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 FOR RESPONDENT

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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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## BRIEF FOR RESPONDENT

## INTRODUCTION

"Vaccination of children against deadly, disabling, but preventable infectious diseases has been one of the most spectacularly effective public health initiatives this country has ever undertaken." H.R. REP. NO. 99-908, pt. 1, at 4 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6345 ("1986 House Report"). For example, between 1934 and 1984, diphtheria, tetanus and pertussis ("DTP") vaccines helped reduce re-

ported cases of pertussis (commonly known as "whooping cough") by 99%. See STAFF OF SUBCOMM. ON HEALTH AND THE ENVIRONMENT, 99th Cong., CHILDHOOD IMMUNIZATIONS 10 (Comm. Print 1986) ("Subcomm. Report"). Inadequate vaccination can lead to sudden outbreaks of infectious but preventable disease, as a recent epidemic of whooping cough that has killed at least five infants in California tragically illustrates.[1]

Petitioners' account of the origins of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. 300aa-1 *et seq.* (the "Vaccine Act"), hardly mentions the spectacular success of childhood vaccination in protecting public health. Nor do Petitioners explain that Congress had *two* goals in enacting the Vaccine Act. One goal, to be sure, was to provide a streamlined and generous administrative compensation scheme for those few children who suffer rare side effects from vaccines. The other goal, which Petitioners barely acknowledge, was to ensure the continued supply of essential childhood vaccines by reducing the burden of civil litigation that had driven a number of vaccine manufacturers from the market, threatening the nation's vaccine supply. See Brief For The United States As *Amicus Curiae*, *Am. Home Prods. Corp.* v. *Ferrari*, No. 08-1120 (Jan. 29, 2010) ("U.S. *Ferrari* Br."), at 2.

An important means of serving the latter goal is the preemption provision of the Vaccine Act, Section 22(b)(1). This provision bars state-law tort liability

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[1] *See* Molly Hennessy-Fiske, *Whooping Cough Fight Broadens,* L.A. TIMES, July 20, 2010, at AA; Jesse McKinley, *Whooping Cough Kills 5 in California; State Declares an Epidemic*, N.Y. TIMES, June 24, 2010, at A15.

against manufacturers of childhood vaccines for all possible claims but two, manufacturing defect and failure to warn:

> 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). By enacting Section 22(b)(1), Congress sought to prevent future threats to the nation's vaccine supply by precluding any recurrent wave of state-law litigation against vaccine manufacturers like the one that had helped prompt enactment of the Vaccine Act.

Other provisions of the Vaccine Act ensure that the safety and efficacy of vaccine design is governed by a comprehensive national regulatory scheme rather than a patchwork of state tort laws. The Act provides for active federal encouragement and funding of vaccine research, 42 U.S.C. 300aa-19, 300aa-27, and for active federal oversight of vaccine development and safety beyond that provided by the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq*. Before approval, vaccines undergo comprehensive clinical trials, and after approval, they are actively monitored for adverse events. Once a vaccine is licensed, its design may not be altered without the prior approval of the Food and Drug Administration ("FDA"). 21 C.F.R. 601.12(b)(2)(i).

Having barred all state-law claims other than manufacturing-defect and failure-to-warn claims, the

Vaccine Act provides for a generous administrative compensation scheme for vaccine-related injuries or deaths, funded by an excise tax on vaccines. Claimants under this scheme need not prove fault; they need show only that they received a vaccine listed in the federal "Vaccine Injury Table" and sustained an injury specified in the Table within the time periods specified in the Table, or prove that a listed vaccine caused an injury. 42 U.S.C. 300aa-11(c)(1)(C). Successful claimants may recover *uncapped* medical expenses, medical care and projected lost earnings, and up to $250,000 for pain and suffering, *id.* 300aa-15(a), and claimants may recover attorney's fees and costs whether or not they receive compensation, *id.* 300aa-15(e). The compensation scheme has awarded to date over ***$1.8 billion***.

Petitioners would rewrite the text and ignore the structure of the Vaccine Act to render Section 22(b)(1) a nullity. In Petitioners' view, vaccine manufacturers must litigate case by case whether they could have sold some alternative vaccine, allegedly safer than the vaccine that was administered to the plaintiff. Preemption, in Petitioners' view, is available only after a manufacturer has gone through a full trial and proved that no differently designed vaccine would have avoided the injury. Thus, in Petitioners' view, the express preclusion of liability in Section 22(b)(1) changed nothing: vaccine injury claimants remain as free after the Act's passage as before to bring all manner of state-law tort claims challenging vaccine safety, with the federal no-fault compensation scheme merely a checkpoint en route to civil litigation under state law.

The Third Circuit properly rejected this misreading of Section 22(b)(1), finding that this provision

categorically preempts state design-defect claims. Accord, U.S. *Ferrari* Br. 9. That interpretation was correct, and the judgment below should be affirmed.

## STATEMENT

### A. The Nature And Role Of Vaccines

Vaccines have "changed humanity" by enabling the near eradication of numerous infectious diseases. National Vaccine Program Office, *Draft Strategic National Vaccine Plan*, at 25 (Nov. 26, 2008), available at www.hhs.gov/nvpo/vacc_plan/2008plan/draftvaccineplan.pdf (last visited July 21, 2010). The necessary predicate for this success is the almost universal vaccination of children, which promotes "herd immunity" and thus reduces the spread of contagious disease even to those who are unimmunized or incompletely immunized. Smallpox and polio have been entirely eradicated in the United States, while the incidence of other diseases has been radically reduced. Centers for Disease Control and Prevention, *Ten Great Public Health Achievements—United States, 1900-1999*, 48 MMWR 241 (Apr. 2, 1999).

Vaccines differ from most drugs in that they are biological products, not precise chemical compounds, and thus some variation is inherent in their production. As the Task Force on Safer Childhood Vaccines, established by the Secretary of Health and Human Services ("HHS") under the Act, has observed, "[s]afety is not a condition that can be absolutely guaranteed" with vaccines. National Institute of Allergy and Infectious Diseases, Task Force on Safer Childhood Vaccines, *Final Report and Recommendations*, at 2 (1998). Vaccines also differ from drugs in that they are administered broadly to a

healthy population. *Ibid.* For these reasons, vaccines are subject to closer federal monitoring than are drugs.

### B. The Genesis Of The Vaccine Act

Protecting public health through the successful vaccination of the population depends upon maintaining a robust and stable supply of vaccines. In enacting the Vaccine Act, Congress recognized and sought to avert the threat to the vaccine supply posed by escalating litigation against vaccine manufacturers. See 1986 House Report at 4-5; see also Charles F. Hagan, *Vaccine Compensation Schemes*, 45 FOOD DRUG COSM. L.J. 477, 479 (1990) ("The increasing liability exposure of childhood vaccine manufacturers has been a significant factor in the decline in the number of these manufacturers.").

In the early 1980s, only a handful of manufacturers produced childhood vaccines. See Subcomm. Report at 85. By 1984, for example, only three commercial companies supplied DTP vaccine for the U.S. market: Lederle Laboratories,[2] Connaught Laboratories, Inc., and Wyeth Laboratories. *Id.* at 67-68. While only eight lawsuits were filed against DTP manufacturers from 1979 through 1981, see Geoffrey Evans, *Update on Vaccine Liability in the United States*, 42 CLINICAL INFECTIOUS DISEASES S130, S134 (2006) ("Evans"), the number of such lawsuits skyrocketed after the 1982 broadcast of "DPT: Vaccine Roulette," a report that alleged dangers from DTP vaccines, see Committee to Review the Adverse Consequences of Pertussis

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[2] Lederle manufactured the TRI-IMMUNOL® vaccine at issue here. In 1994, Wyeth Laboratories' parent company, American Home Products Corporation, acquired Lederle's parent company, American Cyanamid Company. J.A. 132.

and Rubella Vaccines, Division of Health Promotion and Disease Prevention, Institute of Medicine, *Adverse Effects of Pertussis and Rubella Vaccines* 19 (Christopher P. Howson *et al.* eds., 1991).

This escalating wave of litigation imposed crushing litigation costs on vaccine manufacturers and carried the potential for large judgments. See Subcomm. Report at 87; 1986 House Report at 6. In 1985 alone, 219 lawsuits were filed against the three DTP manufacturers. See Evans at S134. Overall, from 1980 to 1986, lawsuits filed against vaccine manufacturers sought more than $3.5 billion in damages. See Derry Ridgway, *No-Fault Vaccine Insurance: Lessons From The National Vaccine Injury Compensation Program*, 24 J. HEALTH POL. POL'Y & L. 59, 60-61 (1999). In 1984, Lederle estimated that its potential liability from DTP vaccine lawsuits was 200 times its annual sales for the vaccine. Subcomm. Report at 69. Such potential liability made it difficult for vaccine manufacturers to obtain affordable product liability insurance. 1986 House Report at 6-7.

Many claims alleged that DTP vaccines, by virtue of their design, were unreasonably dangerous and thus defective products. Congress heard testimony that the plaintiffs in these cases "routinely … contend that the vaccines [manufacturers] sell are not as good as some alternative product, even though our vaccines have been approved by the Government as safe and effective and even though their use is recommended by all responsible medical authorities." *Vaccine Injury Compensation: Hearing on H.R. 1780, H.R. 4777, and H.R. 5184 Before the Subcomm. on Health and the Environment of the H. Comm. on Energy and Commerce*, 99th Cong. 238 (1986) ("1986

Hearing") (statement of Robert B. Johnson, President, Lederle Labs. Div., Am. Cyanamid Co.).

The DTP vaccine litigation crisis caused manufacturers to consider abandoning the vaccine market, putting the supply of essential childhood vaccines at risk in the United States. In late 1984, Connaught and Wyeth Laboratories withdrew from the market. Subcomm. Report at 68.[3] That same year, Lederle, the one remaining manufacturer, experienced production problems. *Id.* at 69.

In considering the Vaccine Act, Congress found that "[t]he number of childhood vaccine manufacturers [had] declined significantly," 1986 House Report at 4, while the few that remained had begun "to question their continued participation in the vaccine market," *id.* at 7. This "unstable and unpredictable childhood vaccine market," *id.* at 5, led to "a short term crisis of availability of DTP vaccine," Subcomm. Report at 68. The shortage became so dire that the Centers for Disease Control and Prevention ("CDC") recommended stretching out the vaccination schedule, even at the cost of diluting children's protection. *Id.* at 69. Congress recognized that the "withdrawal of even a single [additional] manufacturer would present the very real possibility of vaccine shortages, and, in turn, increasing numbers of unimmunized children, and, perhaps, a resurgence of preventable diseases." 1986 House Report at 7.

In addition to considering the threat that civil litigation posed to the vaccine supply, the 99th Congress also considered the concerns of individuals

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[3] Connaught returned to the market in 1985 after obtaining liability insurance coverage for its vaccines. Subcomm. Report at 69-70.

claiming they (or their children) had been injured by vaccines. Congress heard testimony that the tort system was failing to compensate vaccine-related injuries adequately and that the cost of litigation was high and recoveries uncertain and often delayed. See 1986 House Report at 6.

### C. The Vaccine Act

In 1986, Congress enacted the Vaccine Act to respond to both the need to protect the public health by preserving a stable vaccine supply and the desire to find a more effective means than the civil tort system to compensate victims of vaccine-related injuries. In order to avert state tort litigation that might drive vaccine manufacturers from the market, Congress precluded all state-law civil tort liability other than for claims of manufacturing defect and some limited failures to warn. To promote the development and manufacture of even safer and more efficacious vaccines, Congress established a National Vaccine Program providing for comprehensive government involvement in the development, approval, and monitoring of vaccines. And in order to provide swift and reliable compensation to the few who suffer adverse side effects from vaccination, Congress established a generous no-fault administrative compensation system. The Act's preemption and compensation provisions apply solely to the twelve categories of vaccines that are routinely administered to children.[4]

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[4] The twelve currently covered categories of childhood vaccines are listed on the Vaccine Injury Table. 42 C.F.R. 100.3(a). To be listed on the Table, a category of vaccine must be "recommended for routine administration to children" by the CDC, 42 U.S.C. 300aa-14(e)(2), and Congress must fund awards by subjecting that category to the excise tax, Omnibus Budget Recon-

### 1. The Preemption Provision

Section 22(a) of the Vaccine Act provides that "State law shall apply to a civil action brought for damages for a vaccine-related injury or death," except "as provided in subsections (b), (c) and (e) of this section." 42 U.S.C. 300aa-22(a). Section 22(b)(1), immediately following, specifies such limits on state-law civil tort liability:

> 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.

*Id.* 300aa-22(b)(1). Section 22(b)(1) thus bars all civil tort liability against the manufacturers of childhood vaccines covered by the Act provided that the vaccine is "properly prepared" (*i.e.*, made according to its formula) and "accompanied by proper directions and warnings."

Section 22(b)(2) further provides that "a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act and section 262 of this title (including regulations issued under such provisions)," unless a manufacturer engaged in fraud or withheld material information from FDA in obtaining and maintaining

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ciliation Act of 1993, Pub. L. No. 103-66, § 13632(a)(3), 107 Stat. 312, 646 (1993).

approval of the vaccine. 42 U.S.C. 300aa-22(b)(2); see also *id.* 300aa-23(d)(2)(A)-(B).

Section 22(e), an additional preemption provision, makes clear that the federal Act strikes the appropriate balance by limiting the States' ability to go further than the Act itself in eliminating civil liability against vaccine manufacturers. This section provides that "[n]o State may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this part." 42 U.S.C. 300aa-22(e).

### 2. The Development, Approval, And Monitoring Scheme

Childhood vaccines are subject to rigorous and comprehensive regulation under the Federal Food, Drug, and Cosmetic Act. See 21 U.S.C. 301 *et seq.*; 42 U.S.C. 262(a). The Vaccine Act supplements FDA's approval and supervision regime by directing multiple federal agencies to assist industry in promoting research into safer and more efficacious vaccines. See U.S. *Ferrari* Br. 14-15.

*Federal Food, Drug, and Cosmetic Act and regulations*. An applicant for a biologics license must provide extensive information to FDA's Center for Biologics Evaluation and Research ("CBER"), including data on laboratory and clinical studies,[5]

[5] Because vaccines are administered to healthy individuals, clinical trials for vaccines typically require many more study participants than clinical trials for other drugs. Compare Norman W. Baylor & Karen Midthun, *Regulation and testing of vaccines*, in VACCINES 1611, 1617 (Stanley A. Plotkin, *et al*. eds., 5th ed. 2008) (the number of study participants in recent vac-

manufacturing methods, product samples, proposed labels, and addresses of all manufacturing facilities. 21 C.F.R. 601.2. An applicant for a biologics license also must allow CBER to perform an in-depth inspection of the facility and the vaccine manufacturing process to assure compliance with all applicable federal standards. *Id.* 601.20. If, after the clinical trial and related review, FDA determines that the product "meet[s] the applicable requirements," a license "shall be issued" and "shall be valid until suspended or revoked." *Id.* 601.4(a).

To be released, each lot of vaccine must pass safety, sterility, purity, and identity tests. See 21 C.F.R. 610.11, 610.12, 610.13, 610.14; see also J.A. 87-90 (describing the testing process at the time the lot of TRI-IMMUNOL® at issue in this case was released). If FDA determines that a batch, lot, or other quantity of released vaccine presents an imminent or substantial hazard to the public health, the Secretary of HHS must issue an immediate order recalling the product. 42 U.S.C. 262(d)(1). An approved vaccine that is later considered by FDA to have an unsafe design may be removed from the market. 21 C.F.R. 601.5(b)(1)(vi).

Once a vaccine has been approved for distribution, any change to the "qualitative or quantitative formulation" of a vaccine—including a design change—requires re-submission to and re-approval by FDA prior to distribution. 21 C.F.R. 601.12(b)(2)(i). Con-

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cine efficacy trials has ranged from thousands to tens of thousands) with 21 C.F.R. 312.21(c) (describing prescription drug clinical trials as usually including several hundred to several thousand subjects). See also U.S. *Ferrari* Br. 14 ("New childhood vaccines … are put through some of the most exhaustive and largest clinical trials of any FDA-approved product.").

trary to Petitioners' suggestion (Br. 7-8), vaccine manufacturers are *not* free to change the design of a vaccine without prior approval by the government. Regulations allow certain minor changes without pre-approval, see 21 C.F.R. 601.12(c), (d), but design changes are not among them.

Following issuance of a license, the license-holder is obligated to review and to regularly report all adverse experiences reported by users of the product or any member of the public. 21 C.F.R. 600.80. Failure either to make regular reports or to keep records may result in revocation of the license. *Id.* 600.80(j). In addition to the reporting requirements for manufacturers, healthcare providers that administer a vaccine on the Vaccine Injury Table are required by law to report the occurrence of an injury listed on that Table. 42 U.S.C. 300aa-25(b)(1).

To facilitate this reporting scheme, CDC and FDA co-sponsor the Vaccine Adverse Event Reporting System ("VAERS"), a national vaccine safety surveillance program that acts as a central repository for reports of adverse events that occur following vaccination. See 21 C.F.R. 600.2(d), 600.80(c); see also http://vaers.hhs.gov (last visited July 21, 2010). VAERS is used "to detect possible signals of adverse events associated with vaccines."[6] Such "signals" are often used to generate a hypothesis that requires further study. Inter-Agency Vaccine Group, *A Comprehensive Review of Federal Vaccine Safety Programs and Public Health Activities* 18 (Dec. 2008) ("Comprehensive Review"), available at http://www.

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[6] FDA, *Vaccine Adverse Events*, http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/VaccineAdverseEvents/default.htm (last modified Oct. 19, 2009).

hhs.gov/nvpo/nvac/subgroups/vaccinesafety.html#vaccine (last visited July 21, 2010). The Vaccine Safety Datalink ("VSD"), "a collaborative effort between the CDC's Immunization Safety Office and eight managed care organizations,"[7] is an active surveillance system of vaccine-related adverse events that is an "extremely powerful tool to test hypotheses regarding the association of vaccines and health outcomes." Comprehensive Review at 19. VSD "serves an important role in the nation's vaccine safety system by providing the infrastructure for carefully designed epidemiological studies." *Ibid.* There is no VSD counterpart for drugs.

*The Vaccine Act.* The Vaccine Act supplements FDA's extensive regulatory regime, aiming "to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines." 42 U.S.C. 300aa-1; see also *id*. 300aa-2(9), 300aa-6 (providing funding for this effort). As Petitioners neglect to mention (Br. 7 & nn.3-4), the Act creates a National Vaccine Program ("NVP") that enlists a dozen federal agencies (including FDA) to promote the development of improved, safer vaccines for use in immunization programs nationwide. 42 U.S.C. 300aa-27(a)(1).

Additionally, the Vaccine Act adopts a "[m]andate for safer childhood vaccines" and assigns responsibility for that mandate to the Secretary of HHS. 42 U.S.C. 300aa-27. The Secretary is directed to "promote the development of childhood vaccines that

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[7] CDC, *Vaccine Safety Datalink (VSD) Project*, http://www.cdc.gov/vaccinesafety/Activities/vsd.html (last modified Feb. 17, 2010).

result in fewer and less serious adverse reactions" than those on the market at the time, and to "promote the refinement of such vaccines." *Id.* 300aa-27(a)(1). The Secretary is also charged with "mak[ing] or assur[ing] improvements in … the licensing, manufacturing, processing, testing, labeling, warning, use instructions … and research on vaccines, in order to reduce the risks of adverse reactions to vaccines." *Id.* 300aa-27(a)(2); see also *id.* 300aa-27(b) (the Secretary shall "establish a task force on safer childhood vaccines" to make recommendations on vaccine safety and effectiveness). A civil action may be filed against the Secretary for failure to fulfill this role. *Id.* 300aa-31.

Non-governmental perspectives are brought into the process through the National Vaccine Advisory Committee ("NVAC"), 42 U.S.C. 300aa-5, and the Advisory Commission on Childhood Vaccines ("ACCV"), *id.* 300aa-19. These two bodies, which have medical and lay members, are charged with advising HHS and making recommendations to the NVP Director about the implementation of his responsibilities under the Vaccine Act. For example, NVAC is charged with "recommend[ing] research priorities and other measures the Director … should take to enhance the safety and efficacy of vaccines." *Id.* 300aa-5(b)(2). The NVAC and ACCV also are part of the task force on safer childhood vaccines called for by Section 27(b) of the Act. *Id.* 300aa-27(b).

Since the Act became effective, more than 20 childhood vaccines, including new vaccines against pneumococcal disease, meningococcal disease, hepatitis A, and varicella (chickenpox), have obtained FDA approval and been brought to market. See generally FDA, *Vaccines Licensed for Immunization and*

*Distribution in the US With Supporting Documents*, http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093830.htm (last modified June 3, 2010); Immunization Safety Review Committee, Board on Health Promotion and Disease Prevention, Institute of Medicine, *Immunization Safety Review: Vaccines and Autism* 188-90 (2004).

### 3. The Compensation Scheme

The Vaccine Act offsets Section 22(b)(1)'s preclusion of all civil claims other than manufacturing defect and failure to warn by "establish[ing] a scheme of recovery designed to work faster and with greater ease than the civil tort system." *Shalala* v. *Whitecotton*, 514 U.S. 268, 269 (1995). This compensation program, implemented through the Office of Special Masters within the United States Court of Federal Claims known as "Vaccine Court," 42 U.S.C. 300aa-12(c), (d), provides generous no-fault compensation for vaccine-related injury claims.

A claim for vaccine-related injury is asserted by filing a petition in Vaccine Court. 42 U.S.C. 300aa-11(a). The Vaccine Act provides for the creation, and regular update, of the Vaccine Injury Table, which lists symptoms and injuries that medical research has found associated with a covered vaccine. *Id.* 300aa-14. The Table "turns the old maxim on its head by providing that if the *post hoc* event happens fast, *ergo propter hoc*." *Whitecotton*, 514 U.S. at 270. A petitioner who proves that he or she received a listed vaccine and suffered symptoms set forth on the Table has made a *prima facie* case for recovery and need not prove causation; the presumption of causation is rebutted only if HHS demonstrates by a preponderance of the evidence that the injury was

not vaccine-related. 42 U.S.C. 300aa-13(a)(1); *White-cotton*, 514 U.S. at 270-71.

A petitioner claiming a Table injury need not prove that the vaccine was defective in any way. 42 U.S.C. 300aa-11(c)(1)(C)(i), 300aa-13(a). For a non-Table injury, a petitioner must show causation, but again, need not show any defect in the vaccine or misconduct by the manufacturer. *Id.* 300aa-11(c)(1)(C)(ii). Congress recognized that the no-fault compensation program would provide a remedy for some vaccine-related injuries that would not succeed under state tort law. See 1986 House Report at 13 ("because of many States' standards of proof of liability, many vaccine-injured persons are presently without legal remedy under current tort law").[8]

A Vaccine Court petitioner who establishes a vaccine-related injury is entitled to compensation for all medical expenses, remedial care, rehabilitation, counseling, long-term care, projected lost earnings, and up to $250,000 for pain and suffering. 42 U.S.C. 300aa-15(a). To ensure access to the compensation program, Vaccine Court awards attorney's fees and costs to the petitioner, whether or not any compensation is awarded. *Id.* 300aa-15(e). Payments of compensation, fees, and costs to petitioners are funded by an excise tax on vaccines. 26 U.S.C. 9510.

In just two decades, Vaccine Court has awarded more than $1.8 billion to nearly 2,500 petitioners, resulting in an average award exceeding $750,000. Health Resources and Services Administration, *National Vaccine Injury Compensation Program Sta-*

[8] Congress acknowledged that use of the Table would result in awarding compensation "to some children whose illness is not, in fact, vaccine-related." 1986 House Report at 18.

*tistics Report* (July 14, 2010), http://www.hrsa.gov/vaccinecompensation/statistics_report.htm (last visited July 21, 2010).

### D. Pertussis And Pertussis Vaccines

The vaccine at issue in this case, TRI-IMMUNOL®, contributed to a dramatic decrease in illness and death from pertussis—a highly communicable respiratory disease that is especially dangerous to children under two years old and can leave survivors with severe neurologic disorders. Subcomm. Report at 8-10. In 1934, there were 265,269 reported cases of pertussis and 7,518 deaths in the United States. *Id.* at 10. TRI-IMMUNOL® was approved for marketing in the United States on April 27, 1943. J.A. 134, ¶ 11.[9] After forty years of widespread use of TRI-IMMUNOL® and other DTP vaccines, the incidence of pertussis dropped to 2,276 reported cases and only twelve deaths by 1984. Subcomm. Report at 10.

TRI-IMMUNOL® is composed of diphtheria and tetanus toxoids and a "whole-cell" pertussis vaccine component; its pertussis component employs a suspension of whole, killed pertussis cells to stimulate an immune response. J.A. 85, ¶ 7.[10] A handful of

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[9] Following the initial approval, Lederle submitted modified license applications resulting from changes to applicable regulations or updated manufacturing procedures in 1948, 1953, and 1970. J.A. 134-35, ¶¶ 12-16.

[10] The pathogens used in whole-cell DTP vaccines are neither "potent" nor "deadly" as Petitioners assert (Br. 3), but rather are killed during the manufacturing process. The resulting vaccine is safe to the recipient, while conferring immunity against disease. See generally American Academy of Pediatrics, *Questions and Answers about Vaccine Ingredients* (Oct. 2008), http://www.aap.org/immunization/families/faq/Vaccineingredients.pdf (last visited July 21, 2010).

reports in the 1940s and 1950s (see Pet. Br. 17 n.12) raised questions whether the vaccine had caused severe adverse reactions to a few recipients, but these concerns proved illusory.[11] In 1995, HHS removed "residual seizure disorder" (one of the alleged injuries in this case) as a "Table Injury" associated with the DTP vaccine because epidemiological evidence showed that there was no "*medical evidence to support*" a presumed causal relationship. *National Vaccine Injury Compensation Program Revision of the Vaccine Injury Table*, 60 Fed. Reg. 7,678, 7,691 (Feb. 8, 1995) (emphasis added).

Contrary to Petitioners' suggestion (Br. 1, 17-19), Lederle could not have marketed, as of 1992 (the time of the vaccination at issue in this case), some supposedly safer alternative to whole-cell DTP vaccines for infants. Petitioners suggest that one alternative was supposedly Tri-Solgen, a "fractionated cell" vaccine once manufactured by Eli Lilly & Co. But Tri-Solgen was never shown to cause fewer neurological disorders or other severe side effects than whole-cell vaccines (it merely caused less fever and pain at the injection site). *Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review; Proposed Rule*, 50 Fed. Reg. 51,051-52 (Dec. 13, 1985).[12] Although Tri-Solgen was widely used in

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[11] See Kathryn M. Edwards & Michael D. Decker, *Pertussis vaccines*, in VACCINES 467, 485 ("Edwards & Decker") ("For some time, there was substantial suspicion that whole-cell vaccines might be causally related to devastating outcomes such as encephalopathy or sudden infant death syndrome (SIDS), *but several careful epidemiologic studies have largely dispelled these concerns*.") (emphasis added).

[12] The internal Lederle study Petitioners cite (Br. 18) that compares Lederle's vaccine to Lilly's (J.A. 230-34) is not to the contrary. All of the observed reactions were local, not severe.

the 1960s, Eli Lilly withdrew it in the 1970s, and it was never licensed again.

Nor, contrary to Petitioners' suggestion (Br. 19), were acellular pertussis vaccines an available alternative as of 1992 for U.S. children under two years old. Acellular vaccines use characterized and purified parts of the pertussis bacterium to stimulate an immune response.[13] Petitioners point to Japan's licensure of acellular pertussis vaccines in the 1980s for use in infants *two years of age and older*. But that licensure occurred under circumstances that could not occur under the U.S. regulatory system: in the face of an epidemic of whooping cough, the Japanese government permitted acellular pertussis vaccines to go to market with no efficacy testing and only limited clinical studies of the vaccine's safety and ability to provoke an immune response. J.A. 97-98.[14]

FDA licensing of an acellular pertussis vaccine for use in the United States, by contrast, required thorough scientific research, properly designed clini-

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See J.A. 232; see also *Toner v. Lederle Labs.*, 779 F.2d 1429, 1431 (9th Cir. 1986) (Kennedy, J.) (noting that the Lederle internal study "found fewer local reactions associated with Tri-Solgen, but it noted no severe reactions in either cohort due to the restricted number of subjects studied").

[13] "Characterized" refers to identifying the specific component parts of the cell and their biological activity. A "purified" vaccine uses only those parts of the cell believed to stimulate an immune response.

[14] The epidemic, involving more than 13,000 illnesses and 41 deaths, occurred after a steep drop in immunization rates arising from public reaction to media coverage of two infant deaths within 24 hours of receiving a whole-cell DTP vaccination in 1974 and 1975. See E.J. Gangarosa *et al.*, *Impact of anti-vaccine movements on pertussis control: the untold story*, 351 Lancet 356, 357-58 (Jan. 31, 1998); J.A. 97.

cal trials on all relevant age groups, and completion of the FDA regulatory process. For the clinical trials, vaccine manufacturers were permitted to take into account the Japanese experience of administering acellular pertussis vaccine to children two years of age and older. Based in part on studies of that experience, in December 1991, FDA licensed Lederle's ACEL-IMUNE® DTaP vaccine for use as the fourth and fifth doses of the recommended DTP series for children over two years old who had previously been immunized with three or four doses of whole-cell DTP vaccine. J.A. 101.

But as of 1992 (the time of the vaccination at issue in this case), the efficacy of acellular pertussis vaccines in children under two years old had yet to be proven in any clinical trial, and it was not yet known whether acellular vaccine would be as safe and effective for children under two years old as whole-cell vaccine had proven to be over decades of use. J.A. 100-01. To demonstrate the safety and effectiveness of the acellular vaccine for use in children under two years old, nine large-scale clinical efficacy trials were conducted in Europe and Africa involving eleven different acellular pertussis vaccines manufactured by a number of different entities. Edwards & Decker at 489-501.[15] FDA did not approve an acellular pertussis vaccine for use in children under two years old until July 31, 1996. J.A. 33-34.

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[15] One clinical trial specifically focused on an acellular pertussis vaccine developed by the U.S. government. That acellular vaccine was not approved until 1998. Edwards & Decker at 499; CDC, *FDA Approval of a Fourth Acellular Pertussis Vaccine for Use Among Infants and Young Children*, 47 MMWR 934 (Nov. 6, 1998).

### E. Proceedings Below

On April 3, 1995, Petitioners filed a Vaccine Court petition seeking compensation for injuries Hannah Bruesewitz allegedly suffered as the result of a DTP vaccination administered in April 1992. Specifically, Petitioners alleged that Hannah has been diagnosed with "residual seizure disorder" and "developmental delay"—non-Table injuries for DTP vaccines. After an evidentiary hearing, Vaccine Court dismissed their petition with prejudice for failing to establish that the DTP vaccine caused Hannah's injuries. *Bruesewitz* v. *Sec'y of HHS*, No. 95-0266V, 2002 WL 31965744 (Fed. Cl. Dec. 20, 2002). Notwithstanding the denial of the petition, Vaccine Court later awarded Petitioners over $126,000 in attorneys' fees and costs. J.A. 3.

Petitioners rejected Vaccine Court's judgment as to their underlying claims pursuant to Section 21(a) of the Vaccine Act, 42 U.S.C. 300aa-21(a), and filed this *de novo* action, see *id.* 300aa-23(e), against Respondent Wyeth (as successor to American Cyanamid) in Pennsylvania state court in October 2005, asserting claims for design defect (under negligence and strict-liability theories), failure to warn, and manufacturing defect. Respondent removed the action to federal court and moved for summary judgment. After "extensive discovery" (App. 54),[16] the district court granted summary judgment to Respondent on Petitioners' entire complaint. App. 53-99. The district court ruled, *inter alia*, that Section 22(b)(1) of the Vaccine Act expressly preempts Petitioners' design-defect claims. App. 82-87. The court also ruled that Petitioners had failed to raise a genuine issue of

[16] References to "App." are to the petition appendix.

material fact on either their manufacturing-defect claim or their failure-to-warn claim. On the latter claim, the court found that Petitioners had failed to overcome the statutory presumption that Respondent's FDA-approved warnings were proper because they could not show that Respondent had withheld information from FDA or otherwise failed in any regulatory compliance. App. 88-98.

The Third Circuit affirmed. App. 1-52. As to the design-defect claim, the Circuit held that the claim is preempted by Section 22(b)(1), reasoning that the statutory text, structure, and legislative history showed "a 'clear and manifest' expression of congressional intent" to preempt design-defect claims. App. 30. The Circuit observed that Petitioners' construction of the statute, by allowing design-defect claims to be litigated on the merits in virtually every case, would trigger the "very problems which led to instability in the vaccine market and which caused Congress to intervene through the passage of the Vaccine Act." App. 36.[17]

## SUMMARY OF ARGUMENT

Congress enacted the Vaccine Act against a backdrop of increasing design-defect litigation against manufacturers, the exit of some manufacturers from the industry, and a consequent shortage of DTP vaccine. The Act's express preemption provision, Section 22(b)(1), addresses these concerns by preempting state-law tort claims with the exception of

[17] The Third Circuit also affirmed the grant of summary judgment to Respondent on the failure-to-warn and manufacturing-defect claims. App. 43-52. Petitioners did not seek this Court's review of those aspects of the Third Circuit's decision. See Pet. i (addressing only design-defect claim).

two specific carve-outs—failure "properly [to] prepare" the vaccine and failure to "accompan[y] [the vaccine] by proper directions and warnings." Design-defect claims are not carved out from preemption, and any interpretation of the Act that would allow them to be asserted would frustrate Congress's purpose in enacting the Act.

## I

The plain text of Section 22(b)(1) categorically preempts design-defect claims. This conclusion is corroborated by the structure of the Vaccine Act, and is fully consistent with Restatement (Second) of Torts § 402A, comment k (1965).

### A

Section 22(b)(1) broadly preempts state-law tort claims, and then carves out from this preemption manufacturing-defect claims and certain failure-to-warn claims, but *not* design-defect claims. The statute does so by providing for preemption "if the [vaccine-related] 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." In other words, only if the injury or death could have been "avoided" by "prope[r] prepara[tion]" or "proper directions and warnings" may a state-law tort claim be asserted.

Petitioners unpersuasively seek to avoid the plain statutory text by frequently paraphrasing the statute to omit the key modifying phrase that follows the word "unavoidable." And Petitioners' interpretation, by allowing design-defect claims to proceed through trial and putting manufacturers to the expense of establishing case by case that their vaccines employed the safest design, would provide no protection

to manufacturers beyond that which was already provided by state law before the Vaccine Act.

**B**

The broader structure of the Vaccine Act strongly reinforces the import of the plain text of Section 22(b)(1). Specifically, other provisions of the Act achieve through regulation the incentive and compensation goals that would otherwise be met by the tort system.

*First*, as to incentives, the Vaccine Act established a National Vaccine Program that mandates that HHS promote and assure the development of safer vaccines. Congress understood that the complex balancing of public benefits to society against the rare side effects of certain vaccines was best performed by expert federal agencies with a national, public-health perspective rather than by lay juries, sitting in individual cases, that would tend to focus on the alleged side effects of vaccines in disproportion to the indisputable benefits that vaccines provide to parties not before the court. To assist in monitoring existing vaccines and developing ever better ones, the Act strongly encourages manufacturers to disclose adverse events from vaccines by conditioning the preemption of failure-to-warn claims on the manufacturer's reporting of such events to FDA both before and after licensure of the vaccine. And, even before licensure, proposed vaccine designs are subjected to more comprehensive clinical trials than are ordinary drugs or medical devices.

*Second*, as to compensation, the Vaccine Act counterbalances Section 22(b)(1)'s preemption of design-defect civil claims by providing a generous, no-fault administrative compensation scheme. This scheme

does not require claimants to prove that their injuries resulted from a design defect. To date, this compensation scheme has awarded total compensation of over $1.8 billion, or an average of more than $750,000 to each petitioner who received an award. This scheme distinguishes cases such as *Wyeth* v. *Levine*, 129 S. Ct. 1187, 1199 (2009), where this Court found the absence of such an administrative compensation scheme to undermine the defendant's assertion of preemption.

**C**

Petitioners rely heavily on the incorrect notion that Section 22(b)(1) *codified* Restatement (Second) of Torts § 402A, comment k. They assert that Congress embraced the view of *some* courts regarding Comment k before the Act that manufacturers could escape strict liability only by demonstrating case by case that their vaccine employed the safest feasible design.

Petitioners' reliance on Comment k is unpersuasive. Congress did not codify Comment k insofar as Comment k speaks only to a defense to strict-liability claims, whereas Section 22(b)(1) is much broader. Section 22(b)(1) preempts *any* "civil action for damages" (including claims for negligence and breach of implied warranty in addition to strict liability)—unless the claim presented falls within the carve-out for manufacturing-defect and certain failure-to-warn claims. Moreover, Comment k is part of a restatement of the common law of torts, whereas Section 22(b)(1) is part of a comprehensive federal scheme (applicable only to a small number of products, childhood vaccines) that achieves through regulatory means the incentive and compensation goals of tort law.

Even if these differences between Comment k and Section 22(b)(1) could be ignored, Comment k does not assist Petitioners because state courts were deeply divided on its interpretation as of the Vaccine Act's enactment in 1986. Some state courts treated Comment k's protection against design-defect claims as categorically available to approved vaccines and drugs. Others treated such protection as conditional on the manufacturer's showing that it employed the safest design.

## II

Although the plain text of Section 22(b)(1) and the structure of the Vaccine Act make it unnecessary to consult legislative history, the most authoritative piece of that history, the House Energy Committee Report from the 1986 Congress that enacted the Act, further confirms that Congress intended categorically to preempt design-defect claims. Directly addressing the question presented in this case, the Report explained that, "if [claimants] 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."

The 1986 House Report is not trumped by a 1987 report issued in connection with funding the Vaccine Act's compensation program, a measure undertaken by a subsequent Congress. The 100th Congress made no substantive change to provisions, including Section 22(b)(1), that had already been enacted by the 99th Congress in 1986.

## III

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.

## ARGUMENT

### I. THE VACCINE ACT'S PLAIN TEXT PREEMPTS VACCINE DESIGN-DEFECT CLAIMS, AND THE ACT'S STRUCTURE SUPPORTS THIS CONCLUSION

Petitioners assert that Section 22 leaves virtually unchanged the full range of state tort claim opportunities available to plaintiffs before enactment of the Vaccine Act. On Petitioners' view, Section 22(b)(1) allows juries to decide, case by case, that vaccine designs whose safety and efficacy have merited federal government approval for nationwide use are nonetheless defective and should not be on the market. Such a reading is untenable. Section 22(b)(1), by its terms, precludes all state-law tort claims except manufacturing-defect claims and those failure-to-warn claims in which a plaintiff can rebut the statutory presumption in Section 22(b)(2). Section 22(b)(1) thus precludes design-defect claims such as the ones brought here.

Petitioners' argument is likewise belied by the structure of the Vaccine Act, which establishes a comprehensive federal scheme for approving and monitoring existing vaccines and promoting research and development of better ones, and which provides a generous program of no-fault compensation to victims of vaccine side effects.

Petitioners' attempt to draw support from Restatement (Second) of Torts § 402A, comment k is unpersuasive. Congress looked to Comment k for the principle that some products are categorically not defective if properly prepared and accompanied by proper directions and warnings, and treated routine childhood vaccines as such products. Petitioners offer

no explanation why Congress would have intended state tort law, whose disastrous effects on the vaccine supply Congress was intent on averting through passage of the Vaccine Act, to displace standards set by a national vaccine program that was designed "to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines." 42 U.S.C. 300aa-1.

### A. Section 22(b)(1)'s Text Expressly Preempts Design-Defect Claims While Preserving Manufacturing-Defect And Failure-To-Warn Claims

Section 22(b)(1) expressly preempts state law otherwise applicable to vaccine-related injury claims under 42 U.S.C. 300aa-22(a) ("Except as provided in subsections (b), (c), and (e) of this section State law shall apply to a civil action brought for damages for a vaccine-related injury or death."). Section 22(b)(1) 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 word "unavoidable" is immediately modified by the phrase "even though the vaccine was properly prepared and was accompanied by proper directions and warnings." *Ibid.* Section 22(b)(1) thus provides

for preemption except in cases where the claimed side effect would have been "avoided" if the vaccine had been "properly prepared" or "accompanied by proper directions and warnings." Section 22(b)(1) does *not* provide that a side effect might be "avoided" if a vaccine had been "properly designed."

Congress's choice of the definite article, "*the* vaccine," 42 U.S.C. 300aa-22(b)(1) (emphasis added), is consistent only with a reading that preserves manufacturing-defect and failure-to-warn claims, not design-defect claims. "*The* vaccine" refers to the vaccine that was actually administered and is alleged to have caused the vaccine-related injury or death for which the manufacturer is being sued. As to that administered vaccine, a manufacturer may be found liable for manufacturing defect if it did not adhere to the vaccine's FDA-approved specifications, or for failure to warn if the manufacturer did not comply with regulatory requirements or withheld information from FDA.

In carving out from preemption some claims concerning "*the* vaccine" that was actually administered, Congress recognized that proper manufacturing and labeling are within the manufacturer's exclusive control. By contrast, vaccine manufacturers do *not* have discretion to change the design of a vaccine; to do so creates a new vaccine that must be separately approved by FDA after extensive clinical trials. The Vaccine Act leaves assessment of any risks inherent in a vaccine's *design* to a carefully wrought federal regulatory process. It permits civil juries to decide whether a manufacturer defectively produced, or failed to accompany with appropriate warnings, *the* vaccine that was actually administered; but the Act forecloses juries from assessing whether the federal

regulatory process should have approved *a* different, allegedly safer vaccine design.

To avoid the simple and straightforward reading of the text of Section 22(b)(1) that limits the preemption carve-out to manufacturing-defect and failure-to-warn claims, Petitioners repeatedly omit from their quotations of that subsection the fifteen words that follow the word "unavoidable," starting with "even though …." *E.g.*, Br. 25, 29. Those fifteen words, however, are crucial to the meaning of the clause. Had Congress intended to allow claims that a vaccine side effect was avoidable through an alternative design, it would have stopped the clause at the word "unavoidable." It did not. Moreover, the logical and concise way for Congress to embody Petitioners' view would have been to end the preemption provision with the words "unavoidable side effects." That Congress instead selected the language "side effects that were unavoidable even though ...," is a textual indication that the words following the term "unavoidable" are the key to understanding the entire phrase "side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions."

When Petitioners do acknowledge the words that follow and explicate the word "unavoidable," they assert (Br. 38) that those words merely impose additional prerequisites to preclusion of a lawsuit under Section 22(b)(1) on top of the supposed requirement that the manufacturer show that the vaccine employed the safest design. But to support such a reading, Petitioners must twist the order of the words in the statute and draw on the subsection's heading ("Unavoidable adverse side effects; warnings") so that the statute's actual text, "side effects that were

unavoidable even though …," is rephrased as "unavoidable side effects even though …." This misconstrues the subsection's text and misuses its heading, which merely makes a short-form reference to the clear statutory text.[18]

Petitioners contend that it is Respondent that does not give meaning to all the words contained in Section 22(b)(1), arguing that, under Respondent's interpretation, Section 22(b)(1) would read the same way if the conditional phrase "if the injury or death resulted from side effects that were unavoidable" were removed. Br. 39-40. But that is not the case, as then the statute would provide that "[n]o vaccine manufacturer shall be liable in a civil action for damages … *even though* the vaccine was properly prepared and was accompanied by proper directions and warnings." 42 U.S.C. 300aa-22(b)(1) (emphasis added).[19] It makes no sense to read the statute to absolve a manufacturer of liability "even though" it does everything correctly. It does, however, make sense to address side effects that could not have been avoided through proper warnings and manufacturing, and the statute does so by preempting tort claims arising out of vaccine-related injuries that occurred even though the vaccine was properly manufactured and had proper warnings. Only Respondent's reading gives effect to *all* the words in the sentence.

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[18] As this Court held regarding another section of the Vaccine Act, "even if the language of the heading did conflict with the text …, the latter would prevail, since the table heading was obviously meant to be a short form of the text preceding it." *Whitecotton*, 514 U.S. at 274.

[19] Petitioners drop the italicized words "even though" from the statute in their "plain text" argument. See Br. 39.

By effectively stopping the sentence after the word "unavoidable," Petitioners' interpretation would render Section 22(b)(1) meaningless, merely perpetuating the status quo *ante* the Vaccine Act. On Petitioners' reading, manufacturers would face design-defect claims as well as manufacturing-defect and failure-to-warn claims under state law, now just as they did before the Vaccine Act, and could obtain design-defect "preemption" only *after* defending each case on the merits. Moreover, if read as Petitioners propose, Section 22(b)(1) would preempt design-defect claims only under circumstances where the manufacturer would already have won the case on state-law grounds. No State in 1986 imposed (or today imposes) design-defect liability on manufacturers for injuries that could not have been avoided under any circumstances. Thus, on Petitioners' reading, Section 22(b)(1)'s express limitation on civil liability would be superfluous.

Petitioners also place heavy reliance (Br. 32, 35-36) on the word "if," arguing that its conditional nature must mean that Congress intended a case-by-case inquiry into whether a vaccine's side effects were "unavoidable" because the vaccine could have employed a safer design. But the word "if" cannot bear the weight Petitioners assign to it. The natural meaning of the term "if" here simply allows inquiry into whether the side effects at issue were "avoidable" under either of the two circumstances enumerated in Section 22(b)(1)—by "properly prepar[ing]" the administered vaccine or by accompanying that vaccine with "proper directions and warnings."

Finally, Petitioners argue (Br. 36-37) that Congress cannot have meant to preempt design-defect claims because it failed to provide a presumption that FDA-

approved designs are proper along the lines of the presumption set forth in Section 22(b)(2) that FDA-approved warnings are proper. But imposing limits, via a rebuttable presumption, on a failure-to-warn claim that is not preempted cannot suggest that a different claim (design defect) is itself not categorically preempted. The straightforward way to read Section 22(b) as a whole is that it allows civil liability for manufacturing-defect claims without limitation; allows civil liability for failure-to-warn claims limited by the rebuttable presumption that FDA-approved warnings are proper; and categorically preempts all other claims, including design-defect claims.[20]

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[20] Petitioners also point to another statute, 42 U.S.C. 247d-6d ("PREP Act"), in support of their construction of Section 22(b)(1), but this analogy is strained. The PREP Act is irrelevant here. First, it sheds no light on Congress's intent in enacting Section 22(b)(1) because it was enacted some 19 years after the Vaccine Act, for different reasons and under different circumstances. See *Halverson* v. *Slater*, 129 F.3d 180, 186 (D.C. Cir. 1997) (declining to draw inference from different language in statute enacted seven years after enactment of statute at issue). Second, the PREP Act covers vaccines that the Secretary of HHS has deemed necessary to respond to public health emergencies, not the vaccines recommended for routine administration to children covered by Section 22. See 42 U.S.C. 300aa-14(e), 22(b). Third, the PREP Act grants nearly complete legal immunity to manufacturers of the vaccines it covers, while the Vaccine Act balances limitations on civil liability with a no-fault administrative compensation scheme for vaccine-injured persons.

### B. The Structure Of The Vaccine Act, By Promoting Safe And Efficacious Vaccines While Providing Administrative Compensation, Confirms That Section 22(b)(1) Preempts Design-Defect Claims

The overall structure of the Vaccine Act reinforces the textual argument that Section 22(b)(1) preempts all design-defect claims. The structure of the Vaccine Act reflects a determination to change the status quo regarding the research, development, manufacturing, and testing of childhood vaccines. The Act also instituted a generous administrative scheme to provide compensation for vaccine injuries that otherwise would have been sought under state tort law.

*First*, the Vaccine Act established a National Vaccine Program that, unlike any program applicable to ordinary drugs or any program that previously existed for vaccines, mandates that HHS promote, make, and/or assure the development of safer vaccines. 42 U.S.C. 300aa-27(a). The Act ensures that expert federal agencies and advisory committees with a systemic national perspective, not civil juries judging individual claims, will make decisions on appropriate vaccine design. As this Court has observed generally in the area of medical products, "[a] jury … sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court." *Riegel* v. *Medtronic, Inc.*, 552 U.S. 312, 325 (2008).

This is exponentially true in the vaccine context, where, "even though vaccines themselves cause a small number of serious injuries or deaths, their widespread use dramatically reduces fatalities." *Schafer* v. *Am. Cyanamid Co.*, 20 F.3d 1, 4 (1st Cir.

1994) (Breyer, C.J.); see also *ibid.* ("[T]he polio vaccine may itself cause about five annual incidents of paralysis. But, before widespread vaccination, … polio injured, paralyzed, or killed about 57,000.") (citations omitted). Were the relatively few victims of vaccine side effects permitted unfettered resort to civil litigation before lay juries, adverse side effects would assume disproportionate salience and the vital social benefits of vaccines to the nation's population would be discounted. Thus, to achieve the best vaccine design, Congress chose administrative regulation over tort law, mandating that the determination of which vaccine design "achieve[s] the optimal prevention of human infectious diseases … *and* … achieve[s] optimal prevention against adverse reactions to vaccines," 42 U.S.C. 300aa-1 (emphasis added), be made by HHS and FDA, not case by case by juries or judges under a patchwork of state tort laws.

The Vaccine Act's forward-looking research program is supplemented by the powerful incentives imposed upon manufacturers by Section 22(b). Specifically, by allowing failure-to-warn claims if a plaintiff can overcome the presumption set forth in Section 22(b)(2), and by allowing manufacturing-defect claims generally, Section 22(b) strongly encourages vaccine manufacturers to control risks related to the manufacture and administration of a particular vaccine and thus that are within their exclusive power to control. The carve-out for manufacturing-defect claims gives manufacturers a strong incentive to make vaccines according to their FDA-approved specifications. The carve-out for limited failure-to-warn claims gives manufacturers a strong incentive to comply with all regulatory requirements and to make full disclosure of information (including

adverse events) to FDA.[21] But Section 22(b)(1) bars all other state-law civil actions, declining to allow judges and juries to look beyond the production and administration of a particular FDA-approved vaccine to assess whether a supposed alternative, safer vaccine theoretically might have been designed—an area beyond the exclusive control of any manufacturer in such a closely regulated federal system. See U.S. *Ferrari* Br. 15 ("The tort system—in which juries may pay little heed to this social cost/benefit calculus … —is poorly equipped to encourage optimally safe and effective vaccines.")

Congress's decision to allow claims for manufacturing-defect and certain failure-to-warn claims is consistent with this predominantly regulatory scheme. Vaccine design involves complex policy decisions balancing safety and efficacy, and allowing juries to make such decisions would produce varying decisions in different States about whether any given vaccine design is defective and thus should be removed from the market.[22] By contrast, nationwide public health policy choices are not presented in litigation over whether an individual lot of vaccine was manufactured according to its FDA-approved design, or whether a manufacturer has complied with appli-

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[21] Section 22(b)(2) thus provides an alternative means of serving a traditional goal of pharmaceutical tort litigation: to "uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly." *Wyeth* v. *Levine*, 129 S. Ct. at 1202.

[22] This Court has previously recognized that jury verdicts powerfully affect the conduct of manufacturers. *Riegel*, 552 U.S. at 325 ("State tort law that requires a manufacturer's [medical device] to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect.").

cable regulations and provided FDA with all required information before and after a vaccine's licensure so as to enjoy presumptive protection from failure-to-warn claims under 42 U.S.C. 300aa-22(b)(2). Further reflecting the importance of having expert scientists rather than juries weigh the public benefits of vaccines against the cost of their rare side effects, manufacturers are absolutely barred from changing the design of an approved vaccine without prior governmental approval. This feature of the vaccine regulatory scheme distinguishes the warning at issue in *Wyeth* v. *Levine*, which could be changed before approval under a "changes being effected" (CBE) provision. 129 S. Ct. at 1196-99.

*Second*, reflecting Congress's awareness that limiting the liability of manufacturers would limit the ability of injured parties to recover, the Vaccine Act created a no-fault compensation scheme, 42 U.S.C. 300aa-11-17, in which petitioners may receive generous recoveries in Vaccine Court without having to prove any design defect. In the two decades of its operation, Vaccine Court has awarded total compensation of over $1.8 billion, or an average of over $750,000 to each petitioner that has received an award. This administrative compensation scheme distinguishes *Wyeth* v. *Levine* and other cases where this Court found that the absence of an alternative to compensation under tort law weighed against federal preemption. See 129 S. Ct. at 1199 ("Congress did not provide a federal remedy for consumers harmed by unsafe or ineffective drugs in the 1938 statute or in any subsequent amendment."); *Silkwood* v. *Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984) ("It is difficult to believe that Congress would, without comment,

remove all means of judicial recourse for those injured by illegal conduct").[23]

### C. Restatement (Second) Of Torts § 402A, Comment k Is Consistent With The Text And Structure Of The Act In Categorically Precluding Design-Defect Claims

Unable to find in the text or structure of the Vaccine Act any congressional purpose to preserve case-by-case adjudication of supposed vaccine design defects under state law, Petitioners rely heavily on Comment k to Restatement (Second) of Torts § 402A. Br. 29-33, 37, 39, 41, 45-46. Comment k, drafted in 1965, provides that an "[u]navoidably unsafe product[]" may not be subjected to a strict-liability claim so long as it is "properly prepared, and accompanied by proper directions and warning":

> *Unavoidably unsafe products.* There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified,

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[23] Additionally, the scope of the preemption here affects far fewer products than in other recent pharmaceutical preemption cases. Only twelve categories of childhood vaccines will be affected by this Court's ruling here, a fraction of the 11,000 FDA-approved products to which preemption would have applied in *Wyeth* v. *Levine*, 129 S. Ct. at 1202.

> notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician.…

RESTATEMENT (SECOND) OF TORTS § 402A, cmt. k.

Petitioners argue that Section 22(b)(1) of the Vaccine Act "expressly codified" Comment k. Br. 32. That is demonstrably incorrect. Restatement § 402A, to which Comment k is appended, addresses only actions for *strict liability*. Section 22(b)(1), by contrast, is far broader, preempting *any* "civil action for damages"—including claims for negligence, breach of implied warranty, and all other causes of action regarding vaccines manufactured properly and accompanied by proper directions and warnings.

Moreover, while Comment k arises from the common law of torts, Section 22(b)(1) is part of a comprehensive federal regulatory scheme that provides for heavy governmental involvement in research and development, approval and monitoring of vaccines to ensure their safe and efficacious production, and a no-fault compensation program for victims of vaccine-related side effects. Cf. *Toner* v. *Lederle Labs.*, 828 F.2d 510, 514 (9th Cir. 1987) (Kennedy, J.) (in pre-Vaccine Act case, applying Idaho law allowing a negligent design-defect claim against vaccine manufacturer, while noting that "[w]ere we charged with deciding whether jury verdicts are the most sensible way of allocating risks and costs regarding vaccines that have been proved beneficial, we might well

design a different method"). And while Comment k is not confined to any particular type of product, Section 22(b)(1) applies exclusively to the small number of childhood vaccines covered by the Vaccine Act and vital to public health programs.

Although Section 22(b)(1) did not codify Comment k, it looked to "the principle of Comment k,"[24] which is that certain products are not defective because their social utility outweighs their inherent risk. Such products are categorically not subject to strict liability, provided they are properly manufactured and are accompanied by adequate warnings. Section 22(b)(1) is best read as a determination that all routinely administered FDA-approved childhood vaccines are categorically deserving of protection against all tort liability (not just strict liability) arising out of risks inherent in the vaccine, as long as they are "properly prepared" and "accompanied by proper directions and warnings."

Petitioners look to certain pre-Vaccine Act decisions interpreting Comment k to interpret Section 22(b)(1). This interpretive method is flawed because of the significant differences noted above between Section 22(b)(1) and Comment k. But even if those differences were ignored, Petitioners' argument can have no force unless the pre-Vaccine Act cases pointed clearly in the direction of case-by-case analysis of design-defect claims. They did not. The courts were deeply divided on this issue, and thus

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[24] As discussed *infra*, at 47-48, the legislative history does not show that Congress intended to "codif[y] comment k." Pet. Br. 13. Rather, the 1986 House Report stated that Section 22(b)(1) "sets forth the *principle* contained in" Comment k. 1986 House Report at 26 (emphasis added); see also App. 33-36 (Third Circuit opinion).

Petitioners are unaided by the fact that *some* courts as of 1986 interpreted Comment k to put manufacturers to a case-by-case showing that their products were unavoidably unsafe, see, *e.g.*, *Feldman* v. *Lederle Labs.*, 479 A.2d 374, 383-84 (N.J. 1984); Pet. Br. 33-34 & n.17. Numerous *other* courts interpreting state law as of 1986 categorically precluded design-defect claims against products like vaccines whose overwhelming social utility makes them appropriate to market even though they carry some inherent risk.[25] Petitioners offer no reason to sup-

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[25] See, *e.g., Lindsay* v. *Ortho Pharm. Corp.,* 637 F.2d 87, 90 (2d Cir. 1980) (stating that, under New York law, prescription drugs are deemed "unavoidably unsafe products"); *Raynor* v. *Richardson-Merrell, Inc.*, 643 F. Supp. 238 (D.D.C. 1986) (stating that, under District of Columbia law, drugs are unavoidably unsafe products); *Brown* v. *Superior Court*, 227 Cal. Rptr. 768 (Cal. Ct. App. 1986) (rejecting case-by-case approach to Comment k in context of prescription drugs and affirming trial court's ruling that "design defect theory is not available for injury alleged to have been caused by a prescription drug"), *aff'd*, 751 P.2d 470, 481-83 (Cal. 1988) (holding that all prescription drugs are unavoidably unsafe under Comment k); *Stone* v. *Smith, Kline & French Labs.*, 447 So. 2d 1301, 1304 (Ala. 1984) (all drugs and vaccines are within the scope of Comment k); *Baldino* v. *Castagna,* 478 A.2d 807, 810 (Pa. 1984) (stating that a prescription drug manufacturer is not strictly liable if the drug is properly prepared and labeled); *McKee* v. *Moore*, 648 P.2d 21, 23 (Okla. 1982) (stating that prescription drugs and devices are "unavoidably unsafe products"); *McDaniel* v. *McNeil Labs. Inc.,* 241 N.W.2d 822, 828 (Neb. 1976) (concluding that FDA approval precludes finding that a drug is unavoidably unsafe unless the manufacturer submitted inaccurate, incomplete, misleading, or fraudulent information in approval process), overruled by *Freeman* v. *Hoffman-La Roche, Inc.*, 618 N.W.2d 827 (Neb. 2000); *Lewis* v. *Baker, Richardson-Merrell, Inc.*, 413 P.2d 400, 404 (Or. 1966) (same), overruled in part on other grounds, *McEwan* v. *Ortho Pharm. Corp*., 528 P.2d 522 (Or. 1974). See generally *Militrano* v. *Lederle Labs.,* 769

pose that Congress intended to adopt one rather than the other strand of divided state common law.

Moreover, as the Third Circuit correctly found (App. 29-30), Petitioners' reading of Section 22(b)(1), by virtue of Section 22(e) (preempting state laws that "prohibit[t] an individual from bringing a civil action … if such civil action is not barred by this part"), would have the perverse consequence of leaving vaccine manufacturers *worse off* under state law than they were before the Vaccine Act. Under Petitioners' approach, those States with statutes providing categorical Comment k protection to all vaccines would now have to *allow* case-by-case adjudication of design-defect claims in cases covered by the Vaccine Act. Such an outcome cannot be squared with the Act's genesis in congressional concern that the litigation burden on manufacturers was so severe that it threatened the nation's vaccine supply.

### D. The Presumption Against Preemption Has No Bearing On This Case

This Court has described the presumption against preemption as a tiebreaker. See *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431, 448 (2005) ("[E]ven if [the reading favoring preemption] *were just as plausible* as our reading of that text—we would nevertheless have a duty to accept the reading that disfavors pre-emption.") (emphasis added). The presumption has no bearing on this case, however, because the case is not in need of a tiebreaker. Congress's intent to preempt vaccine design-defect

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N.Y.S.2d 839, 844-45 (N.Y. Sup. Ct. 2003) ("[W]hile some courts concluded that a case-by-case analysis was necessary … others concluded that prescription drug manufacturers were generally not liable for design defect claims.").

claims is clear from the text of Section 22(b)(1), and Petitioners' construction of that text is not "as plausible" as Respondent's.

Invocation of the presumption is likewise inappropriate here because *both* parties' proposed interpretations of Section 22(b)(1) would result in some preemption of state law. Under Respondent's reading of Section 22(b)(1), state law would be preempted in those States that allow case-by-case inquiry into the safety of a vaccine's design before conferring Comment k protection. But if Petitioners' reading of Section 22(b)(1) were accepted, then, by virtue of Section 22(e), there would be preemption of state law in those States with statutes providing Comment k protection to all vaccines. Where either party's position will displace some States' existing law, the federalism principle embodied in the presumption against preemption cannot serve as a tiebreaker.

## II. THE LEGISLATIVE HISTORY CONFIRMS THAT SECTION 22(b)(1) PREEMPTS DESIGN-DEFECT CLAIMS

Because the text of Section 22(b)(1) and the structure of the Vaccine Act demonstrate Congress's intent to preempt state-law design-defect claims arising from vaccine-related injuries, the Vaccine Act's legislative history need not be consulted, but if consulted, that history confirms Respondent's and the Third Circuit's interpretation.

### A. The 1986 House Committee Report Affirmed That Vaccine Injuries Other Than Those From Manufacturing Or Warning Defects Should Receive "Recompense In The Compensation System, Not The Tort System"

H.R. Rep. No. 99-908, prepared in 1986 in support of the Vaccine Act by the Committee on Energy and Commerce (the "1986 House Report"), provides "the authoritative source for finding the Legislature's intent." *Garcia* v. *United States*, 469 U.S. 70, 76 (1984) ("Committee Reports on the bill, … '[represent] the considered and collective understanding of those Congressmen involved in drafting and studying proposed legislation.'") (quoting *Zuber* v. *Allen*, 396 U.S. 168, 186 (1969)). Accord, *Eldred* v. *Ashcroft*, 537 U.S. 186, 210 n.16 (2003). The 1986 House Report sets out the rationale for the Vaccine Act and the compensation program, expresses concern that state tort liability will undermine vaccine manufacturers and the nation's vaccine supply, and expresses Congress's intent that the Act's preemption clause be read broadly to preempt state law actions like the one here.

As the Committee explained, "in light of the availability of a comprehensive and fair compensation system," the Vaccine Act established standards of responsibility for manufacturers that were designed to lessen their potential liability for vaccine-related injuries. 1986 House Report at 25. Directly addressing the question presented in this case, the 1986 House Report explains:

> Given the existence of the [no-fault] compensation system in this bill, … [v]accine-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.*

*Id.* at 26 (emphasis added). Thus, the 1986 House Report makes clear that the Vaccine Act differentiates manufacturing-defect and failure-to-warn claims from other claims, including design-defect claims, and allows persons alleging vaccine-related injuries to pursue tort claims under only the former two theories.

In preempting other claims, the Committee recognized that, by the mid-1980s, the "great difficulty in obtaining insurance … coupled with the possibility that vaccine-injured persons may recover substantial awards in tort claims … prompted manufacturers to question their continued participation in the vaccine market." 1986 House Report at 6-7. The Committee further recognized that these circumstances had the potential to create a public health crisis, as the "withdrawal of even a single manufacturer would present the very real possibility of vaccine shortages, and, in turn, increasing numbers of unimmunized children and, perhaps, a resurgence of preventable disease." *Id.* at 7. Through the Vaccine Act, the Committee sought to create "a more stable childhood vaccine market" by giving vaccine manufacturers "a better sense of their potential litigation obligations." *Ibid.*

The 1986 House Report also confirms that, contrary to Petitioners' assertions, Congress did not intend to "codif[y] comment k." Br. 13; see also *id.* at 32, 46-47. Instead, the 1986 House Report explains

that Section 22(b)(1) reflects the "principle" of Comment k. 1986 House Report at 26. Specifically, the 1986 House Report states that the Committee "intends that the principle in Comment K regarding 'unavoidably unsafe' products, i.e., those products which in the present state of human skill and knowledge cannot be made safe, *apply to the vaccines covered in the bill and that such products not be the subject of liability in the tort system*." *Id.* (emphasis added). The Committee thus expressed the view that routinely administered childhood vaccines are *categorically* within "the principle of Comment k," and Petitioners are incorrect to suggest that the 1986 House Report can be read to require a "threshold" judicial determination, case by case, "that a vaccine's side effects ... [were] unavoidable." Br. 47.[26]

### B. A 1987 House Committee Report Cannot Rewrite The Legislative History Of A 1986 Enactment

In the face of this clear indication of contemporaneous congressional intent in the 99th Congress, Petitioners invoke (Br. 50) passages in a 1987 committee report from the *100th Congress* regarding legislation providing appropriations for the Vaccine Act. See H.R. REP. NO. 100-391(I) (1987), reprinted in 1987 U.S.C.C.A.N. 2313-1 ("1987 House Report"). The 1987 House Report states—contrary to the 1986

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[26] Petitioners also incorrectly assert that, "in discussing § 23(c) of the Act, the 1986 House Report confirmed that the *design* defect claims were not eliminated." Br. 46 (emphasis added). The Report actually referred to a "defective vaccine," without specifying that the defect related to design. 1986 House Report at 28. A vaccine could be "defective" based on a manufacturing defect or a failure to warn, the two theories explicitly enumerated as surviving preemption in Section 22(b)(1).

House Report—that the Vaccine Act was not intended "to preclude court actions under applicable law," and that the question "whether vaccines were unavoidably unsafe or not … is left to the courts to determine." *Id.* at 691. The 1987 House Report also claims that the incorporation of Comment k into the Vaccine Act "was not intended to decide as a matter of law the circumstances in which a vaccine should be deemed unavoidably unsafe." *Ibid.*

The 1987 House Report, however, is not a proper guide to determining Congress's intent in enacting the Vaccine Act in 1986. As this Court recently explained, "[l]egislative history … is considered persuasive by some, not because [such statements] reflect the general understanding of the disputed terms, but because the legislators who heard or read those statements presumably voted with that understanding." *District of Columbia* v. *Heller*, 128 S. Ct. 2783, 2805 (2008). Post-enactment statements, in contrast, "could have had no effect on the congressional vote." *Ibid.*; see also *id.* at 2837 n.28 (Stevens, J., dissenting) (post-enactment legislative history is "the least reliable source of authority for ascertaining the intent of any provision's drafters"). Cf. *Oscar Mayer & Co.* v. *Evans*, 441 U.S. 750, 758 (1979) ("'It is the intent of the Congress that enacted [the section] … that controls.'") (quoting *Teamsters* v. *United States*, 431 U.S. 324, 354 n.39 (1977)).

Here, no Member of Congress could have relied on the 1987 House Report's statements about the Act in voting for it, including its preemption provision, in 1986. Rather, those Members who voted in favor of the Act did so with the understanding, expressed in the 1986 House Report, that vaccines that are properly manufactured and accompanied by proper

warnings "not be the subject of liability in the tort system." 1986 House Report at 26. This is so even though Section 22(b)(1) was not effective until the Compensation Fund was funded by the appropriations at issue in the 1987 House Report, as that appropriations bill did not modify or otherwise address the scope of a manufacturer's liability under the Act, which was settled in the 1986 legislation. See Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, Title IV, §§ 4301-07, 101 Stat. 1330 (1987).[27]

Thus, the statements in the 1987 House Report about the Committee's intent in enacting the express preemption provision in 1986—a subject not at issue in the 1987 amendments—is after-the-fact speculation and hearsay. This Court has viewed analogous *post hoc* attempts to amend a statute through legislative history with deserved suspicion. See, *e.g.*, *Exxon Mobil Corp.* v. *Allapattah Servs., Inc.*, 545 U.S. 546, 568, 570 (2005) (recognizing that, in some instances, "unrepresentative committee members—or, worse yet, unelected staffers and lobbyists—… attempt strategic manipulations of legislative history to secure results they were unable to achieve through the statutory text," and "refus[ing] to give any effect to [a *post hoc*] deliberate effort to amend a statute through a committee report").

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[27] Petitioners misleadingly assert, without citation, that the 1987 amendments, which were entitled the "Vaccine Compensation Amendments of 1987," modified several "substantive" provisions of the Act. Br. 51. The amendments addressed only the funding mechanism, the duration of a residual injury, awards of costs, the exhaustion requirement, and federal court jurisdiction. See Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, Title IV, §§ 4301-07, 101 Stat. 1330 (Dec. 22, 1987).

Nor does it avail Petitioners to rely (Br. 45-46) on the 1987 House Report's reference to a 1986 markup session in which the Committee purportedly rejected an express prohibition on design-defect claims. It is the Committee's contemporaneous report of the bill—not a preliminary mark-up session—that offers the authoritative guide to congressional intent. See, *e.g.*, *Garcia*, 469 U.S. at 76.

### C. Other Pieces Of Legislative History Either Are Inconclusive Or Support Respondent's Position

Petitioners offer a hodgepodge of statements by individual Members of Congress, an Executive Branch official, and industry executives that they contend support their interpretation of Section 22(b)(1). None of these snippets, either individually or collectively, justifies disregarding the plain statutory language, confirmed by the 1986 House Report, indicating Congress's intent to preempt all claims against vaccine manufacturers other than manufacturing and warning claims.

Petitioners place surprising emphasis (Br. 47-48) on isolated floor comments and other statements regarding the Vaccine Act by Members of Congress. This Court, however, has long "eschewed reliance on the passing comments of one Member, and casual statements from the floor debates." *Garcia*, 469 U.S. at 76; see also *Weinberger* v. *Rossi*, 456 U.S. 25, 35 n.15 (1982) ("The contemporaneous remarks of a sponsor of legislation are certainly not controlling in analyzing legislative history."). This is particularly true of statements that post-date the enactment of a statute. See, *e.g.*, *Quern* v. *Mandley*, 436 U.S. 725, 736 n.10 (1978) ("[*P*]*ost hoc* observations by a single

member of Congress carry little if any weight."). Accord, *Heintz* v. *Jenkins*, 514 U.S. 291, 298 (1995).[28]

The testimony of industry witnesses cited by Petitioners (Br. 45, 49-50)—none of whom was referred to in the 1986 House Report—is even less relevant in discerning congressional intent. See, *e.g.*, *Kelly* v. *Robinson*, 479 U.S. 36, 51 n.13 (1986) ("[N]one of those statements was made by a Member of Congress, nor were they included in the official Senate and House Reports. We decline to accord any significance to these statements."). In any event, most of the cited testimony is either taken out of context or did not address the version of the bill that was ultimately enacted.

For instance, the statement by Lederle's president, Robert Johnson, in a 1986 subcommittee hearing that the bill would leave "open for litigation" claims "that the vaccines we sell are not as good as some alternative product" was made in response to a provision in H.R. 5184 that barred civil suits except where "the wrongful conduct of the defendant" was the basis of liability. 1986 Hearing at 238-39; National Childhood Vaccine Injury Act of 1986, H.R. 5184, 99th Cong., § 101(a) (1986) (§ 2122(c)(1)). But that provision was not part of the Vaccine Act as enacted. Similarly, Petitioners ignore that, during a 1987 subcommittee hearing, Mr. Johnson expressly

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[28] Likewise, contrary to Petitioners' intimations (Br. 48-49), post-enactment statements by executive officials on behalf of the President cannot show what *Congress* meant when it enacted legislation. Cf. Marc N. Garber & Kurt A. Wimmer, *Presidential Signing Statements As Interpretations Of Legislative Intent: An Executive Aggrandizement Of Power*, 24 HARV. J. LEG. 363 (1987) (arguing that courts should not use presidential signing statements to interpret statutes).

"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-

defect claims, as no reported decision since 1986 in a case that is subject to the Vaccine Act has imposed liability against a vaccine manufacturer on the basis of a design-defect claim. Congress's comprehensive National Vaccine Program provides manufacturers with clear incentives to develop safe and efficacious vaccines without such tort liability.

Petitioners unpersuasively argue that vaccine-injury claimants need state-law tort liability in order to "uncove[r] information about adverse side effects not generally available to federal regulators." Br. 55. As an initial matter, there is no reason to think that manufacturers will have more information than federal regulators concerning adverse side effects, given that the complementary VAERS and VSD systems operate to provide substantial information on such side effects to federal regulators, and given that manufacturers' ongoing disclosure duties are enforced by conditioning the adequate-warnings presumption on manufacturers' compliance with those duties. But even if manufacturers could be assumed to have more information than federal regulators concerning adverse side effects, there is no basis to conclude that a *design*-defect claim (and the discovery that might come with it) is needed for plaintiffs to discover such information. Rather, plaintiffs may assert a manufacturing-defect or a failure-to-warn claim (the types of claims carved out from preemption under Section 22(b)(1)), and obtain discovery regarding adverse side effects through prosecution of those claims.

Petitioners further submit (Br. 58) that the requirement that injured persons must exhaust their Vaccine Court remedies and reject the resulting Vaccine Court judgment before bringing a civil action

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/BiologicsBloodVaccines/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.

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(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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