No. 09-152

IN THE
Supreme Court of the United States

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

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

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

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May 24, 2010

QUESTION PRESENTED

Section 22(b)(1) of the National Childhood Vaccine Injury Act of 1986 precludes liability for certain claims against vaccine manufacturers "if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." 42 U.S.C. § 300aa-22(b)(1).

The question presented is:

Does § 22(b)(1) preclude all vaccine design-defect claims even if the vaccine's side effects were avoidable?

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

CASES

STATUTES AND REGULATIONS

ADMINISTRATIVE MATERIALS

EXECUTIVE MATERIALS

LEGISLATIVE MATERIALS

OTHER MATERIALS

INTRODUCTION

Congress enacted the National Childhood Vaccine Injury Act ("NCVIA") in 1986 and 1987 against a long tradition of state-law design-defect claims against manufacturers for vaccines' injurious side effects. In reaching a historic compromise between vaccine makers seeking complete immunity from design-defect suits and families of victims whose lives had been irretrievably damaged by harmful vaccine side effects, Congress enacted numerous protections for both. Among them was a provision precluding liability for design defects in vaccines "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) (emphasis added).

In April 1992, petitioners Russell and Robalee Bruesewitz experienced one of a parent's worst nightmares when their healthy six-month-old daughter Hannah was injected with respondent Wyeth's Tri-Immunol diphtheria-tetanus-pertussis ("DTP") vaccine. Hannah immediately suffered scores of seizures and has been developmentally impaired ever since. Tri-Immunol, developed in the 1940s, had long been superseded by a more modern design, but Wyeth declined to change its DTP vaccine's design because it viewed the economic costs as outweighing any potential gain in market share. In 1998, Wyeth withdrew Tri-Immunol from the market.

This case presents the question whether the NCVIA categorically precludes all design-defect claims even if the vaccine's side effects were avoidable. The NCVIA's text, the statute's structure, the legislative history, and sound policy all confirm that

Congress intended to foreclose liability only when the harms caused by the vaccine's design were unavoidable, provided that the vaccine had been properly prepared and the warnings were adequate. Congress did not declare all vaccine side effects unavoidable as a matter of law, and it therefore did not preclude claims, like the Bruesewitzes', based on injuries caused by a scientifically outmoded design.

OPINIONS BELOW

The court of appeals' opinion (App.[1] A1-A52) is reported at 561 F.3d 233. The district court's opinion (App. A53-A100) is reported at 508 F. Supp. 2d 430.

JURISDICTION

The court of appeals entered its judgment on March 27, 2009, and denied rehearing on May 6, 2009 (App. A101-A102). The petition for a writ of certiorari was filed on August 4, 2009, and was granted on March 8, 2010 (130 S. Ct. 1734). This Court's jurisdiction rests on 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

Section 22 of the NCVIA, 42 U.S.C. § 300aa-22, is reproduced at App. A104-A106.

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

STATEMENT

A. Statutory And Regulatory Background

1. The history of vaccine regulation

Vaccines consist of potent and potentially deadly pathogens administered to healthy individuals to stimulate the production of immunizing anti-bodies. *See Toner v. Lederle Labs.*, 779 F.2d 1429, 1430 (9th Cir. 1986) (Kennedy, J.). The whole-cell pertussis vaccine administered to Hannah Bruesewitz in 1992 consisted of "whole killed pertussis organisms" and was known by respondent to be "neurotoxic" "as early as the 1950's." *Id.* at 1430-31. Less dangerous "acellular" or "split-cell" versions of the DTP vaccine had been marketed in the United States and abroad by the 1960s, but Wyeth did not pull its whole-cell version from the market until 1998.

Because of their potential safety risks, vaccines historically have been regulated by states pursuant to their traditional police powers. *See*, *e.g.*, *Jacobson v. Massachusetts*, 197 U.S. 11, 38-39 (1905). Congress recognized as much when, in 1813, it initiated a short-lived and unsuccessful effort to regulate vaccines. *See* Act of Feb. 27, 1813, ch. 37, 2 Stat. 806. Enacted amid concerns over contaminated or fraudulent doses of smallpox vaccine, the 1813 Act authorized the President to appoint an agent to preserve and distribute "genuine vaccine matter." *Id.* § 1, 2 Stat. 806. In 1822, Congress repealed the law, *see* Act of May 4, 1822, ch. 50, 3 Stat. 677, concluding that vaccination was "not properly within the province of this Government but of the several States," 39 Annals of Cong. 1634 (1822).

From 1822 until early in the 20th century, state and local governments exercised exclusive authority over vaccination. *See*, *e.g.*, An Act for the Free

Distribution of Genuine Vaccine Matter, 1814 Va. Acts ch. 14, p. 43 (allocating funds for vaccinations); *State v. Hay*, 35 S.E. 459, 461 (N.C. 1900) (noting that the "power of the legislature to authorize county and municipal authorities to require compulsory vaccination has been exercised by nearly every state"). State courts also routinely adjudicated vaccine-related claims under state law.[2]

In 1902, Congress enacted the Biologics Control Act, ch. 1378, 32 Stat. 728. That legislation required any establishment preparing vaccines to obtain a license from the Treasury Secretary. *Id*. § 1, 32 Stat. 728. But it did not displace the primacy of state regulation: in the ensuing decades, state courts regularly adjudicated common-law claims brought by individuals injured by vaccines. Those included claims that manufacturers acted negligently in manufacturing vaccines, *see Baudenbach v. Schwerdtfeger*, 230 N.Y.S. 640 (N.Y. App. Div. 1928); in providing inadequate warnings, *see Carmen v. Eli Lilly & Co.*, 32 N.E.2d 729 (Ind. Ct. App. 1941); and in furnishing for inoculation vaccines that were "not sterile, safe, or suitable for the use for which [they were] intended," *Tremaine v. H.K. Mulford Co.*, 176 A. 212, 212-13 (Pa. 1935).

In 1944, Congress revised and recodified the 1902 law in the Public Health Service Act, ch. 373, 58 Stat. 682 ("PHSA") (codified as amended at 42 U.S.C. § 201 *et seq*.). The PHSA required manufacturers to

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[2] *See Hazen v. Strong*, 2 Vt. 427 (1830); *Abeel v. Clark*, 24 P. 383 (Cal. 1890); *Bissell v. Davison*, 32 A. 348 (Conn. 1894); *Duffield v. School Dist. of Williamsport*, 29 A. 742 (Pa. 1894); *Morris v. City of Columbus*, 30 S.E. 850 (Ga. 1898); *Wyatt v. City of Rome*, 31 S.E. 188 (Ga. 1898); *Blue v. Beach,* 56 N.E. 89 (Ind. 1900).

procure both an establishment and a product license before commercially distributing a vaccine. *Id.* § 351(a), 58 Stat. 702. Those licenses were granted if manufacturers met standards "designed to insure the continued safety, purity, and potency." *Id.* § 351(d), 58 Stat. 702. Although Congress has revised the PHSA and consolidated the two licenses into a single biologics license, *see* Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, § 123(a)(2), (g), 111 Stat. 2296, 2323-24 ("1997 FDA Act"), the applicable statutory criteria by which vaccines are approved remain unchanged, *see* 42 U.S.C. § 262. The PHSA continues to be the primary source of authority for the federal regulation of vaccines, supplemented by various provisions of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq*.

Passage of the PHSA in 1944 did not disturb state law's traditional role in providing compensation to individuals injured by vaccines. Many such claims continued to sound in negligence. *See*, *e.g.*, *Stromsodt v. Parke-Davis & Co.*, 257 F. Supp. 991, 994 (D.N.D. 1966), *aff'd*, 411 F.2d 1390 (8th Cir. 1969); *Givens v. Lederle*, 556 F.2d 1341 (5th Cir. 1977). Courts also permitted strict-liability claims by victims seeking to recover even absent negligence. *See*, *e.g.*, *Davis v. Wyeth Labs., Inc.*, 399 F.2d 121 (9th Cir. 1968); *cf. Gottsdanker v. Cutter Labs.*, 6 Cal. Rptr. 320 (Cal. Ct. App. 1960). Notwithstanding federal regulatory efforts under the PHSA, courts routinely rejected claims that federal regulation of vaccines preempted state tort actions. *See Hurley v. Lederle Labs.*, 863 F.2d 1173, 1176 & n.2 (5th Cir. 1988) (citing cases). Thus, by the latter half of the 20th century, state law had developed a robust

corpus of case law establishing principles of manufacturer liability for vaccine injuries.

2. FDA regulation of vaccines

Since 1972, the Food and Drug Administration ("FDA") has also regulated vaccines and other biologics. *See* 37 Fed. Reg. 12,865 (June 29, 1972). FDA evaluation of a potential new vaccine begins when a sponsor approaches the agency with a product design and requests, via an Investigational New Drug application, authorization to conduct clinical trials. *See* 21 C.F.R. §§ 312.2(a), 312.20-312.38. Such trials aim to gather information about the safety and efficacy of the product in humans. *See id.*

Once clinical trials approach completion and the sponsor believes it has accumulated sufficient data concerning the vaccine's effect in humans, the sponsor may submit an application for a biologics license. *See id.* § 601.2. The sponsor must prove, *inter alia*, that the vaccine is safe, pure, potent, and effective. *See* 42 U.S.C. § 262; FDA, *Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products* 4 (May 1998) ("FDA Guidance"), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM078749.pdf.

FDA defines "safety" as

> relative freedom from harmful effect to persons affected, directly or indirectly, by a product when prudently administered, taking into consideration the character of the product in relation to the condition of the recipient at the time.

21 C.F.R. § 600.3(p).

To demonstrate the vaccine's "safety" under FDA's regulations, the sponsor need not show that it has

adopted the safest feasible design, and FDA does not purport to ensure that drugs are optimally designed.[3] In that respect, FDA is a "passive agency," because "it considers whether to approve vaccine designs only if and when manufacturers come forward with a proposal." *Hurley*, 863 F.2d at 1177; *see also Jones by Jones v. Lederle Labs.*, 695 F. Supp. 700, 711 (E.D.N.Y. 1988) ("[T]he agency takes the drugs and manufacturers as it finds them. While its goal is to oversee inoculation with the best possible vaccine, it is limited to reviewing only those drugs submitted by various manufacturers, regardless of their flaws.").[4]

Once approved, a vaccine's formulation or manufacturing process need not remain static. Rather, any aspect of a vaccine—including design—may be changed on the manufacturer's initiative so long as certain regulations are followed. Before distributing a product incorporating a change, the manufacturer

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[3] *See* Thuy D. Pham & Annette P. Martinez, *The Polio Vaccine and the Restatement (Third) of Torts: Why the Controversies?*, 11 DePaul J. Health Care L. 125, 158-59 (2008) ("[T]he FDA is not per se involved in initiating or conceptualizing . . . vaccine design, nor does the agency actively test for optimum drug design."); George W. Conk, *Is There a Design Defect in the Restatement (Third) of Torts: Products Liability?*, 109 Yale L.J. 1087, 1128-29 (2000) ("FDA does not claim to review products for optimal design.").

[4] FDA's review of vaccine design is no more comprehensive than for other drug products. Many of the same provisions govern both approval processes, *see*, *e.g.*, 21 C.F.R. § 312.2(a), and FDA issues Guidance Documents concerning approval standards that govern biologics and drug products, *see*, *e.g.*, FDA Guidance at 4. In 1997, Congress instructed the Secretary of Health and Human Services ("HHS") to "take measures to minimize differences in the review and approval of [biologics and drug] products." 1997 FDA Act § 123(f), 111 Stat. 2324 (codified at 21 U.S.C. § 355 note).

must assess the impact of the change on the safety and effectiveness of the vaccine. *See* 21 C.F.R. § 601.12. Changes that have a "substantial potential" to affect safety and effectiveness require FDA approval, whereas changes with a "moderate potential" must be submitted to FDA 30 days before implementation to provide the agency an opportunity to require approval. *Id.* § 601.12(b)-(c). Other changes need only be described in an annual report to FDA. *Id.* § 601.12(d).

As FDA has acknowledged, because the number of people exposed to a vaccine during clinical trials is relatively small, harmful side effects often are discovered only after the vaccine is licensed and administered to the general public.[5] FDA has only limited tools for monitoring such developments. One is to condition approval of a vaccine on a manufacturer's commitment to undertake post-marketing studies, or so-called "Phase IV" studies. *See* 21 U.S.C. § 355(*o*)(3); 42 U.S.C. § 262(a)(2)(D), (j); 21 C.F.R. § 601.70. A recent Office of Inspector General review of these studies in the drug context, however, revealed that one-third of the manufacturers' annual status reports were incomplete; even complete reports lacked information that would be useful; and "[m]onitoring postmarketing study commitments is not a top priority at FDA."[6]

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[5] *See* http://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/BiologicsLicenseApplicationsBLAProcess/ucm133096.htm ("Until a vaccine is given to the general population, all potential adverse events cannot be anticipated."); http://www.cdc.gov/vaccinesafety/Vaccine_Monitoring/history.html.

[6] Office of Inspector General, U.S. Dep't of Health & Human Servs., *FDA's Monitoring of Postmarketing Study Commitments*

FDA also conducts limited postmarketing surveillance of adverse events associated with vaccines. In doing so, however, "the Agency relies principally on a ***passive*** adverse event reporting system" that "depend[s] to a great extent on voluntary reporting by the healthcare community."[7] Although manufacturers and health care providers are required to report certain information about adverse events to FDA and a nationwide database known as the Vaccine Adverse Event Reporting System ("VAERS"), FDA has acknowledged that "[p]assive surveillance systems such as VAERS are subject to limitations" because "[v]accine-associated adverse events will inevitably be underreported to an unknown extent." 70 Fed. Reg. 75,180, 75,190 (Dec. 19, 2005). Moreover, FDA does not receive reports about safer alternatives, nor does it have authority to order a manufacturer to adopt a safer alternative design for a licensed vaccine. *See* 21 C.F.R. § 601.5.

3. The NCVIA

In the early 1980s, victims of vaccine-related injuries raised concerns about the cost, speed, and inconsistency of the tort system. *See* H.R. Rep. No. 99-908, pt. 1, at 6 (1986) ("1986 Report"), *reprinted in* 1986 U.S.C.C.A.N. 6344. At the same time, some vaccine manufacturers sought immunity from liability for vaccine-related injuries and deaths. *See id.* Congress considered numerous proposals for legisla-

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ii-iii (June 2006), *available at* http://oig.hhs.gov/oei/reports/oei-01-04-00390.pdf.

[7] Task Force on Risk Mgmt., U.S. Dep't of Health & Human Servs., *Managing the Risks from Medical Product Use: Creating a Risk Management Framework* 12 (May 1999), *available at* http://www.fda.gov/downloads/Safety/SafetyofSpecificProducts/UCM180520.pdf.

tion. One early bill contemplated a voluntary compensation program that preserved state-law rights without modification. *See* H.R. 5810, 98th Cong. § 2101 (1984). Other proposals, championed by the vaccine industry, severely limited the availability of state-law remedies. The House considered a proposal immunizing manufacturers from most claims of strict liability, *see* H.R. 5184, 99th Cong. § 2122(c)(1) (1986), and the Senate considered granting complete immunity to manufacturers of vaccines that had been "tested, manufactured, distributed, and labeled in accordance with [FDA] requirements," *National Childhood Vaccine Injury Compensation Act of 1985 (Part 2): Hearing on S.827 Before the S. Comm. on Labor & Human Resources*, 99th Cong. 16 (1985). Ultimately, Congress rejected those proposals in favor of a compromise approach.

The 1986 legislation. Congress enacted the NCVIA in 1986. *See* Pub. L. No. 99-660, tit. III, 100 Stat. 3743, 3755 (codified as amended at 42 U.S.C. § 300aa-1 *et seq*.). The Act created a no-fault administrative compensation program—the National Vaccine Injury Compensation Program ("Compensation Program")—to supplement the traditional tort system. Congress believed that the Program would provide compensation to victims of vaccine side effects "quickly, easily, and with certainty and generosity," 1986 Report at 3, and thereby "dissuade [victims] from going on to court," H.R. Rep. No. 100-391, pt. 1, at 691 (1987) ("1987 Report"), *reprinted in* 1987 U.S.C.C.A.N. 2313-1.

Congress placed the Compensation Program within a division of the U.S. Court of Federal Claims, colloquially termed "Vaccine Court." *See* 42 U.S.C. § 300aa-12. A claimant seeking more than $1,000 in

damages from a vaccine-related injury or death must submit a petition for compensation with the Vaccine Court before filing a civil action in state or federal court. *See id.* §§ 300aa-11, 300aa-21. A special master considers the petition in an administrative (rather than an adversarial) setting, with subsequent review by the Court of Federal Claims and then the Federal Circuit. *See id.* § 300aa-12(d)-(f).

The Compensation Program applies only to vaccines recommended by CDC for routine administration to children. *See id.* §§ 300aa-11(b), 300aa-14. Covered vaccines are listed in a Vaccine Injury Table maintained by HHS. *See id.* § 300aa-14; 42 C.F.R. § 100.3. The Table also lists selected injuries known to be associated with each vaccine and time limits for the onset of the injuries. *See* 42 U.S.C. § 300aa-14. A claimant who shows by a preponderance of the evidence that he sustained or the vaccine aggravated a listed injury within the specified timeframe (a so-called "Table injury") is presumptively entitled to compensation. *See id.* §§ 300aa-11(c), 300aa-13(a). A claimant who suffered a non-Table injury must show that the vaccine in fact caused the injury. *See id.* A claimant cannot receive compensation, however, if the court finds that the injury was caused by factors unrelated to administration of the vaccine. *See id.* § 300aa-13(a).

Although claimants must begin with a petition to the Vaccine Court, NCVIA § 21 permits victims to bring a "*de novo*" civil action if either of two conditions is satisfied. *Shalala v. Whitecotton*, 514 U.S. 268, 270 (1995). First, a claimant dissatisfied with the special master's decision may elect to decline the award and file a civil action. *See* 42 U.S.C. § 300aa-21(a). Second, if the special master fails to render a

decision within 240 days, the victim may withdraw the petition and proceed with a civil suit. *See id.* § 300aa-21(b)(1), (c). Congress designed the Compensation Program to be an "appealing alternative" to, but not a substitute for, the traditional tort system. 1986 Report at 26; *see Schafer v. American Cyanamid Co.*, 20 F.3d 1, 3 (1st Cir. 1994) (Breyer, C.J.).

Section 22 sets forth "standards of responsibility" to govern civil actions against vaccine manufacturers. 42 U.S.C. § 300aa-22(d); *see id.* § 300aa-23(b)-(d) (referring to determinations of liability "under section 300aa-22"). Subject to three narrow exceptions, the "[g]eneral rule" is that "State law shall apply to a civil action brought for damages for a vaccine-related injury or death." *Id.* § 300aa-22(a). Section 22(b)(1) provides one of those exceptions:

> **(b) Unavoidable adverse side effects; warnings**
>
> **(1)** 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)(2) then specifies that, "[f]or purposes of paragraph (1)," a vaccine ordinarily "shall be presumed to be accompanied by proper directions and warnings" if the manufacturer proves it complied with federal statutory and regula-

tory requirements. *Id.* § 300aa-22(b)(2).[8] Finally, § 22(e) ("Preemption") prohibits states from foreclosing civil actions against vaccine manufacturers if such actions are "not barred by this part." *Id.* § 300aa-22(e).

Section 22(b)(1) codifies comment k to § 402A of the Restatement (Second) of Torts (1965) ("Restatement"). *See*, *e.g.*, 1986 Report at 25 (explaining that the provision that became § 22(b)(1) "sets forth the principle contained in" comment k); 1987 Report at 691 (referring to "codification of Comment (k)"). Comment k carves out an exception to § 402A's strict products-liability rule for certain products that, "in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use." Restatement § 402A cmt. k. It provides that "[t]he seller of such products, . . . with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use." *Id.*

The NCVIA also prescribes a three-stage procedure by which civil actions for vaccine-related injuries must proceed. First, the court determines whether the "vaccine manufacturer is liable under [§ 22]." 42 U.S.C. § 300aa-23(b). The court next determines compensatory and then punitive damages. *See id.* § 300aa-23(c), (d)(1). The Act precludes punitive damages when the manufacturer can demonstrate compliance with applicable federal law. *See id.* § 300aa-23(d)(2).

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[8] Section 22(c) also precludes liability for failure to provide direct warnings to the vaccine recipient. 42 U.S.C. § 300aa-22(c).

The NCVIA's liability provisions reflected a carefully crafted compromise among the interests of victims and manufacturers. Congress did not enact funding for the Compensation Program before the end of the 99th Congress, however. Instead, Congress inserted an unusual provision that the NCVIA would not be effective unless and until Congress enacted further legislation providing funding for the Compensation Program. *See* NCVIA § 323(a), 100 Stat. 3784. Members who voted on the bill did so upon an express understanding that it would have no effect until further legislation was considered in the next Congress. *See*, *e.g.*, 132 Cong. Rec. 30,751, 30,761 (1986) (statement of Rep. Frenzel). Likewise, in signing the Act into law, President Reagan expressed "serious reservations" and enumerated numerous "corrective program changes" he wished to see before the legislation became effective.[9]

The 1987 legislation. When funding of the NCVIA was taken up in 1987, many lawmakers and interest groups attempted to revise the Act. The Reagan Administration expressed disappointment that the Compensation Program "would merely represent an alternative and in many cases preliminary forum to the tort system" and that "[a] showing by the manufacturer that it had complied with all material Federal regulatory requirements . . . would not give rise to a presumption that the vaccine was not defective in design."[10] Vaccine manufacturers

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[9] President Ronald Reagan, Statement on Signing the State Comprehensive Mental Health Plan Bill (Nov. 14, 1986), *available at* http://www.presidency.ucsb.edu/ws/print.php?pid=36733.

[10] *Funding of the Childhood Vaccine Program: Hearing Before the Subcomm. on Select Revenue Measures of the H. Comm. on*

expressed similar reservations and likewise advocated revisiting some of the Act's central provisions. *See* 1987 Hearing at 82, 84, 85, 102.

Fearing the compromises negotiated the year before would unravel, groups representing the families of injured victims insisted that "[t]he new funding law . . . not tamper with existing safeguards of [the NCVIA], . . . includ[ing]: preservation of parents' right to sue vaccine makers . . . in cases involving negligence [or] unreasonably dangerous vaccines." *Id.* at 64.

Ultimately, Congress passed legislation funding the Compensation Program through an excise tax on each vaccine dose. *See* Vaccine Compensation Amendments of 1987, Pub. L. No. 100-203, tit. IV, subtit. D, 101 Stat. 1330, 1330-221; 42 U.S.C. § 300aa-15(i)(2); 26 U.S.C. §§ 4131-4132, 9510. While the 1987 legislation modified the NCVIA's substantive provisions in several respects,[11] Congress left the provisions relating to civil actions against vaccine manufacturers intact. The Committee Report accompanying the 1987 legislation confirmed that

> [i]t is not the Committee's intention to preclude court actions under applicable law. The Committee's intent at the time of considering the Act and in these amendments was and is to leave otherwise applicable law unaffected, except as expressly altered by the Act and the amendments.

Ways and Means, 100th Cong. 18, 25 n.7 (1987) ("1987 Hearing") (statement of Dennis E. Ross, Tax Legislative Counsel, Treasury Department).

[11] For example, Congress transferred jurisdiction over the Compensation Program from the federal district courts to the U.S. Court of Federal Claims. *Compare* NCVIA § 311(a), 100 Stat. 3761, *with* 42 U.S.C. § 300aa-12.

> An amendment to establish as part of this compensation system that a manufacturer's failure to develop safer vaccine was not grounds for liability was rejected by the Committee during its original consideration of the Act. Further, the codification of Comment (k) of The Restatement (Second) of Torts was not intended to decide as a matter of law the circumstances in which a vaccine should be deemed unavoidably unsafe. The Committee stresses that there should be no misunderstanding that the Act undertook to decide as a matter of law whether vaccines were unavoidably unsafe or not. This question is left to the courts to determine in accordance with applicable law.

1987 Report at 691.

B. The History Of The DTP Vaccine

Pertussis, commonly known as "whooping cough," is a bacterial respiratory infection caused by the bacterium *B. pertussis*. *See* Stefania Salmaso, *Pertussis*, *in The Vaccine Book* 211, 212 (Barry R. Bloom & Paul-Henri Lambert eds., 2003) ("Salmaso"). The first pertussis vaccine was approved by the federal government in 1914. *See* Kathyrn M. Edwards & Michael D. Decker, *Pertussis vaccines*, *in Vaccines* 467, 479 (Stanley A. Plotkin, Walter A. Orenstein & Paul A. Offit eds., 5th ed. 2008) ("Edwards & Decker"). That original vaccine was a "whole cell" pertussis vaccine because it consisted of a suspension of inactivated whole *B. pertussis* cells. *See id.* By the 1940s, the whole-cell vaccine was commonly combined with diphtheria and tetanus toxoids to form the DTP vaccine. *See id.* The Wyeth Tri-Immunol vaccine administered to Hannah Bruesewitz was a

whole-cell vaccine initially licensed in the 1940s. *See* JA134-35 (detailing Tri-Immunol's licensing history).

The whole-cell pertussis vaccine has "long been recognized as one of [the] most reactogenic vaccines," causing adverse reactions that include acute encephalopathy, anaphylaxis, and febrile seizures. Edwards & Decker at 485-87; *accord Toner*, 779 F.2d at 1430. Concerns about the vaccine's safety were raised as early as the 1930s; by the late 1940s, two widely cited articles confirmed the vaccine's neurotoxic effect.[12] Lederle Laboratories ("Lederele"), which Wyeth acquired in 1994, "was aware of the neurotoxicity of Tri-Immunol as early as the 1950's." *Id.* at 1431. Criticism of the vaccine's safety increased over the next several decades and prompted action abroad: in 1979, Sweden withdrew use of the whole-cell pertussis vaccine, and Japan abandoned the vaccine in favor of an acellular version in 1981.[13]

The whole-cell vaccine's toxicity prompted scientists to research a less harmful pertussis vaccine. In the 1950s, researchers published a methodology for producing a less toxic vaccine, and, by the 1960s, Eli Lilly had obtained approval from the federal

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[12] *See* Thorvald Madsen, *Vaccination Against Whooping Cough*, 101 J. Am. Med. Ass'n 187 (1933); Louis W. Sauer, *Whooping Cough: A Study in Immunization*, 100 J. Am. Med. Ass'n 239 (1933); Randolph K. Byers & Frederic C. Moll, *Encephalopathies Following Prophylactic Pertussis Vaccine*, 14 Pediatrics 437 (1948); John A. Toomey, *Reactions to Pertussis Vaccine*, 139 J. Am. Med. Ass'n 448 (1948).

[13] *See* Elizabeth Miller, *Progress Towards A New Pertussis Vaccine*, 292 British Med. J. (Clinical Research Edition) 1348, 1348-49 (May 24, 1986).

government to distribute a split-cell vaccine.[14] The vaccine, sold under the trade-name Tri-Solgen, dominated the market because it was "superior" to whole-cell forms. *See* JA245 (internal correspondence noting that Eli Lilly has "half of [the market] because of a superior product"); JA208 (internal correspondence noting that "Eli Lilly[] has successfully developed a non-cellular pertussis vaccine" and "has swung the triple vaccine . . . market in their favor").

In the late 1960s, Lederle conducted internal studies confirming that its whole-cell Tri-Immunol was more reactogenic than Eli Lilly's split-cell Tri-Solgen. *See* JA230-34 (internal correspondence noting "significant differences in reaction rates were observed in infants receiving either Lederle Tri-Immunol or Lilly Tri Solgen"); JA66; Burke, 17 Seton Hall L. Rev. at 569. Lederle's internal correspondence shows that the company tried briefly in the late 1960s to create "an improved pertussis component," but "[d]rop[ped]" the project after concluding that "[t]he effort is not worth it for the total market." JA242; *see* JA245 ("The effort [to develop an acellular version] is certainly not commensurate with the gain.").

In the mid-1970s, Eli Lilly stopped producing Tri-Solgen. Wyeth obtained the right to produce the vaccine, but chose to reformulate the product. *See Graham by Graham v. Wyeth Labs.,* 906 F.2d 1399, 1403 (10th Cir. 1990). Despite the reformulation, Wyeth wanted to keep the Tri-Solgen trade name. *See* JA204-05. FDA denied Wyeth permission to do

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[14] *See* James M. Burke, *DPT Vaccine Controversy: An Assessment of the Liabilities of Manufacturers and Administering Physicians Under Several Legal Theories*, 17 Seton Hall L. Rev. 541, 569 (1987).

so, noting that it might constitute "mislabeling." *Id.* Wyeth never marketed the original formulation of Tri-Solgen and, for the next two decades, Tri-Immunol remained on the market. *See generally* Burke, 17 Seton Hall L. Rev. at 569-70, 573-75.

In 1998—six years after Hannah Bruesewitz received the injection that caused her injuries—Wyeth ceased production of Tri-Immunol. *See* JA135. By that point, it had applied for, and received, a biologics license for "DTaP" vaccine that incorporated an acellular pertussis component. Marketed under the trade name Acel-Imune, the vaccine was approved for use in fourth and fifth doses of childhood vaccination series in December 1991 and for all doses in 1996. *See* JA36. The pertussis component of Acel-Imune is sourced from Japan, where manufacturers have been producing and marketing acellular pertussis vaccines since the 1970s. *See* CDC, *Pertussis Vaccination: Use of Acellular Pertussis Vaccines Among Infants and Young Children*, Morbidity and Mortality Weekly Report, Vol. 46, No. RR-7, at 3 (Mar. 28, 1997), *available at* http://www.cdc.gov/mmwr/PDF/rr/rr4607.pdf. CDC's studies have shown that the acellular pertussis vaccine has comparable efficacy but is associated with fewer adverse events than the whole-cell version. *See id.* at 4; Salmaso at 218, 220. The whole-cell pertussis vaccine is no longer marketed in the United States, Canada, Australia, and several Asian and European countries.

C. Administration Of Wyeth's DTP Vaccine To Hannah Bruesewitz

On April 1, 1992, Hannah Bruesewitz, then a healthy six-month-old baby girl, received her third dose of Wyeth's Tri-Immunol vaccine. *See* App. A6. Within hours, Hannah experienced her first seizure.

See Bruesewitz v. Secretary of HHS, No. 95-0266V, 2002 WL 31965744, at *2 (Fed. Cl. Dec. 20, 2002). Over the next 16 days, Hannah experienced a total of 125 seizures, at times spaced at one every half hour. *See id.* at *2-*4.

Over the ensuing months, Hannah's symptoms progressively worsened. Her medical records note that she was lethargic, exhibited autistic-like features, and was developmentally delayed. *See id.* at *4-*5. At 20 months, she had no discernible speech and comprehended only simple commands. *See id.* at *6. Of eight electroencephalograms ("EEGs") taken between April 1992 and July 1995, seven were abnormal, and a CT scan taken at the end of that period showed diffuse neuronal loss. *See id.* at *5-*7. In the four years that followed her vaccination, Hannah was prescribed numerous medications to treat her symptoms, including Felbatol, which is prescribed for severe epilepsy. *See id.* at *4-*6; JA124; http://www.felbatol.com/felbatol.html.

A neurobehavioral evaluation in 2003 diagnosed Hannah with "pervasive developmental disorder and seizure disorder" and recommended her continued involvement in "intensive high-quality one-on-one intervention," as well as occupational and speech therapy. JA126-27. Now a teenager, Hannah suffers from residual seizure disorder and remains developmentally impaired. She will require a lifetime of supervision and care.

The vaccine dose Hannah received came from a lot associated with an unusually large number of adverse events. By the time of her inoculation, VAERS reported 1 death and 30 adverse events, including 8 reports of convulsions, from the lot; those numbers later rose to 2 deaths and more than 60

adverse events (including 39 emergency room visits). *See* JA202-03. Wyeth and Lederle apparently took deliberate steps to obscure adverse events associated with particular lots of vaccine. Internal correspondence in the 1970s suggested that the company report adverse events individually rather than in a summary fashion, stating that "[w]e would not want several cases in a summary [to] be discovered by Plaintiff's counsel." JA267; *see also* JA252-53. Another internal memorandum was written after eight children in Tennessee died within one week of receiving the DTP vaccine. *See* JA268-69; *see also* JA252-53. It noted that, after the incident, senior management agreed to "limit[] distribution of a large number of vials from a single lot to a single state, county or city health department." JA268. Hannah's physician testified that she would not have administered the particular vaccine dose to Hannah had she known that it came from a lot associated with such a large number of adverse events. *See* JA203.

D. Proceedings Below

1. On April 3, 1995, the Bruesewitzes filed a petition in the Vaccine Court, seeking compensation under the NCVIA for their daughter's injuries. *See* JA1. Just one month before her petition was filed, new regulations eliminated "residual seizure disorder" from the Vaccine Table for DTP. *See Bruesewitz*, 2002 WL 31965744, at *1 n.1. In December 2003, the court dismissed the petition with prejudice after concluding that Hannah suffered only non-Table injuries and had not proved that the DTP vaccine caused her injuries. *Id.* at *17; *but cf. Andreu ex rel. Andreu v. Secretary of HHS*, 569 F.3d 1367, 1374-75 (Fed. Cir. 2009) (reversing special master's finding that parents failed to show causal relation-

ship between whole-cell pertussis vaccine and son's seizures). On February 14, 2003, petitioners elected to reject the court's judgment under § 21. *See* JA2.

2. In October 2005, petitioners filed a complaint against Wyeth in Pennsylvania state court, seeking damages for Hannah's injuries under state law. *See* JA5-6. Wyeth removed the case on diversity grounds to federal district court. *See* JA6, 7. Petitioners' amended complaint alleged that Wyeth negligently failed to develop a safer vaccine and was strictly liable for injuries caused by the vaccine's defective design. *See* JA55-60.

Wyeth moved for summary judgment, arguing that NCVIA § 22(b)(1) expressly preempts liability based on defective design of FDA-approved childhood vaccines, irrespective of whether a safer alternative vaccine existed at the time of vaccination. Despite the district court's invitation to submit an *amicus* brief, FDA and HHS declined, stating that, "[a]fter careful review, HHS and FDA have determined that they do not have views on the issues presented." App. A107.

The court granted Wyeth's motion for summary judgment on petitioners' design-defect claims. The court acknowledged that § 22(b)(1) was "[i]nformed by" comment k of Restatement § 402A. App. A67. The court then analyzed comment k and determined that it

> suggests that the question of whether a particular vaccine is unavoidably unsafe—and therefore subject to the immunity from suit posited by comment k—is a question of fact for a jury to determine. That is, the trier of fact must decide whether the challenged vaccine is the only design available, "in the present state of human knowledge."

App. A83-A84. Notwithstanding those conclusions, the court held that "§ 22(b) is broader than comment k, so that the [NCVIA] preempts state law determinations of whether a vaccine is unavoidably unsafe, and therefore entitled to comment k immunity." App. A85.

3. The Third Circuit affirmed. That court concluded that § 22(b)(1) was an express preemption provision, although it was unable to "resolve from statutory text alone the scope of the express preemption provision." App. A21, A26. Instead, the court relied on § 22's "structure" and legislative history in concluding that it precludes all design-defect claims. App. A27.

First, the court relied heavily on § 22(e), which "prohibits states from foreclosing civil actions that are otherwise 'not barred by this part.'" App. A27-A28. It read that language as "stating that other parts of § 300aa-22 are designed to not only limit liability but bar some claims entirely." App. A28. On that basis, the court concluded that Congress could not have intended "case-by-case analysis of whether particular vaccine side effects are avoidable," because then "every design defect claim [would be] subject to evaluation by a court." App. A29. It thus rejected petitioners' interpretation of § 22(b) because it "does not bar *any* design defect claims." *Id.* (emphasis added). However, the court said it could not determine from structure alone whether § 22(b)(1) preempts all such claims, or only those sounding in strict liability. *See* App. A29, A31.

To resolve that issue, the Third Circuit reviewed the NCVIA's legislative history. In concluding that the Act precluded all design-defect claims, regardless of fault, the court relied on a 1986 House Energy

and Commerce Committee Report. *See* App. A31-A36. The court acknowledged that the report stated that the Act "reflected the principle of Restatement (Second) of Torts § 402A comment k." App. A33. It also recognized that a majority of courts have interpreted comment k as permitting a case-by-case analysis of whether a particular product is unavoidably unsafe. *See id.* However, the court viewed the following language as reflecting Congress's intent to eliminate all design-defect claims: "Vaccine-injured persons will now have an appealing alternative to the tort system. Accordingly, if they cannot demonstrate under applicable law either that a vaccine was improperly prepared or that it was accompanied by improper directions or inadequate warnings should [sic] pursue recompense in the compensation system, not the tort system." 1986 Report at 26. The court gave no weight to the statement in the Committee Report accompanying the 1987 legislation that whether a vaccine's side effects are "unavoidable" must be determined on a case-by-case basis. *See supra* pp. 15-16.[15]

[15] The Third Circuit also suggested that, even if Congress did not preempt all design-defect claims, it preempted petitioners' specific claim regarding the safety of the whole-cell pertussis component of the DTP vaccine. *See* App. A40-A42.

SUMMARY OF ARGUMENT

I. Section 22(b)(1) of the NCVIA exempts vaccine manufacturers from civil liability for vaccine-related injuries only if those injuries resulted from unpreventable side effects. The clause "if the injury or death resulted from side effects that were unavoidable" commands that conclusion. The ordinary definition of the word "unavoidable" is "incapable of being . . . prevented." By 1986, "unavoidable" also had attained a well-accepted legal meaning derived from comment k to Restatement § 402A and confirmed by numerous state and federal courts: a product's safety risks are "unavoidable" only if it is "incapable of being made safe for [its] intended and ordinary use." Restatement § 402A cmt. k.

Congress's use of the conditional word "if" to introduce the clause incorporating "unavoidable" side effects makes clear that a manufacturer is eligible for the liability exemption under § 22(b)(1) only upon a threshold showing that the vaccine's side effects could not have been prevented. Consistent with comment k and the majority of cases interpreting it, § 22(b)(1)'s conditional language contains no legal determination or presumption that all vaccine side effects are "unavoidable," but instead requires manufacturers to make that showing in a particular case. Congress also used conditional language in § 22(b)(2) and § 23(d)(2), which likewise require case-specific determinations. In contrast, when Congress wanted to create a categorical defense to liability for vaccine manufacturers, it did so explicitly without conditional language.

The clause "even though the vaccine was properly prepared and was accompanied by proper directions and warnings" is best read to impose comment k's

two *additional* prerequisites to exemption from liability, namely, that the vaccine be properly manufactured and accompanied by proper directions and warnings. The "even though" clause modifies the clause "if the injury or death resulted from side effects that were unavoidable," rather than just the word "unavoidable," thereby establishing proper manufacturing and proper directions and warnings as additional requirements. Given Congress's clear intent to codify comment k, that reading appropriately harmonizes § 22(b)(1) with comment k's standards, rather than eliminating comment k's core prerequisite that a vaccine be "unavoidably" unsafe. That reading also comports with the presumption against preemption.

II. The NCVIA's legislative history confirms that § 22(b)(1) does not exempt vaccine manufacturers from liability for preventable injuries. The Act's congressional sponsors, the President, and vaccine manufacturers all understood that manufacturers would remain responsible for making their vaccines as safe as possible for patients. Indeed, before the 1986 Act was passed, and then again before the 1987 legislation was enacted, industry representatives—including respondent Lederle's president—expressed dissatisfaction that § 22(b) did *not* immunize manufacturers from suits alleging that side effects could have been prevented by a safer design and urged Congress to enact a blanket immunity from design-related liability for vaccines approved by FDA. But Congress refused to do so. Instead, in enacting the 1987 funding legislation that put the NCVIA into effect, the Energy and Commerce Committee "stresse[d] that there should be no misunderstanding that the Act undertook to decide as a matter of law whether vaccines were unavoidably

unsafe or not. This question is left to the courts to determine in accordance with applicable law." 1987 Report at 691.

III. Interpreting § 22(b)(1) to exempt manufacturers from liability only for unpreventable injuries promotes Congress's purposes of ensuring vaccine safety and providing compensation to innocent victims of vaccine injury. Allowing design-defect claims for preventable harms provides a critical incentive for vaccine manufacturers to conduct adequate research, design their vaccines as safely as possible, and incorporate scientific advances into vaccine design to protect the public from unnecessary harm. Private lawsuits also promote FDA's regulation of vaccines because they help to unearth information about adverse side effects that FDA does not require manufacturers to submit in the regulatory process.

In contrast, eliminating all design-defect claims would not only undermine these social benefits, but also limit fair compensation to children and families injured by unnecessarily harmful vaccines. Indeed, if the decision below is affirmed, injured children would be denied redress even for injuries caused by recklessly designed vaccines or vaccines that a manufacturer knew would cause unnecessary harm. No sound policy justifies such a result. Respondent's dire warnings that vaccine manufacturers will leave the market unless all design-related liability is eliminated lack empirical support, given the success of the Compensation Program in reducing injured parties' need to resort to the tort system, and, in all events, are contrary to the policy balance struck by Congress. Certainly no such fear is warranted here, where respondent voluntarily took the vaccine that caused Hannah Bruesewitz's injuries off the market and other, safer DTP vaccines existed.

ARGUMENT

I. SECTION 22(b) OF THE NCVIA DOES NOT PRECLUDE OR PREEMPT CLAIMS SEEKING COMPENSATION FOR PREVENTABLE VACCINE-RELATED INJURIES

A. Under § 22(b)(1), Manufacturers Are Exempted From Civil Liability Only If The Vaccine's Side Effects Are "Unavoidable"

Section 22(a) provides as a "[g]eneral rule" that "State law shall apply to a civil action brought for damages for a vaccine-related injury or death." 42 U.S.C. § 300aa-22(a). Congress expressly preserved state law as the rule of decision for claims by injured children and their families against vaccine manufacturers, subject only to three exceptions set forth in subsections (b), (c), and (e). The relevant exception here—§ 22(b)—creates a limited exemption from otherwise applicable civil liability under state law "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).

1. Congress's use of the term "unavoidable" exempts vaccine manufacturers from civil liability only if the vaccine's side effects could not have been prevented

In construing statutes, this Court "begin[s], as always, with the text of the statute." *Permanent Mission of India to United Nations v. City of New York*, 551 U.S. 193, 197 (2007); *accord BP Am. Prod. Co. v. Burton*, 549 U.S. 84, 91 (2006) ("We start, of course, with the statutory text."). Here, the plain meaning of the word "unavoidable" is "not avoidable," "incapable of being . . . prevented," or "inevitable." *Webster's Third New International Dictionary* 2483

(2002) ("*Webster's*"). Thus, the plain meaning of the clause "if the injury or death resulted from side effects that were unavoidable" is that manufacturers are immunized from civil liability only if the vaccine's side effects could not have been prevented. If the side effects could have been avoided by a safer design, the product is defective, and the manufacturer is subject to liability for the resulting injuries.

The plain meaning of the term "unavoidable" is bolstered by the term's well-accepted legal meaning in products liability law. The term "unavoidable" is not merely a "generic or descriptive term, but a legal term of art" derived from comment k to Restatement § 402A. *Hamling v. United States*, 418 U.S. 87, 118 (1974); *see Ackley v. Wyeth Labs., Inc.*, 919 F.2d 397, 399 n.1 (6th Cir. 1990) ("The term 'unavoidably unsafe' is a term of art derived from the Restatement.").

Section 402A holds the seller of "any product in a defective condition unreasonably dangerous to the user or consumer" strictly liable for any injuries caused by the product, irrespective of whether the "seller has exercised all possible care in the preparation and sale of his product." Restatement § 402A(1)-(2); *see id.* cmt. a. Strict liability is justified because "the seller, by marketing his product for use and consumption, has undertaken and assumed a special responsibility toward any member of the consuming public who may be injured by it" and "the burden of accidental injuries caused by products intended for consumption [should] be placed upon those who market them, and be treated as a cost of production against which liability insurance can be obtained." *Id.* cmt. c.

Comment k to § 402A creates an exemption from strict liability for "unavoidably unsafe products,"

which are defined as those that, "in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use." *Id.* cmt. k. Such products are not considered "defective" or "*unreasonably* dangerous," and therefore are exempt from strict liability, "notwithstanding the unavoidable high degree of risk which they involve." *Id.* Thus, in the Restatement's parlance, "unavoidable" describes the inherent risks attendant to certain products that, while socially useful, cannot be made safer given the limits of then-prevailing scientific knowledge. *See* Am. L. Prods. Liab. 3d § 17:36, at 17-69 (1997).

Numerous state and federal cases confirmed the settled meaning of the term "unavoidable" prior to the NCVIA's enactment. Those decisions consistently interpreted "unavoidably unsafe" to mean that the product is designed in a way that does not present unnecessary risks of harm.[16] By 1986, "unavoidable"

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[16] *See*, *e.g.*, *Smith ex rel. Smith v. Wyeth Labs., Inc.*, No. Civ.A. 84-2002, 1986 WL 720792, at *5 (S.D. W. Va. Aug. 21, 1986) ("[A] prescription drug is not 'unavoidably unsafe' when its dangers can be eliminated through design changes that do not unduly affect its cost or utility."); *Kearl v. Lederle Labs.*, 218 Cal. Rptr. 453, 463-64 (Cal. Ct. App. 1985) ("unavoidability" turns on "(i) whether the product was designed to minimize—to the extent scientifically knowable at the time it was distributed—the risk inherent in the product, and (ii) the availability . . . of any alternative product that would have as *effectively* accomplished the *full intended purpose* of the subject product"), *disapproved in part by Brown v. Superior Ct.*, 751 P.2d 470 (Cal. 1988); *Feldman v. Lederle Labs.*, 479 A.2d 374, 386 (N.J. 1984) ("unavoidability" turns, in part, on whether there were "other design alternatives within practical and technological limits at the time of distribution") (internal quotations omitted); *Belle Bonfils Mem'l Blood Bank v. Hansen*, 665 P.2d 118, 122 (Colo. 1983) (for comment k to apply, a "product's benefits must not be achievable in another manner"); *Cassisi v. Maytag Co.*,

had acquired a specialized meaning: a product's safety risks are "unavoidable" only when they cannot be eliminated by a safer alternative design.

When Congress uses a term of art in a statute, it intends that term "to have its established meaning." *McDermott Int'l, Inc. v. Wilander*, 498 U.S. 337, 342 (1991). "[W]here Congress borrows terms of art . . . , it presumably knows and adopts the cluster of ideas that were attached to each borrowed word in the body of learning from which it was taken and the meaning its use will convey to the judicial mind unless otherwise instructed." *Morissette v. United States*, 342 U.S. 246, 263 (1952); *see also Buckhannon Bd. & Care Home, Inc. v. West Virginia Dep't of Health & Human Res.*, 532 U.S. 598, 615 (2001) ("Words that have acquired a specialized meaning in the legal context must be accorded their *legal* meaning.") (Scalia, J., concurring). That canon of statutory interpretation is dispositive here: Congress's use of the term "unavoidable" in § 22(b)(1) indicates that it did not eliminate all design-related claims against vaccine manufacturers; rather, it exempted manufacturers from liability only with respect to side effects that could not have been prevented by a safer design. *See Schafer*, 20 F.3d at 3 (NCVIA "forbids the award of compensation for injuries that flow from 'unavoidable side effects'").

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396 So. 2d 1140, 1145-46 (Fla. Dist. Ct. App. 1981) (whether a product is "unavoidably unsafe" largely depends on whether the product is defectively designed); *Racer v. Utterman*, 629 S.W.2d 387, 393 (Mo. Ct. App. 1981) (comment k applies only when a product is "designed as safely as human knowledge makes possible").

2. Section 22(b)(1)'s plain language makes exemption from civil liability conditional upon a case-specific showing that the side effects of the vaccine in question are "unavoidable"

a. By its plain terms, the clause "*if* the injury or death resulted from side effects that were unavoidable" means that, to come within the exemption set forth in § 22(b)(1), a manufacturer must show in a given case that the vaccine in question was, in fact, designed to minimize its inherent risks. The ordinary meaning of the word "if" is "in the event that," "so long as," or "on condition that." *Webster's* at 1124. Congress's use of the conditional tense expresses its clear intent to exempt vaccine manufacturers from civil liability only upon a showing that the vaccine at issue in the lawsuit was designed as safely as possible. *See American Home Prods. Corp. v. Ferrari*, 668 S.E.2d 236, 240 (Ga. 2008) ("The conditional nature of this clause contemplates the occurrence of side effects which are avoidable, and for which a vaccine manufacturer may be civilly liable."), *petition for cert. pending*, No. 08-1120 (U.S. filed Mar. 5, 2009). Notably, nowhere did Congress expressly state or provide that *all* vaccines were unavoidably unsafe.

The plain language of § 22(b)(1) also is consistent with comment k, which Congress expressly codified. Whether a given product is, "in the present state of human knowledge," "incapable of being made safe for [its] intended and ordinary use" requires a case-specific analysis of the product's safety risks compared to available alternatives. Comment k confirms the case-specific nature of the "unavoidable" inquiry: although it recognized that unavoidably unsafe

products are "especially common in the field of drugs" and vaccines, and gave the Pasteur rabies vaccine as an "outstanding example" of such a product, it made clear that some drugs and vaccines might *not* qualify. Restatement § 402A cmt. k ("The same is true of *many other* drugs, vaccines, and the like . . . . It is also true in particular of *many* new or experimental drugs[.]") (emphases added); *see also id.* ("*some products* . . . are quite incapable of being made safe") (emphasis added).

"The drafters of comment k did not intend to grant all manufacturers of prescription drugs a blanket exception to strict liability. Such an exception was proposed at the American Law Institute meeting where section 402A and comment k were adopted, but this proposal was defeated." *Hill v. Searle Labs.*, 884 F.2d 1064, 1069 (8th Cir. 1989). Comment k thus plainly requires, as a threshold matter, a determination that the specific product cannot be made safer within the limits of extant scientific and technological knowledge. A product that *can* be made safer would not qualify for the exemption from strict liability under comment k, and it likewise does not qualify for the exemption under § 22(b)(1). *See* Am. L. Prods. Liab. 3d § 17:36, at 17-67 ("Comment k is not intended to provide all ethical drugs with blanket immunity from strict liability design defect claims, but rather courts must decide the applicability of the doctrine on a case-by-case basis after considering evidence related to the various factors set forth in Comment k.").

Section 22(b)(1)'s plain language also is consistent with the weight of judicial authority interpreting comment k, both in 1986 and today. A majority of states in 1986 required manufacturers to make a

case-specific showing that the product was "unavoidably unsafe" in order to avoid strict products liability.[17] As the court below acknowledged (App. A33 n.9), the majority position favoring a case-by-case approach among state-court decisions has become even more dominant since 1986. *See* Am. L. Prods. Liab. 3d § 17:47, at 17-86 ("Most courts have stated that there is no justification for giving all prescription drug manufacturers blanket immunity from strict liability under Comment k, and that whether

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[17] *See*, *e.g.*, *Ortho Pharm. Corp. v. Heath*, 722 P.2d 410 (Colo. 1986), *overruled on other grounds by Armentrout v. FMC Corp.*, 842 P.2d 175 (Colo. 1992); *Smith ex rel. Smith*, 1986 WL 720792; *Kearl*, 218 Cal. Rptr. 453; *Coursen v. A.H. Robins Co.*, 764 F.2d 1329 (applying Oregon law), *opinion corrected*, 773 F.2d 1049 (9th Cir. 1985); *Feldman*, 479 A.2d 374; *Belle Bonfils*, 665 P.2d 118; *Brochu v. Ortho Pharm. Corp.*, 642 F.2d 652 (1st Cir. 1981) (applying New Hampshire law); *see also Racer*, 629 S.W.2d 387; *Jackson v. Muhlenberg Hosp.*, 232 A.2d 879 (N.J. Super. Ct. Law Div. 1967), *rev'd and remanded on other grounds*, 249 A.2d 65 (N.J. 1969).

The Third Circuit erred when it suggested, relying exclusively on *Militrano ex rel. Militrano v. Lederle Labs.*, 769 N.Y.S.2d 839, 844-45 (N.Y. Sup. Ct. 2003), *aff'd*, 810 N.Y.S.2d 506 (N.Y. App. Div. 2006), that there was no majority rule in 1986. *See* App. A33 n.9. Of the four cases that *Militrano* cited in favor of a categorical approach, *Davis*, 399 F.2d at 128-30, actually adopted a case-by-case approach; a second contained no sustained discussion on the point, *see Christofferson v. Kaiser Found. Hosps.*, 92 Cal. Rptr. 825 (Cal. Ct. App. 1971); and a third was overruled before 1986, *see Lewis v. Baker*, 413 P.2d 400 (Or. 1966), *overruled by McEwen v. Ortho Pharm. Corp.*, 528 P.2d 522 (Or. 1974). The fourth case was overruled after 1986. *See McDaniel v. McNeil Labs., Inc.*, 241 N.W.2d 822, 828-29 (Neb. 1976), *overruled by Freeman v. Hoffman-LaRoche, Inc.*, 618 N.W.2d 827 (Neb. 2000).

a particular drug is unavoidably unsafe should be determined on a case-by-case basis.").[18]

The clear, conditional language of § 22(b)(1), therefore, cannot plausibly be read categorically to exempt *all* vaccines from design-related liability. Congress would not have used the word "if" to introduce the ensuing clause had it intended to foreclose for adjudication the question whether a vaccine's side effects were, in a given case, "unavoidable." That conclusion also follows from the case-by-case inquiry that must be made to determine whether a particular vaccine's method of preparation and warnings are adequate. Structurally, it is implausible to suppose that Congress intended complete immunity for vaccine design defects but a case-by-case analysis of warnings and preparations.

b. Two other provisions of the NCVIA confirm that Congress required a case-specific threshold determination of whether a vaccine's design is unavoidably unsafe. In § 22(b)(2), Congress created a presumption that, for purposes of § 22(b)(1), "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" federal labeling requirements. 42 U.S.C. § 300aa-22(b)(2) (emphasis added). A manufacturer must show such compliance on a case-by-case basis; to find

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[18] *See Weiss v. Fujisawa Pharm. Co.*, Civil Action No. 5:05-527-JMH, 2006 WL 3533072, at *2-*3 & n.3 (E.D. Ky. Dec. 7, 2006) (collecting cases and noting majority position); *Freeman*, 618 N.W.2d at 840 (also acknowledging majority position); *see also*, *e.g.*, *Savina v. Sterling Drug, Inc.*, 795 P.2d 915, 924 (Kan. 1990); *Hill*, 884 F.2d at 1068-69; *Castrignano v. E.R. Squibb & Sons, Inc.*, 546 A.2d 775, 781 (R.I. 1988); *Senn v. Merrell-Dow Pharms., Inc.*, 751 P.2d 215, 218 n.4 (Or. 1988); *Toner v. Lederle Labs.*, 732 P.2d 297, 309 (Idaho 1987).

all vaccines to have complied with federal regulations would read that provision out of the statute. Likewise, in § 23(d)(2), Congress created an exemption from punitive damages "*[i]f* . . . the manufacturer shows that it complied, in all material respects," with those same federal laws (unless it engages in "fraud," "intentional withholding of information" from federal regulators, or "other criminal or illegal activity"). *Id.* § 300aa-23(d)(2) (emphasis added). Again, compliance sufficient to avoid punitive damages can be ascertained only based on the facts of each case. Congress's use of "if" clauses to establish the conditional nature of those provisions reinforces the conclusion that § 22(b)(1) similarly requires a conditional, case-specific analysis.

Furthermore, Congress's omission of a regulatory compliance defense or presumption with respect to design-related liability makes clear that it left the question whether "the injury or death resulted from side effects that were unavoidable" to be adjudicated in each case. "[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Brown v. Gardner*, 513 U.S. 115, 120 (1994) (quoting *Russello v. United States*, 464 U.S. 16, 23 (1983)). That admonition is all the more fitting when the "disparate inclusion [and] exclusion" are within the same statutory section. In so doing, Congress entrusted judges with making individualized determinations.

When Congress intended to exempt manufacturers from design-related liability regardless of whether the side effects were avoidable, it did so explicitly. For example, Congress authorized the Secretary of

HHS to designate a vaccine designed to prevent a pandemic or epidemic as a "covered countermeasure." 42 U.S.C. § 247d-6d(b), (i)(1), (i)(7)(A)(i). A manufacturer of a covered countermeasure is generally "immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration" of the covered countermeasure, including claims relating to "the design" of the countermeasure. *Id.* §§ 247d-6d(a)(1), (2)(B).[19] Congress enacted no such categorical exemption here.

B. The Proviso "Even Though The Vaccine Was Properly Prepared And Was Accompanied By Proper Directions And Warnings" Is Properly Read As Establishing Two Additional Prerequisites To Exemption From Civil Liability

Under comment k, a manufacturer is exempt from strict liability only if its products, in addition to being unavoidably unsafe, "are properly prepared and marketed, and proper warning is given." Restatement § 402A cmt. k; *see also id.* ("Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous."); Am. L. Prods. Liab. 3d § 17:36, at 17-69. Reading the clause "even though the vaccine was properly prepared and was accompanied by proper directions and warnings" to incorporate those

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[19] During the 1970s swine flu pandemic, Congress provided that "[t]he remedy against the United States . . . for personal injury or death arising out of the administration of the swine flu vaccine under the swine flu program shall be exclusive of any other civil action or proceeding for such personal injury or death." 42 U.S.C. § 247b(k)(3) (Supp. I 1977) (repealed 1979).

additional requirements best captures Congress's intent, for four reasons.

First, that interpretation of the "even though" clause best comports with Congress's language in other parts of § 22(b) and the legislative history. Congress repeatedly used the phrase "unavoidable side effects" interchangeably with "side effects that were unavoidable" in describing § 22(b)'s scope. For example, § 22(b)'s heading, which is a "tool[] available for the resolution of a doubt about the meaning of [the] statute," *Almendarez-Torres v. United States*, 523 U.S. 224, 234 (1998), is "[u]navoidable adverse side effects." Likewise, the Energy and Commerce Committee used the phrase "unavoidable side effects" in articulating § 22(b). *See* 1986 Report at 25-26 ("a vaccine manufacturer should not be liable for injuries or deaths resulting from *unavoidable side effects* even through [sic] the vaccine was properly prepared and accompanied by proper directions and warnings") (emphasis added). The phrase "unavoidable side effects" conveys a clear intent to hold manufacturers responsible for preventable vaccine injuries.

Moreover, given that Congress used "unavoidable side effects" synonymously with "side effects that were unavoidable" in both § 22(b)'s heading and the 1986 Report, it clearly did not think that the precise word order would be dispositive in properly construing the statute. The only plausible way to interpret § 22(b) consistent with Congress's interchangeable use of those two formulations ("side effects that were unavoidable" and "unavoidable side effects") is to read the "even though" clause not to modify the well-established meaning of "unavoidable," but rather to establish proper manufacturing

and proper directions and warnings as *additional* requirements.

Second, that interpretation best effectuates Congress's express purpose to codify comment k. The critical threshold issue under comment k is whether a product is "unavoidably unsafe." Only such products are eligible for exemption from strict liability, and, even then, manufacturers of such products must show that they were "properly prepared and accompanied by proper directions and warnings." Congress could not plausibly have intended to eliminate comment k's central threshold requirement—that a product's safety risks be shown to be "unavoidable"—through such indirect language. *See Ferrari*, 668 S.E.2d at 242 ("If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly.") (internal quotations omitted). The better reading preserves that core requirement and harmonizes § 22(b)(1) with well-established standards under comment k.

Third, reading § 22(b) as requiring manufacturers to show that the harm from their vaccines was "unavoidable" gives meaning to the phrase "if the injury or death resulted from side effects that were unavoidable" in § 22(b)(1). As the Georgia Supreme Court noted in *Ferrari*, if Congress had meant to eliminate design-defect claims and preserve only claims alleging manufacturing defect and defective directions and warnings, the straightforward way to have done so would have been to provide that no vaccine manufacturer would be held civilly liable "if . . . the vaccine was properly prepared and was accompanied by proper directions and warnings." Instead, invoking the well-settled term "unavoidable,"

Congress provided that the exemption would apply only "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) (emphasis added). A construction of § 22(b)(1) that eliminates all design-defect claims reads the italicized language out of the statute and thus violates this Court's "cardinal principle of statutory construction that a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant." *TRW Inc. v. Andrews*, 534 U.S. 19, 31, 33 (2002) (internal quotations omitted); *accord Duncan v. Walker*, 533 U.S. 167, 174 (2001) (Court is "especially unwilling" to treat a statutory term as surplusage "when the term occupies so pivotal a place in the statutory scheme").

Fourth, reading § 22(b) to require a manufacturer to show "unavoidable" harm best comports with this Court's longstanding presumption against preemption of state-law claims. As this Court stated in *Altria Group, Inc. v. Good*, 129 S. Ct. 538 (2008):

> When addressing questions of express or implied pre-emption, we begin our analysis with the assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress. That assumption applies with particular force when Congress has legislated in a field traditionally occupied by the States. Thus, when the text of a pre-emption clause is susceptible of more than one plausible reading, courts ordinarily accept the reading that disfavors pre-emption.

Id. at 543 (internal quotations and citations omitted; alteration in original).

The presumption against preemption should be especially strong here, given that Congress imposed a "[g]eneral rule" expressly *preserving* state law, 42 U.S.C. § 300aa-22(a), and the "preemption" provision expressly displaces attempts under state law to *preclude* actions against vaccine manufacturers, *id.* § 300aa-22(e). *See Wyeth v. Levine*, 129 S. Ct. 1187, 1200 (2009) ("The case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them.") (internal quotations omitted; alteration in original).

In sum, the best reading of § 22(b)—the one most consistent with the provision's plain language, the standards set forth in comment k, and this Court's canons of construction—is that a vaccine manufacturer is exempt from civil liability only upon a case-specific showing that the vaccine's side effects were unavoidable, and, even then, only if the vaccine was properly prepared and accompanied by proper directions and warnings.

C. The Third Circuit Misconstrued The Text And Structure Of The NCVIA

The Third Circuit misconstrued § 22's text and its relationship to the NCVIA as a whole. Specifically, the court found a "clear and manifest" congressional intent to preclude design-defect claims based on its reading of § 22(e), App. A30, which prohibits states from foreclosing civil actions that are otherwise "not barred by this part." 42 U.S.C. § 300aa-22(e). The court read "not barred by this part" as implying that

"other parts *of § 300aa-22* are designed to not only limit liability but bar some claims entirely." App. A27-A28 (emphasis added). The court accordingly thought that Congress must have "intended that subsections (b) and (c) should be an outright bar to some claims." App. A28. Relying on that premise, the court rejected petitioners' contention that manufacturers are exempt from liability only upon a showing that the particular vaccine's side effects were unavoidable as "contrary to the structure of the Act because it does not bar any design defect claims" but rather "subject[s] [such claims] to evaluation by a court." App. A29.

That interpretation misunderstands the NCVIA's text and structure. Section 22(e) refers to actions "not barred by this *part*," not actions not barred by this *section*. *See* Lawrence E. Filson, *The Legislative Drafter's Desk Reference* 222-26, 408-10 (1992) (distinguishing "section" and "part"). The provisions of the Act that bar civil actions are § 11(a)(2)(A) and § 21(a), which preclude claimants from "bring[ing]" a civil action if they have not sought compensation from the Vaccine Court first or if they have accepted that court's award. 42 U.S.C. §§ 300aa-11(a)(2)(A), 300aa-21(a); *see also id.* § 300aa-11(a)(2)(B) (referring to a "civil action which is barred under subparagraph (A)"); *id.* § 300aa-23(a) (creating procedures for actions "not barred by section 300aa-11(a)(2) of this title"). Section 22, by contrast, does not forbid "bring[ing]" any claims. Rather, it establishes "standards of responsibility" that preserve state liability rules while creating a narrow exemption if the vaccine's side effects are "unavoidable" (and the vaccine is properly prepared and accompanied by proper directions and warnings). *See supra* pp. 12-13, 28-41.

A standard for determining liability in a civil action is not the same as "barring" a civil action outright.

The 1986 Energy and Commerce Report confirms that Congress was referring in § 22(e) to the exhaustion requirements in § 11(a)(2) and § 21(a). That report stresses that the purpose of § 22(e) was to prevent states from going further than Congress in barring civil actions for vaccine-related injuries or deaths—for example, by creating their own mandatory compensation regimes. *See* 1986 Report at 27 ("State statutes that effectively foreclose individuals from bringing civil actions from vaccine-related injuries or deaths [are] pre-empted by this subsection. The Committee intends for this preemption to apply even where a State has established a compensation system as an alternative to filing civil actions.").

The fact that § 22(b) does not bar any claims, but instead establishes a limited exemption from liability, undermines the sole basis the Third Circuit gave for precluding design-defect claims—namely, that § 22(b) cannot be construed to require a "case-by-case analysis of whether particular vaccine side effects are avoidable." App. A29. Contrary to the Third Circuit's erroneous view, there is nothing unusual or unworkable about an exemption from liability being determined on a case-specific basis on the facts in the record. Such a case-specific determination is not only mandated by the plain language of § 22(b)(1) and consistent with decades of comment k jurisprudence, but also fully consistent with § 22(e) and the structure of the NCVIA as a whole.

II. THE NCVIA'S LEGISLATIVE HISTORY CONFIRMS THAT CONGRESS EXEMPTED MANUFACTURERS FROM LIABILITY ONLY IF THE VACCINE IS UNAVOIDABLY UNSAFE

Analysis of legislative history is a traditional tool of statutory construction. *See Wisconsin Pub. Intervenor v. Mortier*, 501 U.S. 597, 610 n.4 (1991). That history here confirms that Congress did not categorically exempt vaccine manufacturers from all design-related liability. The legislative record demonstrates that Congress, the President, and vaccine manufacturers all understood—both in 1986, when the Act was first passed, and in 1987, when Congress amended the Act and enacted the funding mechanism necessary to give the law effect—that manufacturers would remain responsible for making their vaccines as safe as possible for patients.

A. The 1986 Act's Legislative History Confirms That Congress Intended To Preserve Certain Design-Defect Claims

The legislative record from the 99th Congress in 1986 confirms that Congress exempted vaccine manufacturers from liability only for harm that could not have been prevented by a better design.

In the Energy and Commerce subcommittee hearings on H.R. 5184, which eventually became the NCVIA, industry representatives recognized that § 22(b) would exempt manufacturers from civil liability only upon a case-specific showing that the side effects were truly unavoidable. Indeed, Lederle's president acknowledged that the bill would neither preclude plaintiffs from bringing claims based on failure to adopt a safer alternative vaccine nor make FDA approval a defense to such claims. *See Vaccine*

Injury Compensation: Hearing Before the Subcomm. on Health and the Environment of the H. Comm. on Energy and Commerce, 99th Cong. 238-39 (1986) (statement of Robert Johnson) (noting that the bill would leave "open to litigation" claims "that the vaccines we sell are not as good as some alternative product, even though our vaccines have been approved by the Government as safe and effective"); *id.* at 239 (advocating enactment of a "strong government-standards defense" to design-defect claims); *see also id.* at 227-28 (statement of John Lyons, Executive Vice President, Merck) ("Merck has never sought to be relieved of its responsibility for making vaccines as pure, potent and safe as existing technology permits. *When we have fulfilled that responsibility*, however, unavoidably injured persons should be compensated through the no-fault system; they should not receive awards under our traditionally fault-based tort system."); *id.* at 229 ("[W]e would favor a proposal providing that such compliance [with federal vaccine regulations] would be a defense to any liability, just as it would be under the bill for punitive damage."); *id.* at 132 (statement of Martin H. Smith, President, American Academy of Pediatrics) (stating that § 22(b) exempts manufacturers from liability for "genuinely unavoidable injuries").

Congress did not adopt vaccine manufacturers' proposal to enact a federal regulatory compliance defense to claims asserting defective design. Moreover, the Energy and Commerce Committee specifically rejected a proposed amendment that would have provided that "a manufacturer's failure to develop [a] safer vaccine was not grounds for liability." 1987 Report at 691. As this Court has observed consistently, "[f]ew principles of statutory construction are

more compelling than the proposition that Congress does not intend *sub silentio* to enact statutory language that it has earlier discarded in favor of other language." *INS v. Cardoza-Fonseca*, 480 U.S. 421, 442-43 (1987) (internal quotations omitted); *see also Chickasaw Nation v. United States*, 534 U.S. 84, 93 (2001). Congress's refusal to enact those measures confirms that it did not exempt vaccine manufacturers from design-defect liability for injuries that could have been prevented by a safer alternative design.

The 1986 Energy and Commerce Report accompanying the NCVIA further confirms Congress's intent. The report twice emphasized that § 22(b)(1) codified comment k, which only applies if a given product is "unavoidably unsafe." *See* 1986 Report at 26 (The Committee "intends that the principle in Comment K regarding 'unavoidably unsafe' products . . . apply to the vaccines covered in the bill . . . . [T]he Committee strongly believes that Comment k is appropriate and necessary as the policy for civil actions seeking damages in tort."). Moreover, in discussing § 23(c) of the Act, the 1986 Report confirmed that design-defect claims were not eliminated: "In establishing liability, for example, a plaintiff may demonstrate that the manufacturer produced a *defective vaccine* through clearly criminal behavior if that is what the evidence shows." *Id.* at 28 (emphasis added).

The Third Circuit read the 1986 Report to "support[] the conclusion that the [NCVIA] preempts all design defect claims." App. A35. The language it cited, however, does not support that conclusion. Only after stating that it was adopting comment k—thereby incorporating the requirement that a vaccine be found to be unavoidably unsafe—did the report go on to state 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 should [sic] pursue recompense in the compensation system, not the tort system." 1986 Report at 26. That sentence does not express intent to *eliminate* the threshold requirement that a vaccine's side effects be found to be unavoidable; it merely presumes that requirement to have been satisfied. This interpretation is confirmed by the statement in the same paragraph that Congress's adoption of comment k provides vaccine-injured persons with "an appealing alternative to the tort system," not a replacement for it. *Id.*

Finally, the floor comments immediately prior to House passage of the 1986 law further confirm Congress's intent. Representative Henry Waxman, the NCVIA's main sponsor, stated that, although "the bill would limit [a] child's ability to sue the manufacturer of the vaccine," "[i]f an injury is the result of bad vaccine *or one inadequately researched* or warned of, then the courts could still make awards." 132 Cong. Rec. at 30,760 (emphasis added). That statement tracks the three established requirements of comment k: courts can award compensation if the vaccine is not unavoidably unsafe ("inadequately researched"), improperly prepared ("bad vaccine"), or not accompanied by proper directions and warnings ("inadequately . . . warned of"). *See Toner*, 779 F.2d at 1432 ("The concept of an unavoidably unsafe product seems necessarily to depend on whether research was properly pursued."). Likewise, Representative Mario Biaggi supported the legislation by commenting that it "provides that manufacturers will not be liable for injuries or deaths resulting from unavoidable side effects *if* the vaccine was properly

prepared and accompanied by the proper directions and warnings." 132 Cong. Rec. at 30,762 (emphasis added). Those statements are at odds with any assertion that § 22 categorically exempted manufacturers from all design-related claims.

B. The Legislative History Of The 1987 Funding And Implementing Legislation Further Evidences Congressional Intent To Preserve Design-Defect Claims For Avoidable Side Effects

The legislative record of the 100th Congress also shows that § 22(b) did not exempt vaccine manufacturers from civil liability unless the injuries were caused by side effects that could not have been prevented. In an unusual feature to the legislation, the NCVIA did not take effect until Congress enacted separate legislation to fund it. *See* NCVIA § 323(a), 100 Stat. 3784. In 1987, Congress took up the key questions of whether and how to fund the legislation. In so doing, Congress also considered amendments to the NCVIA. As with those in the 99th Congress, the statements of all involved parties—Congress, the Reagan Administration, and vaccine manufacturers—reflected a shared understanding that § 22(b)(1) does not exempt vaccine manufacturers from design-defect claims for avoidable side effects.

Congressman Waxman reiterated his prior understanding that, "[i]f an injury is the result of bad vaccine or one *inadequately researched* or warned of, then the courts could still make awards." 1987 Hearing at 10, 13 (emphasis added).

The Reagan Administration, too, recognized that § 22(b) did not eliminate all manufacturer liability for design-related vaccine injuries. Speaking on behalf of the President, a Treasury Department official

observed that design-defect claims were not eliminated by § 22(b)(1):

> The [NCVIA] also would modify state tort laws . . . to preclude tort liability for "unavoidable" side effects in the absence of a finding that the vaccine was not properly prepared or was not accompanied by proper warnings.

Id. at 25 n.7 (statement of Dennis Ross). The Administration thus shared Congressman Waxman's view that § 22(b) exempted manufacturers from liability only for "unavoidable side effects," and, even then, only "in the absence of a finding" of manufacturing or labeling defect.

The Administration official then confirmed unequivocally that at least some design-defect claims were preserved by the NCVIA:

> A showing by the manufacturer that it had complied with all material Federal regulatory requirements would give rise to a rebuttable presumption that the vaccine was accompanied by proper warnings (*but would not give rise to a presumption that the vaccine was not defective in design*).

Id. (emphasis added).

Likewise, industry representatives redoubled their efforts to amend the NCVIA because they recognized, as they had in 1986, that § 22 permitted injured persons to bring design-defect claims against manufacturers. Lederle's Robert Johnson acknowledged that "the law provides no new defense at all" to claims that a vaccine's design was defective because of the practicability of a safer alternative. *Id.* at 84. Johnson advocated that "the liability provisions of the 1986 Act should be *amended*" to ensure that

manufacturers will "not face liability under a 'design defect' theory." *Id.* at 85 (emphasis added); *see also id.* at 102 (statement of David J. Williams, Connaught Laboratories) ("Of particular concern are so-called 'design defect' cases. . . . [T]he government standards defense should, at a minimum, be extended to design defect cases.").

Finally, in the section of the Budget Committee Report devoted to the 1987 legislation, the Energy and Commerce Committee specifically rejected the assertion that § 22(b) eliminates design-defect claims through a legislative determination that all vaccines are, as a categorical matter, "unavoidably unsafe":

> [T]he codification of Comment (k) of The Restatement (Second) of Torts was not intended to decide *as a matter of law* the circumstances in which a vaccine should be deemed unavoidably unsafe. The Committee stresses that there should be no misunderstanding that the Act undertook to decide as a matter of law whether vaccines were unavoidably unsafe or not. *The question is left to the courts* to determine in accordance with applicable law.

1987 Report at 691 (emphases added).[20]

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[20] The Third Circuit expressed uncertainty (App. A38-A39) whether "the Committee" referred to the Budget Committee or the Energy and Commerce Committee. Apparently for the same reason, the court doubted the Budget Committee Report's statement that the Energy and Commerce Committee had considered and rejected an amendment in 1986 to eliminate liability on the grounds of "a manufacturer's failure to develop [a] safer vaccine." 1987 Report at 691. Although the Budget Committee compiled and issued the report, the Energy and Commerce Committee wrote and approved the relevant language. Title IV of the report, entitled "Committee on Energy and Commerce," comprises "two Committee Prints approved by

Those 1987 statements provide compelling evidence of Congress's intent in enacting the NCVIA, because the 100th Congress had full power to reconsider the Act's liability provisions and indeed to nullify the NCVIA altogether by not passing the necessary funding legislation. In fact, Congress modified several substantive provisions of the Act, but did not adopt manufacturers' requests to modify the liability exemptions contained in § 22. The views of the 100th Congress, the statements made by the Administration, and the failed requests of vaccine manufacturers during the consideration of the 1987 legislation thus provide persuasive additional evidence that § 22(b) was not intended to provide an exemption from liability for injuries that could have been prevented by a safer design.[21]

III. INCENTIVIZING MANUFACTURERS TO DESIGN VACCINES TO PREVENT AVOIDABLE SIDE EFFECTS SERVES CONGRESS'S PURPOSES

Interpreting § 22(b)(1) to preclude design-defect liability only when the side effect in question was unavoidable serves two of Congress's main purposes in enacting the NCVIA—promoting vaccine safety and ensuring fair compensation to injured victims. *See* 42 U.S.C. § 300aa-1 (Congress sought "to achieve optimal prevention against adverse reactions to vaccines"); 1987 Report at 691 (the "system of Federal

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the Committee on Energy and Commerce for inclusion in the forthcoming reconciliation bill." *Id.* at 380.

[21] By contrast, *United States v. Price*, 361 U.S. 304 (1960), on which the Third Circuit relied (App. A39), stated that the views of a different Congress *15 years later* "form[ed] a hazardous basis for inferring the intent of" the Congress that enacted the provision at issue. *Id.* at 313.

no-fault compensation and other *rights of action* are intended to provide a stable vaccine market with care for the injured and *incentives for safety*") (emphases added). By contrast, providing manufacturers with blanket immunity from such claims would undermine patient safety without advancing any sound public policy.

A. Design-Defect Liability For Preventable Injuries Promotes Vaccine Safety And Fair Compensation To Victims

Preserving manufacturer liability for injuries resulting from preventable side effects advances Congress's purposes in enacting the NCVIA in three ways.

First, design-defect liability for preventable side effects encourages manufacturers to exercise due care in designing vaccines. The duty to compensate children and their families for avoidable injuries supplies a socially beneficial "incentive for safe design by the manufacturer." *Toner v. Lederle Labs.*, 828 F.2d 510, 513 (9th Cir. 1987) (Kennedy, J.); *see also Toner*, 732 P.2d at 310 ("[T]o immunize sellers of products . . . from negligence claims would remove needed incentive[s] for safe design."); *Schafer*, 20 F.3d at 3 ("[T]he Act modifies, but does not eliminate, the traditional tort system, which . . . provide[s] important incentives for the safe manufacture and distribution of vaccines.").

Further, the prospect of compensation for preventable injuries encourages manufacturers to keep up with scientific and technological advances, rather than continuing to market outmoded vaccines like Tri-Immunol for decades, despite the availability of a safer alternative. By contrast, conferring immunity from suit for continuing to sell outmoded vaccines

allows companies like respondent consciously to sacrifice patient safety in favor of increased profit. *See supra* p. 18; JA242, 245. This Court recognized the salutary effects of civil liability in *Bates v. Dow AgroSciences LLC*, 544 U.S. 431 (2005): "'the specter of damage actions may provide manufacturers with added dynamic incentives to continue to keep abreast of all possible injuries stemming from use of their product[s] *so as to forestall such actions through product improvement*.'" *Id.* at 451 (quoting *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1541-42 (D.C. Cir. 1984)) (emphasis added); *see also id.* at 450 (noting "the importance of providing an incentive to manufacturers to use the utmost care in the business of distributing inherently dangerous items").

A majority of state courts, too, have recognized that requiring case-specific showings that harmful side effects could not have been prevented promotes the public interest by incentivizing improved product design:

> [W]e believe that the policy reasons supporting a blanket approach are countervailed by those supporting a more selective application of the comment. . . .
>
> We believe that a more selective application will encourage, rather than discourage, improvements in prescription products. . . . [A] product which is as safe as current testing and research permits should be protected. The reverse is also true; a product which is not as safe as current technology can make it should not be protected.

Adams v. G.D. Searle & Co., 576 So. 2d 728, 732 (Fla. Dist. Ct. App. 1991); *see also*, *e.g.*, *Ferrari*, 668 S.E.2d at 242; *Toner*, 732 P.2d at 307.

In contrast, holding that the NCVIA precludes *all* design-related liability would not only vitiate the incentives for optimal vaccine design, but also undermine the public welfare by permitting manufacturer misconduct to go undeterred. *See* App. A35. Under the decision below, an injured child such as Hannah Bruesewitz cannot seek redress even if she can show, as respondent's own correspondence indicates, that the manufacturer *knew* its vaccine would cause harm that could be avoided by another design already on the market. *See supra* pp. 23-24. No sound policy reason supports insulating manufacturers from liability for such egregious misconduct, and nothing in the NCVIA or its legislative history supports such a draconian result.[22]

Second, allowing design-defect claims for avoidable side effects complements FDA regulation of vaccine safety. FDA does not condition approval of a vaccine on the design being the safest among reasonably available alternatives. Nor does it ensure that licensed vaccines keep pace with technological and scientific advances. *See supra* pp. 6-9. Thus, although state and federal law have parallel objectives—both seek to promote vaccine safety—only the civil justice system provides manufacturers with the incentive to continue to improve the safety of their products beyond FDA's minimum requirements. *See Bates*, 544 U.S. at 451. Indeed, this Court recognized in *Wyeth v. Levine* that the federal regime regulating

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[22] By ensuring optimal vaccine design, design-defect claims for avoidable injuries also promote public confidence in vaccine safety, which, in turn, promotes childhood immunization. *See*, *e.g.*, Wash. Rev. Code Ann. § 70.95M.115 note (Supp. 2010) (limiting mercury content in certain vaccines "to maintain public confidence in vaccine programs, so that the public will continue to seek vaccinations").

drugs, which is comparable in relevant respects to the federal regime regulating vaccines, does not create the same incentives as state law for manufacturers to act reasonably. *See* 129 S. Ct. at 1197-98.

Civil actions also help promote FDA's regulation of vaccines by uncovering information about adverse side effects not generally available to federal regulators. In *Levine*, this Court recognized shortcomings in FDA's ability to collect information on products: "manufacturers have superior access to information about their" products, as compared to FDA, a condition that is "especially" true in "the postmarketing phase as new risks emerge." *Id.* at 1202; *see also supra* p. 9 (describing FDA's limited postmarketing surveillance). By "uncover[ing] unknown drug hazards" and "motivat[ing] injured persons to come forward with information," *Levine*, 129 S. Ct. at 1202, civil actions help to bridge FDA's informational gap.

Moreover, as this Court also recognized in *Levine*, throughout FDA's history, well-respected independent observers have found that the agency lacks the resources and tools to serve as the sole protector of public health. *See id.* at 1202 n.11. A recent consensus report from the Institute of Medicine found that "[f]unding for vaccine safety monitoring and research has not grown commensurate with the widening task (e.g., a growing list of recommended vaccines) and parallel investment in vaccine supply."[23] And a House Committee on Government Reform study found "significant conflicts of interest" within FDA's Vaccines and Related Biological Products

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[23] Institute of Medicine, *Priorities for the National Vaccine Plan* 2:17-18 (Dec. 2009).

Advisory Committee and CDC's Advisory Committee on Immunizations Practices. Majority Staff of H. Comm. on Gov't Reform, 106th Cong., Conflicts of Interest in Vaccine Policy Making 16 (Aug. 21, 2000) ("Gov't Reform Report"), *available at* http://www.generationrescue.org/pdf/3.5.pdf; *see id.* at 1 ("[C]onflict of interest rules employed by the FDA and the CDC have been weak, enforcement has been lax, and committee members with substantial ties to pharmaceutical companies have been given waivers to participate in committee proceedings.").[24] Such reports demonstrate the important role that private civil lawsuits play in complementing FDA regulation and promoting vaccine safety.

Third, ensuring that the courthouse doors remain open to claimants seeking recovery for injuries resulting from avoidable vaccine side effects promotes Congress's goal of compensating these innocent victims. Although the Compensation Program was "designed to work faster and with greater ease than the civil tort system" in handling the mine-run case, *Whitecotton*, 514 U.S. at 269, it was not designed to supplant tort law's compensatory function. *See*, *e.g.*, 1986 Report at 3 (liability provisions "deal[] with the *additional remedies* that are available to vaccine-injured persons should they elect to reject a judgment and award made under the compensation program and to take action directly against a vaccine manufacturer") (emphasis added).

Court actions are essential because they provide injured victims with tools not available in the Vaccine

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[24] The Report focused on Wyeth's RotaShield vaccine, which was pulled from the market due to serious adverse reactions just 13 months after FDA approval. *See* Gov't Reform Report at 8-9.

Court. Significantly, because special masters "adjudicate [claims] informally, within strict time limits, subject to similarly expeditious review," *Whitecotton*, 514 U.S. at 270 (citations omitted), Vaccine Court claimants "do not have a right to conduct discovery."[25] *See* 42 U.S.C. § 300aa-12(d)(2)(E), (d)(3). Discovery is purely at the discretion of special masters, who normally do not permit it. *See id.* § 300aa-12(d)(3) ("There may be no discovery in a proceeding on a petition other than the discovery required by the special master."); *Deloatch* Order at 3 (collecting cases).

Given the limitations of the Compensation Program, the right to seek judicial relief is critical. *See* 1986 Report at 16 (referring to the "wider inquiry . . . appropriate in a civil action"). Without discovery, causation—which is extremely difficult in vaccine cases—would be nearly impossible to prove. Moreover, only through civil discovery—which uncovered, for example, the internal correspondence showing that respondent knew that the whole-cell pertussis component of Tri-Immunol was more toxic than Tri-Solgen's split-cell version, but nevertheless abandoned efforts to improve its vaccine for economic reasons, *see* JA242, 245—will claimants be able to gather evidence necessary to bring such public health threats to light. Congress preserved victims' right to seek relief through the civil justice system precisely because the Vaccine Court process contains limits.

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[25] Published Ruling Quashing Subpoena at 3, *Deloatch v. Secretary of HHS*, No. 1:09-vv-00171-UNJ (Fed. Cl. Apr. 27, 2010) ("*Deloatch* Order").

B. Design-Defect Liability Would Not Destabilize The Vaccine Market

Echoing arguments made by respondent, the Third Circuit expressed concern that vaccine manufacturers would exit the market and destabilize the vaccine supply without full immunity from all design-defect claims. *See* App. A35-A36; *see also* Br. in Opp. 16-19, 23 (arguing that a "new litigation threat" will cause manufacturers to leave the market). As an initial matter, the Third Circuit cited no empirical data to support that concern, "and[] the claim does not prove itself." *Schafer*, 20 F.3d at 6.

In all events, that policy argument merely reiterates the objections that Congress heard and rejected more than 20 years ago. Those objections ring especially hollow given the unprecedented steps Congress took to "reduc[e] the litigation and insurance costs" for manufacturers. *Id.* at 4. Through the Compensation Program, the federal government relieves manufacturers of the primary burden of compensating victims of vaccine-related injuries. Congress also "discourage[d] victims from bringing . . . traditional tort cases by providing fairly generous, more easily obtainable, Vaccine Court awards." *Id.* at 4-5. "A victim who obtains such an award may hesitate to give up that bird in the hand in return for a larger, but more speculative, tort law award. And, a petitioner to whom the Vaccine Court gives nothing may see no point in trying to overcome tort law's yet more serious obstacles to recovery." *Id.* at 5.

For claimants who elect to reject the Vaccine Court's judgment and file a civil action, Congress enacted numerous additional measures to reduce manufacturers' liability exposure: immunity from damages for "unavoidable" side effects and a limited

regulatory compliance presumption of adequate warnings to support it (§ 22(b)(1), (2)); application of the learned intermediary doctrine and elimination of claims based on failure to provide direct warnings to patients (§ 22(c)); a tripartite trial procedure (§ 23(b), (c), (d)(1)); and a heightened standard for punitive damages (§ 23(d)(2)). But, despite manufacturers' fervent requests, Congress declined to go farther by eliminating *all* design-defect liability for vaccine injuries. And Congress certainly made no effort to relieve manufacturers like Wyeth of liability for preventable harms caused by outmoded vaccines subsequently withdrawn from the market. Those considered legislative policy choices warrant this Court's respect.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted,

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May 24, 2010