SUPREME COURT OF THE UNITED STATES

No. 09–152

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

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

[February 22, 2011]

JUSTICE BREYER, concurring.

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

I

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

> "cannot demonstrate under applicable law either that a vaccine was improperly prepared or that it was accompanied by improper directions or inadequate warnings [they] should pursue recompense in the

> compensation system, not the tort system." H. R. Rep. No. 99–908, pt. 1, p. 24 (1986) (hereinafter H. R. Rep.).

The Report lists two specific kinds of tort suits that the clause does not pre-empt (suits based on improper manufacturing and improper labeling), while going on to state that compensation for other tort claims, *e.g.*, design-defect claims, lies in "the [NCVIA's no-fault] compensation system, not the tort system." *Ibid.*

The strongest contrary argument rests upon the Report's earlier description of the statute as "set[ting] forth the principle contained in Comment k" (of the Restatement Second of Torts' *strict liability* section, 402A) that "a vaccine manufacturer should not be liable for injuries or deaths resulting from *unavoidable* side effects." *Id.*, at 23 (emphasis added). But the appearance of the word "unavoidable" in this last-mentioned sentence cannot provide petitioners with much help. That is because nothing in the Report suggests that the statute means the word "unavoidable" to summon up an otherwise unmentioned third exception encompassing suits based on design defects. Nor can the Report's reference to comment *k* fill the gap. The Report itself refers, not to comment *k*'s details, but only to its "*principle,*" namely, that vaccine manufacturers should *not* be held liable for unavoidable injuries. It says nothing at all about who—judge, jury, or federal safety agency—should decide whether a safer vaccine could have been designed. Indeed, at the time Congress wrote this Report, different state courts had come to very different conclusions about that matter. See Cupp, Rethinking Conscious Design Liability for Prescription Drugs: The *Restatement (Third)* Standard Versus a Negligence Approach, 63 Geo. Wash. L. Rev. 76, 79 (1994–1995) ("[C]ourts [had] adopted a broad range of conflicting interpretations" of comment *k*). Neither the word "unavoid-

able" nor the phrase "the principle of Comment k" tells us which courts' view Congress intended to adopt. Silence cannot tell us to follow those States where juries decided the design-defect question.

II

The legislative history describes the statute more generally as trying to protect the lives of children, in part by ending "the instability and unpredictability of the childhood vaccine market." H. R. Rep., at 7; see *ante,* at 2–3. As the Committee Report makes clear, routine vaccination is "one of the most spectacularly effective public health initiatives this country has ever undertaken." H. R. Rep., at 4. Before the development of routine whooping cough vaccination, for example, "nearly all children" in the United States caught the disease and more than 4,000 people died annually, most of them infants. U. S. Dept. of Health and Human Services, Centers for Disease Control and Prevention, What Would Happen if We Stopped Vaccinations? http://www.cdc.gov/vaccines/vac-gen/whatifstop.htm (all Internet materials as visited Feb. 17, 2011, and available in Clerk of Court's case file); Preventing Tetanus, Diphtheria, and Pertussis Among Adolescents: Use of Tetanus Toxoid, Reduced Diptheria Toxoid and Acellular Pertussis Vaccines, 55 Morbidity and Mortality Weekly Report, No. RR–3, p. 2 (Mar. 24, 2006) (hereinafter Preventing Tetanus) (statistics for 1934–1943), http://www.cdc.gov/mmwr/PDF/rr/rr5503.pdf; U. S. Dept. of Health and Human Services, Centers for Disease Control and Prevention, Epidemiology and Prevention of Vaccine-Preventable Diseases 200 (11th ed. rev. May 2009). After vaccination became common, the number of annual cases of whooping cough declined from over 200,000 to about 2,300, and the number of deaths from about 4,000 to about 12. Preventing Tetanus 2; Childhood Immunizations, House Committee on Energy and Com-

merce, 99th Cong., 2d Sess., 10 (Comm. Print 1986) (hereinafter Childhood Immunizations).

But these gains are fragile; "[t]he causative agents for these preventable childhood illnesses are ever present in the environment, waiting for the opportunity to attack the unprotected individual." Hearing on S. 827 before the Senate Committee on Labor and Human Resources, 99th Cong., 2d Sess., pt. 2, pp. 20–21 (1985) (hereinafter Hearings) (testimony of the American Academy of Pediatrics); see California Dept. of Public Health, Pertussis Report (Jan. 7, 2011), www.cdph.ca.gov/programs/immunize/Documents/PertussisReport2011–01–07.pdf (In 2010, 8,383 people in California caught whooping cough, and 10 infants died). Even a brief period when vaccination programs are disrupted can lead to children's deaths. Hearings 20–21; see Gangarosa et al., Impact of Anti-Vaccine Movements on Pertussis Control: The Untold Story, 351 Lancet 356–361 (Jan. 31, 1998) (when vaccination programs are disrupted, the number of cases of whooping cough skyrockets, increasing by orders of magnitude).

In considering the NCVIA, Congress found that a sharp increase in tort suits brought against whooping cough and other vaccine manufacturers between 1980 and 1985 had "prompted manufacturers to question their continued participation in the vaccine market." H. R. Rep., at 4; Childhood Immunizations 85–86. Indeed, two whooping cough vaccine manufacturers withdrew from the market, and other vaccine manufacturers, "fac[ing] great difficulty in obtaining [product liability] insurance," told Congress that they were considering "a similar course of action." H. R. Rep., at 4; Childhood Immunizations 68–70. The Committee Report explains that, since there were only one or two manufacturers of many childhood vaccines, "[t]he loss of any of the existing manufacturers of childhood vaccines . . . could create a genuine public health hazard"; it "would present the very real possibility of vaccine short-

ages, and, in turn, increasing numbers of unimmunized children, and, perhaps, a resurgence of preventable diseases." H. R. Rep., at 5. At the same time, Congress sought to provide generous compensation to those whom vaccines injured—as determined by an expert compensation program. *Id.,* at 5, 24.

Given these broad general purposes, to read the preemption clause as preserving design-defect suits seems anomalous. The Department of Health and Human Services (HHS) decides when a vaccine is safe enough to be licensed and which licensed vaccines, with which associated injuries, should be placed on the Vaccine Injury Table. 42 U. S. C. §300aa–14; *ante,* at 3–4; A Comprehensive Review of Federal Vaccine Safety Programs and Public Health Activities 13–15, 32–34 (Dec. 2008), http://www.hhs.gov/nvpo/nvac/documents/vaccine-safety-review.pdf. A special master in the Act's compensation program determines whether someone has suffered an injury listed on the Injury Table and, if not, whether the vaccine nonetheless caused the injury. *Ante,* at 3–4; §300aa–13. To allow a jury in effect to second-guess those determinations is to substitute less expert for more expert judgment, thereby threatening manufacturers with liability (indeed, strict liability) in instances where any conflict between experts and nonexperts is likely to be particularly severe—instances where Congress intended the contrary. That is because potential tort plaintiffs are unlikely to bring suit unless the specialized compensation program has determined that they are not entitled to compensation (say, because it concludes that the vaccine did not cause the injury). Brief for United States as *Amicus Curiae* 28 ("99.8% of successful Compensation Program claimants have accepted their awards, foregoing any tort remedies against vaccine manufacturers"). It is difficult to reconcile these potential conflicts and the resulting tort liabilities with a statute that seeks to diminish

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

III

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

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

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

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

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