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NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Timber & Lumber Co.,* 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

Syllabus

BRUESEWITZ ET AL. *v.* WYETH LLC, FKA WYETH, INC., ET AL.

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

No. 09–152. Argued October 12, 2010—Decided February 22, 2011

The National Childhood Vaccine Injury Act of 1986 (NCVIA or Act) created a no-fault compensation program to stabilize a vaccine market adversely affected by an increase in vaccine-related tort litigation and to facilitate compensation to claimants who found pursuing legitimate vaccine-inflicted injuries too costly and difficult. The Act provides that a party alleging a vaccine-related injury may file a petition for compensation in the Court of Federal Claims, naming the Health and Human Services Secretary as the respondent; that the court must resolve the case by a specified deadline; and that the claimant can then decide whether to accept the court's judgment or reject it and seek tort relief from the vaccine manufacturer. Awards are paid out of a fund created by an excise tax on each vaccine dose. As a *quid pro quo,* manufacturers enjoy significant tort-liability protections. Most importantly, the Act eliminates manufacturer liability for a vaccine's unavoidable, adverse side effects.

Hannah Bruesewitz's parents filed a vaccine-injury petition in the Court of Federal Claims, claiming that Hannah became disabled after receiving a diphtheria, tetanus, and pertussis (DTP) vaccine manufactured by Lederle Laboratories (now owned by respondent Wyeth). After that court denied their claim, they elected to reject the unfavorable judgment and filed suit in Pennsylvania state court, alleging, *inter alia,* that the 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. Wyeth removed the suit to the Federal District Court. It granted Wyeth summary judgment, holding that the relevant Pennsylvania law was preempted by 42 U. S. C. §300aa–22(b)(1), which

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provides that "[n]o 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." The Third Circuit affirmed.

Held: The NCVIA preempts all design-defect claims against vaccine manufacturers brought by plaintiffs seeking compensation for injury or death caused by a vaccine's side effects. Pp. 7–19.

(a) Section 300aa–22(b)(1)'s text suggests that a vaccine's design is not open to question in a tort action. If a manufacturer could be held liable for failure to use a different design, the "even though" clause would do no work. A vaccine side effect could always have been avoidable by use of a different vaccine not containing the harmful element. The language of the provision thus suggests the design is not subject to question in a tort action. What the statute establishes as a complete defense must be unavoidability (given safe manufacture and warning) with respect to the particular design. This conclusion is supported by the fact that, although products-liability law establishes three grounds for liability—defective manufacture, inadequate directions or warnings, and defective design—the Act mentions only manufacture and warnings. It thus seems that the Act's failure to mention design-defect liability is "by deliberate choice, not inadvertence." *Barnhart* v. *Peabody Coal Co.*, 537 U. S. 149, 168. Pp. 7–8.

(b) Contrary to petitioners' argument, there is no reason to believe that §300aa–22(b)(1)'s term "unavoidable" is a term of art incorporating Restatement (Second) of Torts §402A, Comment *k,* which exempts from strict liability rules "unavoidably unsafe products." "Unavoidable" is hardly a rarely used word, and cases interpreting comment *k* attach special significance only to the term "unavoidably unsafe products," not the word "unavoidable" standing alone. Moreover, reading the phrase "side effects that were unavoidable" to exempt injuries caused by flawed design would require treating "even though" as a coordinating conjunction linking independent ideas when it is a concessive, subordinating conjunction conveying that one clause weakens or qualifies the other. The canon against superfluity does not undermine this Court's interpretation because petitioners' competing interpretation has superfluity problems of its own. Pp. 8–12.

(c) The structure of the NCVIA and of vaccine regulation in general reinforces what §300aa–22(b)(1)'s text suggests. Design defects do not merit a single mention in the Act or in Food and Drug Administration regulations that pervasively regulate the drug manufacturing process. This lack of guidance for design defects, combined with

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the extensive guidance for the two liability grounds specifically mentioned in the Act, strongly suggests that design defects were not mentioned because they are not a basis for liability. The Act's mandates lead to the same conclusion. It provides for federal agency improvement of vaccine design and for federally prescribed compensation, which are other means for achieving the two beneficial effects of design-defect torts—prompting the development of improved designs, and providing compensation for inflicted injuries. The Act's structural *quid pro quo* also leads to the same conclusion. The vaccine manufacturers fund an informal, efficient compensation program for vaccine injuries in exchange for avoiding costly tort litigation and the occasional disproportionate jury verdict. Taxing their product to fund the compensation program, while leaving their liability for design defect virtually unaltered, would hardly coax them back into the market. Pp. 13–16.

561 F. 3d 233, affirmed.

SCALIA, J., delivered the opinion of the Court, in which ROBERTS, C. J., and KENNEDY, THOMAS, BREYER, and ALITO, JJ., joined. BREYER, J., filed a concurring opinion. SOTOMAYOR, J., filed a dissenting opinion, in which GINSBURG, J., joined. KAGAN, J., took no part in the consideration or decision of the case.

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-

[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 t extual indication leads to the same conclu - sion. Products-liability law establishes a classic and well known triumvirate of grounds for liability: defecti ve manufacture, inadequ ate directions or warnings, and defective design.[36] If all three were intended to be pre - served, 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 tha t manufacturers would b e 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." Barn- hart v. Peabody Coal Co., 537 U. S. 149, 168 (2003). Ex- pressio unius, exclusio alterius .

B

The dissent's principa l textual argument is mistaken . We agree with its premise that " 'side effects that were unavoidable' must refer to side effects caused by a vac- cine's design."[37] We do not comprehend, however, th e second step of its reasoning, which is that the use of the conditional term "if " in the introductory ph rase "if the injury or death resulted from sid e effects th at were un - avoidable" "plainly implies that some side effects stem- ming from a vaccine's design are 'unavoidable,' while

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We doubt th at Congress would in tr oduce such an amor phous test by implica tion when it otherwise mi cromanages vaccine manufa cturer s. See infra , at 13–14. We have no idea how mu ch mor e expensive an alterna tive design can be before it "compromis[es]" a vaccine's cost or how much efficacy an alterna tive design can sacrifice t o im prove safety. Neither does the dissent. And neithe r will the judges who must rule o n motions to d ismiss, motions for summar y judg ment, and motions fo r judg ment as a matter of law . Which means that the test would pr oba- bly have no real-world effect.

[36] W. Keeton, D. Dobbs, R. Keeton, & D. Owe n, Prosser and Keeton on Law of Tor ts 695 (5th ed. 1984); Restatement (Th ir d) of Tor ts §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 §§211.1et 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 & Williams, 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.

SUPREME COURT OF THE UNITED STATES

No. 09–152

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

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

[February 22, 2011]

JUSTICE BREYER, concurring.

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

I

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

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

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

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

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

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

II

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

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

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

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

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

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

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

III

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

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

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

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

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

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 SOTOMAYOR, with whom JUSTICE GINSBURG joins, dissenting.

Vaccine manufacturers have long been subject to a legal duty, rooted in basic principles of products liability law, to improve the designs of their vaccines in light of advances in science and technology. Until today, that duty was enforceable through a traditional state-law tort action for defective design. In holding that §22(b)(1) of the National Childhood Vaccine Injury Act of 1986 (Vaccine Act or Act), 42 U. S. C. §300aa–22(b)(1), pre-empts all design defect claims for injuries stemming from vaccines covered under the Act, the Court imposes its own bare policy preference over the considered judgment of Congress. In doing so, the Court excises 13 words from the statutory text, misconstrues the Act's legislative history, and disturbs the careful balance Congress struck between compensating vaccine-injured children and stabilizing the childhood vaccine market. Its decision leaves a regulatory vacuum in which no one ensures that vaccine manufacturers adequately take account of scientific and technological advancements when designing or distributing their products. Because nothing in the text, structure, or legislative history of the Vaccine Act remotely suggests that Congress intended such a result, I respectfully dissent.

I

A

Section 22 of the Vaccine Act provides "[s]tandards of responsibility" to govern civil actions against vaccine manufacturers. 42 U. S. C. §300aa–22. Section 22(a) sets forth the "[g]eneral rule" that "State law shall apply to a civil action brought for damages for a vaccine-related injury or death." §300aa–22(a). This baseline rule that state law applies is subject to three narrow exceptions, one of which, §22(b)(1), is at issue in this case. Section 22(b)(1) provides:

> "No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." §300aa–22(b)(1).

The provision contains two key clauses: "if the injury or death resulted from side effects that were unavoidable" (the "if" clause), and "even though the vaccine was properly prepared and was accompanied by proper directions and warnings" (the "even though" clause).

Blackletter products liability law generally recognizes three different types of product defects: design defects, manufacturing defects, and labeling defects (e.g., failure to warn).[1] The reference in the "even though" clause to a "properly prepared" vaccine "accompanied by proper directions and warnings" is an obvious reference to two such defects—manufacturing and labeling defects. The plain terms of the "even though" clause thus indicate that

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[1] W. Keeton, D. Dobbs, R. Keeton, & D. Owen, Prosser and Keeton on Law of Torts 695 (5th ed. 1984).

§22(b)(1) applies only where neither kind of defect is present. Because §22(b)(1) is invoked by vaccine manufacturers as a defense to tort liability, it follows that the "even though" clause requires a vaccine manufacturer in each civil action to demonstrate that its vaccine is free from manufacturing and labeling defects to fall within the liability exemption of §22(b)(1). [2]

Given that the "even though" clause requires the absence of manufacturing and labeling defects, the "if" clause's reference to "side effects that were unavoidable" must refer to side effects caused by something other than manufacturing and labeling defects. The only remaining kind of product defect recognized under traditional products liability law is a design defect. Thus, "side effects that were unavoidable" must refer to side effects caused by a vaccine's design that were "unavoidable." Because §22(b)(1) uses the conditional term "if," moreover, the text plainly implies that some side effects stemming from a vaccine's design are "unavoidable," while others are avoidable. See Webster's Third New International Dictionary 1124 (2002) ("if" means "in the event that," "so long as," or "on condition that"). Accordingly, because the "if" clause (like the "even though" clause) sets forth a condition to invoke §22(b)(1)'s defense to tort liability, Congress must also have intended a vaccine manufacturer to demonstrate in each civil action that the particular side effects of a vaccine's design were "unavoidable."

Congress' use of conditional "if" clauses in two other provisions of the Vaccine Act supports the conclusion that §22(b)(1) requires an inquiry in each case in which a manufacturer seeks to invoke the provision's exception to

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[2] See Silkwood v. Kerr-McGee Corp., 464 U. S. 238, 255 (1984); Brown v. Earthboard Sports USA, Inc., 481 F. 3d 901, 912 (CA6 2007) ("'[F]ederal preemption is an affirmative defense upon which the defendants bear the burden of proof'" (quoting Fifth Third Bank v. CSX Corp., 415 F. 3d 741, 745 (CA7 2005))).

state tort liability. In §22(b)(2), Congress created a presumption that, for purposes of §22(b)(1), "a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with" federal labeling requirements. 42 U. S. C. §300aa–22(b)(2). Similarly, in §23(d)(2), Congress created an exemption from punitive damages "[i]f . . . the manufacturer shows that it complied, in all material respects," with applicable federal laws, unless it engages in "fraud," "intentional and wrongful withholding of information" from federal regulators, or "other criminal or illegal activity." §300aa–23(d)(2). It would be highly anomalous for Congress to use a conditional "if" clause in §§22(b)(2) and 23(d)(2) to require a specific inquiry in each case while using the same conditional "if" clause in §22(b)(1) to denote a categorical exemption from liability. Cf. Erlenbaugh v. United States, 409 U. S. 239, 243 (1972) ("[A] legislative body generally uses a particular word with a consistent meaning in a given context").

Indeed, when Congress intends to pre-empt design defect claims categorically, it does so using categorical (e.g., "all") and/or declarative language (e.g., "shall"), rather than a conditional term ("if"). For example, in a related context, Congress has authorized the Secretary of Health and Human Services to designate a vaccine designed to prevent a pandemic or epidemic as a "covered countermeasure." 42 U. S. C. §§247d–6d(b), (i)(1), (i)(7)(A)(i). With respect to such "covered countermeasure[s]," Congress provided that subject to certain exceptions, "a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure," §247d–6d(a)(1) (emphasis added), including specifically claims relating to

"the design" of the countermeasure, §247d–6d(a)(2)(B).

The plain text and structure of the Vaccine Act thus compel the conclusion that §22(b)(1) pre-empts some—but not all—design defect claims. Contrary to the majority's and respondent's categorical reading, petitioners correctly contend that, where a plaintiff has proved that she has suffered an injury resulting from a side effect caused by a vaccine's design, a vaccine manufacturer may invoke §22(b)(1)'s liability exemption only if it demonstrates that the side effect stemming from the particular vaccine's design is "unavoidable," and that the vaccine is otherwise free from manufacturing and labeling defects. [3]

B

The legislative history confirms petitioners' interpretation of §22(b)(1) and sheds further light on its pre-emptive scope. The House Energy and Commerce Committee Report accompanying the Vaccine Act, H. R. Rep. No. 99–908, pt. 1 (1986) (hereinafter 1986 Report), explains in relevant part:

> "Subsection (b)—Unavoidable Adverse Side Effects; Direct Warnings.—This provision sets forth the principle contained in Comment K of Section 402A of the Restatement of Torts (Second) that a vaccine manufacturer should not be liable for injuries or deaths resulting from unavoidable side effects even though the vaccine was properly prepared and accompanied by proper directions and warnings.
>
> "The Committee has set forth Comment K in this bill because it intends that the principle in Comment K regarding 'unavoidably unsafe' products, i. e., those products which in the present state of human skill and knowledge cannot be made safe, apply to the vac-

[3] This leaves the question of what precisely §22(b)(1) means by "unavoidable" side effects, which I address in the next section.

> cines covered in the bill and that such products not be the subject of liability in the tort system." Id. , at 25–26.

The Report expressly adopts comment k of §402A of the Restatement of Torts (Second) (1963–1964) (hereinafter Restatement), which provides that "unavoidably unsafe" products—i.e., those that "in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use"—are not defective. [4] As "[a]n outstanding example" of an "[u]navoidably unsafe" product, comment k cites "the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected";

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[4] Comment k provides as follows:

"Unavoidably unsafe products. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk." Restatement 353–354.

"[s]ince the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve." Id., at 353. Comment k thus provides that "seller[s]" of "[u]navoidably unsafe" products are "not to be held to strict liability" provided that such products "are properly prepared and marketed, and proper warning is given." Ibid.

As the 1986 Report explains, Congress intended that the "principle in Comment K regarding 'unavoidably unsafe' products" apply to the vaccines covered in the bill. 1986 Report 26. That intent, in turn, is manifested in the plain text of §22(b)(1)—in particular, Congress' use of the word "unavoidable," as well as the phrases "properly prepared" and "accompanied by proper directions and warnings," which were taken nearly verbatim from comment k. 42 U. S. C. §300aa–22(b)(1); see Restatement 353–354 ("Such a[n unavoidably unsafe] product, properly prepared, and accompanied by proper directions and warning, is not defective"). By the time of the Vaccine Act's enactment in 1986, numerous state and federal courts had interpreted comment k to mean that a product is "unavoidably unsafe" when, given proper manufacture and labeling, no feasible alternative design would reduce the safety risks without compromising the product's cost and utility. [5] Given Con-

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[5] See, e.g., Smith ex rel. Smith v. Wyeth Labs., Inc., No. Civ. A 84–2002, 1986 WL 720792, *5 (SD W. Va., Aug. 21, 1986) ("[A] prescription drug is not 'unavoidably unsafe' when its dangers can be eliminated through design changes that do not unduly affect its cost or utility"); Kearl v. Lederle Labs., 172 Cal. App. 3d 812, 830, 218 Cal. Rptr. 453, 464 (1985) ("unavoidability" turns on "(i) whether the product was designed to minimize—to the extent scientifically knowable at the time it was distributed—the risk inherent in the product, and (ii) the availability . . . of any alternative product that would have as effectively accomplished the full intended purpose of the subject product"), disapproved in part by Brown v. Superior Ct., 44 Cal. 3d 1049, 751 P. 2d 470 (1988); Belle Bonfils Memorial Blood Bank v. Hansen, 665 P. 2d 118,

gress' expressed intent to codify the "principle in Comment K," 1986 Report 26, the term "unavoidable" in §22(b)(1) is best understood as a term of art, which incorporates the commonly understood meaning of "unavoidably unsafe" products under comment *k* at the time of the Act's enactment in 1986. See *McDermott Int'l, Inc.* v. *Wilander*, 498 U. S. 337, 342 (1991) ("[W]e assume that when a statute uses . . . a term [of art], Congress intended it to have its established meaning"); *Morissette* v. *United States*, 342 U. S. 246, 263 (1952) (same).[6] Similarly, courts applying

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122 (Colo. 1983) ("[A]pplicability of comment k . . . depends upon the coexistence of several factors," including that "the product's benefits must not be achievable in another manner; and the risk must be unavoidable under the present state of knowledge"); see also 1 L. Frumer & M. Friedman, Products Liability §§8.07[1]–[2], pp. 8–277 to 8–278 (2010) (comment *k* applies "only to defects in design," and there "must be no feasible alternative design which on balance accomplishes the subject product's purpose with a lesser risk" (internal quotation marks omitted)). To be sure, a number of courts at the time of the Vaccine Act's enactment had interpreted comment *k* to preclude design defect claims categorically for certain kinds of products, see *Hill* v. *Searle Labs.*, 884 F. 2d 1064, 1068 (CA8 1989) (collecting cases), but as indicated by the sources cited above, the courts that had construed comment *k* to apply on a case-specific basis generally agreed on the basic elements of what constituted an "unavoidably unsafe" product. See also n. 8, *infra*. The majority's suggestion that "judges who must rule on motions to dismiss, motions for summary judgment, and motions for judgment as a matter of law" are incapable of adjudicating claims alleging "unavoidable" side effects, *ante*, at 7–8, n. 35, is thus belied by the experience of the many courts that had adjudicated such claims for years by the time of the Vaccine Act's enactment.

[6]The majority refuses to recognize that "unavoidable" is a term of art derived from comment *k*, suggesting that "'[u]navoidable' is hardly a rarely used word." *Ante*, at 10. In fact, however, "unavoidable" is an extremely rare word in the relevant context. It appears exactly *once* (*i.e.*, in §300aa–22(b)(1)) in the entirety of Title 42 of the U. S. Code ("Public Health and Welfare"), which governs, *inter alia*, Social Security, see 42 U. S. C. §301 *et seq.*, Medicare, see §1395 *et seq.*, and several other of the Federal Government's largest entitlement programs. The singular rarity in which Congress used the term supports the conclu-

comment k had long required manufacturers invoking the defense to demonstrate that their products were not only "unavoidably unsafe" but also properly manufactured and labeled.[7] By requiring "proper[] prepar[ation]" and "proper directions and warnings" in §22(b)(1), Congress plainly intended to incorporate these additional comment k requirements.

The 1986 Report thus confirms petitioners' interpretation of §22(b)(1). The Report makes clear that "side effects that were unavoidable" in §22(b)(1) refers to side effects stemming from a vaccine's design that were "unavoidable." By explaining what Congress meant by the term "unavoidable," moreover, the Report also confirms that whether a side effect is "unavoidable" for purposes of §22(b)(1) involves a specific inquiry in each case as to whether the vaccine "in the present state of human skill and knowledge cannot be made safe," 1986 Report 26—i.e., whether a feasible alternative design existed that would have eliminated the adverse side effects of the vaccine without compromising its cost and utility. See Brief for Kenneth W. Starr et al. as Amici Curiae 14–15 ("If a particular plaintiff could show that her injury at issue was avoidable . . . through the use of a feasible alternative design for a specific vaccine, then she would satisfy the plain language of the statute, because she would have demonstrated that the side effects were not unavoidable"). Finally, the Report confirms that the "even though" clause is properly read to establish two additional prerequisites—proper manufacturing and proper labeling—to qualify for

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sion that "unavoidable" is a term of art.

[7] See, e.g., Brochu v. Ortho Pharmaceutical Corp., 642 F. 2d 652, 657 (CA1 1981); Needham v. White Labs., Inc., 639 F. 2d 394, 402 (CA7 1981); Reyes v. Wyeth Labs., 498 F. 2d 1264, 1274–1275 (CA5 1974); Davis v. Wyeth Labs., 399 F. 2d 121, 127–129 (CA9 1968); Feldman v. Lederle Labs., 97 N. J. 429, 448, 479 A. 2d 374, 384 (1984); see also Toner v. Lederle Labs., 112 Idaho 328, 336, 732 P. 2d 297, 305 (1987).

§22(b)(1)'s liability exemption. [8]

In addition to the 1986 Report, one other piece of the Act's legislative history provid es further confirmation of the petition ers' textual reading of §22(b)(1). When Congress enacted the Vaccine Act in 1986, it did not initially include a source of pay ment for th e no-fault compensation program th e Act established. The Act thus "made the compensation program and accompanying tort reforms contingent on the enactment of a tax to pro vide fundin g

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[8] Respondent suggests an alter nativ e readin g of th e 1986 Report. According to respondent, "the principle in Comment K" i s simply that of nonlia bility for "una voidably unsafe" products, and thus Congress' stated intent in the 1986 Report to apply the "principle i n Comment K " to "the vaccines covered in the bill" means that Congress viewed the covered vaccin es as a class to be " 'unavoidably unsafe.' " 1986 Report 25–26; Brief for Respondent 42. The concurrence makes a similar argument. Ante, at 1–2 (opin ion of BREYER, J.). This inter pretation fin ds some support in th e 1986 Report, which states th at "if [in jured individua ls] cannot demonstra te under applicable law either that a vaccine was improperly prepared or that it was accompanied by improper direct ions or ina dequate warnings [they] should purs ue recompense in the compensation system, no t th e tort system." 1986 Report 26. It also finds some support in th e pre-Vaccine Act case law, which reflected considerable di sagreement in the courts over " whether comment k applie s to phar maceutic al pr oducts across the board or only on a case-by-case basis." Ausness, Unavoidably Unsafe Products and Strict Products Lia bil ity: W hat Lia bil ity Rule Should b e Applied to the Seller s of Pharmaceutical Pr oducts? 78 Ky. L. J. 705, 708, and n. 11 (1989–1990) (collecting cases). This interp retation, however, is under - mined by the fact that Congress has never direct ed the Food and Dru g Administratio n (FDA) or any other fe deral agency to review vaccines for opt imal vaccine design, see infra , at 20–22, and n. 19, and th us it seems highly unlikely tha t Congress intended to elim inate the tr aditional mechanism for such review (i.e., design defect lia bili ty), particu - lar ly given its ex pr ess retention of state tor t law in the Vaccine Act, see 42 U. S. C. §300aa–22(a). In any event, to th e extent th ere is ambiguity as to how pr ecisely Congress intended the "pr inciple in C omment K" to apply t o the covered vaccin es, that ambiguity is explicitly resolved in petitioner s' favor by the 1987 House Energy and Commerce Commit tee Report , H. R. Rep. No. 100–391, pt. 1, pp. 690–691 (hereinafter 1987 Report). See in fra th is page and 11–12.

for the compensation." 1987 Report 690. In 1987, Congress passed legislation to fund the compensation program. The House Energy and Commerce Committee Report[9] accompanying that legislation specifically stated that "the codification of Comment (k) of The Restatement (Second) of Torts was not intended to decide as a matter of law the circumstances in which a vaccine should be deemed unavoidably unsafe." Id., at 691. The Committee noted that "[a]n amendment to establish . . . that a manufacturer's failure to develop [a] safer vaccine was not grounds for liability was rejected by the Committee during its original consideration of the Act." Ibid. In light of that rejection, the Committee emphasized that "there should be no misunderstanding that the Act undertook to decide as a matter of law whether vaccines were unavoidably unsafe or not," and that "[t]his question is left to the courts to determine in accordance with applicable law." Ibid.

To be sure, postenactment legislative history created by a subsequent Congress is ordinarily a hazardous basis from which to infer the intent of the enacting Congress. See Sullivan v. Finkelstein, 496 U. S. 617, 631–632 (1990) (SCALIA, J., concurring in part). But unlike ordinary postenactment legislative history, which is justifiably given little or no weight, the 1987 Report reflects the intent of the Congress that enacted the funding legislation necessary to give operative effect to the principal provisions of the Vaccine Act, including §22(b)(1).[10] Congress in

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[9] The Third Circuit's opinion below expressed uncertainty as to whether the 1987 Report was authored by the House Budget Committee or the House Energy and Commerce Committee. See 561 F. 3d 233, 250 (2009). As petitioners explain, although the Budget Committee compiled and issued the Report, the Energy and Commerce Committee wrote and approved the relevant language. Title IV of the Report, entitled "Committee on Energy and Commerce," comprises "two Committee Prints approved by the Committee on Energy and Commerce for inclusion in the forthcoming reconciliation bill." 1987 Report 377, 380.

[10] The majority suggests that the 1987 legislation creating the fund-

1987 had a number of options before it, including adopting an entirely different compensation scheme, as the Reagan administration was proposing; [11] establishing different limitations on tort liability, including eliminating design defect liability, as pharmaceutical industry leaders were advocating; [12] or not funding the compensation program at all, which would have effectively nullified the relevant portions of the Act. Because the tort reforms in the 1986 Act, including §22(b)(1), had no operative legal effect unless and until Congress provided funding for the compensation program, the views of the Congress that enacted that funding legislation are a proper and, indeed, authoritative guide to the meaning of §22(b)(1). Those views, as reflected in the 1987 Report, provide unequivocal confir-

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ing mechanism is akin to appropriations legislation and that giving weight to the legislative history of such legislation "would set a dangerous precedent." Ante, at 18. The difference, of course, is that appropriations legislation ordinarily funds congressional enactments that already have operative legal effect; in contrast, operation of the tort reforms in the 1986 Act, including §22(b)(1), was expressly conditioned on the enactment of a separate tax to fund the compensation program. See §323(a), 100 Stat. 3784. Accordingly, this Court's general reluctance to view appropriations legislation as modifying substantive legislation, see, e.g., TVA v. Hill , 437 U. S. 153, 190 (1978), has no bearing here.

[11] See 1987 Report 700 (describing the administration's alternative proposal).

[12] See, e.g., Hearings on Funding of the Childhood Vaccine Program before the Subcommittee on Select Revenue Measures of the House Committee on Ways and Means, 100th Cong., 1st Sess., 85 (1987) ("[T]he liability provisions of the 1986 Act should be amended to assure that manufacturers will not be found liable in the tort system if they have fully complied with applicable government regulations. In particular, manufacturers should not face liability under a 'design defect' theory in cases where plaintiffs challenge the decisions of public health authorities and federal regulators that the licensed vaccines are the best available way to protect children from deadly diseases" (statement of Robert B. Johnson, President, Lederle Laboratories Division, American Cyanamid Co.)).

mation of petitioners' reading of §22(b)(1).

In sum, the text, structure, and legislative history of the Vaccine Act are fully consistent with petitioners' reading of §22(b)(1). Accordingly, I believe §22(b)(1) exempts vaccine manufacturers from tort liability only upon a showing by the manufacturer in each case that the vaccine was properly manufactured and labeled, and that the side effects stemming from the vaccine's design could not have been prevented by a feasible alternative design that would have eliminated the adverse side effects without compromising the vaccine's cost and utility.

II

In contrast to the interpretation of §22(b)(1) set forth above, the majority's interpretation does considerable violence to the statutory text, misconstrues the legislative history, and draws the wrong conclusions from the structure of the Vaccine Act and the broader federal scheme regulating vaccines.

A

As a textual matter, the majority's interpretation of §22(b)(1) is fundamentally flawed in three central respects. First, the majority's categorical reading rests on a faulty and untenable premise. Second, its reading functionally excises 13 words from the statutory text, including the key term "unavoidable." And third, the majority entirely ignores the Vaccine Act's default rule preserving state tort law.

To begin, the majority states that "[a] side effect of a vaccine could always have been avoidable by use of a differently designed vaccine not containing the harmful element." Ante, at 7. From that premise, the majority concludes that the statute must mean that "the design of the vaccine is a given, not subject to question in the tort action," because construing the statute otherwise would

render §22(b)(1) a nullity. Ibid. A tort claimant, according to the majority, will always be able to point to a differently designed vaccine not containing the "harmful element," and if that were sufficient to show that a vaccine's side effects were not "unavoidable," the statute would preempt nothing.

The starting premise of the majority's interpretation, however, is fatally flawed. Although in the most literal sense, as the majority notes, a side effect can always be avoided "by use of a differently designed vaccine not containing the harmful element," ibid., this interpretation of "unavoidable" would effectively read the term out of the statute, and Congress could not have intended that result. Indeed, §22(b)(1) specifically uses the conditional phrase "if the injury or death resulted from side effects that were unavoidable," which plainly indicates that Congress contemplated that there would be some instances in which a vaccine's side effects are "unavoidable" and other instances in which they are not. See *supra*, at 3. The majority's premise that a vaccine's side effects can always be "avoid[ed] by use of a differently designed vaccine not containing the harmful element," ante, at 7, entirely ignores the fact that removing the "harmful element" will often result in a less effective (or entirely ineffective) vaccine. A vaccine, by its nature, ordinarily employs a killed or weakened form of a bacteria or virus to stimulate antibody production;[13] removing that bacteria or virus might remove the "harmful element," but it would also necessarily render the vaccine inert. As explained above, the legislative history of the Vaccine Act and the cases interpreting comment k make clear that a side effect is

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[13] See American Academy of Pediatrics, Questions and Answers about Vaccine Ingredients (Oct. 2008), http://www.aap.org/immunization/families/faq/Vaccineingredients.pdf (all Internet materials as visited Feb. 18, 2011, and available in Clerk of Court's case file).

"unavoidable" for purposes of §22(b)(1) only where there is no feasible alternative design that would eliminate the side effect of the vaccine without compromising its cost and utility. See *supra*, at 7. The majority's premise—that side effects stemming from a vaccine's design are always avoidable—is thus belied by the statutory text and legislative history of §22(b)(1). And because its starting premise is invalid, its conclusion—that the design of a vaccine is not subject to challenge in a tort action—is also necessarily invalid.

The majority's reading suffers from an even more fundamental defect. If Congress intended to exempt vaccine manufacturers categorically from all design defect liability, it more logically would have provided: "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 vaccine was properly prepared and was accompanied by proper directions and warnings." There would have been no need for Congress to include the additional 13 words "the injury or death resulted from side effects that were unavoidable even though." See *TRW Inc.* v. *Andrews*, 534 U. S. 19, 31 (2001) (noting "cardinal principle of statutory construction that a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant" (internal quotation marks omitted)).

In *Bates* v. *Dow Agrosciences LLC*, 544 U. S. 431 (2005), this Court considered an analogous situation where an express pre-emption provision stated that certain States "'shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.'" Id., at 436 (quoting 7 U. S. C. §136v(b) (2000 ed.)). The *Bates* Court stated:

> "Conspicuously absent from the submission s by [respondent] and the Uni ted States i s any plausible alternative interpretatio n of 'in addition to or different from' that would give that ph rase meaning. Instead, they appea r to favor reading those words ou t of the statute, wh ich would l eave the following: 'Su ch State shall not impose or continue in effect any require ments for labeling or packaging.' This a mputated version of [the statute] would no doubt have clearly and succinctly commanded the pre-emption of all state requirements concerning la beling. Th at Congress added the remainder of the provision is e vidence of its intent to draw a distinction between state label ing requirements that are pre-empted and th ose that are not." 544 U. S., at 448–449.

As with the statutory interpre tati on rejected by this Cou r t in Bates, t he majority 's interpret ation of §22(b)(1) functionally excises 13 words out of th e statute, i ncluding th e key term "u navoidable." See Duncan v. Walke r, 533 U. S. 167, 174 (2001) ("We are especially unwillin g" to treat a statutory te rm as surplusage "when the term occupies so pivotal a pl ace in the statutory s cheme"). Although the resulting "amputated version" of the statutory provision "would no doubt have clearly and succinctl y commanded the pre-emption of all state" desig n defect claims, the fac t "[t]hat Congress added the remai nder of the provision" is strong evid ence of its intent not t o pre-empt design defect claims categorically. Bates, 544 U. S., at 449; see also Americ an Home Prod s. Corp. v. Ferr ari , 284 Ga. 384, 393, 668 S. E. 2d 236, 242 (2008) (" 'If Congress had intended to deprive injured parties of a long available fo rm of compensation, it s urely would have expressed that intent more clearly' " (quoting Bates, 544 U. S., at 449)), cert. pendin g, No. 08–1120.

Stri kingly, the majority concedes that its interpretation

renders 13 words of the statute entirely superfluous. See ante, at 12 ("The intervening passage ('the injury or death resulted from side effects that were unavoidable even though') is unnecessary. True enough"). Nevertheless, the majority contends that "the rule against giving a portion of text an interpretation which renders it superfluous . . . applies only if verbosity and prolixity can be eliminated by giving the offending passage, or the remainder of the text, a competing interpretation." Ibid. According to the majority, petitioners' reading of §22(b)(1) renders the "even though" clause superfluous because, to reach petitioners' desired outcome, "[i]t would suffice to say 'if the injury or death resulted from side effects that were unavoidable'—full stop." Ibid. As explained above, however, the "even though" clause establishes two additional prerequisites—proper manufacturing and proper labeling—to qualify for §22(b)(1)'s exemption from liability. Contrary to the majority's contention, then, the "even though" clause serves an important function by limiting the scope of the preemption afforded by the preceding "if" clause.[14]

The majority's only other textual argument is based on

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[14] In this manner, the "even though" clause functions in a "concessive subordinat[ing]" fashion, ante, at 11, in accord with normal grammatical usage. According to the majority, however, the "even though" clause "clarifies the word that precedes it" by "delineat[ing]" the conditions that make a side effect "unavoidable" under the statute. Ante, at 7. The majority's interpretation hardly treats the clause as "concessive," and indeed strains the meaning of "even though." In the majority's view, proper manufacturing and labeling are the sole prerequisites that render a vaccine's side effects unavoidable. Thus, an injurious side effect is unavoidable because the vaccine was properly prepared and labeled, not "even though" it was. The two conjunctions are not equivalent: The sentence "I am happy even though it is raining" can hardly be read to mean that "I am happy because it is raining." In any event, the more fundamental point is that petitioners' interpretation actually gives meaning to the words "even though," whereas the majority concedes that its interpretation effectively reads those words entirely out of the statute. See supra this page.

the expressio unius, exclusio alterius canon. According to the majority, because blackletter products liability law generally recognizes three different types of product defects, "[i]f all three were intended to be preserved, it would be strange [for Congress] to mention specifically only two"—namely, manufacturing and labeling defects in the "even though" clause—"and leave the third to implication." Ante, at 8. The majority's argument, however, ignores that the default rule under the Vaccine Act is that state law is preserved. As explained above, §22(a) expressly provides that the "[g]eneral rule" is that "State law shall apply to a civil action brought for damages for a vaccine-related injury or death." 42 U. S. C. §300aa–22(a). Because §22(a) already preserves state-law design defect claims (to the extent the exemption in §22(b)(1) does not apply), there was no need for Congress separately and expressly to preserve design defect claims in §22(b)(1). Indeed, Congress' principal aim in enacting §22(b)(1) was not to preserve manufacturing and labeling claims (those, too, were already preserved by §22(a)), but rather, to federalize comment k-type protection for "unavoidably unsafe" vaccines. The "even though" clause simply functions to limit the applicability of that defense. The lack of express language in §22(b)(1) specifically preserving design defect claims thus cannot fairly be understood as impliedly (and categorically) pre-empting such traditional state tort claims, which had already been preserved by §22(a).[15]

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[15] This Court, moreover, has long operated on "the assumption that the historic police powers of the States are not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." Altria Group, Inc. v. Good, 555 U. S. ___, ___ (2008) (slip op., at 5) (internal quotation marks and alteration omitted). Given the long history of state regulation of vaccines, see Brief for Petitioners 3–6, the presumption provides an additional reason not to read §22(b)(1) as pre-empting all design defect claims, especially given Congress' inclusion of

The majority also suggests that if Congress wished to preserve design defect claims, it could have simply provided that manufacturers would be liable for "defective manufacture, defective directions or warning, and defective design." Ante, at 8 (internal quotation marks omitted). Putting aside the fact that §22(a) already preserves design defect claims (to the extent §22(b)(1) does not apply), the majority's proposed solution would not have fully effectuated Congress' intent. As the legislative history makes clear, Congress used the term "unavoidable" to effectuate its intent that the "principle in Comment K regarding 'unavoidably unsafe' products . . . apply to the vaccines covered in the bill." 1986 Report 26; see also 1987 Report 691. At the time of the Vaccine Act's enactment in 1986, at least one State had expressly rejected comment k,[16] while many others had not addressed the applicability of comment k specifically to vaccines or applied comment k to civil actions proceeding on a theory other than strict liability (e.g., negligence[17]). A statute

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an express saving clause in the same statutory section, see 42 U. S. C. §300aa–22(a), and its use of the conditional "if" clause in defining the pre-emptive scope of the provision. See Bates v. Dow Agrosciences LLC, 544 U. S. 431, 449 (2005) ("In areas of traditional state regulation, we assume that a federal statute has not supplanted state law unless Congress has made such an intention clear and manifest" (internal quotation marks omitted)).

[16] See Collins v. Eli Lilly Co., 116 Wis. 2d 166, 197, 342 N. W. 2d 37, 52 (1984) ("We conclude that the rule embodied in comment k is too restrictive and, therefore, not commensurate with strict products liability law in Wisconsin"). Collins did, however, "recognize that in some exigent circumstances it may be necessary to place a drug on the market before adequate testing can be done." Ibid. It thus adopted a narrower defense (based on "exigent circumstances") than that recognized in other jurisdictions that had expressly adopted comment k.

[17] See, e.g., Kearl, 172 Cal. App. 3d, at 831, n. 15, 218 Cal. Rptr., at 465, n. 15 ("[T]he unavoidably dangerous product doctrine merely exempts the product from a strict liability design defect analysis; a plaintiff remains free to pursue his design defect theory on the basis of

that simply stated that vaccine manufacturers would be liable for "defective design" would be silent as to the availability of a comment k-type defense for "unavoidably unsafe" vaccines, and thus would not have fully achieved Congress' aim of extending greater liability protection to vaccine manufacturers by providing comment k-type protection in all civil actions as a matter of federal law.

B

The majority's structural arguments fare no better than its textual ones. The principal thrust of the majority's position is that, since nothing in the Vaccine Act or the FDA's regulations governing vaccines expressly mentions design defects, Congress must have intended to remove issues concerning the design of FDA-licensed vaccines from the tort system. Ante, at 13. The flaw in that reasoning, of course, is that the FDA's silence on design defects existed long before the Vaccine Act was enacted. Indeed, the majority itself concedes that 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."[18] Ibid. And yet it is undisputed that prior to the Act, vaccine manufacturers had long been subject to liability under state tort law for defective vaccine design. That the Vaccine Act did not itself set forth a comprehensive regulatory scheme with respect to design defects is thus best understood to mean not that Congress suddenly decided to change course sub silentio and pre-empt a

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negligence"); Toner, 112 Idaho, at 340, 732 P. 2d, at 309–310 ("The authorities universally agree that where a product is deemed unavoidably unsafe, the plaintiff is deprived of the advantage of a strict liability cause of action, but may proceed under a negligence cause of action").

[18] See 42 U. S. C. §262(a)(2)(C)(i)(I) ("The Secretary shall approve a biologics license application . . . on the basis of a demonstration that . . . the biological product that is the subject of the application is safe, pure, and potent").

longstanding, traditional category of state tort law, but rather, that Congress intended to leave the status quo alone (except, of course, with respect to those aspects of state tort law that the Act expressly altered). See 1987 Report 691 ("It is not the Committee's intention to preclude court actions under applicable law. The Committee's intent at the time of considering the Act . . . was . . . to leave otherwise applicable law unaffected, except as expressly altered by the Act").

The majority also suggests that Congress necessarily intended to pre-empt design defect claims since the aim of such tort suits is to promote the development of improved designs and provide compensation for injured individuals, and the Vaccine Act "provides other means for achieving both effects"—most notably through the no-fault compensation program and the National Vaccine Program. Ante, at 14, and nn. 57–60 (citing 42 U. S. C. §§300aa–1, 300aa–2(a)(1)–(3), 300aa–3, 300aa–25(b), 300aa–27(a)(1)). But the majority's position elides a significant difference between state tort law and the federal regulatory scheme. Although the Vaccine Act charges the Secretary of Health and Human Services with the obligation to "promote the development of childhood vaccines" and "make or assure improvements in . . . vaccines, and research on vaccines," §300aa–27(a), neither the Act nor any other provision of federal law places a legal duty on vaccine manufacturers to improve the design of their vaccines to account for scientific and technological advances. Indeed, the FDA does not condition approval of a vaccine on it being the most optimally designed among reasonably available alternatives, nor does it (or any other federal entity) ensure that licensed vacdnes keep pace with technological and scientific advances. [19] Rather, the function of ensuring

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[19] See, e.g., Hurley v. Lederle Labs., 863 F. 2d 1173, 1177 (CA5 1988) ("[T]he FDA is a passive agency: it considers whether to approve

that va ccines are optimally desi gned in light of existing science and technology has tra ditionally been left to the States th rough the im position of damages for design defects. Cf. Bat es, 544 U. S., at 451 (" '[T]he specter of damage actions may provide manufa cturers with added dynamic incentives to continue to keep abreast of all possible injuries ste mming from use of their product[s] so as to forestall such actions through product im provement' "); Wyeth v. Levine, 555 U. S. ___, ___ (2009) (slip op., at 22–

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vaccine designs only if and when manufa cturers come forwa rd wit h a proposal"); Jones v. Lederle Lab s., 695 F. Supp. 700, 711 (EDNY 1988) ("[T]he agency takes th e drugs and manufa cture rs as it finds them. While it s goal is to oversee inoculation with the bes t possible vaccine, it is lim ited to reviewing o nly those drugs submit ted by various manufacturers, regardless of their fla ws"). Alt hough the FDA has authority under existing regulations to revoke a manufactu rer's biologics licenses, that authority can be exercised only where (as relevan t here) "[t]he licensed product is not safe and effectiv e for all of i ts inte nded uses." 21 CFR §601.5(b)(1)(vi) (2010); see §600.3(p) (defin ing "safety" as "r elativ e freedom from harm ful effect to persons affected, direct ly or indirect ly, by a pr oduct when prudently admin istered, taking into consideratio n the character of the pr oduct in r elati on to the condition of the re cipient at the time "). The r egulation does not author ize the F DA to r evoke a biologics license for a manufacture r's failur e to adopt an optima l vaccine design in light of exi sting s cience and technology. See Conk, Is There a Design Defe ct in t he Restatement (Third) of Torts: Products Liabi lity ? 109 Yale L. J. 1087, 1128–1129 (1999–2000) ("The FDA does not claim to rev iew pr oducts for optimal desig n . . . . FDA r eview thu s asks less of drug . . . manufac tur ers than the c ommon l aw of pr oducts liab ility a sks of other kind s of manufact urers"). At oral argument, counsel for amicus United States stated that the Centers for Disease Control and P revention (CDC) routin ely performs comparative analyses of vaccines that ar e alr eady on th e market. See Tr. of Oral Ar g. 44–45; id., at 52–53 (describing CDC's comparison of Sabin and Salk poli o vaccines). Neit her t he Unit ed States nor any of t he part ies, however, has represented that CDC examin es whet her a safer alternative vaccine could have been designed given practical and s cientific limits , the central inq uiry in a state tort law action for design defect. CDC does not issue biologics licen ses, moreover, and thus has no authority to requir e a manufactu rer to adopt a differ ent vaccine design.

23) (noting that the FDA has "traditionally regarded state law as a complementary form of drug regulation" as "[s]tate tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly"). [20] The importance of the States' traditional regulatory role is only underscored by the unique features of the vaccine market, in which there are "only one or two manufacturers for a majority of the vaccines listed on the routine childhood immunization schedule." Brief for Respondent 55. The normal competitive forces that spur innovation and improvements to existing product lines in other markets thus operate with less force in the vaccine market, particularly for vaccines that have already been released and marketed to the public. Absent a clear statutory mandate to the contrary, there is no reason to think that Congress intended in the vaccine context to eliminate the traditional incentive and deterrence functions served by state tort liability in favor of a federal regulatory scheme providing only carrots and no sticks. [21] See Levine, 555 U. S., at ___ (slip op., at 18) ("The

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[20] Indeed, we observed in Levine that the FDA is perpetually understaffed and underfunded, see 555 U. S., at ___, n. 11 (slip op., at 22, n. 11), and the agency has been criticized in the past for its slow response in failing to withdraw or warn about potentially dangerous products, see, e.g., L. Leveton, H. Sox, & M. Soto, Institute of Medicine, HIV and the Blood Supply: An Analysis of Crisis Decisionmaking (1995) (criticizing FDA response to transmission of AIDS through blood supply). These practical shortcomings reinforce the conclusion that "state law offers an additional, and important, layer of consumer protection that complements FDA regulation." Levine, 555 U. S., at ___ (slip op., at 23).

[21] The majority mischaracterizes my position as expressing a general "skeptic[ism] of preemption unless the congressional substitute operate[s] like the tort system." Ante, at 16. Congress could, of course, adopt a regulatory regime that operates differently from state tort systems, and such a difference is not necessarily a reason to question Congress' pre-emptive intent. In the specific context of the Vaccine Act, however, the relevant point is that this Court should not lightly assume

case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there is between them." (internal quotation marks and alteration omitted)).

III

In enacting the Vaccine Act, Congress established a carefully wrought federal scheme that balances the competing interests of vaccine-injured persons and vaccine manufacturers. As the legislative history indicates, the Act addressed "two overriding concerns": "(a) the inadequacy—from both the perspective of vaccine-injured persons as well as vaccine manufacturers—of the current approach to compensating those who have been damaged by a vaccine; and (b) the instability and unpredictability of the childhood vaccine market." 1986 Report 7. When viewed in the context of the Vaccine Act as a whole, §22(b)(1) is just one part of a broader statutory scheme that balances the need for compensating vaccine-injured children with added liability protections for vaccine manufacturers to ensure a stable childhood vaccine market.

The principal innovation of the Act was the creation of the no-fault compensation program—a scheme funded entirely through an excise tax on vaccines.[22] Through that

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that Congress intended sub silentio to displace a longstanding species of state tort liability where, as here, Congress specifically included an express saving clause preserving state law, there is a long history of state-law regulation of vaccine design, and pre-emption of state law would leave an important regulatory function—i.e., ensuring optimal vaccine design—entirely unaddressed by the congressional substitute.

[22] The majority's suggestion that "vaccine manufacturers fund from their sales" the compensation program is misleading. Ante, at 15. Although the manufacturers nominally pay the tax, the amount of the tax is specifically included in the vaccine price charged to purchasers. See CDC Vaccine Price List (Feb. 15, 2011), http://www.cdc.gov/

program, Congress relieved vaccine manufacturers of the burden of compensating victims of vaccine-related injuries in the vast majority of cases[23]—an extremely significant economic benefit that "functionally creat[es] a valuable insurance policy for vaccine-related injuries." Reply Brief for Petitioners 10. The structure and legislative history, moreover, point clearly to Congress' intention to divert would-be tort claimants into the compensation program, rather than eliminate a longstanding category of traditional tort claims. See 1986 Report 13 ("The Committee anticipates that the speed of the compensation program, the low transaction costs of the system, the no-fault nature of the required findings, and the relative certainty and generosity of the system's awards will divert a significant number of potential plaintiffs from litigation"). Indeed, although complete pre-emption of tort claims would have eliminated the principal source of the "unpredictability" in the vaccine market, Congress specifically chose not to pre-empt state tort claims categorically. See 42 U. S. C. §300aa–22(a) (providing as a "[g]eneral rule" that "State law shall apply to a civil action brought for damages for a vaccine-related injury or death"). That decision reflects Congress' recognition that court actions are essential

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vaccines/programs/vfc/cdc-vac-price-list.htm. Accordingly, the only way the vaccine manufacturers can be said to actually "fund" the compensation program is if the cost of the excise tax has an impact on the number of vaccines sold by the vaccine manufacturer. The majority points to no evidence that the excise tax—which ordinarily amounts to 75 cents per dose, 26 U. S. C. §4131(b)—has any impact whatsoever on the demand for vaccines.

[23] See Brief for United States as Amicus Curiae 28 ("Department of Justice records indicate that 99.8% of successful Compensation Program claimants have accepted their awards, foregoing any tort remedies against vaccine manufacturers"); S. Plotkin, W. Orenstein, & P. Offit, Vaccines 1673 (5th ed. 2008) (noting that "[v]irtually all . . . petitioners, even those who were not awarded compensation" under the compensation program, choose to accept the program's determination).

because they provide injured persons with significant procedural tools—including, most importantly, civil discovery—that are not available in administrative proceedings under the compensation program. See §§300aa–12(d)(2)(E), (d)(3). Congress thus clearly believed there was still an important function to be played by state tort law.

Instead of eliminating design defect liability entirely, Congress enacted numerous measures to reduce manufacturers' liability exposure, including a limited regulatory compliance presumption of adequate warnings, see §300aa–22(b)(2), elimination of claims based on failure to provide direct warnings to patients, §300aa–22(c), a heightened standard for punitive damages, §300aa–23(d)(2), and, of course, immunity from damages for "unavoidable" side effects, §300aa–22(b)(1). Considered in light of the Vaccine Act as a whole, §22(b)(1)'s exemption from liability for unavoidably unsafe vaccines is just one part of a broader statutory scheme that reflects Congress' careful balance between providing adequate compensation for vaccine-injured children and conferring substantial benefits on vaccine manufacturers to ensure a stable and predictable childhood vaccine supply.

The majority's decision today disturbs that careful balance based on a bare policy preference that it is better "to leave complex epidemiological judgments about vaccine design to the FDA and the National Vaccine Program rather than juries." *Ante*, at 15.[24] To be sure, reasonable minds can disagree about the wisdom of having juries weigh the relative costs and benefits of a particular vaccine design. But whatever the merits of the majority's

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[24] JUSTICE BREYER's separate concurrence is even more explicitly policy driven, reflecting his own preference for the "more expert judgment" of federal agencies over the "less expert" judgment of juries. *Ante*, at 5.

policy preference, the decision to bar all design defect claims against vaccine manufacturers is one that Congress must make, not this Court.[25] By construing §22(b)(1) to

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[25] Respondent notes that there are some 5,000 petitions alleging a causal link between certain vaccines and autism spectrum disorders that are currently pending in an omnibus proceeding in the Court of Federal Claims (Vaccine Court). Brief for Respondent 56–57. According to respondent, a ruling that §22(b)(1) does not pre-empt design defect claims could unleash a "crushing wave" of tort litigation that would bankrupt vaccine manufacturers and deplete vaccine supply. Id., at 28. This concern underlies many of the policy arguments in respondent's brief and appears to underlie the majority and concurring opinions in this case. In the absence of any empirical data, however, the prospect of an onslaught of autism-related tort litigation by claimants denied relief by the Vaccine Court seems wholly speculative. As an initial matter, the special masters in the autism cases have thus far uniformly rejected the alleged causal link between vaccines and autism. See Brief for American Academy of Pediatrics et al. as Amici Curiae 20–21, n. 4 (collecting cases). To be sure, those rulings do not necessarily mean that no such causal link exists, cf. Brief for United States as Amicus Curiae 29 (noting that injuries have been added to the Vaccine Injury Table for existing vaccines), or that claimants will not ultimately be able to prove such a link in a state tort action, particularly with the added tool of civil discovery. But these rulings do highlight the substantial hurdles to recovery a claimant faces. See Schafer v. American Cyanamid Co., 20 F. 3d 1, 5 (CA1 1994) ("[A] petitioner to whom the Vaccine Court gives nothing may see no point in trying to overcome tort law's yet more serious obstacles to recovery"). Trial courts, moreover, have considerable experience in efficiently handling and disposing of meritless products liability claims, and decades of tort litigation (including for design defect) in the prescription-drug context have not led to shortages in prescription drugs. Despite the doomsday predictions of respondent and the various amici cited by the concurrence, ante, at 6–7, the possibility of a torrent of meritless lawsuits bankrupting manufacturers and causing vaccine shortages seems remote at best. More fundamentally, whatever the merits of these policy arguments, the issue in this case is what Congress has decided, and as to that question, the text, structure, and legislative history compel the conclusion that Congress intended to leave the courthouse doors open for children who have suffered severe injuries from defectively designed vaccines. The majority's policy-driven decision to the contrary usurps Congress' role and deprives such vaccine-injured children of a key remedy that Congress intended them to have.

pre-empt all design defect claims against va ccine manu-facturers f or covered vaccines, the majority's decision leaves a regulatory va cuum in which no one—neither the FDA nor any other federal agency, nor state and federa l juries—ensures that vaccine manufacturers adequately take accoun t of scientific and technological advancements. This concern is especially acute with respec t to vaccin es that have already been relea sed and marketed to the public. Manufacturers , given the lack of robust competi-tion in the vaccine market, will often have little or n o incentive to improve the designs of vaccines that are al-ready generating signi ficant profi t margins. Nothing i n the text, str ucture, or legislative history remo tely suggest s that Congre ss intended that result.

I respectfully dissent.