supplemental expert reports filed by both parties post-hearing, [and] the testimony of fact witnesses on behalf of [the injured child and his] medical records." *Snyder*, 2009 WL 332044, at *8. Each of the special master's decisions have been affirmed by the Court of Federal Claims; of the two cases that have been further appealed, one has been affirmed by the Federal Circuit and the other is still pending before that court. *See supra.*

In March 2010, special masters in three additional "test" cases issued voluminous opinions evaluating evidence based on the theory that thimerosal-containing vaccines alone can cause autism. *See Dwyer v. Secretary of HHS*, 2010 WL 892250 (Fed. Cl. March 12, 2010); *King v. Secretary of HHS*, 2010 WL 892296 (Fed. Cl. March 12, 2010); *Mead v. Secretary of HHS*, 2010 WL 892248 (Fed. Cl. March 12, 2010). Once again—upon consideration of a "massive" record—each of the special masters concluded that the vaccines in question did not cause autism. *King*, 2010 WL 892296, at *12. *See Dwyer*, 2010 WL 892250, at *7; *Mead*, 2010 WL 892248, at *5.

at http://www.hrsa.gov/vaccinecompensation/statistics_report.htm.[5]

After the Vaccine Court has issued a final judgment, a petitioner may accept or reject it. 42 U.S.C. § 300aa-21(a).[6] Although a party who rejects the Vaccine Court's judgment may pursue certain *limited* claims in state or federal court, design defect

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[5] Certain of petitioners' amici make much of the fact that the majority of claims filed today involve so-called "off-Table" injuries which require proof of causation. *See* Br. Marguerite Willner 22; Br. National Vaccine Information Center, *et al*. 14. Yet it would not appear that claimants have been unduly hampered by the burden of proof on causation, as amici suggest. In 2009—and to date, in 2010—compensation has been paid in over 70% of adjudicated non-autism cases. *See* National Vaccine Injury Compensation Program, *Statistics Report* (June 7, 2010). And while amici bemoan the Secretary's removal of certain injuries from the Vaccine Injury Table, *see* Br. Marguerite Willner 21-22; Br. National Vaccine Information Center, *et al*. 15-16, Congress "anticipate[d] that the research on vaccine injury and vaccine safety [then] ongoing * * * [would] soon provide more definitive information about the incidence of vaccine injury and that, when such information [were] available, the Secretary * * * [might] propose to revise the Table." H.R. Rep. No. 99-908, at 18. Thus, the Act specifically provides for the removal of injuries through notice-and-comment rulemaking. *See* 42 U.S.C. § 300aa-14(c). As contemplated by Congress, the original table was modified "to make it consistent with current medical and scientific knowledge regarding adverse events associated with certain vaccines." HHS, *National Vaccine Injury Compensation Program Revision of the Vaccine Injury Table*, 60 Fed. Reg. 7678, 7678 (Feb. 8, 1995).

[6] The Vaccine Act also authorizes petitioners to "opt out" of a VICP proceeding if a special master has not resolved his or her petition within 240 days or if the Court of Federal Claims has not completed its review of a special master's decision within 420 days of the date on which the petition was filed. *See* 42 U.S.C. § 300aa-21(b).

claims are not among them. *Id.* § 300aa-21(a), (b). As the Third Circuit correctly held, Congress expressly preempted "*all* design defect claims, including those based in negligence." *Bruesewitz*, 561 F.3d at 248 (emphasis added). *See* 42 U.S.C. § 300aa-22(b)(1). If an injured person has such a claim, he or she "should pursue recompense in the compensation system, not the tort system." H.R. Rep. No. 99-908, at 26. The preemption of all design defect claims is critical to Congress's objective of stabilizing the vaccine market and safeguarding the Nation's vaccine supply. As the Third Circuit explained: "Congress[] belie[ved] that an alternate compensation system would reduce awards and create a stable, predictable basis for estimating liability." *Bruesewitz*, 561 F.3d at 247. Indeed, as the legislative history makes clear, Congress "believe[d] that once this system [was] in place and manufacturers ha[d] a better sense of their potential litigation obligations, a more stable childhood vaccine market [would] evolve." H.R. Rep. No. 99-908, at 7.

III. PETITIONERS' INTERPRETATION OF THE VACCINE ACT POSES A THREAT TO THE FUTURE PRODUCTION AND DEVELOPMENT OF VACCINES.

Contrary to all clear indications of congressional intent, petitioners maintain that the Vaccine Act preempts design defect claims "*only* upon a threshold showing that the vaccine's side effects could not have been prevented." Pet. Br. 25 (emphasis added). As the Third Circuit below concluded, that interpretation of the Act is simply wrong. *See Bruesewitz*, 561 F.3d at 246. As the Third Circuit explained, if the Act is interpreted "to allow case-by-case analysis of

whether particular vaccine side effects are avoidable," then "*every* design defect claim is subject to evaluation by a court." *Id.* (emphasis added).

If that were the case, "[e]ach of the objectives extolled [in the Vaccine Act's legislative history] would be undermined." *Id.* at 249. Thus, petitioners' interpretation of the statute—which allows judges *and juries* to decide whether a particular vaccine can be made safer[7]—threatens a resurgence of "the very problems which led to instability in the vaccine market and which caused Congress to intervene through the passage of the Vaccine Act" in the first place. *Id.* That threat is extremely palpable, as the recent decisions issued by the Vaccine Court in the OAP promise to unleash a barrage of claims in the courts. *See supra* at 20-21 n.4. Thus, adoption of petitioners' interpretation could drive vaccine manufacturers from the market and halt the future production and development of childhood vaccines in this country.

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[7] As this Court noted in *Riegal* v. *Medtronic, Inc.*, 552 U.S. 312, 325 (2008), with respect to medical devices, juries cannot be expected to conduct the cost-benefit analysis performed by expert regulators in balancing a device's safety and efficacy. "A jury * * * sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped the benefits are not represented in court." *Id.* That concern applies with even greater force with respect to vaccines, which benefit not only those who have been immunized but those who have not, and which thus directly benefit society at large. *See supra* at 13. In making recommendations for childhood vaccines, public officials and others have carefully "balance[d] scientific evidence of benefits for each person and to society against the potential costs and risks for vaccination for the individual and programs." *General Recommendations on Immunization*, *supra*, at 1.

In the Supreme Court of the United States

No. 09-152

RUSSELL BRUESEWITZ, ET AL., PETITIONERS

v.

WYETH, INC., FKA WYETH LABORATORIES, ET AL.

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

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING RESPONDENTS

INTEREST OF THE UNITED STATES

This case concerns the limitations that Congress placed on tort remedies in the National Childhood Vaccine Injury Act of 1986. The Secretary of Health and Human Services (Secretary or HHS) is responsible under the Act and other laws for promoting the development, supply, and widespread use of safe, pure, and potent vaccines, and is the respondent to petitions for compensation under the Act. At the Court's invitation, the United States filed an amicus brief at the petition stage in *American Home Products Corp.* v. *Ferrari*, petition for cert. pending, No. 08-1120 (filed Mar. 5, 2009), which presents the same question as this case.

STATEMENT

1. The National Childhood Vaccine Injury Act of 1986 (Vaccine Act or Act), Pub. L. No. 99-660, Tit. III, 100 Stat. 3755 (42 U.S.C. 300aa-1 *et seq.*), was enacted in response to "two overriding concerns": "the inadequacy —from both the perspective of vaccine-injured persons as well as vaccine manufacturers—of [a tort-based] approach to compensating those who have been damaged by a vaccine," and "the instability and unpredictability of the childhood vaccine market" due to vaccine manufacturers' fear of tort liability. H.R. Rep. No. 908, 99th Cong., 2d Sess. 7 (1986) (*1986 Report*). Accordingly, the Act is designed to encourage "development and distribution of vaccines that will further enhance the public health," and to compensate individuals injured by such vaccines by means other than tort law. *Ibid.*

The Act furthers the public health by, *inter alia*, establishing a National Vaccine Program in HHS, implemented through a comprehensive plan to fund and coordinate vaccine research, licensing, and distribution, and to encourage public acceptance of immunization. 42 U.S.C. 300aa-1 to 300aa-3. The National Vaccine Advisory Committee established under the Act conducts studies and offers advice on research priorities and other matters. 42 U.S.C. 300aa-5. The Act also advances the public health through the collection and dissemination of information about vaccines, including adverse events potentially related to vaccine administration, and through promoting the development of safer vaccines. 42 U.S.C. 300aa-25 to 300aa-28.

The National Vaccine Injury Compensation Program (Compensation Program) established by the Act pays "no-fault" monetary awards to individuals found to be injured by vaccines subject to the Act. The Compensa-

tion Program is secured by the Vaccine Injury Compensation Trust Fund (Trust Fund) which is supported by an excise tax on each vaccine dose. 42 U.S.C. 300aa-10 to 300aa-19; 26 U.S.C. 4131, 9510. The Compensation Program covers categories of vaccines that have been formally recommended for routine administration to children by the Centers for Disease Control and Prevention (CDC), 42 U.S.C. 300aa-14(e)(2) and (2)(A); vaccines in those categories are, almost universally (see note 6, *infra*), licensed by the Food and Drug Administration (FDA) as biological products, see Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.*; 42 U.S.C. 262; 21 C.F.R. Pts. 600-601.

To receive compensation for a vaccine-related injury or death, the injured party (or his legal representative) must file a petition in the Court of Federal Claims (CFC), naming the Secretary as respondent. 42 U.S.C. 300aa-11(a), 300aa-12(a) and (b). The claimant must show by a preponderance of the evidence that he received a vaccine listed on the Vaccine Injury Table (Table), 42 C.F.R. 100.3, and suffered a corresponding listed injury, or that a vaccine listed on the Table in fact caused or significantly aggravated any injury. 42 U.S.C. 300aa-11(c), 300aa-13(a). The claimant need not establish any defect in the vaccine, any fault by the manufacturer, or even the identity of the manufacturer.

A petition for compensation is initially heard by a special master, whose decision is reviewable by the CFC, and in turn by the Federal Circuit. 42 U.S.C. 300aa-12(c)-(f). Relative to the tens of millions of childhood vaccine doses administered annually, the number of petitions filed in the CFC is very small—reflecting the extraordinary safety of the covered vaccines. Since the first few years of the Compensation Program (which

saw several thousand claims for injuries that pre-dated the effective date of the Act), there typically have been 100 to 200 ordinary claims filed annually.[1] In the past decade, more than half of those claims have been compensated through settlement or a CFC decision, with an average award of approximately $836,000. See Health Res. & Servs. Admin., HHS, *National Vaccine Injury Compensation Program Post-1988 Statistics Report* (July 14, 2010) (*Statistics Report*) http://www.hrsa.gov/vaccinecompensation/docs/StatisticsReport.pdf. The CFC compensates for current and future medical costs; costs of rehabilitation, counseling, and special education; lost earning capacity; and pain and suffering. 42 U.S.C. 300aa-15(a). To ensure representation, the Compensation Program awards reasonable attorneys' fees and costs (including expert witness fees) even if there is no award to the claimant, provided the petition was brought in good faith and with a reasonable basis. 42 U.S.C. 300aa-15(e).

The Act forbids a claimant from immediately resorting to a civil action for damages against the vaccine's manufacturer. Rather, he must first file a petition under the no-fault scheme and seek a judgment from the CFC. 42 U.S.C. 300aa-11(a)(2)-(3). If the claimant elects to reject that judgment (and any award), or withdraws his petition after the special master or CFC fails to render a judgment within specified time periods, then

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[1] Not counted among these ordinary claims are more than 5600 petitions—about 5000 still pending—that assert a causal link between certain vaccines and autism spectrum disorders. Those cases have been consolidated before the CFC in the Omnibus Autism Proceeding (OAP). See U.S. Pet. Stage Amicus Br. at 4-5, *American Home Prods. Corp. v. Ferrari*, petition for cert. pending, No. 08-1120 (filed Mar. 5, 2009).

No. 09-152

IN THE

Supreme Court of the United States

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

v.

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

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

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QUESTION PRESENTED

Section 22(b)(1) of the National Childhood Vaccine Injury Act of 1986 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).

The question presented is:

Does Section 22(b)(1) preempt vaccine design-defect claims categorically, or must a vaccine manufacturer also show, case by case, that the side effects at issue could not have been avoided by some differently designed vaccine?

RULE 29.6 STATEMENT

Respondent Wyeth, Inc. is now known as Wyeth LLC. Wyeth LLC states that it has a parent corporation, Pfizer Inc., and that Pfizer Inc. owns 10% or more of Respondent's membership interests.

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Congress's concern that allowing design-defect claims against manufacturers would potentially jeopardize the vaccine supply is just as applicable today as it was in 1986. The number of vaccine manufacturers has not increased since then, and the threat that design-defect claims will be asserted against those few manufacturers continues to be substantial. Some 5,000 petitions alleging a supposed causal link between vaccines and childhood autism are currently pending in Vaccine Court. No scientific support for either of two causation theories has been found in any of the six autism test cases tried to date. Vaccine Court petitioners faced with such adverse results might well bring a crushing wave of state-law claims, including design-defect claims, if Section 22(b)(1) is interpreted not to preempt them.

Experience under the Vaccine Act since its enactment has shown that the Act has succeeded in accomplishing through regulatory means the incentive and compensation goals of the tort system. Over twenty new childhood vaccines have been brought to market since the effective date of the Act; adverse events are promptly reported to the government under the VAERS system; and over $1.8 billion in compensation has been awarded to petitioners by Vaccine Court. Thus, no policy consideration supports restricting the scope of the preemption provision that Congress enacted in 1986.

"disagree[d]" with any interpretation of the Act that would permit design-defect claims, explaining that Lederle "firmly believe[d] that this is exactly the opposite of what Congress intended." *Funding of the Childhood Vaccine Program: Hearing Before the Subcomm. on Select Revenue Measures of the H. Comm. on Ways and Means*, 100th Cong. 84-85 (1987).

In sum, the contemporaneous 1986 House Report, which offers the clearest and most authoritative guide to Congress's intent, confirms Congress's purpose to preempt all state-law claims against vaccine manufacturers other than manufacturing-defect and failure-to-warn claims. Petitioners may not rewrite that history by relying on an after-the-fact committee report or selective statements by Members or witnesses.

III. THE PURPOSE AND POLICY OF THE VACCINE ACT SUPPORT THE CATEGORICAL PREEMPTION OF DESIGN-DEFECT CLAIMS

Petitioners conclude their brief by arguing that their interpretation of Section 22(b)(1) serves Congress's purposes in enacting the Vaccine Act. These arguments are unpersuasive.

Petitioners first assert (Br. 52-54) that, without design-defect claims, manufacturers will lack sufficient incentive to develop new and improved vaccines. This assertion is not borne out by the development of new vaccines since the Act became effective. Over twenty new vaccines have been brought to market since enactment of the Vaccine Act in 1986. See *supra* at 28. This development cannot be attributed to potential tort liability for design-

may deter the claimant from bringing the civil action. But exhaustion affords manufacturers no reliable shield against having to litigate those claims where petitioners have no scientific basis for claiming causation; having lost in Vaccine Court, such petitioners have little to lose by forging ahead with a civil suit, however tenuous.

Finally, Petitioners speculate (Br. 59) that there is no real danger of vaccine manufacturers exiting the industry were design-defect claims allowed to be asserted in every case. This speculation, however, is belied by history. A deluge of cases alleging design-defect claims helped drive Wyeth Laboratories from the market in 1984. Congress was not willing to tolerate the risk that such events would recur, concluding that the "withdrawal of even a single [additional] manufacturer would present the very real possibility of vaccine shortages." 1986 House Report at 7.

The vaccine market today is subject to disruption just as it was in 1986, as there are still only one or two manufacturers for a majority of the vaccines listed on the routine childhood immunization schedule. See Food & Drug Administration, *Complete List of Vaccines Licensed for Immunization and Distribution in the US*, http://www.fda.gov/BiologicsBlood Vaccines/Vaccines/ApprovedProducts/ucm093833.htm (last modified June 3, 2010). If Section 22(b)(1) is interpreted to allow the assertion of design-defect claims, the threat to the vaccine supply from civil litigation would be at least as severe as in 1986. It is easy to *allege* that a vaccine causes a particular affliction (because nearly every child receives vaccines in the first six months of life, before most neurodevelopmental disorders first manifest) and

that some alternative vaccine design supposedly could have been employed.

For example, since 2001, over 350 civil actions (most involving design-defect claims) have been filed against vaccine manufacturers that allege that childhood vaccines caused the recipient to develop autism. Evans at S134. Another 5,000 petitions alleging neurological injury from childhood vaccines are currently pending in the "Omnibus Autism Proceeding" in Vaccine Court. See *National Vaccine Injury Compensation Program Statistics Report*, *supra*. Petitioners in these cases have the burden to prove causation because their claimed injuries are not on the Vaccine Injury Table—a circumstance that reflects the broad and deep scientific consensus outside of litigation that childhood vaccines do not cause autism.[29] Two different causation theories were presented in six test cases drawn from the omnibus proceeding, and, after full evidentiary hearings, Special Masters rejected both theories, in all six test cases, as scientifically unsupportable.[30] Were this Court to hold that the

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[29] *See* FDA, *Thimerosal in Vaccines*, http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/ucm096228.htm (last modified March 31, 2010); CDC, *Frequently Asked Questions About Thimerosal (Ethylmercury)*, http://www.cdc.gov/vaccinesafety/Concerns/Thimerosal/thimerosal_faqs.html#6 (last modified Feb. 17, 2010); Immunization Safety Review Committee, Board on Health Promotion and Disease Prevention, Institute of Medicine, *Immunization Safety Review: Vaccines and Autism* 7 (2004).

[30] Regarding the first theory (that Measles Mumps Rubella vaccine combined with other vaccines that contain the preservative thimerosal supposedly causes autism), see *Hazlehurst* v. *Sec'y of HHS*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Feb. 12, 2009), sustained, 88 Fed. Cl. 473 (2009), *aff'd*, 604 F.3d 1343 (Fed. Cir. 2010); *Cedillo* v. *Sec'y of HHS*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Feb. 12, 2009), sustained, 89 Fed. Cl. 158

Vaccine Act does not preempt design-defect claims, claimants in the omnibus proceeding could be emboldened to pursue a flood of civil actions.

As the American Academy of Pediatrics has explained, the consequences of such litigation for the vaccine supply (and ultimately for public health) could be devastating. See Brief *Amici Curiae* Of The American Academy Of Pediatrics *et al.* In Support Of Petitioners, *Am. Home Prods. Corp.* v. *Ferrari*, No. 08-1120 (Apr. 8, 2009), at 7. Thus, the purpose and policy of the Vaccine Act, like its text, structure and legislative history, support an interpretation of Section 22(b)(1) that precludes state-law design-defect claims categorically.

(2009), appeal docketed, No. 10-5004 (Fed. Cir. argued June 10, 2010); *Snyder* v. *Sec'y of HHS*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Feb. 12, 2009), sustained, 88 Fed. Cl. 706 (2009).

Regarding the second theory (that thimerosal by itself causes autism), see *Dwyer* v. *Sec'y of HHS*, No. 03-1202V, 2010 WL 892250 (Fed. Cl. Mar. 12, 2010); *King* v. *Sec'y of HHS*, No. 03-584V, 2010 WL 892296 (Fed. Cl. Mar. 12, 2010); *Mead* v. *Sec'y of HHS*, No. 03-215V, 2010 WL 892248 (Fed. Cl. Mar. 12, 2010).

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted,

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July 23, 2010

No. 09-152

In the
Supreme Court of the United States

RUSSELL BRUESEWITZ, ET AL.

Petitioners,

v.

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

Respondent.

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

BRIEF OF GLAXOSMITHKLINE LLC, MERCK SHARP & DOHME CORP. (FORMERLY KNOWN AS MERCK & CO., INC.), AND SANOFI PASTEUR INC. AS *AMICI CURIAE* IN SUPPORT OF RESPONDENT

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2005, at A1 (modified vaccine developed in Germany "essentially trades potency for safety").

Petitioners nonetheless argue, as a policy matter, that vaccine companies *should* be subject to vaccine-related injury claims whenever plaintiffs can claim that another vaccine design is allegedly safer than the one approved by FDA. In their view, subjecting vaccine companies to state tort liability would "incentiviz[e] manufacturers to design vaccines to prevent avoidable side effects." Pet. Br. at 51.

In reality, history has exposed the fragility of the vaccine industry and the attendant dangers of that instability. Petitioners' proposal to alter the status quo that has prevailed for nearly 25 years would ignore that history. Vaccine companies would face the new burden of defending against speculative allegations that safer alternatives were available in courts across the country. And vaccine companies would find themselves facing the real possibility that state courts would find that they ought to have distributed a vaccine that the FDA did not — and would not — license.

B. The Thimerosal Litigation Confirms That The Risk of Substantial Litigation Is Far From Hypothetical.

The state of thimerosal litigation, which gave rise to the related petition for certiorari in *American Home Products Corporation v. Ferrari* (No. 08-1120), amply demonstrates that litigation fears in this case are real. Thimerosal was developed in the late 1920s as a preservative to

prevent the growth of potentially life-threatening microbial contaminants in vaccines, such as bacteria and fungi, and was used extensively from 1930 on. It prevents serious adverse effects such as the staphylococcus infection that killed 12 of 21 children inoculated with a diphtheria vaccine that lacked a preservative in 1928. Unlike other vaccine preservatives used at the time, thimerosal does not tend to reduce the potency of the vaccines that it protects. *See* Jeffrey P. Baker, *Mercury, Vaccines, and Autism*, Am. J. Pub. Health vol. 98(2), at 244-53 (2008).

Allegations linking thimerosal to the onset of autism erupted in the early 2000s. Every government public health agency and reputable scientific body to address the question has rejected the hypothesis that thimerosal-containing pediatric vaccines ever caused or contributed to autism. These include the Institute of Medicine of the National Academy of Sciences, the World Health Organization, the U.S. Centers for Disease Control and Prevention, the American Academy of Pediatrics, the U.K. Committee on the Safety of Medicines, and the European Agency for the Evaluation of Medicinal Products.[2] As of 2008, at

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[2] *See, e.g.*, Immunization Safety Review Committee, Institute of Medicine, *Immunization Safety Review: Vaccines and Autism* (2004); WHO, *Statement on Thiomersal* (Aug. 2003), http://www.who.int/vaccine_safety/topics/thiomersal/statement200308/en/print.html; WHO, *Position of the Global Advisory Committee on Vaccine Safety regarding concerns raised by recent paper about the safety of thiomersal-containing vaccines* (May 2003), http://www.who.int/vaccine_safety/topics/thiomersal/statement/en/print.html; European Agency for the

least eight major studies had examined the effect of reductions or removal of thimerosal as a preservative from vaccines, and all demonstrated that autism rates failed to decline despite the removal of thimerosal. The most notable scientific analysis of the literature, undertaken by a panel of world-renowned experts appointed by the Institute of Medicine, decisively concluded that "the evidence favors rejection of a causal relationship between thimerosal-containing vaccines and autism." *Immunization Safety Review*, at 7.

Nonetheless, between 1999 and 2009, *5,600* claims relating to autism were filed in the Vaccine Court. *See* Health Resources & Services Administration, *National Vaccine Injury Compensation Program Statistics Report* (July 14, 2010) ("*Statistics Report*"), http://www.hrsa.gov/vaccinecompensation/statistics_report.htm. Of that figure, approximately 718 cases have been concluded without compensation, with the vast

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Evaluation of Medicinal Products, *Public Statement on Thiomersal in Vaccines for Human Use* (Mar. 2004), www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500003904; U.K. Committee on Safety of Medicines, *Further Data Support Safety of Thiomersal in Vaccines* (Feb. 2003), http://www.mhra.gov.uk/Safetyinformation/Safetywarningsalertsandrecalls/Safetywarningsandmessagesformedicines/CON2015721; CDC, *Thimerosal & Vaccines*, http://www.cdc.gov/flu/about/qa/thimerosal.htm; American Academy of Pediatrics, *What Parents Should Know About Thimerosal*, *available at* http://www.aap.org/immunization/families/ingredients.html#thimerosal; American Academy of Pediatrics, *Study Fails To Show A Connection Between Thimerosal And Autism* (2003).

majority of remaining cases pending. *Id.* In February 2009, the Vaccine Court issued opinions in three test cases finding that there was no proof of causation supporting the claimants' theory that a combination of thimerosal with the MMR vaccine could cause autism.[3] In March 2010, the Vaccine Court ruled in another three test cases that thimerosal-containing vaccines do not cause autism.[4]

Approximately 5,000 claims, however, are still pending in the Omnibus Autism Proceeding before the Vaccine Court. *See Statistics Report*; *accord* U.S. Br. in *Am. Home Prods. Corp. v. Ferrari*, No. 08-1120 (U.S. Mar. 5, 2009), at 5, 17. Over 350 civil actions have been filed against vaccine manufacturers in various courts across the country alleging that childhood vaccines cause autism. And in October 2008, in *American Home Products Corporation v. Ferrari,* the Georgia Supreme Court construed the preemptive scope of the Vaccine Act

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[3] *See Cedillo v. Sec'y of Health & Human Servs.*, No. 98-916V, 2009 WL 331968, at *9-11 n.16 (Fed. Cl. Feb. 12, 2009), *aff'd*, 89 Fed. Cl. 158 (2009); *Hazlehurst v. Sec'y of Health & Human Servs.*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 473 (2009), *aff'd*, 603 F.3d 1343 (Fed. Cir. 2010); *Snyder v. Sec'y of Health & Human Servs.*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 706 (2009).

[4] *See Mead ex rel. Mead v. Sec'y of Health & Human Servs.*, No. 03-215V, 2010 WL 892248 (Fed. Cl. Mar. 12, 2010); *King ex rel. King v. Sec'y of Health & Human Servs.*, No. 03-548V, 2010 WL 892296 (Fed. Cl. Mar. 12, 2010); *Dwyer ex rel. Dwyer v. Sec'y of Health & Human Servs.*, No. 03-1202V, 2010 WL 892250 (Fed. Cl. Mar. 12, 2010).

narrowly and paved the way for a suit against manufacturers alleging that a child suffered neurological injuries from exposure to FDA-approved vaccines containing thimerosal.

As the thimerosal litigation demonstrates, the possibility of potentially destabilizing litigation is not a mere matter of speculation should the Court reject preemption. The potential flood sits behind a temporary dam in the Vaccine Court — and the consequence of construing § 22(b)(1) not to preempt such claims would be dramatic. The scientific community has uniformly rejected these claims. But that will not prevent the thousands of claimants who have already filed in Vaccine Court (and the others who have already filed in court) from seeking a contrary conclusion from a jury. The costs of fighting these suits, even if none results in a finding of liability, would be daunting for an industry Congress sought to preserve and foster.

The thimerosal story highlights the particular susceptibility of vaccine companies to tort suits — regardless of their scientific merits — simply because a wide variety of illnesses happen to manifest themselves in early childhood at the time when children are vaccinated. *See* FDA, *VAERS Overview*, http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/VaccineAdverseEvents/Overview/default.htm. While some of those suits may be brought under manufacturing defect or failure-to-warn theories, history teaches that design-defect claims — that invite juries to reconsider whether a vaccine should

ever have been approved by regulatory authorities — pose the greatest threat to the industry's viability. Unleashing design-defect claims attacking, for example, the use of thimerosal despite the lack of any reliable scientific evidence for such claims, would hardly incentivize vaccine manufacturers to produce safer products. Rather, it would risk the needless withdrawal of safe and effective products from the marketplace and could bury vaccine companies in ever-greater litigation costs.

III. CONGRESS SUBJECTED VACCINE DESIGN TO A DETAILED FEDERAL REGULATORY SCHEME THAT IS ILL-SERVED BY STATE TORT CLAIMS.

Petitioners strain to downplay federal regulation of vaccines and to brandish design-defect liability as the solution to some purported regulatory gap. *See* Pet. Br. at 27, 54-56. But petitioners' portrayal of vaccine regulation as lax and deficient does not square with reality. The federal regulatory scheme governing vaccines is almost unparalleled in its detail and depth.

Precisely because vaccines have been "one of the most spectacularly effective public health initiatives this country has ever undertaken," H.R. Rep. No. 99-908, at 4, the government has made safe vaccines a critical priority. The CDC is the single largest purchaser and distributor of vaccines in the United States. *See* IOM Report, at 119. The National Institutes of Health ("NIH") fund one-third of all vaccine research funding. *Id.* And FDA oversees a comprehensive regulatory process