NOTE

WHEN INJURY IS UNAVOIDABLE: THE VACCINE ACT'S LIMITED PREEMPTION OF DESIGN DEFECT CLAIMS

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INTRODUCTION

WHATEVER the ultimate outcome, the proceedings before the federal "Vaccine Court" concerning the alleged vaccine-autism link are unlikely to end the litigation over the issue.[1] A final ruling against the petitioners in Vaccine Court—an adjudicatory body formed to provide an alternative to traditional tort litigation in civil court—will probably lead many of the 4,900 vaccine-autism claimants[2] to seek relief under traditional theories of tort liability. Even if they are somehow able to prevail in Vaccine Court, the limited damages afforded under the federal program[3] could result in a significant number of claimants rejecting judgment and seeking a higher award in state courts. Among the claims most likely to be raised is that manufacturers defectively designed vaccines by using

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[1] Gordon Shemin, Comment, Mercury Rising: The Omnibus Autism Proceeding and What Families Should Know Before Rushing Out of Vaccine Court, 58 Am. U. L. Rev. 459, 462–64 (2008). See generally Autism General Order #1, In re Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder or a Similar Neurodevelopmental Disorder, Autism Master File (Fed. Cl. July 3, 2002), available at http://www.uscfc.uscourts.gov/sites/default/files/autism/Autism+General+Order1.pdf (establishing omnibus autism proceeding to deal with the rising number of claims concerning the autism-vaccine link); Shemin, supra, at 478–90 (2008) (discussing generally the history of the Omnibus Autism Proceeding).

[2] See Autism Update–April 23, 2008, In re Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder or a Similar Neurodevelopmental Disorder, Autism Master File, 7 (Fed. Cl. Apr. 23, 2008), available at http://www.uscfc.uscourts.gov/sites/default/files/autism/autism_update_4_23_08.pdf.

[3] See 42 U.S.C. § 300aa-15 (2006). Where the vaccine does not result in death, damages in the National Vaccine Injury Compensation Program are limited to actual and reasonable projected unreimbursable medical and rehabilitation expenses.

thimerosal, the mercury-based preservative that is alleged to have triggered autism in some children. While the claim of a vaccine-autism link has been advocated with fervor,[4] the scientific evidence to support the conclusion that vaccines have triggered autism is relatively scant.[5]

In addition to the considerable difficulty parents of autistic children will face in proving their claim, they are likely to have trouble even getting in the door. The National Childhood Vaccine Injury Act of 1986 ("Vaccine Act")[6] requires would-be plaintiffs to seek relief first in Vaccine Court,[7] but allows them to seek redress in state court if they are not satisfied with their Vaccine Court judgment.[8] The Vaccine Act, however, places limits on state law actions that potential plaintiffs can pursue if unsatisfied with the Vaccine Court's judgment. Among other restrictions, the Vaccine Act bars recovery where the injury was "unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings."[9] In recent opinions, the U.S. Court of Appeals for the Third Circuit and the Supreme Court of Georgia—both dealing with cases involving neurological injuries alleged to have resulted from the injection of thimerosal-containing vaccines into children—have disagreed as to whether this provision of the Vaccine Act categorically preempts state courts from hearing design

[4] People with such varying perspectives as Robert Kennedy, Jr., author David Kirby, and actor-celebrities Jim Carrey and Jenny McCarthy have all actively advocated the vaccine-autism link. Shemin, supra note 1, at 480 nn.108–09. See, e.g., David Kirby, Evidence of Harm xi–xvi (2005); Jim Carrey, The Judgment on Vaccines Is In???, The Huffington Post, Apr. 22, 2009, available at http://www.huffingtonpost.com/jim-carrey/the-judgment-on-vaccines_b_189777.html; Robert Kennedy, Jr., Deadly Immunity, Rolling Stone, June 20, 2005, available at http://www.rollingstone.com/politics/story/7395411/deadly_immunity; Jeffrey Kluger, Jenny McCarthy on Autism and Vaccines, Time, Apr. 1, 2009, available at http://www.time.com/time/health/article/0,8599,1888718,00.html.

[5] See Shemin, supra note 1, at 478–82 (discussing the lack of scientific support for the vaccine-autism theory and the volumes of evidence against such a causal connection); see also Institute of Medicine, Immunization Safety Review: Vaccines and Autism 1–7 (2004); Study Finds Vaccine Preservative is Not Linked to Risks of Autism, N.Y. Times, Jan. 8, 2008, at A18 (citing California epidemiological study finding no link between receipt of thimerosal-containing vaccines and autism incidence).

[6] 42 U.S.C. §§ 300aa-1 to 300aa-34 (2006).

[7] Id. § 300aa-11(a).

[8] Id. § 300aa-21(a).

[9] Id. § 300aa-22(b)(1).

defect claims, or only bars recovery on such claims where the court finds that the injury was an unavoidable side effect of the vaccine.[10] The U.S. Supreme Court is likely to resolve the matter at some point in the near future.[11]

This Note analyzes the question currently before the Court: whether the Vaccine Act preempts all state law design defect claims. Part I presents the Vaccine Act's preemption provisions and discusses the cases that have considered the Act's preemptive effect on state design defect claims. Part II addresses the Supreme Court's recent decisions in the area of express products liability preemption, concentrating particularly on two tools the Court has employed regularly to give meaning to potentially unclear preemption provisions: the presumption against preemption and the plain meaning doctrine. I argue that the Court has turned increasingly to these two doctrines in express preemption cases in order to avoid resorting to legislative history and to allow greater ex ante reliance on the meaning the Court will give to unclear preemption clauses. Part III examines the problems with the statutory interpretation of those courts finding "full preemption," and presents an alternative interpretation that construes the Vaccine Act's preemptive effect more narrowly. Applying the plain meaning doctrine and the presumption against preemption, Part III argues that courts should adopt this narrower reading. Part IV considers the legislative history of the Vaccine Act and the background tort law that informed Congress in drafting the Act's preemption provisions. While courts adopting the full preemption reading of the statute have relied upon the history and background law of the Vaccine Act to support their interpretation, my analysis suggests that neither actually supports their position. This Note then concludes that there is little support for the proposition that Congress intended to preempt all design defect claims against vaccine manufacturers. Moreover, concern about an influx of tort suits arguing that vaccines cause au-

[10] See Bruesewitz v. Wyeth Inc., 561 F.3d 233, 235 (3d Cir. 2009) [hereinafter *Bruesewitz II*] (holding that the Vaccine Act preempted all design defect claims); Am. Home Prods. Corp. v. Ferrari, 668 S.E.2d 236, 237–38 (Ga. 2008) [hereinafter *Ferrari II*] (holding that the Vaccine Act does not preempt all state-law-based design defect claims, but rather only claims where the injurious side effects of the vaccine were unavoidable).

[11] See Petition for Writ of Certiorari, Bruesewitz v. Wyeth Inc., 78 U.S.L.W. 3082, at i (U.S. Aug. 4, 2009) (No. 09-152).

tism does not justify a strained reading of the Vaccine Act in order to find those claims barred outright.

I. THE VACCINE ACT

A. The Vaccine Act's Preemption Provisions

The Vaccine Act was enacted in response to shortages in the vaccine supply during the early 1980s. Several manufacturers had already left the market, while others threatened to follow suit.[12] Fears of escalating prices and supply shortages prompted Congress to pass the Vaccine Act, which created the National Vaccine Injury Compensation Program ("Program"). Under the Program, children who suffer injuries as a result of receiving vaccines are entitled to receive compensation by filing a petition with the Vaccine Court.[13]

The Vaccine Act contains two distinct sets of preemption provisions. The first group generally bars civil damages actions for vaccine-related injuries or deaths until a petition for compensation has made its way through the Program.[14] Thus, prior to filing a civil action for damages against a vaccine manufacturer or administrator, a party must bring a Program petition for compensation.[15] If the petitioner elects to accept the judgment of the Vaccine Court, then that person is permanently barred from bringing a civil action for damages against a vaccine manufacturer or administrator related

[12] See Vaccine Injury Compensation: Hearing on H.R. 5810 Before the Subcomm. on Health and the Environment of the H. Comm. on Energy and Commerce, 98th Cong. 234 (1984) [hereinafter 1984 House Hearings] (statement of Robert J. Johnson, President, Lederle Labs. Div., Am. Cyanimid Co.) ("Against [a] record of unrivaled success in conquering diseases, we have a situation in this country where manufacturers are abandoning the vaccine business under an unprecedented onslaught of unpredictable litigation."); see also Institute of Medicine, Vaccine Supply and Innovation 27–28 (1985) [hereinafter IOM 1985 Report].

[13] If the Secretary of Health and Human Services disputes the petitioner's entitlement to compensation, the matter is adjudicated before a special master of the U.S. Court of Federal Claims. 42 U.S.C. § 300aa-12(e)(1) (2006).

[14] Id. § 300aa-11(a). This preemption provision also bars damages actions that are less than $1000. Id. Alternatively, petitioners may opt out of the Program 240 days after filing the petition if the special master assigned to the case has not yet reached a decision or 420 days after filing the petition if the court has failed to enter a judgment. Id. § 300aa-21(b).

[15] Id. § 300aa-11(a)(2).

to the same injury or incident.[16] Alternatively, the petitioner can appeal or elect to reject the judgment.[17] Upon rejection of judgment, the petitioner is free to file a civil action for damages against the manufacturer or administrator of the vaccine as long as the claims alleged are not preempted by other provisions.[18]

The second group of the Vaccine Act's preemption provisions concerns the remedies available to petitioners once they have opted to reject the Vaccine Court's judgment.[19] A saving clause preserves for parties all rights available under state law, except as delineated in three subsections of Section 22.[20] One of those three, Subsection (b), is the focus of this Note.[21] This subsection shields manufacturers from liability where the injury "resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings."[22] Nowhere in the Act is "properly prepared" defined or further clarified. As to proper directions and warnings, Section 22(b) creates a rebuttable presumption that manufacturers who complied with all material requirements of the Federal Food, Drug, and

[16] Id. § 300aa-21(a).

[17] Id. If the petitioner chooses to appeal, then upon the completion of the appeals process, the special master will issue a judgment, which the petitioner will have ninety days to elect to accept or reject. Id.

[18] Id. §§ 300aa-21 to 300aa-22. Critically, state limitations periods are stayed for the duration of time that the petition is in Vaccine Court, from the date of filing until the date of election. Id. § 300aa-16(c). This is why many petitioners who participated in the Omnibus Autism Proceeding will be free to file civil actions on a thimerosal-based theory of causation, even though thimerosal has not been present in most childhood vaccines since 2001.

[19] See generally id. §§ 300aa-22 to 300aa-23.

[20] Id.§ 300aa-22(b), (c), (e).

[21] The other two listed exceptions to the general preservation of state law rights of action contained in § 300aa-22(a) are Subsections (c) and (e). Subsection (c) protects manufacturers from liability for failure to directly warn of potential dangers, thus adopting the so-called "learned intermediary doctrine." Id.§ 300aa-22(c). Subsection (e) preempts any efforts to override the saving clause of Subsection (a) in that it prevents states from establishing or enforcing any law that "prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this part." Id. § 300aa-22(e). In addition, § 23(d)(2) shields manufacturers from punitive damages in cases where they complied with all material requirements of the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, unless there is a showing of fraud or other criminal misconduct notwithstanding that material compliance. Id. § 300aa-23(d)(2).

[22] Id. § 300aa-22(b).

Cosmetic Act ("FDCA")[23] and the Public Health Service Act ("PHSA")[24] offered proper directions and warnings for the vaccine at issue.[25]

B. Cases Interpreting Section 22(b) Preemption Under the Vaccine Act

The question of whether the language concerning unavoidable injuries poses a bar to all claims of defective design has been percolating in the courts since 2004. In five cases, courts have found Section 22(b) to preempt design defect claims completely.[26] Those five cases followed similar theories of causation and procedural histories. In all five, the plaintiffs alleged that vaccines administered to infants triggered injuries. In three of the five, the plaintiffs alleged that the thimerosal component of the vaccine or vaccines in question triggered autism spectrum disorder ("ASD") or a separate de-

[23] 21 U.S.C. §§ 301–399 (2006).

[24] 42 U.S.C. §§ 201–300ii-4 (2006).

[25] 42 U.S.C. § 300aa-22(b) (2006). In full, the subsection reads:

> (b) Unavoidable adverse side effects; warnings
>
> (1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.
>
> (2) For purposes of paragraph (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 all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] and section 262 of this title (including regulations issued under such provisions) applicable to the vaccine and related to vaccine-related injury or death for which the civil action was brought unless the plaintiff shows—
>
> (A) that the manufacturer engaged in the conduct set forth in subparagraph (A) or (B) of section 300aa-23(d)(2) of this title, or
>
> (B) by clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with such Act and section (and regulations issued under such provisions).

Id.

[26] See *Bruesewitz II*, 561 F.3d 233, 235 (3d Cir. 2009); Sykes v. Glaxo-SmithKline, 484 F. Supp. 2d 289, 301–03 (E.D. Pa. 2007); Blackmon v. Am. Home Prods. Corp., 328 F. Supp. 2d 659, 662–66 (S.D. Tex. 2004); Militrano v. Lederle Labs., 810 N.Y.S.2d 506, 508 (N.Y. App. Div. 2006); Wright v. Aventis Pasteur, Inc., No. 3861, 2008 Phila. Ct. Com. Pl. LEXIS 221, at *20–21 (Pa. Ct. Com. Pl. Aug. 27, 2008).

velopmental disorder;[27] in the other two, the plaintiffs argued that the design of the vaccines, but not specifically the inclusion of thimerosal, caused the children's neurological conditions.[28] In all five cases, the plaintiffs had satisfied the deferral provisions of the Vaccine Act by filing a petition for Program compensation and subsequently leaving the Program without accepting an award of compensation. Accordingly, only the second set of preemptive provisions—governing post-Program remedies—was at issue in these cases.

The leading opinion finding that the Vaccine Act effectuates a full preemption of design defect claims came from the Third Circuit in *Bruesewitz v. Wyeth*, released in March 2009.[29] In its opinion, the court first established that Section 22(b) was intended to have at least some preemptive effect, and then set about determining the scope of that effect.[30] Without first carefully examining the provisions in question, the Third Circuit concluded that it could not "resolve from statutory text alone the scope of the express preemption provision"; accordingly, the court turned to the language, purpose, structure, and legislative history of the Vaccine Act for guidance.[31] Considering these elements, the Third Circuit concluded that Congress must have intended to bar at least some state law design defect claims, but that a reading calling for a case-by-case analysis of avoidability would not keep any such claims out of court altogether.[32] Noting that the case-by-case reading would have actually expanded plaintiffs' access to courts in the few states that already

[27] See *Sykes*, 484 F. Supp. 2d at 292; *Blackmon*, 328 F. Supp. 2d at 661–62; *Wright*, 2008 Phila. Ct. Com. Pl. LEXIS 221, at *3.

[28] See Bruesewitz v. Wyeth, Inc., 508 F. Supp. 2d 430, 434–35 (E.D. Pa. 2007); *Militrano*, 810 N.Y.S.2d at 507. It is worth noting that this question did not even arise until nearly two decades after the enactment of the Vaccine Act. This is in large part a testament to the success of the Program in satisfying potential plaintiffs with plausible claims for compensation. It also demonstrates the uniqueness of (a) the near-complete absence of scientific support for the thimerosal theory, so as to create a likelihood of dismissal in even the no-fault Program, and (b) the strength of either the conviction or monetary interests of the proponents of the theory, or both. See Sharon Begley, Anatomy of a Scare, Newsweek, Mar. 2, 2009, at 42, 44–47.

[29] *Bruesewitz II*, 561 F.3d at 235. The analysis of the Third Circuit closely tracks that of the various trial courts mentioned above that found full preemption.

[30] Id. at 243.

[31] Id. at 245.

[32] Id. at 246.

had barred design defect claims for injuries resulting from receipt of prescription drugs, the Third Circuit concluded that such an interpretation was clearly contrary to legislative intent.[33]

The *Bruesewitz* court relied heavily on the Vaccine Act's legislative history to support its conclusion that Section 22(b) should be read to bar all design defect claims. The court cited extensively from a House committee report indicating that the clause of the Vaccine Act protecting manufacturers from liability for injuries "that were unavoidable" was inserted to incorporate the principle of Comment k of Section 402A of the Second Restatement of Torts into the Act.[34] From this language, the court extrapolated that Congress intended to deem all vaccines covered by the Vaccine Act to be "unavoidably unsafe" (at least where properly manufactured and labeled) and thus not subject to design defect liability.[35] The opinion also quoted another part of the same House report, which indicated that if potential plaintiffs "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."[36] Based in large part on these passages, the Third Circuit concluded that Congress intended Section 22(b) to bar all design defect claims.[37]

In so holding, the Third Circuit rejected the Georgia Supreme Court's analysis in *American Home Products Corp. v. Ferrari*, decided in October 2008.[38] In *Ferrari*, plaintiffs had brought suit against the vaccine manufacturer for defectively designing vaccines to include thimerosal, which they alleged to have caused neuro-

[33] Id.

[34] Id. at 247–48 (citing H. Rep. No. 99-908, at 25–26 (1986)). Comment k states that manufacturers are not liable for certain inherently dangerous products when injury was unavoidable, so long as the product was properly prepared and accompanied by proper directions and warnings. Restatement (Second) of Torts § 402A cmt. k (1965) ("Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous."). The language regarding preparation, directions, and warnings seems to be employed to disclaim any effect on liability for defective manufacture or failure to warn. Id. See infra Section IV.B for a more comprehensive examination of integration of Comment k.

[35] *Bruesewitz II*, 561 F.3d at 248–49.

[36] Id. at 248 (quoting H. Rep. No. 99-908, at 26 (1986)).

[37] Id.

[38] 668 S.E.2d 236 (Ga. 2008).

logical damage to their son.[39] The trial court agreed with those courts which had already decided the issue and dismissed the design defect claim, but the intermediate appellate court reversed. The Court of Appeals in *Ferrari* found the language of Section 22(b), taken alone, to be susceptible to two plausible readings: one barring all design defect claims and one merely requiring a showing that the injury was not "unavoidable" for the design defect claim to proceed.[40] But then the court read the presumption against preemption as applied in *Bates v. Dow Agrosciences LLC*[41] to impose an obligation on courts, when faced with two plausible statutory readings, always to choose the one that disfavors preemption regardless of which reading is more plausible, without consideration of the legislative history or other external interpretive aids.[42]

The Georgia Supreme Court granted a writ of certiorari and affirmed the appeals court's decision while repudiating its analysis. The court found that the intermediate court incorrectly interpreted *Bates* to bar consideration of legislative history when faced with two plausible statutory interpretations.[43] The court, however, found that Congress' incorporation of Comment k of Section 402A of the Second Restatement of Torts did not necessarily mean that Congress intended to bar all design defect claims. The court observed that most states that have adopted Comment k consider the issue of whether a particular injury was avoidable to be a question of fact for the jury to decide.[44] With this understanding of background principles, the court found that the text of Section 22(b) favored an

[39] Id. at 237.

[40] Ferrari v. Am. Home Prods. Corp., 650 S.E.2d 585, 590 (Ga. Ct. App. 2007) [hereinafter *Ferrari I*].

[41] Bates v. Dow Agrosciences LLC, 544 U.S. 443 (2005).

[42] *Ferrari I*, 650 S.E.2d at 590.

[43] *Ferrari II*, 668 S.E.2d at 238. *Bates* can, however, be fairly read to compel application of an interpretation disfavoring preemption where that interpretation is *more* textually plausible than, or even *as* textually plausible as, an alternative reading favoring broader preemptive scope. See infra Section II.A. But the Court of Appeals in *Ferrari I* made no judgment as to which of the two possible readings of § 22(b) was more plausible; it held only that both were plausible. Accordingly, the Supreme Court of Georgia was probably right to repudiate the intermediate court's analysis. The relative plausibility of the two interpretations of § 22(b) is discussed infra Section III.A; the application of the presumption against preemption to § 22(b) is discussed in greater detail infra Section III.C.

[44] *Ferrari II*, 668 S.E.2d at 239.

interpretation calling for a case-by-case determination of the unavoidability of the injury.[45] The court noted that this interpretation would give operative effect to the "unavoidable" clause, while the *Bruesewitz* approach did not.[46] The court also found the legislative history evidence presented by the other courts to be unpersuasive.[47] Applying the presumption against preemption, the court held that the defendants had failed to demonstrate the "clear and manifest" congressional purpose required for federal law to have preemptive effect against the plaintiff's claim.[48]

II. PRINCIPLES OF STATUTORY INTERPRETATION IN EXPRESS PRODUCTS LIABILITY PREEMPTION

Perhaps the single most consistent theme in the U.S. Supreme Court's express products liability preemption cases is an even greater than usual frustration with efforts to determine legislative intent. For a variety of different types of products, Congress has considered the question of preemption and then adopted ambiguous or contradictory language, leaving it to the courts to decide what preemptive effect, if any, the statute will have.[49] To deal with Congress' intentional or inadvertent ambiguity, the Court has increasingly resorted to two doctrines: the plain meaning rule and the presumption against preemption. Together, these doctrines have allowed courts to avoid consideration of the complicated and contradictory legislative history of preemption provisions. At the same

[45] Id. at 240.

[46] Id. This issue is discussed in greater detail infra Section III.A.

[47] Id. at 240–41. The *Ferrari II* court's interpretation of the legislative history is discussed infra Section IV.A.

[48] Id. at 242.

[49] Some commentators view this tendency as a deliberate attempt by Congress to evade hard choices between competing interest groups on preemption questions. See James A. Henderson, Jr. & Aaron D. Twerski, Products Liability: Problems and Process 424 (5th ed. 2004) ("Congress quite clearly has sought to placate both industry and consumers by speaking out of both sides of its mouth."); Catherine M. Sharkey, Products Liability Preemption: An Institutional Approach, 76 Geo. Wash. L. Rev. 449, 450 (2008) ("To be sure, with the stroke of a pen Congress could definitively determine when its product regulations displace state common law. Instead, Congress repeatedly punts . . . ."); see also Caleb Nelson, Preemption, 86 Va. L. Rev. 225, 302 n.235 (2000) ("When members of Congress focus on a particular issue but fail to reach a collective decision about how to resolve it, they sometimes compromise by enacting intentionally ambiguous language that transfers the issue to the courts.").

time, where applied consistently, the two rules allow for some degree of predictability in what is otherwise a rather unstable body of law.

A. The Plain Meaning Doctrine

The Supreme Court has robustly applied the plain meaning rule in express products liability preemption cases. In applying the plain meaning rule, the Court declares that when Congress uses a certain word (for example, "requirements") in a statute, the word will be interpreted to have preemptive effect within a certain defined scope, regardless of the presumption against preemption or any legislative history that may suggest a contrary congressional intent.[50] A strong application of the plain meaning rule allows the Court to avoid resorting to legislative history to resolve ambiguities in the text and leads to a greater degree of consistency in judicial interpretations of preemption provisions.

The Court's treatment of provisions containing the word "requirements" exemplifies this practice. In *Cipollone v. Liggett Group, Inc.*, the Court distinguished between the ban on states mandating "statements" in the 1965 act and the ban on states imposing new "requirements" in the 1969 act.[51] The four-Justice plurality found that even though legislative history suggested that the provisions were intended to target positive state legislative enactments, the plain meaning of "requirements" in the 1969 act "reaches beyond" positive legislative enactments.[52] Since then, the Court has consistently held that statutory provisions barring state "requirements" preempt at least some common law duties in addi-

[50] For a critique of the court's use of the plain meaning doctrine in other preemption cases, see Michael Gadeberg, Presumptuous Preemption: How "Plain Meaning" Trumped Congressional Intent in *Engine Manufacturers Assoc. v. South Coast Air Quality Management District*, 32 Ecology L.Q. 453, 478–80 (2005). Gadeberg argues that the Court was too quick to apply the plain meaning doctrine in the case—*Engine Manufacturers Association v. South Coast Air Quality Management District*, 541 U.S. 246, 252 (2004)—because another provision of the Clean Air Act rendered the preemption provision at issue ambiguous. Id. at 480–82.

[51] 505 U.S. 504, 519–20 (1992).

[52] Id. at 521. The Court was at least partly driven by a desire to give some meaning to "requirements" that went beyond the meaning of "standards" from the 1965 act, reasoning that Congress must have had *something* in mind in changing the wording. Id. at 521 & n.19.

tion to positive legislative enactments, while words that the Court deems less sweeping, such as "standards," do not.[53]

The Court is willing to apply this rule even in the face of clear legislative history to the contrary. In *Riegel v. Medtronic, Inc.*, the Court considered Section 360k(a) of the Medical Device Amendment ("MDA") to the Food, Drug and Cosmetics Act.[54] Section 360k(a) bars certain state law requirements concerning the safety and effectiveness of covered medical devices.[55] Petitioners and amici offered significant evidence that Congress never intended the MDA to bar state law tort claims of any sort.[56] But the Court, in an opinion written by Justice Scalia, held for the first time that negligence, defect, and implied warranty claims in fact do create "requirements" related to the safety or effectiveness of devices within the meaning of Section 360k(a).[57] Rejecting the need to resort to the legislative history because the statutory language was clear,[58] Justice Scalia articulated the new rule that, barring some positive indication in the statute to the contrary, the Court would always find the word "requirements" to preempt common law duties in addition to state statutory enactments.[59] In so holding, Justice Scalia recognized Congress' reliance interest in being able to predict courts' interpretations of statutory language.[60]

[53] See Riegel v. Medtronic, Inc., 128 S. Ct. 999, 1008 (2008); Bates v. Dow Agrosciences LLC, 544 U.S. 431, 443 (2005); Medtronic, Inc. v. Lohr, 518 U.S. 470, 496 (1996).

[54] 128 S. Ct. at 1010.

[55] 21 U.S.C. § 360k(a) (2006).

[56] *Riegel*, 128 S. Ct. at 1014–16 (Ginsburg, J., dissenting).

[57] Id. at 1007–09.

[58] Id. at 1009 ("The operation of a law enacted by Congress need not be seconded by a committee report on pain of judicial nullification.").

[59] Id. at 1008.

[60] Id. ("Congress is entitled to know what meaning this Court will assign to terms regularly used in its enactments."). This comment evinces concern for the ex ante effects of Court rulings. The Court's prior decisions on the meaning of "requirements" would have had no bearing on Congress' intent in using the word in the MDA, which was enacted in 1976, well before the Court first found "requirements" to include common law claims in *Cipollone*. Although the initial determination—originating in *Cipollone*—that use of the term "requirements" bars common law claims is at least somewhat arbitrary, Justice Scalia's rule does succeed in giving order to the analysis going forward. See Caleb Nelson, What is Textualism?, 91 Va. L. Rev. 347, 391 (2005) (discussing Justice Scalia's support for rule-based interpretive approaches in order to "help courts discern Congress's likely intent not because they reflect careful study of

While the Supreme Court has applied the plain meaning rule to provisions regarding state "requirements" to overcome the presumption against preemption[61] and find common law duties to be preempted, it has indicated a willingness to use the plain meaning doctrine to restrict the scope of preemption provisions as well. In *Riegel*, *Bates v. Dow Agrosciences LLC*, and *Medtronic v. Lohr*, the Court found that preemption provisions that only proscribed state requirements that were "different from or in addition to" federal requirements allowed for "parallel" state enforcement of federal regulations.[62] In other words, as long as the state law only penalized conduct that was already prohibited under federal standards, preemption provisions containing the parallel enforcement clause would not prevent liability under the state's "parallel" law. This was a fairly straightforward matter of statutory interpretation: the Court deemed all competing interpretations of the statutes implausible because such interpretations would have required reading the "different from or in addition to" language completely out of the statute.[63] While not stated as clearly as the rule regarding the use of the word "requirements," it seems likely after these three cases that the Court will always construe bars on different or additional requirements to allow for parallel state enforcement of federal requirements. Thus, the Court appears willing to apply the plain meaning doctrine to uphold narrower or broader interpretations of statutory preemption provisions.

As Justice Scalia indicated in his *Riegel* opinion, a robust application of the plain meaning rule can serve an important ex ante role.[64] Prospectively, if Congress uses the word "requirements" in its preemption provisions, Congress—and the industry groups that lobby it—will know what meaning the Court will give that word. Other words that Congress uses in place of "requirements" will be judged according to whether they seem more or less sweeping. Thus, it will be at least somewhat more difficult for Congress to

what Congress does on its own, but simply because members of Congress know that the courts use them").

[61] See infra Section II.B.

[62] See *Riegel*, 128 S. Ct. at 1013; Bates v. Dow Agrosciences LLC, 544 U.S. 431, 448–49 (2005); Medtronic, Inc. v. Lohr, 518 U.S. 470, 496–97 (1996).

[63] See, e.g., *Bates*, 544 U.S. at 448–49.

[64] 128 S. Ct. at 1008–09; see also supra note 60.

appease interest groups and at the same time ultimately punt the question of preemption to the courts.

B. The Presumption Against Preemption

The presumption against preemption has been inconsistently applied in various areas of preemption law.[65] But in express products liability preemption cases, the presumption appears to exert considerable force where the statute lacks a plain meaning and the reading disfavoring preemption is at least as plausible as the one favoring preemption. In these situations, the presumption should work as a sort of tiebreaker, compelling adoption of the narrower reading instead of the reading favoring preemption, and instead of turning to the legislative history to overcome the deadlock.

The current state of the presumption came into focus in *Bates v. Dow Agrosciences LLC*.[66] *Bates* involved a statute that prohibited state requirements that were "in addition to or different from" those of the federal statute.[67] The defendant manufacturer argued that the statute barred all related state requirements, while the plaintiffs contended that the language should be construed to bar only state requirements that were not parallel to the federal requirements.[68] The Court found the plaintiffs' reading to be more plausible.[69] In so holding, the Court concluded that the presumption compelled courts to adopt a reading disfavoring preemption as long as that reading is at least as plausible as any competing inter-

[65] See Nelson, Preemption, supra note 49, at 292 (discussing the "various forms" that the presumption against preemption has taken).

[66] 544 U.S. 431 (2005).

[67] Id. at 436 (quoting 7 U.S.C. § 136v(b) (2006)).

[68] Id. at 447–48.

[69] Id. at 449. In fact, it found Dow's reading implausible, thus mooting the presumption in this instance (since the Court would not adopt an implausible reading of a statute, presumption or not). But in the critical passage in which the Court reaffirmed and defined the scope of the presumption, it proceeded on the assumption that Dow's reading *was* plausible. Id. ("Even if Dow had offered us a plausible alternative reading of § 136v(b)—indeed, even if its alternative were just as plausible as our reading of that text—we would nevertheless have a duty to accept the reading that disfavors pre-emption.").

pretations,[70] and probably without regard for legislative history to the contrary.[71]

The Court's 2008 decision in *Riegel v. Medtronic, Inc.* raised speculation about the presumption's death, but those rumors appear to have been greatly exaggerated.[72] In *Riegel*, eight Justices agreed that the language of the preemption provision in question was clear. The majority opinion, by Justice Scalia, did not even mention the presumption. The Court held that traditional tort duties were "requirements" related to the safety and effectiveness of medical devices.[73] But later in 2008, the Court confirmed the presumption's health in *Altria Group Inc. v. Good*.[74] In *Good*, the Court seemed to acknowledge that a broader reading of the preemption provision in the Federal Cigarette Labeling and Advertising Act ("Labeling Act") was at least plausible. Applying the presumption, however, it held that fraudulent misrepresentation and concealment claims were not "based on" cigarette safety within the meaning of the federal Labeling Act.[75] Most recently, in *Wyeth v. Levine*, an implied preemption case, the Court once again affirmed the vitality of the presumption against preemption.[76]

Even the most skeptical Justices may acknowledge that the presumption compels a reading disfavoring preemption when that reading is as plausible as, or more plausible than, a reading favoring preemption. In *Levine*, the dissent only criticized the presump-

[70] Id. The negative inference, however, was that the presumption would not be sufficient for a *less* plausible interpretation disfavoring preemption to be chosen over a *more* plausible interpretation favoring preemption.

[71] In his opinion, Justice Stevens did cite legislative history in support of his narrower preemptive reading. Id. at 452 n.26. However, the rule he articulated concerning application of the presumption—prior to any mention of the legislative history of the relevant statute—indicates that it was based upon a reading of the statutory text itself, not upon reference to any extra-statutory interpretive aids. See id. at 449 (referring to application of the presumption to a competing "reading of that [statute's] text").

[72] 128 S. Ct. 999, 1010 (2008).

[73] Id.

[74] 129 S. Ct. 538, 543 (2008).

[75] Id. at 547.

[76] 129 S. Ct. 1187, 1194–95 (2009) ("[P]articularly in those [cases] in which Congress has 'legislated . . . in a field which the States have traditionally occupied,' . . . we 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" (quoting *Lohr*, 518 U.S. at 485)).

tion's application in cases of implied conflict preemption.[77] Dissenting in *Good*, Justice Thomas criticized the presumption against preemption, but only insofar as it has been used to "distort the statutory text" and to "unreasonably interpret expressly preemptive federal laws."[78] Yet, in cases where the interpretation disfavoring preemption is the most plausible reading, the presumption merely forecloses the use of extrinsic materials to divine legislative motive. Because the Justices who appear to be most opposed to the presumption are also those most opposed to the use of extrastatutory legislative materials, it is unlikely that this use of the presumption would draw their ire. Indeed, in his *Good* dissent, Justice Thomas even appeared willing to accept Justice Stevens' application of the presumption in *Bates* to situations where the competing interpretations are equally plausible.[79]

Bates and the cases since indicate that the presumption against preemption applies where there are two equally plausible interpretations of a preemption provision, or where the reading disfavoring preemption is more plausible than the one that favors preemption. Moreover, there is some indication that the Court may apply this rule based purely upon a reading of the preemption language in question, without resort to nonstatutory legislative history, in an attempt to break the tie between competing interpretations. As such, the presumption provides an effective default rule for choosing an interpretation without resorting to extrinsic interpretive aids where Congress embeds unclear preemptive commands within a statute. If applied consistently in the future, it will also have the ex ante effect of allowing Congress—and interest groups favoring preemption—to have a better idea of how ambiguous preemptive language will be construed. Thus, the presumption will make it

[77] Id. at 1229–30 (Alito, J., dissenting).

[78] 129 S. Ct. at 557–58.

[79] Id. at 557–58. At the same time, as support for the proposition that the presumption is dead or dying, Justice Thomas cited its absence from Justice Scalia's majority's opinion in *Riegel*. But in that case, eight Justices—including Justice Stevens, author of the majority opinions in *Bates* and *Good*—agreed that the language of the preemptive provision was clear, meaning that the reading favoring preemption was the only plausible textual interpretation. Only if the presumption against preemption were so strong as to require courts to override a statute's plain meaning would it be apposite in such circumstances. The Court has never suggested that it is.

harder for Congress to "punt" to courts on express preemption questions.[80]

C. A Two-Step Approach

Along with the plain meaning rule, the Court has applied a robust version of the presumption against preemption in order to resolve seemingly intractable interpretive disputes. Together, the rules form a two-step approach to resolving conflicting preemptive commands without resorting to legislative history or other extrinsic interpretive aids. First, if the term in question has been defined by the Court in a similar context, whether involving the same statute or a different one, it is highly likely that the Court will find the language unambiguously to have that same meaning. Similarly, if the preemption provision is for some other interpretive reason far more susceptible to one meaning than others, then the Court will again find the provision to be unambiguous, and the inquiry will end there.

Second, where prior Court interpretations and traditional canons of statutory interpretation fail to give clear meaning to the terms of the statute, the Court will apply the presumption against

[80] This argument is different from what Einer Elhauge calls the "preference-eliciting" rationale for the presumption against preemption. That argument relies on the claim that Congress is more likely to overturn a Court ruling disfavoring preemption than one favoring preemption. See Roderick Hills, Against Preemption: How Federalism Can Improve the National Legislative Process, Univ. of Mich. Pub. Law Working Paper No. 27, at 22 (2003) ("[W]here a statute is ambiguous, the court ought to interpret the preemptive force of federal statutes to burden interest groups favoring preemption, on the assumption that these pro-preemption groups—overwhelmingly, business and industry groups—are more capable of promoting a vigorous debate in Congress than their opponents."). See generally Einer Elhauge, Statutory Default Rules: How to Interpret Unclear Legislation 151–55 (2008); Einer Elhauge, Preference-Eliciting Statutory Default Rules, 102 Colum. L. Rev. 2162, 2164–68 (2002). What empirical data exist, however, show that Congress hardly ever responds to the Court's preemption decisions, no matter which way it decides. See Note, New Evidence on the Presumption Against Preemption: An Empirical Study of Congressional Responses to Supreme Court Preemption Decisions, 120 Harv. L. Rev. 1604, 1605 (2007). Thus, if the goal is eliciting preferences, the presumption has not been effective. Instead, I argue that a consistently-applied presumption would make it more difficult ex ante for Congress to appease interest groups favoring preemption with intentionally ambiguous statutory language, since those parties would know that courts would apply the presumption against them. The inability to satisfy those groups with ambiguous language could make Congress more willing to decide the preemption question one way or the other in the first instance.

preemption, opting for the reading disfavoring preemption where it is at least as plausible as the interpretation favoring preemption. Thus, under the proposed framework, the Supreme Court will refer to legislative history only where the provision in question is reasonably susceptible to two different meanings and the reading favoring preemption is at least somewhat more plausible than the reading disfavoring preemption. Otherwise, the Court will rely on the plain meaning rule and the presumption against preemption to resolve the great majority of express products liability preemption disputes.

III. INTERPRETING SECTION 22(B) CORRECTLY

All of the courts that have considered the issue have concluded, at least implicitly, that the language of Section 22(b) is susceptible to two readings: one barring state law design defect claims outright, and one merely preventing recovery on such claims where the injury was unavoidable. Accordingly, they resorted to the legislative history of the Vaccine Act to resolve the ambiguity. But it is not so clear that courts should do so. In this Part, applying the principles set forth in Part II, I argue that courts may be obliged to accept the interpretation disfavoring preemption without consideration of any extrinsic interpretive aids such as legislative history. In Section III.A, I apply conventional canons of statutory construction and argue that the narrower reading of Section 22(b) may in fact be the only plausible textual interpretation of the provision. In Section III.B, I consider the possible role of FDA's biologics approval process in giving meaning to the term "unavoidable" in Section 22(b). I argue that Congress did not intend to incorporate FDA determinations into the preemption provisions at issue, and so under the Supreme Court's recent decisions in *Riegel v. Medtronic, Inc.* and *Wyeth v. Levine*, courts should not look to those determinations. Finally, in Section III.C, I apply the presumption against preemption as the Court has recently construed it and conclude that even if the interpretation favoring preemption is somewhat plausible, the interpretation disfavoring preemption is more plausible, and thus should be adopted.

A. Plausible Interpretation(s) of the Provision

As a general rule of construction, courts will not ascribe a strained meaning to statutory language, particularly when that interpretation would render certain words in the statute superfluous.[81] The Supreme Court has applied this doctrine in at least one express preemption case. In *Bates*, the Court rejected the manufacturer's argument that parallel state requirements were preempted because that effectively would read the "in addition to or different from" language of the preemption provision completely out of the statute.[82] The Court found such a reading to be implausible.[83]

Just as the interpretation rejected in *Bates* would have required reading words out of the statute, to conclude that all design defect claims are barred by the Vaccine Act, a court would have to ignore part of Section 22(b). If the drafters of the statute had intended for language that allowed only manufacturing defect and failure-to-warn claims, they had a very simple option at their disposal: they could have omitted the words "that were unavoidable" from the provision.[84] The result would have been a statute that shielded vaccine manufacturers from liability in civil actions where "the injury or death resulted from side effects even though the vaccine was properly prepared and was accompanied by proper directions and warnings." This language would have preserved manufacturing defect and failure-to-warn liability while protecting vaccine manufacturers from liability for defective design where the vaccine was properly prepared.[85]

[81] See, e.g., Dole Food Co. v. Patrickson, 538 U.S. 468, 476–77 (2003); Mertens v. Hewitt Assocs., 508 U.S. 248, 258 (1993).

[82] Bates v. Dow Agrosciences LLC, 544 U.S. 431, 448–49 (2005).

[83] Id. at 448.

[84] If one construes "properly prepared" to allow claims whenever vaccines were not prepared in accordance with the FDA-approved design specifications, then a finished product that deviates from that approved design could be deemed improperly prepared and a suit therefore would be allowed. This would be true whether the deviation was a result of an unapproved change in design or a defect in the manufacturing process. In any event, this plausible reading does not change the answer to the question here, which is whether vaccine manufacturers can ever be held liable for defective design when the vaccine conformed to FDA-approved specifications.

[85] This alternative mirrors the Court's finding in *Bates* that if Congress had intended to bar parallel requirements, it could have left the "in addition to or different from" language out of the provision, resulting in an "amputated version" that "would no doubt have clearly and succinctly commanded the pre-emption of *all* state require-

Indeed, the courts which have found total preemption of design defect claims have read the "unavoidable" phrase completely out of the statute. Of the five, the two courts which have tried hardest to explain the language of Section 22(b) were the federal district courts in *Blackmon v. American Home Products Corp.*[86] and *Sykes v. Glaxo-SmithKline*.[87] The court in *Blackmon* found that Section 22(b) expressly preserved manufacturing defect and failure-to-warn claims; it held that under the statute, those two claims are "the variables that determine whether a claimant may sue the manufacturer."[88] This reading ignores the unavoidable side effects phrase altogether, except to say that it signals incorporation of Comment k for all vaccines.[89] But as noted above, barring all design defect claims through incorporation of Comment k could have been achieved by omitting the clause altogether.

In *Sykes*, the district court attempted to reconcile the language with its understanding of the drafters' intent by construing the provision (a) to bar recovery for injuries resulting from unavoidable side effects and (b) to define unavoidable side effects as those which occur despite proper preparation, directions, and warnings.[90] This move by the court does not, however, cure the interpretive problem. Under the *Sykes* analysis of Section 22(b), the unavoidable side effects phrase does no work whatsoever—it could still be eliminated altogether without changing the provision's preemptive scope.[91] Such an interpretation violates the "settled rule that a stat-

ments concerning labeling." *Bates*, 544 U.S. at 449. Alternatively, the drafters of § 22(b) could have kept the phrase "that were unavoidable," and also stated that all side effects that resulted from products covered by the Vaccine Act were to be considered unavoidable for purposes of § 22(b). Either approach would have given operative effect to each word of the provision and would have served to bar all design defect claims outright.

[86] 328 F. Supp. 2d 659 (S.D. Tex. 2004).

[87] 484 F. Supp. 2d 289 (E.D. Pa. 2004). In *Bruesewitz II*, the Third Circuit did not make a serious effort to explain the language of § 22(b), instead noting that "it is always possible to construct through hindsight an alternate structure for a statute with alternative wording that would render it more clear." *Bruesewitz II*, 561 F.3d 233, 246 (3d Cir. 2009).

[88] *Blackmon*, 328 F. Supp. 2d at 664 (emphasis added).

[89] Id.

[90] Sykes v. Glaxo-SmithKline, 484 F. Supp. 2d 289, 300 (E.D. Pa. 2007).

[91] None of the five courts proposed an alternate reading of § 22(b) that gives operative effect to "that were unavoidable." Even if a court found some claim besides failure-to-warn, defective manufacture, and defective design that the clause purportedly

ute must, if possible, be construed in such fashion that every word has some operative effect."[92] The failure to give such operative meaning to every word contained within the provision may render the *Blackmon-Sykes* interpretation implausible, just like the manufacturer's interpretation in *Bates*.

A reading of Section 22(b) that calls for a case-by-case analysis of avoidability does not suffer from the same defect as the *Blackmon-Sykes* analysis. Under this reading, the "that were unavoidable" clause is interpreted as a partial bar to design defect claims: for recovery to be allowed on a design defect theory, it requires a concomitant finding that the injury at issue was avoidable, for example, through the use of a feasible alternative design. This interpretation gives operative effect to every word of the section. Under this interpretation, manufacturers are shielded from liability where: (a) the vaccine was properly manufactured, (b) the vaccine was accompanied by proper directions and warnings, and (c) the injury resulted from side effects that were unavoidable. If any one of those conditions is lacking, then the manufacturer is subject to civil liability under the saving clause of Section 22(a).[93] In effect, the provision creates a general rule requiring the injury to have been avoidable in order for plaintiffs to recover from manufacturers, and then carves out individual exceptions to this rule for manufacturing and warning defect liability. By not specifically mentioning design defect liability, the provision contemplates that the general requirement of avoidability applies to those claims. While the statute is inartfully drafted under any interpretation, this reading at least gives meaning to every word of the provision.[94]

preserved, it is hard to imagine that the court could draw a distinction that would have the clause preserve that other claim but not defective design claims where the injury was avoidable.

[92] United States v. Nordic Village, Inc., 503 U.S. 30, 36 (1992).

[93] This interpretation would not give rise to manufacturing defect or failure-to-warn liability despite proper preparation and proper directions and warnings where the injury was nevertheless avoidable. Definitionally, *im*proper preparation is a requisite element to a finding of defective manufacture, and *im*proper direction or warning is a requisite element to a finding of failure-to-warn liability. Accordingly, the word "unavoidable" only modifies actions for claims other than defective manufacture and failure to warn: it would allow recovery only where the injury was avoidable, for example, through use of a safer feasible design.

[94] While I have argued that the language of § 22(b) must be read in a very strained manner to bar all design defect claims, it must be admitted that if Congress meant to

Moreover, contrary to the Third Circuit's opinion in *Bruesewitz*,[95] examining Section 22(b) in the context of the statute lends support to an interpretation that stops short of full preemption of design defect claims. There is nothing in the statute's structure or stated purpose to contradict a reading of the Vaccine Act as allowing such defect claims. As discussed above,[96] while the Program establishes a mandatory national compensation program, the Act expressly contemplates the preservation of state law tort claims and even gives Program claimants three separate opportunities to leave the Program and file suit under state law.[97] The saving clause of Section 22(a) establishes a default rule of not preempting state law claims, while Section 22(e) bars states from establishing new laws curtailing Program claimants' right to sue under state law.[98] Section 22(b) itself appears to preserve all manufacturing defect claims,[99] and the same section, read in conjunction with Section 22(c), bars only some failure-to-warn claims.[100] In this context, a total bar on design defect claims would be the exception of the Vaccine Act,

establish a requirement of avoidability for design defect recovery, it had clearer ways to say that, too. It could have simply said that design defect claims are only barred where the injury was unavoidable, or that such claims are not barred where the injury was avoidable. But because the "that were unavoidable" clause does not modify manufacturing and warning defect claims, see supra note 91, mentioning the specific claims to which the clause did apply would have been unnecessary, though not unhelpful.

[95] See *Bruesewitz II*, 561 F.3d at 235 (3d Cir. 2009).

[96] See infra Section III.A.

[97] Those opportunities arise 240 days from filing a petition for Program compensation, 420 days from filing, and upon rejection of the Program's judgment at the end of proceedings. 42 U.S.C. § 300aa-21(b) (2006); see supra note 14 and accompanying text.

[98] 42 U.S.C. § 300aa-22(a), (e) (2006).

[99] By only prohibiting actions where the injury occurs despite proper preparation, § 22(b) implicitly preserves all claims where the injury occurs due to *im*proper preparation. 42 U.S.C. § 300aa-22(b) (2006).

[100] Section 22(b) creates a presumption that covered vaccines are accompanied by proper directions and warnings where the manufacturer complied with the requirements of the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act. That presumption may be rebutted by a showing (a) that the manufacturer engaged in fraud or intentional misconduct with regard to information relating to the safety and effectiveness of the vaccine, or (b) by clear and convincing evidence that the manufacturer was negligent despite conforming to the statutory requirements. 42 U.S.C. § 300aa-22(b)(2) (2006). Section 22(c) protects manufacturers from liability for failure to warn directly through adoption of the so-called learned intermediary doctrine. Id. § 300aa-22(c).

not the rule. Therefore, in addition to being the most plausible reading of the text itself, a reading of Section 22(b) that bars only some defective design claims would be most consistent with the structure and scope of the Act taken in full.[101] This interpretation is thus an eminently plausible reading of the statute. If it stands as the only plausible interpretation, then courts are bound to follow it.[102] Applying the robust version of the plain meaning rule as discussed in Part II, the Supreme Court seems particularly likely to find the language of Section 22(b) to be clear.

B. Rejecting a Regulatory Definition of "Unavoidable"

The Supreme Court's analysis in *Riegel v. Medtronic, Inc.* suggests that the agency approval process is another possible source of meaning for the terms of the preemption provision. In *Riegel*, in the course of determining whether the "requirements" at issue included tort duties, the Court closely considered the statutory language in the context of the relevant regulatory scheme. It distinguished the requirements at issue in *Medtronic, Inc. v. Lohr* on these contextual grounds. In *Lohr*, the Court held that Section 360k(a) of the Medical Device Amendment did not bar design defect claims for devices approved through the Section 510(k) substantial equivalence approval process.[103] That process, the Court noted, was one based primarily on equivalence to a legally marketed device, and not on safety.[104] In contrast, *Riegel* involved an application of the same section to products approved through FDA's premarket approval ("PMA") process rather than through the Section 510(k) process. The PMA process, the Court noted in

[101] In *Sykes v. Glaxo-SmithKline*, the trial judge found that allowing a case-by-case determination of avoidability would frustrate the purpose of the Vaccine Act to keep these cases out of the courts. 484 F. Supp. 2d 289, 301–02 (E.D. Pa. 2007). But considering the Vaccine Act's general preservation of state law tort claims, this argument would seem to prove too much.

[102] See Robinson v. Shell Oil Co., 519 U.S. 337, 340 (1997); see also Riegel v. Medtronic Inc., 128 S. Ct. 999, 1009 (2008) (declining to consider agency interpretation where "statute itself speaks clearly to the point at issue"); Bates v. Dow Agrosciences LLC, 544 U.S. 431, 448–49 (2005) (citing manufacturer's failure to offer a plausible alternative reading of the statutory provision).

[103] See Medtronic, Inc. v. Lohr, 518 U.S. 470, 493–94 (1996).

[104] Id. at 493.

Riegel, "is focused on safety, not equivalence."[105] To prove the point, the opinion walked through the "rigorous regime" of PMA in great detail.[106] Considering the thoroughness of the premarket approval process, the Court concluded that tort duties conflicted with established federal requirements with regard to the safety and effectiveness of devices that had survived the PMA process.[107]

One could interpret *Riegel* to require examination of the scope and emphasis of the relevant regulatory scheme in determining the reach of the preemptive provision against state tort claims.[108] A court looking to give meaning to "unavoidable" could, therefore, refer to FDA regulation of vaccines to fill the gap. Biologics (such as vaccines) are licensed by FDA under Section 351 of the Public Health Service Act.[109] Like the PMA process, the biologics licensure process is a rigorous premarket approval system that focuses on the safety of the biologic at issue.[110] Accordingly, applying *Riegel*'s rationale, one could plausibly infer that FDA, through its approval process, has already filtered out those vaccines that are designed in an avoidably unsafe manner, leaving only those which are unavoidably unsafe. If this is the case, then "that were unavoidable" could be read to bar all design defect claims where the

[105] 128 S. Ct. at 1007.

[106] Id. at 1004–05.

[107] Id. at 1007, 1011.

[108] Prior to the Court's ruling in *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), one plausibly could have interpreted *Riegel* to require examination of the scope and emphasis of the relevant regulatory scheme in determining the reach of the preemptive provision against state tort claims, regardless of whether Congress actually intended to import regulatory findings into the statute. Such a rule would be consistent with the "tort as regulation" approach advanced by various scholars. See Sharkey, supra note 49, at 474–75, 479–80 (suggesting that agency determinations affecting preemptive scope may be entitled to deference of their own force); see also Thomas W. Merrill, Preemption and Institutional Choice, 102 Nw. U. L. Rev. 727, 755 (2008) (identifying regulatory nature of state common law); Peter H. Schuck, FDA Preemption of State Tort Law in Drug Regulation: Finding the Sweet Spot, 13 Roger Williams U. L. Rev. 73, 75–76 (2008) (recognizing the competing compensatory and regulatory aims of tort law).

[109] 42 U.S.C. § 262 (2006).

[110] See id. § 262(a)(2)(C) (requiring that approved biologics be "safe, pure, and potent"); see also 21 CFR § 601.2 (2009) (describing detailed requirements for biologics licensing applications).

vaccine was manufactured in accordance with an FDA-approved design.[111]

After the Supreme Court's recent decision in *Wyeth v. Levine*, it seems clear that the *Riegel* analysis only extends as far as statutes that refer, expressly or implicitly, to the regulatory scheme to give meaning to its terms. Indeed, in *Riegel* itself, the Court looked to FDA regulations to determine whether the agency had established "requirements" within the meaning of Section 360k(a) that may have been contradicted by state law claims.[112] A provision barring different state requirements implies that courts must find (a) which federal regulations are properly covered by the preemption provision, (b) whether certain state laws constitute "requirements" within the meaning of the preemption provision, and (c) whether those state law requirements do indeed conflict with the federal requirements.[113] Since the "requirements" language naturally involves an examination of the relevant regulatory scheme and determination of which state laws actually conflict with it, the rigor of the approval process was necessarily implicated in *Lohr* and *Riegel*. But it is a different question where the preemption provision does not refer to the regulatory framework. In *Levine*, the Court affirmed the principle that congressional intent is the touchstone of preemption inquiries.[114] If Congress did not mean to refer to the biologics licensure process to give meaning to "unavoidable" in the Vaccine Act, then the approval process will not be relevant to that determination.

Thus, only if Section 22(b) can be read to incorporate FDA's determinations of vaccine design safety should the biologics licensure process guide courts in defining "unavoidable" as employed in Sec-

[111] As an interpretive matter, this reading still suffers from the same defect as the *Blackmon-Sykes* reading if one reads "properly prepared" to include all claims in which the vaccine was prepared in accordance with FDA-approved design specifications.

[112] 128 S. Ct. at 1006–07.

[113] See id. at 1006. This framework has not been seriously disputed; the real question arises when certain federal regulations and state law claims fit into the three categories.

[114] Wyeth v. Levine, 129 S. Ct. 1187, 1194 (2009). The Court also noted: "[A]gencies have no special authority to pronounce on pre-emption *absent delegation by Congress* . . . ." Id. at 1201 (emphasis added).

tion 22(b).[115] For two related reasons, this is not the best reading of the Vaccine Act. First, the general purpose of the Program is compensatory, not regulatory, and so its preemption provisions should probably be considered in the same way. The Act hardly imposes any new requirements on manufacturers, and for the most part, the FDCA's and PHSA's regulatory requirements remain far in the background of the law.[116] Neither the Vaccine Act nor any other part of the Public Health Service Act attempts to bar state law requirements for vaccines. Instead, as discussed above, the Vaccine Act expressly preserves state law claims in most instances.[117] The Vaccine Act generally does not contemplate the underlying regulatory framework in the course of establishing its rules for compensation and liability, and so it is difficult to imagine that Congress intended implicitly to import them in this one circumstance. In this sense, the Vaccine Act is quite different from the law at issue in *Lohr* and *Riegel*, the Medical Device Amendment, which was entirely regulatory in nature, and which expressly barred nonparallel state requirements.[118] It made sense in that context to conclude that Congress looked to the regulations it was enacting to give meaning

[115] It is at least theoretically possible that design defect claims would nevertheless be impliedly preempted as an obstacle to federal regulation in the field. See generally Geier v. Am. Honda Motor Co., 529 U.S. 861, 864–65, 868 (2000) (finding implied preemption despite inapplicability of express preemption clause). After the Court's recent decision in *Wyeth v. Levine*, however, it is extremely unlikely that a court would find obstacle preemption here. Applying *Levine* by analogy, the only conflict between federal regulation of vaccines and state tort liability is the degree to which Congress intended the Vaccine Act remedy to be exclusive. Section 22 addresses the scope of this conflict precisely, and so there would be no argument that the conflict extends beyond that contemplated by the express preemption provisions. See *Levine*, 129 S. Ct. at 1199–1201 (narrowly construing the scope of obstacle preemption).

[116] There are two arguably regulatory components in the Vaccine Act. The first part, codified at 42 U.S.C. §§ 300aa-1 to 300aa-6 (2006), establishes the National Vaccine Advisory Committee, charged with issuing a report and recommending ways to encourage the availability of a safe and adequate vaccine supply. The Committee lacked the power to issue any new regulations or otherwise bind manufacturers. More substantially, the Vaccine Act also created new requirements for manufacturers to maintain records with regard to the testing and manufacture of vaccines, with civil sanctions for noncompliance. 42 U.S.C. § 300aa-28 (2006).

[117] See supra notes 96–101 and accompanying text.

[118] See 21 U.S.C. § 360k(a) (2006). See generally 21 U.S.C. § 360e-f (2006). The Medical Device Amendment authorized FDA to regulate medical devices for the first time.

to the terms of the preemption provision. It makes much less sense to conclude that Congress did so here.

Second, in drafting the Vaccine Act, where Congress did intend for compliance with federal regulations to protect vaccine manufacturers from state liability, it said so clearly. Under Section 22(b), compliance with FDCA and PHSA labeling requirements creates a rebuttable presumption that the vaccine contained proper directions and warnings.[119] Section 23(d) also protects manufacturers from punitive damages where the manufacturer complied with all FDCA and PHSA requirements, except in cases of fraud or other misconduct.[120] Since, when it intended to incorporate regulatory requirements in the Vaccine Act, Congress did so explicitly, it seems likely that it did not intend to do so here. It would, therefore, require an expansion of *Riegel* for the agency approval process to factor into express preemption questions like this one, when Congress had no discernible intent to involve agency regulatory actions in the determination of preemptive effect. The Court's analysis in *Levine* suggests that no such expansion is forthcoming.

C. Applying the Presumption Against Preemption

As discussed in Part II, the Court has applied the presumption against preemption in situations like this one, in which the textual interpretation disfavoring preemption is at least as plausible as the one favoring preemption.[121] The provision at issue here is most analogous to the one in *Bates*, where the Court applied the presumption against preemption in the course of adopting a reading which disfavored preemption over an alternative interpretation which favored preemption.[122] As in that case, the interpretation favoring preemption here requires "reading . . . words out of the statute."[123] The Court held in *Bates* that courts have a duty in such situations, where the more plausible reading disfavors preemption,

[119] 42 U.S.C. § 300aa-22(b)(2) (2006). The presumption is rebutted upon a showing that the manufacturer engaged in fraud or misconduct, or upon a showing of clear and convincing evidence that the manufacturer was nevertheless negligent. Id. at 300aa-22(b)(2)(A)–(B).

[120] Id. § 300aa-23(d)(2).

[121] See supra Section I.A.

[122] Bates v. Dow Agroscience LLC, 544 U.S. 431, 449 (2005).

[123] Id. at 448.

to adopt that reading over less (or equally) plausible readings with broader preemptive effect.[124]

The same principle should apply here with equal force. Courts should opt for the interpretation of Section 22(b) that disfavors preemption. If the full preemption reading is not textually plausible, as I have argued, then there is no support for its adoption, presumption or not. Particularly in the context of the Supreme Court's application of the plain meaning rule in express preemption cases, the full preemption reading appears particularly implausible. But even if the full preemption reading is to be considered at least somewhat plausible despite its interpretive defect, it is clear that the interpretation disfavoring preemption is more textually plausible because (a) it does not require a strained interpretation of Section 22(b), and (b) the narrower interpretation is more consistent with the Vaccine Act read in full. Accordingly, the presumption against preemption should compel courts to adopt the narrower reading of Section 22(b). Only if a court finds the full preemption reading to be plausible and declines to apply the presumption would it turn to the legislative history of the Act. The next Part addresses this possibility.

IV. EXTRASTATUTORY EVIDENCE OF THE MEANING OF SECTION 22(B)

In the preceding Part, I argued that the language of Section 22(b) is not susceptible to a reading that categorically preempts all design defect claims against vaccine makers. In addition, I suggested that the general purpose and structure of the Vaccine Act, as far as can be determined from the statutory language itself, support the conclusion that at least some state law design defect claims were to be preserved. To the extent that the "full preemption" reading is not textually plausible, it cannot be revived by nonstatutory evidence of Congress' intent. But as discussed in Section III.B, courts have nevertheless held that the history of the Vaccine Act and the relevant background tort law strongly suggest that Congress intended to bar all such claims. In this Part, I argue that the history and background law do not support the full preemption reading; at most, they send mixed signals about Congress' intent

[124] Id. at 448–49.

with regard to defective design claims against vaccine manufacturers. This ambiguity further reinforces my conclusion in Part III that courts should adopt the reading disfavoring preemption.

A. Legislative History of the Vaccine Act

The courts that adopted the "full preemption" reading of Section 22(b) emphasized that the Vaccine Act was conceived in response to rising prices and a threatened supply shortage that resulted, at least in part, from mounting litigation costs.[125] This is undoubtedly true.[126] But for three related reasons, that fact does not lead inexorably to the conclusion that Congress intended to preempt all design defect claims. First, as discussed in Part III, the text of the Vaccine Act as passed clearly contemplates the preservation of many tort claims, so the conclusion that Congress sought generally to foreclose state law remedies is overbroad.[127] Second, the legislative history of the Vaccine Act suggests that Congress considered and rejected language that would have barred all design defect claims, or at least those proceeding on a strict liability theory. Third, it is not apparent that Congress or parties involved in the lawmaking process believed that Section 22(b) as enacted barred all design defect claims. This Section discusses the latter two issues.

The preemptive language eventually adopted in the Act was the result of a compromise between a no-preemption option and a stronger alternative that would have barred most or all design defect claims. The earliest iteration of the Vaccine Act called for an opt-in no-fault federal program that expressly preserved state law

[125] See, e.g., Bruesewitz v. Wyeth Inc., No. 07-3794, at 32 (3d Cir. Mar. 27, 2009); Bruesewitz v. Wyeth, Inc., 508 F. Supp. 2d 430, 438 (E.D. Pa. 2007); Sykes v. Glaxo-SmithKline, 484 F. Supp. 2d 289, 297 (E.D. Pa. 2007); Blackmon v. Am. Home Prods. Corp., 328 F. Supp. 2d 659, 663 (S.D. Tex. 2004).

[126] In 1984, two of the three U.S. marketers of the diphtheria-tetanus-pertussis (DTP) vaccine pulled out of the market, citing the high cost of litigation related to the products. See 1984 House Hearings, supra note 12 (statement of Robert B. Johnson, President, Lederle Labs. Div., Am. Cyanimid Co.); IOM 1985 Report, supra note 12, at 27–28 (1985). During the same time period, the price per dose of required childhood vaccines increased dramatically, a development for which manufacturers blamed high litigation costs. See 1984 House Hearings, supra note 12, at 239 (statement of Robert B. Johnson).

[127] See supra notes 96–101 and accompanying text.

rights without modification.[128] The next version of the bill, H.R. 5184, however, swung to the other end of the spectrum. As with the Vaccine Act as passed, H.R. 5184 required would-be plaintiffs to file suit against the government before seeking recovery directly against vaccine manufacturers,[129] and Section 2122(b) of that Act contained essentially the same language as what became Section 22(b).[130] But the section governing post-Program remedies also contained a separate provision immunizing manufacturers from almost all strict liability claims, thus creating a dual requirement for defective design liability—avoidability and wrongful conduct.[131] Similarly, in the Senate, the Committee on Labor and Human Resources considered an amendment to the bill that would have offered manufacturers full immunity from civil suit where they produced the drug in compliance with FDA requirements.[132] Both immunity provisions were ultimately excluded from the final bill. That both House and Senate committees considered and rejected provisions that would have substantially limited the scope of design

[128] National Childhood Vaccine-Injury Compensation Act, H.R. 5810, 98th Cong. §§ 2101(a)–(b), 2101(d)(1)–(2) (1984).

[129] National Childhood Vaccine Injury Compensation Act of 1986, H.R. 5184, 99th Cong. § 2111(a)(1)–(2) (1986).

[130] H.R. 5184 § 2122(b). The only material difference between § 2122(b) of H.R. 5184 and § 22(b) of the Vaccine Act was that § 2122(b) did not create a presumption of proper warning where the manufacturer complied with regulatory requirements. Id.

[131] Id. § 2122(c). The two exceptions were for claims alleging (a) breach of express manufacturer warranty and (b) material deviations from the manufacturer's design specifications or performance standards. Id. at § 2122(c)(2)(A)–(B). The provision would seem to have required a showing of negligence for all claims except those alleging breach of express warranty and defective manufacture. This language posed a bar that extended beyond that created by the relevant part of § 22(b). While the requirement of fault stiffened the burden for would-be plaintiffs, it did not moot the language of § 22(b) altogether: in the absence of a safer feasible alternative design, the "that were unavoidable" clause would disallow defective design liability even if a jury found negligent design.

[132] See National Childhood Vaccine Injury Compensation Act of 1985: Hearing on S. 827 Before the S. Comm. on Labor and Human Resources, 99th Cong. 14–16 (1985) (statement of Martin H. Smith, M.D., President, Am. Acad. of Pediatrics) (describing and expressing support for amendment proposed by Sen. Christopher Dodd of Connecticut, which would have granted immunity to manufacturers if the "vaccine were tested, manufactured, distributed, and labeled in accordance with Food and Drug Administration requirements").

defect claims suggests that Congress did not intend to bar all such claims with the language that it did adopt.[133]

Moreover, there is good reason to believe that participants in the lawmaking process did not think that the "unavoidable" language barred all design defect claims. At hearing, the American Academy of Pediatrics ("AAP"), cited as having co-written the original version of the legislation,[134] stated its position that the provision, when combined with the section barring strict liability claims, attempted to strike a balance by holding manufacturers responsible for "injuries caused by actual negligence" but granting them relief from suits for "genuinely unavoidable injuries."[135] Nevertheless, AAP expressed concern that Section 2122 would allow "understandably sympathetic courts and juries . . . to find ways to compensate victims of adverse reactions to childhood vaccines" even in the absence of fault—an indication that AAP did not believe that the language would serve as a bar to all design defect claims.[136] Vaccine manufacturers also interpreted Section 2122(b) as failing to offer protection from design defect tort claims. The president of manufacturer Lederle Laboratories indicated his company's position that H.R. 5184 left "the tort option open and unlimited in all cases in which a jury might choose to characterize a manufacturer's con-

[133] This conclusion is weakened by the fact that the rejected immunity provisions would have barred claims other than design claims, so it could plausibly be argued that they were not intended to have any effect on design defect liability. The rejected House proposal would have also barred failure-to-warn claims in the absence of negligence, and the rejected Senate proposal would have given manufacturers a regulatory compliance defense for all possible tort claims. But the proposals do suggest that when Congress intended to impose sweeping limitations on state law claims, it did so with stronger and clearer language than that employed in § 22(b). Because that stronger language is absent from the Act as passed, the language ultimately adopted should not be read to do the same amount of work as—or more work than—the rejected proposals.

[134] See Chris Collins & John Hanchette, Writers of Compensation Bills Switch Public and Private Roles, *in* The Vaccine Machine 22, 22 (1984). According to Collins and Hanchette, the 1984 version of the bill was co-written by Stephan E. Lawton, a lobbyist for AAP, and Jeffrey H. Schwartz, the leader of a parental advocacy group. Id.

[135] Vaccine Injury Compensation: Hearing on H.R. 1780, H.R. 4777, and H.R. 5184 Before the Subcomm. on Health and the Environment of the H. Comm. on Energy and Commerce, 99th Cong. 132 (1986) (statement of Martin H. Smith, M.D., President, Am. Acad. of Pediatrics).

[136] Id. at 134. AAP's discussion of recovery due to "adverse reactions" suggests that it was most concerned about injuries that occurred even though the vaccine was properly prepared. See id.

duct as 'wrongful'"; by way of example, he suggested a future design defect claim in which a jury decided, on scant evidence, that there was in fact a feasible safer alternative.[137] Similarly, vaccine maker Merck & Co. proposed that the bill be modified to grant manufacturers a regulatory compliance defense against tort claims.[138] Industry stakeholders thus did not believe that Section 2122 of H.R. 5184, with its even stronger preemptive provisions than ultimately adopted (requiring avoidability and wrongful conduct), completely barred design defect claims.

Courts, including the Third Circuit in *Bruesewitz II*, have pointed to the report of the House Committee on Energy and Commerce that accompanied the Vaccine Act to the House floor[139] as evidence that Congress intended to preempt all state law design defect claims.[140] The first passage from the report that the courts cite states that the committee intended in Section 22(b) to apply the principle of Comment k of Section 402A of the Second Restatement of Torts to vaccines covered by the Vaccine Act.[141] As I explain in the next Section, this statement alone does nothing to resolve the disagreement over the proper interpretation of the principle.[142] The second passage that the courts cite, however, seems more clearly to indicate an intent to bar most design defect claims. It states that if would-be plaintiffs "cannot demonstrate under applicable law either that a vaccine was improperly prepared or that it was accompanied by improper directions or inadequate

[137] Id. at 237–38 (statement of Robert B. Johnson, President, Lederle Labs. Div., Am. Cyanamid Co.). Johnson referred to the bill's inability to eliminate tort claims where juries find that "the vaccines [manufacturers] sell are not as good as some alternative product, even though our vaccines have been approved by the Government as safe and effective." Id. at 238.

[138] Id. at 229 (statement of John E. Lyons, Executive Vice President, Merck & Co., Inc.).

[139] H.R. Rep. No. 99-908, pt. 1, at 26 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6367.

[140] See *Bruesewitz II*, 561 F.3d 233, 250–51 (3d Cir. 2009); Bruesewitz v. Wyeth, Inc., 508 F. Supp. 2d 430, 442, 445 (E.D. Pa. 2007); Sykes v. Glaxo-SmithKline, 484 F. Supp. 2d 289, 300 (E.D. Pa. 2007); Blackmon v. Am. Home Prods. Corp., 328 F. Supp. 2d 659, 664–65 (S.D. Tex. 2004); Militrano v. Lederle Labs., 810 N.Y.S.2d 506, 508 (N.Y. App. Div. 2006); Wright v. Aventis Pasteur, Inc., No. 3861, 2008 WL 4144386 (Pa. Ct. Com. Pl. Aug. 27, 2008).

[141] H.R. Rep. No. 99-908, pt. 1, at 25–26 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6366–67.

[142] See infra Section IV.B.

warnings [they] should pursue recompense in the compensation system, not the tort system."[143] In *Ferrari*, the Georgia Supreme Court noted the committee's use of the optional "should" instead of "must," and the preceding sentence discussing the Program's status as an "appealing alternative," rather than a mandatory one, to the tort system.[144] While this parsing perhaps weakens the force of the majority interpretation, it nevertheless seems more plausible to read the sentence to evince some intent to foreclose liability for claims other than for defects in preparation, directions, and warnings.[145]

The more significant problem for proponents of the full preemption reading is that this single sentence in the House committee report is the only place in the legislative history where Congress manifests such an intent. As discussed earlier in this Section, neither Congress nor stakeholders appeared to believe, during the drafting process, that Section 22(b) as enacted would have such an effect.[146] After the Vaccine Act cleared the House committee, there were further indications that Congress did not believe that Section 22(b) barred all such claims. In a statement made upon presenting the bill to the full House for a vote, the Act's chief sponsor, Representative Henry Waxman of California, stated unequivocally that civil claims alleging that vaccines were "inadequately researched"—a claim that would be barred under the full preemption reading—would be preserved under Section 22(b).[147] Moreover, the

[143] H.R. Rep. No. 99-908, pt. 1, at 26 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6367.

[144] *Ferrari II*, 668 S.E.2d 236, 240–41 (Ga. 2008).

[145] If the committee had really wanted to demonstrate the optional nature of the advice to go through the program where there was no defect in preparation or warnings, the committee could have said "may" instead of "should." Alternatively, while in the course of discussing the claims alleging improper preparation and improper directions and warnings that § 22(b) implicitly recognizes, the report could also have recognized claims where injury was otherwise avoidable.

[146] See supra notes 134–145 and accompanying text.

[147] 132 Cong. Rec. 30,760 (1986). Representative Waxman gave the same example in an op-ed piece published a week earlier in The Washington Post. See Henry A. Waxman, When a Vaccine Injures a Child: A No-Fault Way to Compensate, Wash. Post, Oct. 9, 1986, at A27. A claim of "inadequate research" most likely falls into the category of defective design. It suggests a claim that exists even though the vaccine was prepared in accordance with design specifications and contained directions and warnings that accord with FDA requirements, because research into the vaccine's possible designs did not adequately consider avoidable safety risks. See generally An-

following year, the same committee that had voted the Vaccine Act to the House floor clarified its intentions with regard to Comment k. In the course of commenting on a bill (ultimately enacted into law) authorizing appropriations for the payment of Program awards, it made clear that "the codification of Comment (k) [in the Vaccine Act] was not intended to decide as a matter of law the circumstances in which a vaccine should be deemed unavoidably unsafe."[148] While subsequent legislative history is normally regarded with some skepticism,[149] here it came just one year after the enactment of the original bill; it accompanied an appropriations bill necessary for the Vaccine Act to take effect; and it came from the

notation, Burden of Proving Feasibility of Alternative Safe Design in Products Liability Action Based on Defective Design, 78 A.L.R.4th 154, 13 (Supp. 2009) (noting that breach of manufacturer's duty to expertly "test, inspect, research, and experiment" is evidence of existence of safer feasible alternative); Kristin Cordier Karnezis, Annotation, Products Liability: Modern Cases Determining Whether Product is Defectively Designed, 96 A.L.R.3d 22, 35 (2009). An inadequate research claim could plausibly fall into the category of failure-to-warn—but such a claim would clearly be barred by the regulatory compliance defense provision for failure-to-warn claims under § 22(b).

[148] H.R. Rep. No. 100-391, at 691 (1987), *reprinted in* 1987 U.S.C.C.A.N. 2313-1, 2313-365. The report continued: "The Committee stresses that there should be no misunderstanding that the Act undertook to decide as a matter of law whether vaccines were unavoidably unsafe or not. This question is left to the courts to determine in accordance with applicable law." Id. The report also noted that the committee had considered, and rejected, an amendment to the Vaccine Act to shield a manufacturer from liability for failure to "develop [a] safer vaccine." Id. The Georgia Supreme Court considered the language of the 1987 report in deciding *Ferrari II*. 668 S.E.2d at 241. In *Bruesewitz II*, however, the Third Circuit declined to accord any weight to the 1987 report because it apparently believed that the comments came not from the House Energy and Commerce Committee, which had jurisdiction over the Vaccine Act, but from the House Budget Committee, which did not. *Bruesewitz II*, 561 F.3d 233, 250 (3d Cir. 2009). Indeed, as the Third Circuit notes, the comments were part of a Budget Committee report on the Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203 (1987). Id. at 249; H. R. Rep. No. 100-391, at 1 (1987), *reprinted in* 1987 U.S.C.C.A.N. 2313-1, 2313-2. But the comments in question were within a title containing official recommendations reported from the Committee on Energy and Commerce, and accompanied by an official letter of transmittal from that committee's chairman, Representative John D. Dingell of Michigan. H.R. Rep. No. 100-391, at 377–79 (1987), *reprinted in* 1987 U.S.C.C.A.N. 2313-1, 2313-197 to 2313-199. The *Bruesewitz* court apparently failed to notice this important fact.

[149] See District of Columbia v. Heller, 128 S. Ct. 2783, 2837 n.28 (2008); Doe v. Chao, 540 U.S. 614, 626–27 (2004).

same committee that had sent the original act to the House floor. Thus, it may be entitled to some weight.[150]

Considered as a whole, the legislative history of the Vaccine Act offers substantial support for the reading disfavoring categorical preemption of design defect claims. At the same time, one sentence of the House committee report provides the sole support for the reading favoring full preemption of design defect claims. From the perspective of the proponents of full preemption, then, the history is at best inconclusive. Considering the statutory language and the contradictory nature of the legislative history, a single sentence from a committee report cannot be sufficient to justify the adoption of a less plausible reading of a statute.[151]

B. Implications of Comment K

However unclear the legislative history may be as to the intended scope of Section 22(b), the legislative history is clear that Congress intended to incorporate into Section 22(b) the principle of Comment k of Section 402A of the Second Restatement of Torts—whatever that principle may be.[152] Thus, the "full preemption" position may be salvageable if it can be clearly ascertained

[150] The Supreme Court has given weight to subsequent history when it concerns a bill, ultimately enacted, that is closely related to the original law that is the subject of the dispute. See Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 492 (2001) (Breyer, J., concurring); FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 137–39 (2000).

[151] See Riegel v. Medtronic, Inc., 128 S. Ct. 999, 1009 (2008) ("The operation of a law enacted by Congress need not be seconded by a committee report on pain of judicial nullification."); see also Exxon Mobil Corp. v. Allapattah Servs., Inc., 545 U.S. 546, 567–71 (2005); Burlington N. R.R. Co. v. Okla. Tax Comm'n, 481 U.S. 454, 461 (1987). In *Exxon Mobil*, 545 U.S. at 567–68, a House committee report indicated that the statute in question, 28 U.S.C. § 1367, was not intended to modify the requirement, established in *Zahn v. International Paper Company*, 414 U.S. 291, 301 (1973), that each plaintiff in a diversity suit must individually satisfy the amount-in-controversy requirement of the statute creating diversity jurisdiction, 28 U.S.C. § 1332. Noting language in a working paper by a subcommittee of the Federal Court Study Committee suggesting that § 1367 might overrule *Zahn*, the Court found that, taken as a whole, the legislative history of § 1367 was "far murkier than selective quotation from the House Report would suggest." Id. at 569–70. It declined to give weight to the House report because it did not "accord[] with the best reading of the statute's text." Id. at 571. The situation here is quite analogous.

[152] See H.R. Rep. No. 100-391, at 691 (1987), *reprinted in* 1987 U.S.C.C.A.N. 2313-1, 2313-365; H.R. Rep. No. 99-908, pt. 1, at 25–26 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6366–67.

that by invoking Comment k, Congress intended to bar all design defect claims. An examination of the language and history of Comment k, the majority approach in applying the comment, and the manner in which Section 22(b) incorporates it all suggest, however, that Congress probably intended to implement a case-by-case factual determination of the avoidability of injuries rather than a blanket bar on design defect claims.

Neither the language nor the history of Comment k resolves the question of whether courts applying it should adopt the categorical or case-by-case approach. The comment speaks of products that, "in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use."[153] It notes that such products are "especially common in the field of drugs."[154] The comment states that such unavoidably unsafe products, when "properly prepared and accompanied by proper directions and warning," are not defective.[155] Yet except to require proper preparation, directions, and warnings, and to examine the product's safety in the context of the "present state of knowledge," the comment does not explain how courts should go about determining when products are unavoidably unsafe. What little indication the comment does provide suggests that the determination was not meant to be made across classes of products.[156] This interpretation is consistent with Comment k's drafting history, which shows that the comment was adopted as a half-measure when a stronger proposal to exempt all prescription drugs from Section 402A liability failed to pass.[157]

[153] Restatement (Second) of Torts § 402A cmt. k (1965).

[154] Id.

[155] Id. (internal punctuation omitted).

[156] The language that such products are "especially common in the field of drugs" is some indication that the drafters of Comment k intended for at least a product-by-product approach, not a fully categorical approach. Likewise, the language concerning proper preparation, directions, and warnings can also be read to require a case-by-case determination of the defense's applicability.

[157] For a history of Comment k's drafting, see Joseph A. Page, Generic Product Risks: The Case Against Comment k and for Strict Tort Liability, 58 N.Y.U. L. Rev. 853, 864–72 (1983). According to Page, upon the failure of the drafting committee to reach a consensus on prescription drug exemption from inherent risk liability, what resulted was a comment that "failed to delineate in any meaningful way either the breadth of its coverage or its purpose." Id. at 866.

The longstanding majority approach is to analyze Comment k's applicability on a case-by-case basis. Courts that have adopted Comment k consider, as questions of fact,

> (1) whether the product could have been designed in a safer manner, (2) whether a safer alternative product could have been available to accomplish the same intended purpose as the product in question, and (3) whether the benefits of the product outweigh the interest in promoting enhanced accountability on the part of the manufacturer.[158]

The majority of courts conduct this analysis for prescription drugs, despite Comment k's reference to drugs as a class which contains "especially common" examples of unavoidably unsafe products for which there should be no liability for injuries resulting from "inherent" risks.[159] Absent indication to the contrary, Con-

[158] Am. L. Prods. Liab. 3d § 17:36 (1987). That section also notes: "Comment k is not intended to provide all ethical drugs with blanket immunity from strict liability design defect claims, but rather courts must decide the applicability of the doctrine on a case-by-case basis after considering evidence related to the various factors set forth in Comment k." Id.

[159] Restatement (Second) of Torts § 402A cmt. k (1965); see Joanne Rhoton Galbreath, Annotation, Products Liability: What is an "Unavoidably Unsafe" Product, 70 A.L.R. 4th 16, 41–47 (1989); Am. L. Prods. Liab. 3d § 17:47 (1987) ("Most courts have stated that there is no justification for giving all prescription drug manufacturers blanket immunity from strict liability under Comment k, and that whether a particular drug is unavoidably unsafe should be determined on a case-by-case basis."). The Georgia Supreme Court found similarly in *Ferrari II*: "Only a few jurisdictions have held that any prescription drug is deemed unavoidably unsafe and, thus, that strict liability for defective design is barred." 668 S.E.2d 236, 239 (Ga. 2008). A minority of courts has interpreted Comment k to offer blanket immunity from strict liability claims for prescription drug makers. See, e.g., Hackett v. G.D. Searle & Co., 246 F. Supp. 2d 591, 595 (W.D. Tex. 2002) (applying Texas law); Fellows v. USV Pharm. Corp., 502 F. Supp. 297, 300 (D. Md. 1980) (applying Maryland law); Stone v. Smith, Kline & French Labs., 447 So. 2d 1301, 1304 (Ala. 1984); Brown v. Superior Court, 751 P.2d 470, 476–77 (Cal. 1988); Grundberg v. Upjohn Co., 813 P.2d 89, 95 (Utah 1991). It is important to note that many of these minority states, including California and Texas, did not adopt a blanket immunity rule for prescription drugs until after enactment of the Vaccine Act. Thus, that subsequent adoption of a broader reading of Comment k could not have informed § 22(b)'s drafters' understanding of Comment k. Other courts that have spoken on the issue have adopted the case-by-case approach to applying Comment k. See, e.g., Brochu v. Ortho Pharm. Corp., 642 F.2d 652, 657 (1st Cir. 1981) (applying New Hampshire law); Singer v. Sterling Drug, Inc., 461 F.2d 288, 290–91 (7th Cir. 1972) (applying Indiana law); Amore v. G.D. Searle & Co., 748 F. Supp. 845, 853–54 (S.D. Fla. 1990) (applying Florida law); Kociemba v. G.D. Searle & Co., 680 F. Supp. 1293, 1301 (D. Minn. 1988) (applying Minnesota law); Graham v.

gress presumptively legislates against the background of law in existence at the time.[160] The majority interpretation in effect at the time of Section 22(b)'s drafting was that Comment k called for a case-by-case analysis of inherent risks in defective design actions.[161] Unless Congress has expressly manifested a contrary intent, Congress's adoption of Comment k indicates an intention to incorporate that dominant understanding.[162]

Congress has not spoken directly to the contrary in the Vaccine Act. In fact, as discussed earlier in this Note, the language of Section 22(b) and the purpose and structure of the Act suggest strongly that Congress intended to adopt the majority interpretation of Comment k.[163] The conditional nature of the statutory language is particularly notable: it bars claims if the injury resulted from side effects that were unavoidable, suggesting that—despite proper preparation, directions, and warnings—claims are permitted if the injury resulted from side effects that were avoidable.[164] Thus, far from saving the analysis of the courts that found full preemption, the language, history, and prevailing interpretation of Comment k all suggest that Section 22(b) requires a case-by-case analysis of avoidability in actions alleging defective design.

Wyeth Labs., 666 F. Supp. 1483, 1497 (D. Kan. 1987) (applying Kansas law); Bryant v. Hoffman-LaRoche, Inc., 585 S.E.2d 723, 728 (Ga. Ct. App. 2003); Toner v. Lederle Labs., 732 P.2d 297, 306 (Idaho 1987); Pollard v. Ashby, 793 S.W.2d 394, 400 (Mo. Ct. App. 1990); Freeman v. Hoffman-La Roche, Inc., 618 N.W.2d 827, 840 (Neb. 2000); Feldman v. Lederle Labs., 479 A.2d 374, 383 (N.J. 1984); White v. Wyeth Labs., 533 N.E.2d 748, 752 (Ohio 1988); Senn v. Merrell-Dow Pharms., 751 P.2d 215, 218 n.4 (Or. 1988); Castrignano v. E.R. Squibb & Sons, 546 A.2d 775, 781 (R.I. 1988).

[160] See Nat'l Archives & Records Admin. v. Favish, 541 U.S. 157, 168–69 (2004) (assuming that Congress legislated with understanding of background common law norm of allowing families control over images of deceased kin in enacting the Freedom of Information Act); Meyer v. Holley, 537 U.S. 280, 285 (2003) (construing implied federal housing discrimination cause of action to include vicarious liability claim because of assumption that Congress creates tort actions "against a legal background of ordinary tort-related . . . rules and consequently intends its legislation to incorporate those rules").

[161] See cases cited, supra note 159.

[162] See cases cited, supra note 159; see also United States v. Texas, 507 U.S. 529, 534 (1993) ("In order to abrogate a common-law principle, the statute must speak directly to the question addressed by the common law." (internal quotation marks omitted)).

[163] See sources cited, supra notes 93–102 and accompanying text.

[164] 42 U.S.C. § 300aa-22(b)(1) (2006); see also *Ferrari II*, 668 S.E.2d at 240 (Ga. 2008).

CONCLUSION

I have argued that the Supreme Court should not read the Vaccine Act to preempt all state law claims alleging defective design. The language of the relevant provision of the Act would have to be read in a strained manner to have such broad preemptive effect. Canons of statutory interpretation do not allow such a reading. This is particularly true in the realm of express products liability preemption, in which the Supreme Court has robustly applied the plain meaning rule and the presumption against preemption to avoid reliance on legislative history or other extrinsic interpretive aids. However, even if courts do look to the legislative history and the applicable background tort law to resolve the dispute about the meaning of Section 22(b), neither appears to support the case for full preemption. Specifically, neither the legislative history nor the background tort law support the broader interpretation as conclusively as would be required to overcome the presumption that a more plausible reading of the statute is the one that Congress intended—particularly when that reading disfavors preemption.

It is no coincidence that the Vaccine Act was in force for seventeen years before courts were asked to decide whether the Act barred design defect claims. The Vaccine Act's opt-out model largely has been successful at reducing the number of civil claims alleging injuries resulting from receipt of vaccines.[165] Clarifying that design defect claims are not completely preempted is unlikely to change the Vaccine Act's success rate: petitioners who prevail in the Program will still feel compelled to take the bird in hand rather

[165] See Daniel A. Cantor, Comment, Striking a Balance Between Product Availability and Product Safety: Lessons From the Vaccine Act, 44 Am. U. L. Rev. 1853, 1859–60 (1995) (noting difficulties plaintiffs face in proving design defects in state law actions and arguing that the Program offers an attractive alternative); Derry Ridgway, No-Fault Vaccine Insurance: Lessons from the National Vaccine Injury Compensation Program, 24 J. Health Pol. Pol'y & L. 59, 78–79 (1999) (concluding that the Program has been effective at incentivizing would-be plaintiffs—and their lawyers—to accept Vaccine Court judgments rather than risk losing in civil court). But see Katherine E. Strong, Proving Causation Under the Vaccine Injury Act: A New Approach For a New Day, 75 Geo. Wash. L. Rev. 426, 446–58 (2007) (arguing that the preponderance standard imposed on Program petitioners is too strict and advocating an easier benefit-of-the-doubt standard to help the Program achieve its goals of keeping claims out of the tort system).

than reject judgment and try their luck in the tort system.[166] Meanwhile, those who are denied recovery in the no-fault Program are highly unlikely to have any greater luck under state law. And Program attorneys, whose fees are paid by the government when they make a prima facie case in Vaccine Court,[167] will still have little incentive to encourage petitioners to file suit under state law.[168]

That more thimerosal-related tort suits are likely to be filed in the months or years to come does not prove that the Vaccine Act is broken. While the special masters have made efforts to interpret their powers creatively in an attempt to accommodate autism claimants,[169] the Program was simply not designed to address the massive scale of the autism litigation.[170] But there is no reason to believe that this will become the norm.[171] The sheer scope of the public health crisis that autism presents has led to the birth of a cottage industry of lawyers, "experts," journalists, and celebrities who stand to benefit, in some way, from the promotion of the

[166] Virtually all petitioners who receive a favorable judgment in the Program elect to accept that judgment rather than reject it and file civil suit. See Office of Management and Budget, Detailed Information on the Vaccine Injury Compensation Program Assessment (2005), available at http://www.whitehouse.gov/omb/expectmore/detail/10003807.2005.html (showing that, in 2004, not a single petitioner rejected a favorable Program judgment and pursued a civil remedy, and further showing comparable data for prior years).

[167] 42 U.S.C. § 300aa-15(e) (2006).

[168] See Ridgway, supra note 165, at 78 (suggesting that Program payment of attorney fees while petition is pending in Vaccine Court gives attorneys little incentive to convince petitioners to file civil suit against manufacturers).

[169] See Shemin, supra note 1, at 482–90. The Vaccine Act does not contemplate the self-styled "omnibus proceeding" that the special masters designed to consolidate autism claims into a series of test cases. Shemin argues that the special masters have interpreted their powers a little *too* creatively, leading to concerns that trial courts may not recognize participation in the Omnibus Autism Proceeding as constituting the requisite exhaustion of the Vaccine Act remedy. Id. at 491–99.

[170] See id. at 512 (noting that the Vaccine Court's eight special masters "may be ill-equipped to process the remaining 4900 autism claims in a timely fashion").

[171] Nonautism Program petition volume has remained remarkably stable since 1992. Except for 1999, in which 410 nonautism petitions were filed, nonautism petition volume has fluctuated between 84 and 242 per year, with 163 filed in 2008, the most recent year for which data have been finalized. See Health Resources and Services Administration, U.S. Department of Health and Human Services, National Vaccine Injury Compensation Program: Statistics Report (Oct. 20, 2009), available at http://www.hrsa.gov/Vaccinecompensation/Docs/StatisticsReport.pdf.

thimerosal-autism link.[172] This public and private pressure has distorted the normal incentive structure that has led post-Program petitioners not to file suit against manufacturers in the overwhelming majority of instances. There will probably be more civil claims against vaccine manufacturers related to thimerosal and autism once the Omnibus Autism Proceedings conclude, but there is no reason to believe that this will become a trend that affects nonthimerosal vaccine litigation.

Nor should concerns about the forthcoming wave of thimerosal litigation itself lead courts to find design defect claims to be preempted. Plaintiffs in those cases are unlikely to succeed, but not because Congress meant to prevent them from seeking redress in civil courts once the Vaccine Act failed to provide a remedy. Rather, even if they can show that there was a feasible alternative design that did not include thimerosal for the purposes of proving avoidability, their claims will probably still fail because they will have trouble presenting a credible scientific theory of causation. Early results demonstrate the substantiality of this hurdle for plaintiffs.[173] If Congress decides in the future to shield manufacturers from liability for injuries, avoidable or not, resulting from receipt of vaccines prepared in accordance with FDA-approved designs, it knows how to do so. That, however, is not the balance that Congress contemplated in the Vaccine Act.

[172] See Begley, supra note 28, at 45–46; sources cited, supra note 4 and accompanying text.

[173] Defendant-manufacturers have already had success, in early thimerosal cases, with the argument that the plaintiffs' expert witnesses and scientific theory are not credible. Three federal district courts applying the rule of *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993), and one state court applying *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), denied plaintiffs the ability to present their theory of causation because of scientific implausibility and, accordingly, dismissed the actions before trial. See Redfoot v. B.F. Ascher & Co., 2007 WL 1593239, at *18–19 (N.D. Cal. June 1, 2007); Doe v. Ortho-Clinical Diagnostics, 440 F. Supp. 2d 465, 475–76, 478–79 (M.D.N.C. 2006); Easter v. Aventis Pasteur, Inc., 358 F. Supp. 2d 574 (E.D. Tex. 2005) ; Blackwell v. Sigma Aldrich, Inc., No. 24-C-04-004829, at 23 (Baltimore, Md., City Cir. Ct. Dec. 21, 2007).