# SUPREME COURT OF THE UNITED STATES

No. 09–152

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

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

[February 22, 2011]

JUSTICE SCALIA delivered the opinion of the Court.

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

## I

### A

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

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[1] 42 U. S. C. §300aa–22(b)(1).

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

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

cines became, one might say, victims of their own success. They had been so effective in preventing infectious diseases that the public became much less alarmed at the threat of those diseases,[4] and much more concerned with the risk of injury from the vaccines themselves.[5]

Much of the concern centered around vaccines against diphtheria, tetanus, and pertussis (DTP), which were blamed for children's disabilities and developmental delays. This led to a massive increase in vaccine-related tort litigation. Whereas between 1978 and 1981 only nine product-liability suits were filed against DTP manufacturers, by the mid-1980's the suits numbered more than 200 each year.[6] This destabilized the DTP vaccine market, causing two of the three domestic manufacturers to withdraw; and the remaining manufacturer, Lederle Laboratories, estimated that its potential tort liability exceeded its annual sales by a factor of 200.[7] Vaccine shortages arose when Lederle had production problems in 1984.[8]

Despite the large number of suits, there were many complaints that obtaining compensation for legitimate vaccine-inflicted injuries was too costly and difficult.[9] A

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[4] See Mortimer, Immunization Against Infectious Disease, 200 Science 902, 906 (1978).

[5] See National Vaccine Advisory Committee, A Comprehensive Review of Federal Vaccine Safety Programs and Public Health Activities 2–3 (Dec. 2008) (hereinafter NVAC), http://www.hhs.gov/nvpo/nvac/documents/vaccine-safety-review.pdf (as visited Feb. 18, 2011, and available in Clerk of Court's case file).

[6] See Sing & Willian, Supplying Vaccines: An Overview of the Market and Regulatory Context, in Supplying Vaccines: An Economic Analysis of Critical Issues 45, 51–52 (M. Pauly, C. Robinson, S. Sepe, M. Sing, & M. William eds. 1996).

[7] See *id.,* at 52.

[8] See Centers for Disease Control, Diptheria-Tetanus-Pertussis Vaccine Shortage, 33 Morbidity and Mortality Weekly Report 695–696 (Dec. 14, 1984).

[9] See Apolinsky & Van Detta, Rethinking Liability for Vaccine Injury, 19 Cornell J. L. & Pub. Pol'y 537, 550–551 (2010); T. Burke, Lawyers,

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

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

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

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

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

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

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

[13] See 42 U. S. C. §300aa–11(a)(1).

[14] See §300aa–12(d)(3).

[15] See §300aa–12(e), (g).

[16] See §300aa–21(a).

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

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

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

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

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

[19] See §300aa–13(a)(1)(B).

[20] See §300aa–11(c)(1)(C)(ii).

[21] See §300aa–15(a).

[22] See §300aa–15(e).

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

[24] See 42 U. S. C. §300aa–11(a)(2).

ure to warn if they have complied with all regulatory requirements (including but not limited to warning requirements) and have given the warning either to the claimant or the claimant's physician.[25] They are immunized from liability for punitive damages absent failure to comply with regulatory requirements, "fraud," "intentional and wrongful withholding of information," or other "criminal or illegal activity."[26] And most relevant to the present case, the Act expressly eliminates liability for a vaccine's unavoidable, adverse side effects:

> "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."[27]

B

The vaccine at issue here is a DTP vaccine manufactured by Lederle Laboratories. It first received federal approval in 1948 and received supplemental approvals in 1953 and 1970. Respondent Wyeth purchased Lederle in 1994 and stopped manufacturing the vaccine in 1998.

Hannah Bruesewitz was born on October 20, 1991. Her pediatrician administered doses of the DTP vaccine according to the Center for Disease Control's recommended childhood immunization schedule. Within 24 hours of her April 1992 vaccination, Hannah started to experience

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[25] See §300aa–22(b)(2), (c). The immunity does not apply if the plaintiff establishes by clear and convincing evidence that the manufacturer was negligent, or was guilty of fraud, intentional and wrongful withholding of information, or other unlawful activity. See §§300aa–22(b)(2), 300aa–23(d)(2).

[26] §300aa–23(d)(2).

[27] §300aa–22(b)(1).

seizures.[28] She suffered over 100 seizures during the next month, and her doctors eventually diagnosed her with "residual seizure disorder" and "developmental delay."[29] Hannah, now a teenager, is still diagnosed with both conditions.

In April 1995, Hannah's parents, Russell and Robalee Bruesewitz, filed a vaccine injury petition in the United States Court of Federal Claims, alleging that Hannah suffered from on-Table residual seizure disorder and encephalopathy injuries.[30] A Special Master denied their claims on various grounds, though they were awarded $126,800 in attorney's fees and costs. The Bruesewitzes elected to reject the unfavorable judgment, and in October 2005 filed this lawsuit in Pennsylvania state court. Their complaint alleged (as relevant here) that defective design of Lederle's DTP vaccine caused Hannah's disabilities, and that Lederle was subject to strict liability, and liability for negligent design, under Pennsylvania common law.[31]

Wyeth removed the suit to the United States District Court for the Eastern District of Pennsylvania, which granted Wyeth summary judgment on the strict-liability and negligence design-defect claims, holding that the Pennsylvania law providing those causes of action was preempted by 42 U. S. C. §300aa–22(b)(1).[32] The United States Court of Appeals for the Third Circuit affirmed.[33] We granted certiorari. 559 U. S. ___ (2010).

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[28] See *Bruesewitz* v. *Secretary of Health and Human Servs.*, No. 95–0266V, 2002 WL 31965744, *3 (Ct. Cl., Dec. 20, 2002).

[29] 561 F. 3d 233, 236 (CA3 2009).

[30] See *id.,* at *1.

[31] See 561 F. 3d at 237. The complaint also made claims based upon failure to warn and defective manufacture. These are no longer at issue.

[32] See *id.,* at 237–238.

[33] *Id.,* at 235.

## II

## A

We set forth again the statutory text at issue:

> "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."[34]

The "even though" clause clarifies the word that precedes it. It delineates the preventative measures that a vaccine manufacturer *must* have taken for a side-effect to be considered "unavoidable" under the statute. Provided that there was proper manufacture and warning, any remaining side effects, including those resulting from design defects, are deemed to have been unavoidable. State-law design-defect claims are therefore preempted.

If a manufacturer could be held liable for failure to use a different design, the word "unavoidable" would do no work. A side effect of a vaccine could *always* have been avoidable by use of a differently designed vaccine not containing the harmful element. The language of the provision thus suggests that the *design* of the vaccine is a given, not subject to question in the tort action. What the statute establishes as a complete defense must be unavoidability (given safe manufacture and warning) *with respect to the particular design*. Which plainly implies that the design itself is not open to question.[35]

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[34] 42 U. S. C. §300aa–22(b)(1).

[35] The dissent advocates for another possibility: "[A] side effect is 'unavoidable' . . . where there is no feasible alternative design that would eliminate the side effect of the vaccine without compromising its cost and utility." *Post*, at 15 (opinion of SOTOMAYOR, J.). The dissent makes no effort to ground that position in the text of §300aa–22(b)(1).

A further textual indication leads to the same conclusion. Products-liability law establishes a classic and well known triumvirate of grounds for liability: defective manufacture, inadequate directions or warnings, and defective design.[36] If all three were intended to be preserved, it would be strange to mention specifically only two, and leave the third to implication. It would have been much easier (and much more natural) to provide that manufacturers would be liable for "defective manufacture, defective directions or warning, and defective design." It seems that the statute fails to mention design-defect liability "by deliberate choice, not inadvertence." *Barnhart* v. *Peabody Coal Co.*, 537 U. S. 149, 168 (2003). *Expressio unius, exclusio alterius.*

B

The dissent's principal textual argument is mistaken. We agree with its premise that "'side effects that were unavoidable' must refer to side effects caused by a vaccine's *design*."[37] We do not comprehend, however, the second step of its reasoning, which is that the use of the conditional term "if" in the introductory phrase "if the injury or death resulted from side effects that were unavoidable" "plainly implies that some side effects stemming from a vaccine's design are 'unavoidable,' while

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We doubt that Congress would introduce such an amorphous test by implication when it otherwise micromanages vaccine manufacturers. See *infra*, at 13–14. We have no idea how much more expensive an alternative design can be before it "compromis[es]" a vaccine's cost or how much efficacy an alternative design can sacrifice to improve safety. Neither does the dissent. And neither will the judges who must rule on motions to dismiss, motions for summary judgment, and motions for judgment as a matter of law. Which means that the test would probably have no real-world effect.

[36] W. Keeton, D. Dobbs, R. Keeton, & D. Owen, Prosser and Keeton on Law of Torts 695 (5th ed. 1984); Restatement (Third) of Torts §2 (1999).

[37] *Post*, at 3.

others are avoidable."[38] That is not so. The "if" clause makes total sense whether the design to which "unavoidable" refers is (as the dissent believes) any feasible design (making the side effects of the design used for the vaccine at issue avoidable), or (as we believe) the particular design used for the vaccine at issue (making its side effects unavoidable). Under the latter view, the condition established by the "if" clause is that the vaccine have been properly labeled and manufactured; and under the former, that it have been properly *designed*, labeled, and manufactured. Neither view renders the "if" clause a nullity. Which of the two variants must be preferred is addressed by our textual analysis, and is in no way determined by the "if" clause.

Petitioners' and the dissent's textual argument also rests upon the proposition that the word "unavoidable" in §300aa–22(b)(1) is a term of art that incorporates comment *k* to Restatement (Second) of Torts §402A (1963–1964).[39] The Restatement generally holds a manufacturer strictly liable for harm to person or property caused by "any product in a defective condition unreasonably dangerous to the user."[40] Comment *k* exempts from this strict-liability rule "unavoidably unsafe products." An unavoidably unsafe product is defined by a hodge-podge of criteria and a few examples, such as the Pasteur rabies vaccine and experimental pharmaceuticals. Despite this lack of clarity, petitioners seize upon one phrase in the comment *k* analysis, and assert that by 1986 a majority of courts had made this a *sine qua non* requirement for an "unavoidably unsafe product": a case-specific showing that the product was "quite incapable of being made safer for

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[38] *Ibid.*

[39] See Brief for Petitioners 29.

[40] Restatement §402A, p. 347.

[its] intended . . . use."[41]

We have no need to consider the finer points of comment *k*. Whatever consistent judicial gloss that comment may have been given in 1986, there is no reason to believe that §300aa–22(b)(1) was invoking it. The comment creates a special category of "unavoidably unsafe products," while the statute refers to "side effects that were unavoidable." That the latter uses the adjective "unavoidable" and the former the adverb "unavoidably" does not establish that Congress had comment *k* in mind. "Unavoidable" is hardly a rarely used word. Even the cases petitioners cite as putting a definitive gloss on comment *k* use the precise phrase "unavoidably unsafe product";[42] none attaches special significance to the term "unavoidable" standing alone.

The textual problems with petitioners' interpretation do

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[41] *Id.,* Comment *k*, p. 353; Petitioners cite, *inter alia*, *Kearl* v. *Lederle Labs.*, 172 Cal. App. 3d 812, 828–830, 218 Cal. Rptr. 453, 463–464 (1985); *Belle Bonfils Memorial Blood Bank* v. *Hansen*, 665 P. 2d 118, 122 (Colo. 1983).

Though it is not pertinent to our analysis, we point out that a large number of courts disagreed with that reading of comment *k*, and took it to say that manufacturers did not face strict liability for side effects of properly manufactured prescription drugs that were accompanied by adequate warnings. See, *e.g., Brown* v. *Superior Court*, 227 Cal. Rptr. 768, 772–775 (Cal. App. 1986), (officially depublished), aff'd 44 Cal. 3d 1049, 751 P. 2d 470 (1988); *McKee* v. *Moore*, 648 P. 2d 21, 23 (Okla. 1982); *Stone* v. *Smith, Kline & French Labs.*, 447 So. 2d 1301, 1303–1304 (Ala. 1984); *Lindsay* v. *Ortho Pharm. Corp.*, 637 F. 2d 87, 90–91 (CA2 1980) (applying N. Y. law); *Wolfgruber* v. *Upjohn Co.*, 72 App. Div. 2d 59, 61, 423 N. Y. S. 2d 95, 96 (1979); *Chambers* v. *G. D. Searle & Co.*, 441 F. Supp. 377, 380–381 (D Md. 1975); *Basko* v. *Sterling Drug, Inc.*, 416 F. 2d 417, 425 (CA2 1969) (applying Conn. law).

[42] See, *e.g., Johnson* v. *American Cyanamid Co.*, 239 Kan. 279, 285, 718 P. 2d 1318, 1323 (1986); *Feldman* v. *Lederle Labs.*, 97 N. J. 429, 440, 446–447, 479 A. 2d 374, 380, 383–384 (1984); *Belle Bonfils Memorial Blood Bank supra*, at 121–123; *Cassisi* v. *Maytag Co.*, 396 So. 2d 1140, 1144, n. 4, 1146 (Fla. App. 1981); *Racer* v. *Utterman*, 629 S. W. 2d 387, 393 (Mo. App. 1981).

not end there. The phrase "even though" in the clause "even though the vaccine was properly prepared and [labeled]" is meant to signal the unexpected: unavoidable side effects persist *despite* best manufacturing and labeling practices.[43] But petitioners' reading eliminates any opposition between the "even though" clause—called a concessive subordinate clause by grammarians—and the word "unavoidable."[44] Their reading makes preemption turn equally on unavoidability, proper preparation, and proper labeling. Thus, the dissent twice refers to the requirements of proper preparation and proper labeling as "two additional prerequisites" for preemption independent of unavoidability.[45] The primary textual justification for the dissent's position depends on that independence.[46] But linking independent ideas is the job of a coordinating junction like "and," not a subordinating junction like "even though."[47]

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[43] The dissent's assertion that we treat "even though" as a synonym for "because" misses the subtle distinction between "because" and "despite." See *post,* at 17, n. 14. "Even though" is a close cousin of the latter. See Webster's New International Dictionary 709, 2631 (2d ed. 1957). The statement "the car accident was unavoidable despite his quick reflexes" indicates that quick reflexes could not avoid the accident, and leaves open two unstated possibilities: (1) that other, unstated means of avoiding the accident besides quick reflexes existed, but came up short as well; or (2) that quick reflexes were the only possible way to avoid the accident. Our interpretation of §300aa–22(b)(1) explains why we think Congress meant the latter in this context. (Incidentally, the statement "the car accident was unavoidable because of his quick reflexes" makes no sense.)

[44] See W. Follett, Modern American Usage: A Guide 61 (1966).

[45] *Post*, at 9, 17.

[46] *Post*, at 3–5.

[47] The dissent responds that these "additional prerequisites" act "in a concessive, subordinating fashion," *post,* at 17, n. 14 (internal quotation marks and brackets omitted). But that is no more true of the dissent's conjunctive interpretation of the present text than it is of *all* provisions that set forth additional requirements—meaning that we could eliminate "even though" from our English lexicon, its function being entirely

Petitioners and the dissent contend that the interpretation we propose would render part of §300aa–22(b)(1) superfluous: Congress could have more tersely and more clearly preempted design-defect claims by barring liability "if . . . the vaccine was properly prepared and was accompanied by proper directions and warnings." The intervening passage ("the injury or death resulted from side effects that were unavoidable even though") is unnecessary. True enough. But the rule against giving a portion of text an interpretation which renders it superfluous does not prescribe that a passage which could have been more terse does not mean what it says. The rule applies only if verbosity and prolixity can be eliminated by giving the offending passage, or the remainder of the text, a competing interpretation. That is not the case here.[48] To be sure, petitioners' and the dissent's interpretation gives independent meaning to the intervening passage (the supposed meaning of comment *k*); but it does so only at the expense of rendering the remainder of the provision superfluous. Since a vaccine is not "quite incapable of being made safer for [its] intended use" if manufacturing defects could have been eliminated or better warnings provided, the entire "even though" clause is a useless appendage.[49] It would suffice to say "if the injury or death resulted from side effects that were unavoidable"—full stop.

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performed by "and." No, we think "even though" has a distinctive concessive, subordinating role to play.

[48] Because the dissent has a superfluity problem of its own, its reliance on *Bates* v. *Dow Agrosciences LLC*, 544 U. S. 431 (2005), is misplaced. See *id.,* at 449 (adopting an interpretation that was "the only one that makes sense of each phrase" in the relevant statute).

[49] That is true regardless of whether §300aa–22(b)(1) incorporates comment *k*. See Restatement §402A, Comment *k*, pp. 353, 354 (noting that "unavoidably unsafe products" are exempt from strict liability "with the qualification that they are properly prepared and marketed, and proper warning is given").

## III

The structure of the NCVIA and of vaccine regulation in general reinforces what the text of §300aa–22(b)(1) suggests. A vaccine's license spells out the manufacturing method that must be followed and the directions and warnings that must accompany the product.[50] Manufacturers ordinarily must obtain the Food and Drug Administration's (FDA) approval before modifying either.[51] Deviations from the license thus provide objective evidence of manufacturing defects or inadequate warnings. Further objective evidence comes from the FDA's regulations—more than 90 of them[52]—that pervasively regulate the manufacturing process, down to the requirements for plumbing and ventilation systems at each manufacturing facility.[53] Material noncompliance with any one of them, or with any other FDA regulation, could cost the manufacturer its regulatory-compliance defense.[54]

Design defects, in contrast, do not merit a single mention in the NCVIA or the FDA's regulations. Indeed, the FDA has never even spelled out in regulations the criteria it uses to decide whether a vaccine is safe and effective for its intended use.[55] And the decision is surely not an easy one. Drug manufacturers often could trade a little less efficacy for a little more safety, but the safest design is not always the best one. Striking the right balance between safety and efficacy is especially difficult with respect to vaccines, which affect public as well as individual health. Yet the Act, which in every other respect micromanages manufacturers, is silent on how to evaluate competing designs. Are manufacturers liable only for failing to em-

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[50] See 42 U. S. C. §262(a), (j); 21 CFR §§601.2(a), 314.105(b) (2010).
[51] See §601.12.
[52] See §§211.1 *et seq.*, 600.10–600.15, 600.21–600.22, 820.1 *et seq.*
[53] See §§211.46, 211.48.
[54] See 42 U. S. C. §300aa–22(b)(2).
[55] Hutt, Merrill, & Grossman, Food and Drug Law, at 685, 891.

ploy an alternative design that the FDA has approved for distribution (an approval it takes years to obtain[56])? Or does it suffice that a vaccine design has been approved in other countries? Or could there be liability for failure to use a design that exists only in a lab? Neither the Act nor the FDA regulations provide an answer, leaving the universe of alternative designs to be limited only by an expert's imagination.

Jurors, of course, often decide similar questions with little guidance, and we do not suggest that the absence of guidance alone suggests preemption. But the lack of guidance for design defects combined with the extensive guidance for the two grounds of liability specifically mentioned in the Act strongly suggests that design defects were not mentioned because they are not a basis for liability.

The mandates contained in the Act lead to the same conclusion. Design-defect torts, broadly speaking, have two beneficial effects: (1) prompting the development of improved designs, and (2) providing compensation for inflicted injuries. The NCVIA provides other means for achieving both effects. We have already discussed the Act's generous compensation scheme. And the Act provides many means of improving vaccine design. It directs the Secretary of Health and Human Services to promote "the development of childhood vaccines that result in fewer and less serious adverse reactions."[57] It establishes a National Vaccine Program, whose Director is "to achieve optimal prevention of human infectious diseases . . . and to achieve optimal prevention against adverse reactions."[58] The Program is to set priorities for federal vaccine research, and to coordinate federal vaccine safety and effi-

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[56] See Sing & William, Supplying Vaccines, at 66–67.

[57] 42 U. S. C. §300aa–27(a)(1).

[58] §300aa–1.

cacy testing.[59] The Act requires vaccine manufacturers and health-care providers to report adverse side effects,[60] and provides for monitoring of vaccine safety through a collaboration with eight managed-care organizations.[61] And of course whenever the FDA concludes that a vaccine is unsafe, it may revoke the license.[62]

These provisions for federal agency improvement of vaccine design, and for federally prescribed compensation, once again suggest that §300aa–22(b)(1)'s silence regarding design-defect liability was not inadvertent. It instead reflects a sensible choice to leave complex epidemiological judgments about vaccine design to the FDA and the National Vaccine Program rather than juries.[63]

And finally, the Act's structural *quid pro quo* leads to the same conclusion: The vaccine manufacturers fund from their sales an informal, efficient compensation program for vaccine injuries;[64] in exchange they avoid costly tort litigation and the occasional disproportionate jury verdict.[65] But design-defect allegations are the most speculative and difficult type of products liability claim to

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[59] See §§300aa–2(a)(1)–(3), 300aa–3.

[60] See §300aa–25(b).

[61] See NVAC 18–19.

[62] See 21 CFR §601.5(b)(1)(vi) (2010).

[63] The dissent quotes just part of this sentence, to make it appear that we believe complex epidemiological judgments ought to be assigned in that fashion. See *post*, at 26. We do not state our preference, but merely note that it is Congress's expressed preference—and in order to preclude the argument that it is absurd to think Congress enacted such a thing, we assert that the choice is reasonable and express some of the reasons why. Leaving it to the jury may (or may not) be reasonable as well; we express no view.

[64] See 42 U. S. C. §300aa–15(i)(2); Pub. L. 99–660, §323(a), 100 Stat. 3784. The dissent's unsupported speculation that demand in the vaccine market is inelastic, see *post*, at 24, n. 22, sheds no light on whether Congress regarded the tax as a *quid pro quo*, most Members of Congress being neither professional economists nor law-and-economics scholars.

[65] See 42 U. S. C. §§300aa–11(a)(2), 300aa–22.

litigate. Taxing vaccine manufacturers' product to fund the compensation program, while leaving their liability for design defect virtually unaltered, would hardly coax manufacturers back into the market.

The dissent believes the Act's mandates are irrelevant because they do not spur innovation in precisely the same way as state-law tort systems.[66] That is a novel suggestion. Although we previously have expressed doubt that Congress would quietly preempt product-liability claims without providing a federal substitute, see *Medtronic, Inc.* v. *Lohr*, 518 U. S. 470, 486–488 (1996) (plurality opinion), we have never suggested we would be skeptical of preemption unless the congressional substitute operated like the tort system. We decline to adopt that stance today. The dissent's belief that the FDA and the National Vaccine Program cannot alone spur adequate vaccine innovation is probably questionable, but surely beside the point.

## IV

Since our interpretation of §300aa–22(b)(1) is the only interpretation supported by the text and structure of the NCVIA, even those of us who believe legislative history is a legitimate tool of statutory interpretation have no need to resort to it. In any case, the dissent's contention that it would contradict our conclusion is mistaken.

The dissent's legislative history relies on the following syllogism: A 1986 House Committee Report states that §300aa–22(b)(1) "sets forth the principle contained in Comment k of Section 402A of the Restatement of Torts (Second);"[67] in 1986 comment *k* was "commonly understood" to require a case-specific showing that "no feasible alternative design" existed; Congress therefore must have intended §300aa–22(b)(1) to require that showing.[68] The

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[66] See *post*, at 21–24.

[67] H. R. Rep. No. 99–908, pt. 1, p. 25 (1986) (hereinafter 1986 Report).

[68] *Post*, at 7–8.

syllogism ignores unhelpful statements in the Report and relies upon a term of art that did not exist in 1986.

Immediately after the language quoted by the dissent, the 1986 Report notes the difficulty a jury would have in faithfully assessing whether a feasible alternative design exists when an innocent "young child, often badly injured or killed" is the plaintiff.[69] Eliminating that concern is why the Report's authors "strongly believ[e] that Comment k is appropriate and necessary as the policy for civil actions seeking damages in tort."[70] The dissent's interpretation of §300aa–22(b)(1) and its version of "the principle in Comment K" adopted by the 1986 Report leave that concern unaddressed.

The dissent buries another unfavorable piece of legislative history. Because the Report believes that §300aa–22(b)(1) should incorporate "the principle in Comment K" and because the Act provides a generous no-fault compensation scheme, the Report counsels injured parties who cannot prove a manufacturing or labeling defect to "pursue recompense in the compensation system, not the tort system."[71] That counsel echoes our interpretation of §300aa–22(b)(1).

Not to worry, the dissent retorts, a Committee Report by a later Congress "authoritative[ly]" vindicates its interpretation.[72] Post-enactment legislative history (a contradiction in terms) is not a legitimate tool of statutory interpretation. See *Jones* v. *United States*, 526 U. S. 227, 238

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[69] 1986 Report, at 26; see *ibid.* ("[E]ven if the defendant manufacturer may have made as safe a vaccine as anyone reasonably could expect, a court or jury undoubtedly will find it difficult to rule in favor of the 'innocent' manufacturer if the equally 'innocent' child has to bear the risk of loss with no other possibility of recompense").

[70] *Ibid.*

[71] *Ibid.*

[72] *Post*, at 12. This is a courageous adverb since we have previously held that the only authoritative source of statutory meaning is the text that has passed through the Article I process. See *Exxon Mobil Corp.* v. *Allapattah Services, Inc.*, 545 U. S. 546, 568 (2005).

(1999); *United States* v. *Mine Workers*, 330 U. S. 258, 281–282 (1947). Real (pre-enactment) legislative history is persuasive to some because it is thought to shed light on what legislators understood an ambiguous statutory text to mean when they voted to enact it into law. See *Exxon Mobil Corp.* v. *Allapattah Services, Inc.*, 545 U. S. 546, 568 (2005). But post-enactment legislative history by definition "could have had no effect on the congressional vote," *District of Columbia* v. *Heller*, 554 U. S. 570, 605 (2008).

It does not matter that §300aa–22(b)(1) did not take effect until the later Congress passed the excise tax that funds the compensation scheme,[73] and that the supposedly dispositive Committee Report is attached to that funding legislation.[74] Those who voted on the relevant statutory language were not necessarily the same persons who crafted the statements in the later Committee Report; or if they were did not necessarily have the same views at that earlier time; and no one voting at that earlier time could possibly have been informed by those later statements. Permitting the legislative history of subsequent funding legislation to alter the meaning of a statute would set a dangerous precedent. Many provisions of federal law depend on appropriations or include sunset provisions;[75] they cannot be made the device for unenacted statutory revision.

That brings us to the second flaw in the dissent's syllogism: Comment *k* did not have a "commonly understood meaning"[76] in the mid-1980's. Some courts thought it required a case-specific showing that a product was "unavoidably unsafe"; many others thought it categorically exempted certain types of products from strict liability.[77]

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[73] Pub. L. 99–960, §323(a), 100 Stat. 3784.

[74] H. R. Rep. No. 100–391, pt. 1, p. 701 (1987).

[75] See, *e.g.,* Pub. L. 104–208, §§401, 403(a), 110 Stat. 3009–655 to 3009–656, 3009–659 to 3009–662, as amended, note following 8 U. S. C. §1324a (2006 ed., Supp. III) (E-Verify program expires Sept. 30, 2012).

[76] *Post*, at 8.

[77] See n. 39, *supra; post*, at 7–8, n. 5.

When "all (or nearly all) of the" relevant judicial decisions have given a term or concept a consistent judicial gloss, we presume Congress intended the term or concept to have that meaning when it incorporated it into a later-enacted statute. *Merck & Co.* v. *Reynolds*, 559 U. S. ___, ___ (2010) (SCALIA, J., concurring in part and concurring in judgment) (slip op., at 5). The consistent gloss represents the public understanding of the term. We cannot make the same assumption when widespread disagreement exists among the lower courts. We must make do with giving the term its most plausible meaning using the traditional tools of statutory interpretation. That is what we have done today.

* * *

For the foregoing reasons, we hold that the National Childhood Vaccine Injury Act preempts all design-defect claims against vaccine manufacturers brought by plaintiffs who seek compensation for injury or death caused by vaccine side effects. The judgment of the Court of Appeals is affirmed.

*It is so ordered.*

JUSTICE KAGAN took no part in the consideration or decision of this case.