No. 09-152

In the Supreme Court of the United States

RUSSELL BRUESEWITZ, ET AL., PETITIONERS

v.

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

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

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING RESPONDENTS

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QUESTION PRESENTED

The National Childhood Vaccine Injury Act of 1986 provides that "[n]o vaccine manufacturer shall be liable in a civil action" for any injury that "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 whether that provision preempts state law claims against a vaccine manufacturer based on alleged defects in the design of a vaccine subject to the Act.

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases: Page

Statutes, regulations and rules: Page

Statutes, regulations and rules—continued: Page:

Statutes, regulations and rules—continued: Page:

Miscellaneous: Page

Miscellaneous—Continued: Page

Miscellaneous—Continued: Page

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INTEREST OF THE UNITED STATES

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

STATEMENT

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

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

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

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

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

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

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

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

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

he may bring a civil action against the manufacturer. 42 U.S.C. 300aa-11(a)(2)(A), 300aa-21(a)-(b).

Such civil actions are governed by state law, subject to several limitations in the Act. See 42 U.S.C. 300aa-22 (Section 22). Among these limitations is the provision at issue here:

> No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

42 U.S.C. 300aa-22(b)(1) (Section 22(b)(1)). Under 42 U.S.C. 300aa-22(e) (Section 22(e)), a State is barred from further limiting such claims: "No State may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this part."

3. Petitioners' daughter experienced seizures after her third dose of a diphtheria-tetanus-pertussis (DTP) vaccine. She ultimately suffered residual seizure disorder and developmental delay. Pet. App. A6. Petitioners pursued a timely but unsuccessful petition for compensation in the CFC, and rejected the CFC's judgment pursuant to 42 U.S.C. 300aa-21(a)(1). J.A. 1-2. They then sued the vaccine's manufacturer—respondents in this Court—in Pennsylvania state court, alleging (as relevant here) that toxins inherent in the vaccine's design caused their daughter's injuries. Following removal of the case, the district court granted summary judgment for respondents, holding that the Act pre-

empted petitioners' design-defect claims. See Pet. App. A9-A11.

The court of appeals affirmed. Pet. App. A1-A52. The court noted that Section 22(b)(1)'s bar "primarily relates to design defect claims," because the other types of products liability claims (*i.e.*, for manufacturing or labeling defects) are dealt with in the "subordinate clause introduced by 'even though.'" *Id.* at A27. The court rejected petitioners' position that the term "unavoidable" called for a "case-by-case analysis of whether particular vaccine side effects are avoidable," because that reading "does not bar any design defect claims" and instead would make "every design defect claim * * * subject to evaluation by a court." *Id.* at A29. The Court further concluded that the Act preempts all design defect claims irrespective of whether they sound in negligence or strict liability. *Id.* at A31-A36.

SUMMARY OF ARGUMENT

Congress intended, through the express preemption language of Section 22(b)(1), to exempt vaccine manufacturers from tort liability for the designs of their FDA-licensed vaccines, while offering, through other provisions of the Vaccine Act, compensation to the injured. The result of the Act is a robust federal framework that encourages the development of even safer vaccines and that provides compensation where Congress deemed it appropriate.

A. Section 22(b)(1) bars claims against a vaccine manufacturer for injuries that "resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." The text thus identifies injuries traceable to two familiar types of product defects (manu-

facturing and labeling defects) as avoidable, while designating what remains (injuries from side effects inherent in the vaccine's design) as unavoidable. That latter category of injury is at issue here, and Section 22(b)(1) bars civil damage suits against manufacturers on such a theory.

Section 22(b)(1) was drawn, in part, from Comment k to Section 402A of the Restatement (Second) of Torts, which makes the same distinction among theories of product liability. Comment k concerns "[u]navoidably unsafe" products, which are those that "in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use." Restatement (Second) of Torts (Restatement) § 402A cmt. k (Comment k) at 353 (1965) (emphasis omitted). Under Comment k, such an unavoidably unsafe product—which the Act in effect deems vaccines to be—is not defective in its design, though it still exposes its manufacturer to liability for manufacturing and labeling defects. The legislative history of Section 22(b)(1) makes the same distinction: An injured vaccine recipient who "cannot demonstrate under applicable law either that a vaccine was improperly prepared or that it was accompanied by improper warnings should pursue recompense in the compensation system, not the tort system." *1986 Report* 26.

Congress enacted the Vaccine Act (and Section 22(b)(1) in particular) in significant part to alleviate the large and potentially unknowable tort liability that vaccine manufacturers faced. That exposure had increasingly led manufacturers to cease production of vital vaccines, which in turn threatened vaccine shortages and the resurgence of preventable disease. On petitioners' reading, Section 22(b)(1) would fail of its purpose, be-

cause it would offer vaccine manufacturers no more protection than the limited state law defense they already enjoyed under the narrowest reading of Comment k. Indeed, petitioners' reading would expose vaccine manufacturers to *greater* tort liability than they faced before the Act, because Section 22(e), which preempts state laws restricting tort remedies that are not barred by the Act, would strip manufacturers of strong design-defect defenses offered by some state laws.

B. The structure of the Vaccine Act as a whole, and the regulatory background against which it was enacted, confirm Congress's strategy of removing design-based claims from the tort system, and relying instead on a panoply of federal programs and regulations assuring safe vaccine design and on a no-fault compensation system offering a remedy to injured individuals.

Just like today, when the Vaccine Act was passed, all vaccines were subjected to a rigorous FDA licensing process, including some of the most thorough examinations and largest clinical trials that FDA utilizes. After licensing, a manufacturer may not alter its vaccine's design without prior FDA approval. Post-licensing safety monitoring of vaccines under the Act is more comprehensive than other classes of FDA-approved products because not only manufacturers but also health care providers are required to report adverse events. In addition, using authorities granted in the Act, HHS has established a strong partnership with health care organizations to give its researchers access to high-quality data for researching immunization safety questions. And the federal government conducts and funds more than $2 billion of vaccine research annually.

The Compensation Program, for its part, has fulfilled Congress's objective of establishing a comprehensive,

fast, and fair system for making awards to individuals injured by vaccines covered by the Act. In matters ranging from the burden of proof and rules of decision, through the availability of legal representation and discovery, to the remedies awarded, the Compensation Program is as favorable to claimants—and in some respects, decidedly more favorable—than the tort system. Because the Act is structured to ensure that compensation is available whenever tort remedies are preempted, those who are injured are not left without a remedy.

ARGUMENT

MANUFACTURERS MAY NOT BE HELD CIVILLY LIABLE FOR THE DESIGN OF A VACCINE SUBJECT TO THE ACT

A. Section 22's Text, Structure, Purpose, And History Show That It Preempts Claims Against Manufacturers Based On Vaccine Design

Section 22(b)(1) expressly preempts state law. See, *e.g.*, Pet. App. A20-A22. The task therefore is to "identify the domain expressly pre-empted." *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 484 (1996) (citation omitted). The preemptive reach of Section 22(b)(1) turns on what Congress intended to convey by invoking the term of art "unavoidable." Petitioners contend that the term calls for a "case-specific" approach (Br. 35), under which a claim is not preempted if the plaintiff shows that the side effects could have been avoided by some alternative design. Br. 29. Respondents, however, are correct in their contention (Br. 24) that "unavoidable"—when read alongside the modifying phrase that follows it—forbids tort claims challenging a vaccine's design, but preserves claims asserting that the injury or death could have been avoided by proper preparation or proper directions and warnings.

1. Section 22's text and structure preempt claims based on vaccine design

a. Section 22(b)(1) bars claims against a vaccine manufacturer based on an injury or death that "resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." The subordinate "even though" clause following the word "unavoidable" singles out two of the familiar categories of product liability law: manufacturing defects (*i.e.*, claims that the vaccine was not "properly prepared") and labeling defects (*i.e.*, claims that the vaccine was not "accompanied by proper directions and warnings"). The modifying clause thus explicates the universe of side effects that are *not* "unavoidable"—those caused by manufacturing defects or improper labeling. Excluded from that clause is the remaining category of product liability claims—those alleged to result from the vaccine's FDA-licensed design. Under the Act, those side effects *are* "unavoidable." The result is that Section 22(b)(1) bars one theory of liability (design defect), while leaving in place two others (manufacturing and labeling defects), subject to other limitations in the Act.[2]

The Vaccine Act and related laws provide a clear standard for deciding whether a manufacturing defect exists and whether the vaccine was properly labeled. The vaccine's license, issued by FDA under 42 U.S.C. 262, speaks to those subjects in detail. See 21 C.F.R. 601.2(a). In addition, the Vaccine Act creates a presumption that a vaccine is properly labeled if the manu-

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[2] Section 22(b)(1)'s bar on claims challenging vaccine design is limited: it applies only to damage claims, only to vaccines on the Table, and only to claims against manufacturers.

facturer complied in all material respects with the FDCA, with 42 U.S.C. 262 (which concerns licensing of biological products), and with implementing regulations. 42 U.S.C. 300aa-22(b)(2). The Vaccine Act thus promotes safety by tying protection from liability to compliance with the comprehensive federal regulatory scheme. By contrast, nowhere does the Act or any other law offer a standard for design-defect claims. For example, for the plaintiff to prove the existence of a safer alternative vaccine, would the alternative vaccine simply have to be available in a lab somewhere? Or would it have to be available for sale? Must it have been licensed by FDA? Congress's silence on questions like those reinforces the conclusion based on the text of Section 22(b)(1) that Congress removed issues concerning the design of FDA-licensed vaccines from the tort system.

b. Petitioners argue (Br. 28-29) that "unavoidable" should be given a dictionary definition of "'incapable of being . . . prevented' or 'inevitable.'" That argument begs the question of what measures the Act contemplates a manufacturer can take to avoid side effects. A particular side effect might have been avoided by using an unlicensed, untested vaccine of unknown potency that exists only in a laboratory. Yet no one suggests the possibility of that kind of avoidance would be reason to hold a vaccine manufacturer liable. Rather, to understand what side effects are "unavoidable," the "[s]tatutory language must be read in context" because a word "gathers meaning from the words around it." *Jones* v. *United States*, 527 U.S. 373, 389 (1999) (citation omitted). Here, in the context of the subordinate "even though" clause that follows it, "unavoidable" refers to side effects that are inherent risks of the FDA-approved

vaccine even when it is properly manufactured and labeled.

Petitioners also rely (Br. 32) on the conditional nature of the phrase "if the injury or death resulted from side effects that were unavoidable." 42 U.S.C. 300aa-22(b)(1). That phrasing does not assist petitioners. The United States agrees that Section 22(b)(1) states a condition for non-liability; the dispute is over its content—*i.e.*, the meaning of "unavoidable."

Petitioners further suggest (Br. 39-40) that if Congress had intended to bar all liability based on vaccine design, it could have said so more clearly or in different words. But "it is always possible to construct through hindsight an alternate structure for a statute with alternative wording that would render it more clear." Pet. App. A28. Here, the import of Section 22(b)(1) is evident—on its own terms, and (as explained below) in the context of the structure and purposes of the Act as a whole. Relatedly, petitioners criticize respondents for "read[ing] * * * language out of the statute." Pet. Br. 40. That criticism misunderstands the text: the overall "if" clause specifies the condition under which a suit is barred by reference to alleged causes of the claimed injury, while the subordinate "even though" clause elaborates upon that condition by specifying that a manufacturer may be liable if its vaccine is not properly prepared and labeled. Ironically, *petitioners'* reading makes the "even though" phrase unnecessary. If injuries from defective design are "[]avoidable" within that word's plain meaning, then so too are injuries from mismanufacturing and insufficient labeling; there would be no purpose to singling out the latter categories in their own clause.

2. *Section 22's purpose and legislative history show that Congress intended to preempt claims against manufacturers based on vaccine design*

Section 22(b)(1) is integrally related to other provisions of the Act—such as those that demand government vigilance over vaccines at all stages from development through administration to the population at large, and those that award compensation to individuals who are injured by vaccines. See pp. 19-30, *infra*. Section 22(b)(1)'s purpose and legislative history illuminate how it fits with those provisions of the broader Act, and confirm that Congress intended that manufacturers would not be held liable for the designs of their vaccines.

a. The *1986 Report* explains (at 25-26) that the term "unavoidable" in Section 22(b)(1) was drawn from Comment k to Section 402A of the Restatement (Second) of Torts, which concerns "*[u]navoidably unsafe products.*" Comment k at 353 (caption). Comment k recognizes that "[t]here are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use," and offers a vaccine as a prototypical example. *Ibid.* Under Comment k, such a product is "not defective" or "*unreasonably* dangerous" as a matter of law, and the seller cannot be held liable for the consequences of its use if it was "properly prepared and marketed" and accompanied by "proper warning." *Id.* at 354. Section 22(b)(1) adopts that special principle of non-liability.

The *1986 Report* states that the Committee "intends that the principle in Comment K regarding 'unavoidably unsafe' products * * * apply to the vaccines covered in the bill and that such products not be the subject of liability in the tort system." *1986 Report* 26. In other words, vaccines covered by the Act are categorically

deemed "unavoidably unsafe products," if properly prepared and labeled, and thus not subject to design-defect claims. Petitioners contend (Br. 30-31, 46) that this passage of the *1986 Report* and the use of "unavoidable" in the Act indicate that Congress wanted courts to (1) evaluate case-by-case whether a given vaccine was an unavoidably unsafe product, and then (2) apply on that basis either ordinary liability principles from Restatement § 402A, or else Comment k's special principle of non-liability for unavoidably unsafe products. That contention is mistaken. The Act relieves courts from the former task; the *1986 Report* explains (at 26) that "the principle * * * regarding 'unavoidably unsafe' products"—the principle of non-liability—should always apply if the vaccine has been properly manufactured and labeled.

The *1986 Report* goes on explicitly to tie Section 22(b)(1) to the Compensation Program, and to underscore the consequence of applying "the principle in Comment K * * * to the vaccines covered in the bill":

> Given the existence of the [no-fault] compensation system in this bill, * * * [v]accine-injured persons will now have an appealing alternative to the tort system. Accordingly, if they cannot demonstrate under applicable law either that a vaccine was improperly prepared or that it was accompanied by improper directions or inadequate warnings [they] should pursue recompense in the compensation system, not the tort system.

1986 Report 26.

b. An "overriding concern[]" that prompted the Act was fear of "instability and unpredictability of the childhood vaccine market" from the threat of large tort liabil-

ity. *1986 Report* 7. That concern lay at the heart of the Act's liability reform, and yet petitioners' reading would mean that Section 22(b)(1) would not address that problem. Critically, although some States in 1986 accorded vaccines categorical immunity, see Resp. Br. 43 n.25, and some States in 1986 conditioned the manufacturer's defense on a case-by-case showing that Comment k applied, see Pet. Br. 34 n.17, no State in 1986 left vaccine manufacturers without even the prospect of invoking Comment k case-by-case. Thus, on petitioners' view, Congress achieved *nothing* in Section 22(b)(1) because it preempts liability only for conduct that state tort law would never have held tortious in the first place. Respondents' view, by contrast, respects Congress's determination to address the burden of litigation and the threat of large and unpredictable tort judgments against vaccine manufacturers.

c. Petitioners also rely on language in a 1987 committee report that post-dated passage of the Act, and statements in hearings on the accompanying legislation. Br. 48-51 (citing, *inter alia*, H.R. Rep. No. 391, 100th Cong., 1st Sess. 691 (1987) (*1987 Report*)). According to that report, the codification of Comment k "was not intended to decide as a matter of law the circumstances in which a vaccine should be deemed unavoidably unsafe." *1987 Report* 691.

Neither the *1987 Report* nor statements in the hearings are persuasive authority for interpreting the Act as passed in 1986. Both were prepared after Section 22(b)(1) became law and therefore "could have had no

effect on the congressional vote." *District of Columbia* v. *Heller*, 128 S. Ct. 2783, 2805 (2008).[3]

Petitioners note (Br. 48, 51) that Section 22(b)(1) did not become effective until the Compensation Program was funded by the appropriations that were the subject of the *1987 Report*, and so "the 100th Congress had full power to reconsider the Act's liability provisions." But Congress always retains the power to repeal or amend a law. See, *e.g.*, *United States* v. *Winstar Corp.*, 518 U.S. 839, 873 & n.19 (1996) (plurality opinion). What matters is that the Members of Congress who voted in 1986 for the Act as a whole, and for the Compensation Program and Section 22(b)(1) in particular, did so with the understanding not of some later document or hearing testimony, but rather of the *1986 Report* that vaccine design should "not be the subject of liability in the tort system." *1986 Report* 26.

3. Section 22's dual preemption provisions reinforce the conclusion that petitioners' claims are preempted

Petitioners argue that their reading of Section 22(b)(1) comports with a background assumption that state police powers are not preempted. Br. 40-41 (citing *Altria Group, Inc.* v. *Good*, 129 S. Ct. 538, 543 (2008)).

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[3] The *1987 Report* also states (at 691) that when the House Committee on Energy and Commerce considered the original Act in 1986, it rejected an amendment providing that "a manufacturer's failure to develop [a] safer vaccine was not grounds for liability." See *Markup Hearing on H.R. 5546 Before the House Comm. on Energy & Commerce*, 99th Cong., 2d Sess. 46-54 (1986) (rejecting amendment). But the proceedings within a single committee's markup session are likewise not an authoritative guide to what Congress understood and intended in passing a bill. Rather, "the authoritative source for finding the Legislature's intent lies in the Committee Reports on the bill." *Eldred* v. *Ashcroft*, 537 U.S. 186, 209 n.16 (2003) (citation omitted).

That argument is mistaken. To begin with, the text, structure, purpose, and history of the Act as a whole and Section 22(b)(1) in particular dispel any such assumption here. Moreover, such a background assumption cannot be productively invoked in light of the highly unusual structure of Section 22, which contains *two opposing* preemption provisions, Section 22(b)(1) and Section 22(e). Considered together, those provisions cast even more doubt on petitioners' reading. The former limits certain claims against manufacturers (to ensure a stable vaccine supply), while the latter bars state restrictions on plaintiffs' causes of action beyond the restrictions the Act imposes (to ensure adequate tort remedies).

Those provisions operate in tandem to provide, roughly, that claims forbidden by the Act are barred (irrespective of state law), and that claims not forbidden by the Act must be permitted to proceed (irrespective of state law). Consequently, whenever Section 22(b)(1) does not preempt a cause of action, Section 22(e) *does* preempt a state law barring such an action. Conversely, a holding that Section 22(b)(1) preempts a cause of action means that Section 22(e) does not have preemptive effect. Either way, some state laws are preempted; the only question is which ones.

Thus, if petitioners' view of Section 22(b)(1) prevailed, Section 22(e) would preempt state laws that give vaccine manufacturers more protection than mere case-by-case application of Comment k. For example, some States have statutory provisions that give vaccine manufacturers a stronger defense to design defect claims than would case-by-case application of Comment k. See, *e.g.*, Mich. Comp. Laws Ann. § 600.2946(5) (West 2003), discussed in *Taylor* v. *SmithKline Beecham Corp.*, 658 N.W.2d 127 (Mich. 2003) (defense based on FDA

approval);[4] Utah Code Ann. § 78B-6-703(2) (2008). Section 22(e) would also threaten States that have adopted Comment k by statute, to the extent interpretation of those statutes deviates from petitioners' view of Section 22(b)(1). See, *e.g.*, N.J. Stat. Ann. § 2A:58C-3(a) (West 2000).[5]

Thus, on petitioners' view, Congress not only did nothing to shield manufacturers from design defect claims (see p. 15, *supra*), but it preemptively forbade States from offering such protection. Ironically, the Act then would expose manufacturers to *greater* liability for their vaccine designs than they would face under state law alone. That is irreconcilable with Congress's "overriding concern[]" about "instability and unpredictability of the childhood vaccine market." *1986 Report* 7.

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[4] This statute was also the subject of *Warner-Lambert Co., LLC* v. *Kent*, 552 U.S. 440 (2008) (per curiam) (affirming by an equally divided Court).

[5] The preemptive effect of petitioners' position would be broader still if Section 22(e) reached not only positive law but common law as well, because it would abrogate the protection that vaccine manufacturers enjoy in many States under judicial decisions according categorical exemption of FDA-approved drugs from design-defect liability. See Resp. Br. 43 & n.25 (citing cases "categorically preclud[ing] design-defect claims against products like vaccines"). Indeed, contrary to the narrow reading of Section 22(e) they now advance, Pet. Br. 42-43, petitioners argued below that Section 22(e) required Pennsylvania law to recognize a strict liability cause of action for a vaccine design defect, even though its courts had refused to do so. See Dkt. 29 at 18-19; Pet. C.A. Reply Br. 10. That may not, however, be the best construction of Section 22(e). Cf. *Sprietsma* v. *Mercury Marine*, 537 U.S. 51, 63 (2002) (construing language similar to Section 22(b)(1) not to preempt state common law).

B. The Act's Overall Structure Confirms Section 22's Preemptive Effect

The federal government has a unique policy governing childhood vaccines, and that policy differs from those governing most pharmaceuticals and medical devices. In the Vaccine Act, Congress adopted an affirmative and comprehensive national policy favoring development and widespread administration of childhood vaccines. See 42 U.S.C. 300aa-2 (responsibilities of the National Vaccine Program). Section 22(b)(1) reflects Congress's judgment that holding manufacturers liable for the design of their vaccines would unacceptably undermine the Act and its animating policy. Instead, other features of the Act furnish substitutes for the tort system in promoting safety and providing compensation to injured vaccine recipients.

1. The Act is a central component of a statutory framework that creates proven incentives for improving vaccine safety

By design and in practice, the Vaccine Act, building upon preexisting laws that regulate vaccines, features close federal involvement in (1) ensuring that only safe, pure, and potent vaccines are brought to market, (2) identifying adverse events associated with vaccines on the market, and (3) funding and encouraging vaccine research and improvement. Indeed, the Act specifically commands the Secretary to "promote the development of childhood vaccines that result in fewer and less serious adverse reactions * * * and promote the refinement of such vaccines." 42 U.S.C. 300aa-27(a)(1).

a. Today, as in 1986, all vaccines covered by the Act and released to the market must first undergo the rigorous FDA licensing process for biological products. See

21 U.S.C. 301 *et seq.*; 42 U.S.C. 262; 21 C.F.R. Pts. 600-601; cf. *Riegel* v. *Medtronic, Inc.*, 552 U.S. 312, 317 (2008) ("Premarket approval is a rigorous process.") (internal quotation marks and citation omitted). New childhood vaccines in particular are put through some of the most thorough examinations and largest clinical trials of any FDA-approved product.

For example, development of new vaccines for rotavirus gasteroenteritis (a severe diarrheal disease) began in the early 1980s and, after clinical trials involving more than 130,000 participants, culminated in FDA licensing of the vaccines in 2006 and 2007. See H. Fred Clark et al., *Rotavirus Vaccines*, *in Vaccines* 719-720 (Stanley Plotkin et al. eds., 5th ed. 2008) (*Vaccines*); Roger I. Glass & Umesh D. Parashar, *The Promise of New Rotavirus Vaccines*, 354 New Eng. J. Med. 75, 76 (2006). FDA's Center for Biologics Evaluation and Research informs this Office that a typical vaccine license application takes thousands of hours to review, covers 40-80 volumes of data and information, and demands a team of 8-12 FDA personnel including medical officers, scientists, consumer safety officers, and inspectors. Once licensed and manufactured, each lot of vaccine must be rigorously tested before release. See 21 C.F.R. Pt. 610.[6]

A license reflects the detailed manufacturing process for the vaccine, as well as its labeling, container, and other matters. See 21 C.F.R. 601.2(a). A vaccine manufacturer may not alter the design of its vaccine without

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[6] The Act also covers an unlicensed vaccine undergoing FDA-regulated clinical trials that is in a category listed on the Table. In addition, some vaccines administered abroad to federal employees and their dependents would be covered by the Act, see 42 U.S.C. 300aa-11(c)(1)(B)(i)(II), but may not be subject to FDA regulation.

FDA's prior approval. See 21 C.F.R. 601.12(b) and (b)(2)(i). That also was true under regulations in effect when the Vaccine Act was passed; those required prior FDA approval of any "[i]mportant proposed changes," 21 C.F.R. 601.12 (1986), which included any design changes. Congress therefore could not have expected vaccine manufacturers to alter the designs of their vaccines unilaterally. The situation here thus differs materially from *Wyeth* v. *Levine*, 129 S. Ct. 1187 (2009), in which this Court concluded that the drug manufacturer could have unilaterally remedied a labeling defect using FDA's "Changes Being Effected" regulation, 21 C.F.R. 314.70(c). See *Levine*, 129 S. Ct. at 1196-1197.

Routine childhood vaccines typically have such a low rate of unavoidable serious side effects (sometimes numbering in the single digits per million doses) that they may not be discovered even in massive clinical trials. The Act therefore mandates stringent post-licensing monitoring by requiring that both vaccine manufacturers and health care providers report side effects (and other contraindicating reactions) to HHS through the Vaccine Adverse Event Reporting System (VAERS). 42 U.S.C. 300aa-25(b); see http://vaers.hhs.gov. Pediatricians and other children's health care providers are uniquely well-positioned to learn of and observe adverse events that occur after vaccination, and mandatory reporting by them makes post-approval monitoring of vaccines even more comprehensive than parallel systems applicable to drugs and non-vaccine biological products. Compare 42 U.S.C. 300aa-25(b) (vaccines), with 21 C.F.R. 600.80 (biological products, including vaccines); 21 U.S.C. 355(k)(1); and 21 C.F.R. 314.80 (drugs).

Because VAERS depends on self-reporting, however, its data alone are not sufficient for sound public health

policy decisions. VAERS data are instead used to trigger further investigation, often employing the Vaccine Safety Datalink (VSD). VSD, which was developed primarily on the authority of 42 U.S.C. 300aa-2(a)(7)-(8) and 300aa-27(a), is a partnership between the federal government and several private managed care organizations. The VSD project includes a database with high-quality medical and vaccination data on about 5.5 million patients annually, which is used by researchers affiliated with CDC and under CDC contract to investigate immunization safety questions. See CDC, *Vaccine Safety Datalink (VSD) Project*, http://www.cdc.gov/vaccinesafety/Activities/vsd.html (last modified Feb. 17, 2010).

Vaccine safety and innovation are also encouraged through government-funded and government-conducted research. The National Institutes of Health (NIH)—the primary federal agency charged with conducting and supporting biomedical research—reports funding each year about $1.7 billion of general vaccine research and an additional amount, totaling more than $500 million, on HIV/AIDS vaccine research. See NIH, *Estimates of Funding for Various Research, Condition, and Disease Categories*, http://report.nih.gov/rcdc/categories (last modified Mar. 23, 2010). The Act requires the Director of the National Vaccine Program to coordinate such funding and research activities throughout the government. See 42 U.S.C. 300aa-2(a)(1)-(2).

In addition, the determination of which vaccines are administered to children, and thus which are manufactured and sold, is strongly influenced by expert governmental and nongovernmental entities—such as the Public Health Service (PHS), CDC, the Advisory Committee on Immunization Practices (ACIP), and the American

Academy of Pediatrics (AAP). For example, in 1999 PHS, ACIP, and AAP expressed the view that it would be preferable not to expose children to even the small amounts of mercury in the vaccine preservative thimerosal, provided vaccine supply, safety, and potency could be maintained without its use.[7] Over the next three years, manufacturers developed and obtained licenses for thimerosal-free (or trace thimerosal) childhood vaccines, and ceased production of childhood vaccines containing thimerosal. Congress anticipated exactly this sort of process in, for example, recognizing CDC's key role in establishing vaccination recommendations. See 42 U.S.C. 300aa-14(e).

b. Events surrounding the withdrawal of the Rotashield vaccine illustrate how well this system functions in practice. Rotashield was licensed in late 1998 for immunization against rotavirus, which causes severe diarrheal disease. Clinical trials identified a slight—but not statistically significant—increase among recipients in incidents of intussusception, a form of bowel collapse. FDA therefore required as a condition of licensure that the manufacturer commit to post-licensing studies. CDC recommended the vaccine for routine administration to children in March 1999. CDC, *Recommended Childhood Immunization Schedule—United States, 1999*, 48 MMWR 12 (1999).

Out of the approximately 1.5 million doses administered between September 1998 and June 1999, VAERS reports identified ten incidents of intussusception. Those reports prompted CDC to initiate studies using

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[7] See, *e.g.*, AAP & PHS, *Thimerosal in Vaccines*, 48 Morbidity & Mortality Wkly. Rep. (MMWR) 563-565 (1999); ACIP, *Recommendations Regarding the Use of Vaccines that Contain Thimerosal as a Preservative*, 48 MMWR 996-998 (1999).

the VSD and other methods in June 1999, and the next month CDC recommended suspending use of Rotashield based on VAERS and VSD data. CDC, *Intussusception Among Recipients of Rotavirus Vaccine—United States, 1998-1999*, 48 MMWR 577 (1999). The manufacturer suspended distribution, and three months later it withdrew Rotashield altogether, explaining that it had "evaluated the additional cases of intussusception reported to VAERS as well as preliminary data from the ongoing epidemiological studies conducted by CDC [that] will be publicly discussed at [an] upcoming [ACIP] meeting." *Wyeth Lederle Vaccines Voluntarily Withdraws from the Market Its Rotavirus Vaccine RotaShield®*, PR Newswire, Oct. 15, 1999. CDC then formally withdrew its recommendation for routine use of rotavirus vaccine. CDC, *Withdrawal of Rotavirus Vaccine Recommendation*, 48 MMWR 1007 (1999). FDA revoked the Rotashield license, and research into other rotavirus vaccines continued, culminating in licensing several years later of new vaccines after broad clinical trials, see p. 20, *supra*.

Thus, in the space of about one year, a vaccine was licensed and recommended for routine administration, adverse events raised a concern, further studies were conducted, and the manufacturer withdrew the vaccine knowing the government and physician community were ready to respond. Tort litigation played no role in Rotashield's withdrawal; indeed, to the government's knowledge, no tort suit ever proceeded over a Rotashield injury. The Table was amended to add intussusception as an injury for rotavirus vaccine, 67 Fed. Reg. 48,558 (2002), and those injured received compensation.

c. Petitioners nonetheless assert (Br. 52-56) that imposing tort liability on vaccine designs will promote

the Act's goal of ensuring safe and potent vaccines. But unusual features about vaccines show that this is wrong; indeed, such liability could, perversely, stall innovations in safety. As noted above, the side effects of childhood vaccines can be so rare that they are not evident until millions of doses have been administered, meaning that a manufacturer may be unable realistically to assess its potential liability before marketing a vaccine. Public health would be undermined if manufacturers reacted by foregoing research and development of new vaccines.

As explained in our amicus brief (at 18-20) at the petition stage in *Ferrari*, *supra*, current research offers several examples of vaccine development strategies and techniques that promise significant advantages in safety and potency over currently marketed vaccines, but that could result in rare side effects that are currently unknown. Such side effects would, on petitioners' view, be "[]avoidable" if they were not associated with the form of the vaccine now on the market, and a basis for holding an innovative manufacturer liable. Coupled with federal vigilance over new vaccine designs, Section 22(b)(1) removes the tort system's disincentive to such vaccine innovation.

2. *Congress established the Compensation Program as a sound substitute for the tort system*

The Compensation Program has fulfilled Congress's related goal of establishing a "comprehensive and fair compensation system," *1986 Report* 25, that "work[s] faster and with greater ease than the civil tort system," *Shalala* v. *Whitecotton*, 514 U.S. 268, 269 (1995), and "goes far beyond even the most exp[a]nsive ruling issued by a court in a vaccine case," *1986 Report* 26. Congress saw the Compensation Program as the critical counter-

part to Section 22(b)(1)'s withdrawal of certain tort remedies. See *ibid.*

a. The Compensation Program is as favorable to claimants—and in some respects, decidedly more favorable—than the tort system. This is exactly what Congress envisioned:

- The Compensation Program is faster. Data from Congress's survey of vaccine tort suits in the early 1980s suggest that such suits took, on average, three to four years to resolve. See Staff of the Subcomm. on Health & the Environment of the House Comm. on Energy & Commerce, 99th Cong., 2d Sess., *Childhood Immunizations* 86-87 (Comm. Print 1986). Petitions in the CFC are typically resolved in two to three years, see *Statistics Report* n.1, which often includes delays sought by the claimant.

- Legal representation is readily available in the Compensation Program because it awards attorneys' fees and costs (including expert fees), even to many unsuccessful claimants. See 42 U.S.C. 300aa-15(e)(1). Under the prevailing "American Rule," the tort system offers no such inducement, even for victorious plaintiffs. See *Alyeska Pipeline Serv. Co.* v. *Wilderness Soc'y*, 421 U.S. 240, 247 (1975).

- In the Compensation Program, "informal and cooperative exchange of information is the ordinary and preferred practice," Fed. Cl. Vaccine R. 7(a), but formal discovery is available on a satisfactory showing that it is "reasonable and necessary," 42 U.S.C. 300aa-12(d)(3)(B); see Fed. Cl. Vaccine R. 7(b). Special masters have, on appro-

priate showings, permitted extensive discovery. See, *e.g.*, *Cedillo* v. *Secretary of Health & Human Servs.*, No. 98-916V, 2009 WL 331968, at *9 (Fed. Cl. Feb. 12, 2009), aff'd, 89 Fed. Cl. 158 (2009), appeal pending, No. 2010-5004 (Fed. Cir. argued June 10, 2010). The government stays neutral when a claimant seeks discovery from vaccine manufacturers, leaving the claimant to face the same opponent she would in the tort system.

- Proceedings in the CFC are more flexible and less formal. For example, the formal rules of evidence do not apply, and parties may receive decisions based on written records without the burden of a trial. See 42 U.S.C. 300aa-12(d)(2); Fed. Cl. Vaccine R. 8(b)-(e).
- The burden of proof—preponderance of the evidence—is the same in both systems. And in Table injury cases, the injury is presumed to be caused by the vaccine, absent a contrary showing by the Secretary. See 42 U.S.C. 300aa-13(a)(1).
- The Compensation Program never requires proof of who manufactured the vaccine, which can be a stumbling block in the tort system, cf. *Shackil* v. *Lederle Labs.*, 561 A.2d 511 (N.J. 1989) (rejecting "market-share liability" theory advanced by plaintiff who could not identify manufacturer). Nor does the Compensation Program require proof of fault, as negligence claims do. See also *1986 Report* 13 ("[M]any vaccine-injured persons are presently without legal remedy under current tort law. * * * [M]any of these persons will be compensated for their injuries under the compensation system.").

- Substantial funds are available to pay awards under the Compensation Program, even if unexpected events place a significant demand on the Trust Fund, see *Vaccine Injury Compensation Trust Fund* 5, ftp://ftp.publicdebt.treas.gov/dfi/tfmb/dfivi0610.pdf, and so far over $1.8 billion has been awarded, *Statistics Report* tbl. III. Awards are ample because they cover the same generally recognized special damages as the tort system, cover lost earning capacity, and include amounts for pain and suffering (subject to a cap). See 42 U.S.C. 300aa-15(a). Department of Justice records indicate that 99.8% of successful Compensation Program claimants have accepted their awards, foregoing any tort remedies against vaccine manufacturers.

b. The Act itself and the Secretary's management of the Vaccine Injury Table ensure a close fit between the Act's preemptive reach and its compensatory promise. To be included on the Table, a category of vaccine must be "recommended for routine administration to children" by CDC. 42 U.S.C. 300aa-14(e)(2) and (2)(A). Later legislation further requires that Congress act to subject the category of vaccine to the excise tax. Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66, § 13632(a)(3), 107 Stat. 646. Thus, the categories of vaccines on the Table reflect the concurrent judgments of expert scientists at CDC and of Congress.

Significantly, the Table controls the Act's scope for both compensation and preemption purposes, ensuring that compensation is potentially available whenever tort remedies are preempted. The Compensation Program requires proof that the injured party received a

vaccine on the Table. See 42 U.S.C. 300aa-11(c)(1)(A), 300aa-13(a)(1)(A). And Section 22(b)(1) preempts only claims for "vaccine-related injury or death," which is by definition limited to injuries "associated with one or more of the vaccines set forth in the Vaccine Injury Table," 42 U.S.C. 300aa-33(5). Thus, in contrast to the situation in *Levine*, 129 S. Ct. at 1199, where preemption would have left the injured party without a remedy, the Act ensures that every individual injured by a covered vaccine has a complete remedy available in at least one forum.

One of petitioners' amici complains (Willner Amicus Br. 21-22, 27-31) about the Secretary's revisions to the Table. But despite the availability of citizen suits to compel changes to the Table, 42 U.S.C. 300aa-31(a), the Secretary's management of the Table has been challenged only rarely, and never successfully. New vaccines have been added to the Table without associated injuries when there was no sound evidence of such injuries. *E.g.*, 62 Fed. Reg. 7687 (1997) (*inter alia*, adding varicella vaccine with no injuries specified). New vaccines have been added with an associated injury. *E.g.*, 67 Fed. Reg. at 48,558 (*inter alia*, adding live, oral, rhesus-based rotavirus vaccines associated with intussusception). Injuries have been added for existing vaccines. *E.g.*, 62 Fed. Reg. at 7687, 7688 (*inter alia*, adding thrombocytopenic purpura for measles-containing vaccines).[8] And injuries have also been removed or mod-

[8] Significantly, amendments adding injuries or new vaccines to the Table have retroactive effect in that they allow claimants injured within eight years before the amendment—including previously unsuccessful claimants—to obtain compensation using the revised Table. See 42 U.S.C. 300aa-16(b). The tort system, of course, includes no similar exception to finality.

ified based on improved knowledge. *E.g.*, 60 Fed. Reg. 7686-7689 (1995) (*inter alia*, shortening the period for onset of anaphylaxis, modifying the definition of "encephalopathy," and removing the injury of hypotonic-hyporesponsive episode for pertussis vaccines).

This is exactly the give-and-take Congress expected. See, *e.g.*, 42 U.S.C. 300aa-14(c); Vaccine Act § 312, 100 Stat. 3779 (directing the Secretary to undertake studies of associations between certain vaccines and injuries and to make corresponding revisions to the Table). And when an injury is not listed on, or has been removed from, the Table for a listed vaccine, the Act still affords all claimants the opportunity to prove a non-Table causation claim. 42 U.S.C. 300aa-11(c)(1)(C)(ii).

3. Congress foreclosed design-based liability because it would disserve the Act's central purposes

Petitioners offer no sound explanation for how design-defect tort liability would be harmonious with the framework of the Vaccine Act.

a. The natural effect of holding a manufacturer liable for its product's design would be to induce it to (1) withdraw the product, (2) ameliorate the defect, or (3) pay compensation to injured users. Each of these alternatives is unavailable or would disserve the Act's central purposes.

Withdrawal of the vaccine. Without question, Congress did not want manufacturers to withdraw their vaccines from the market for fear of design-defect liability. That was exactly the crisis that precipitated the Act. See Resp. Br. 5-8.[9] Recent tragic events in California

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[9] Congress and the Secretary have since demonstrated a similar concern in responding to threats like the H1N1 influenza pandemic. See 42 U.S.C. 247d-6d (added by the Public Readiness and Emergency

are a reminder that underimmunization readily leads to the resurgence of preventable disease. See Molly Hennessy-Fiske, *California Declares Whooping Cough Epidemic*, L.A. Times, July 20, 2010, at AA1.

Withdrawal of a vaccine is particular damaging because vaccines are administered not only to immunize individuals, but also "to reduce transmission of infection and thereby to prevent disease even in non-vaccinated individuals, thus to protect communities," a phenomenon known as "herd immunity." Paul E.M. Fine & Kim Mulholland, *Community Immunity, in Vaccines* 1573. Herd immunity serves the moral imperative to protect immunologically defenseless members of society, such as the very young, the very old, and those suffering from certain diseases. Guaranteeing that a vaccine is potent enough to ensure that a disease is contained or eradicated in this way entails trade-offs between safety and potency. See *Schafer* v. *American Cyanamid Co.*, 20 F.3d 1, 4 (1st Cir. 1994) (Breyer, C.J.); cf. *Riegel*, 552 U.S. at 325 (discussing effects of "[s]tate tort law that requires a manufacturer's [product] to be safer, but hence less effective"). The tort system—in which juries may pay little heed to this calculus, see *ibid.*—is poorly equipped to encourage such optimally safe and potent vaccines. That is why Congress recognized through the Act that expert regulators, in conjunction with the medical community, should control the availability and withdrawal of a given vaccine.

Preparedness Act, Pub. L. No. 109-146, Div. C, § 2, 119 Stat. 2818) (barring all liability for designated vaccines and other countermeasures, except for cases of "willful misconduct"); 74 Fed. Reg. 30,294 (2009) (designating H1N1 vaccine—which, unlike the trivalent seasonal influenza vaccine, is not subject to the Vaccine Act—for such protection).

Although petitioners and their amici hold up as a model Japan's experience withdrawing the DTP vaccine and turning to a DTaP vaccine, that episode was in fact the antithesis of sound public health policy. Japan began DTP vaccination in 1947; by 1974, it recorded limited pertussis cases and no deaths. Then, two infants died shortly after DTP vaccination in 1974-1975. Although investigation later established that the whole-cell pertussis component had not caused the deaths, the Ministry of Health suspended DTP vaccination, and public panic caused pertussis vaccination rates to drop to just ten percent. A pertussis epidemic ensued and led to 13,000 recorded cases and 41 deaths in 1979.[10] E.J. Gangarosa et al., *Impact of Anti-Vaccine Movements on Pertussis Control: The Untold Story*, 351 Lancet 356, 357-358 (1998); Institute of Med., *Adverse Effects of Pertussis and Rubella Vaccines* 18 (Christopher P. Howson et al. eds., 1991). That experience is a powerful illustration that "even though vaccines themselves cause a small number of serious injuries or deaths, their widespread use dramatically reduces fatalities." *Schafer*, 20 F.3d at 4. In contrast to Japan, the United States unquestionably avoided similarly extensive suffering and deaths by continuing to promote widespread DTP vaccination.

Ameliorating the defect. Design changes are not easily made to vaccines; it typically takes years of careful study with large groups to determine the safety and potency of a candidate vaccine. See p. 20, *supra*. Studies on new versions of existing vaccines are all the more difficult because medical ethics and study design considerations generally preclude testing the new vaccine on

[10] For comparison, on a population-adjusted basis, that death rate from just one disease is about the same as the rate of all serious injuries and all deaths combined caused by all vaccines subject to the Act.

a population that has enjoyed access to the proven old vaccine.

Petitioners suggest that manufacturers have "continu[ed] to sell outmoded vaccines" that "cause harm that could be avoided by another design already on the market." Br. 52, 54. It is unclear to what vaccine "already on the market" petitioners refer. See Br. 19-21. Assuming, however, that petitioners refer to Japan's early use of a DTaP vaccine (see Br. 19), they again offer an unsound model. Japan began administering a DTaP vaccine based on safety and potency studies too limited to support FDA licensing. As FDA explained at the time, the existing pertussis "vaccine is a very effective one," albeit poorly understood, and "[a]ny move to make [it] safer by modifying it is fraught with the danger of altered efficacy which cannot be adequately assessed without an extensive field trial." 50 Fed. Reg. 51,007 (1985). Moreover, trials of several candidate DTaP vaccines conducted by PHS in Sweden in 1986 were associated with serious adverse events. Jann Storsaeter et al., *Mortality and Morbidity from Invasive Bacterial Infections During a Clinical Trial of Acellular Pertussis Vaccines in Sweden*, 7 Pediatric Infectious Disease J. 637 (1988). Petitioners imply (Br. 19) that the United States was inappropriately slow to license a DTaP vaccine, but in fact the United States was the first country (after Japan) to do so. Japan took a serious public health risk, and was fortunate. But there was no quick path to improving pertussis vaccines in the United States that had the scientific rigor demanded by federal law.

Paying compensation. The Compensation Program serves the compensatory function of product liability law. See pp. 14, 25, *supra*. The Act's requirement that

vaccine-injured persons proceed first to the Compensation Program, 42 U.S.C. 300aa-11(a)(2)-(3), expresses Congress's clear intent that manufacturers not be the primary source of compensation for injuries. The Compensation Program is a "no fault" scheme analogous to other "no fault" schemes that supplant tort law. Within that framework, the vaccine excise tax that funds the Compensation Program is analogous to an insurance premium. And as with any "no fault" scheme, the Act's design is to award compensation outside the tort system.

b. These same considerations do not apply to manufacturing and labeling defects, which is why Section 22(b)(1) treats such claims differently. Unlike the sometimes unpredictable or undesirable results of changing a vaccine's design, withdrawal of a mismanufactured or mislabeled lot of vaccine is always highly desirable. Labeling defects can sometimes be corrected without discarding the vaccine, and a manufacturing defect at worst requires destruction of a particular lot. In either case, the effects on the public health are transient, if they are felt at all. Similarly, unlike changing a vaccine's fundamental design, correcting manufacturing and labeling defects is always feasible, relatively quick to implement, and independently required by law. A vaccine's biologics license reflects the manufacturing methods and labels submitted by the manufacturer. See 21 C.F.R. 601.2(a). Presumably, a manufacturer that obtains a license is readily capable of meeting the license's specifications, and indeed is required to do so by 42 U.S.C. 262(a)(1)(A).

Although the Compensation Program permits compensation for injuries from mismanufactured or mislabled vaccines, damages paid by a manufacturer are also a suitable compensation mechanism. Manufactur-

ers have thorough control over their manufacturing and labeling practices, they must adhere to the vaccine's license requirements, and they are in a clearly superior position to avoid injuries from such defects. That is far less so for injuries due to a vaccine's design, given the intense federal involvement in, and restrictions on, vaccine development and design change.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted.

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