J. E01004/10

2011 PA Super 9

JACQUELINE WRIGHT and HOWARD WRIGHT, parents and natural guardians of JARED WRIGHT, a minor child and in their own right,	:	IN THE SUPERIOR COURT OF PENNSYLVANIA
Appellants	:	
v.	:	
AVENTIS PASTEUR, INC., MERCK & CO., INC., AMERICAN HOME PRODUCTS D/B/A WYETH, WYETH LABORATORIES, WYETH-AYERST, WYETH-AYERST LABORATORIES, WYETH LEDERLE, WYETH LEDERLE VACCINES, and LEDERLE LABORATORIES C/O CT CORPORATION SYSTEMS,	:	
Appellees	:	No. 336 EDA 2008

Appeal from the Order entered December 31, 2007
in the Court of Common Pleas of Philadelphia County, Civil Division,
at No(s): No. 003861
May Term 2003

BEFORE: FORD ELLIOT, P.J., STEVENS, GANTMAN, PANELLA, DONOHUE, SHOGAN, ALLEN, LAZARUS, and MUNDY, J.J.

OPINION BY MUNDY, J.: Filed: January 11, 2011

Appellants, Jacqueline and Howard Wright in their own right and as parents and natural guardians of Jared Wright, a minor child, appeal from the trial court's order granting summary judgment in favor of Appellees, Aventis Pasteur, Inc., Merck & Co. Inc., and Wyeth (hereinafter "Vaccine Defendants"). For the reasons that follow, we reverse the order in part, affirm the order in part, and remand for proceedings consistent with this opinion.

We summarize the relevant facts and lengthy procedural history as follows. Minor Appellant, Jared Wright, was born on July 8, 1997. Less than one month after his birth, on July 31, 1997, Minor Appellant received his first vaccine that contained the preservative thimerosal, a hepatitis B vaccine manufactured by Merck. Over the course of the next fifteen months, Minor Appellant was injected with multiple vaccines containing thimerosal.[1] By October 27, 1998, Minor Appellant received his purported sixteenth and final vaccine containing thimerosal.

Thimerosal contains ethyl mercury. Prior to 1998, thimerosal was used prevalently in Food and Drug Administration ("FDA") approved formulas of certain childhood vaccines. In 1998, however, the FDA recommended that manufacturers remove thimerosal from vaccines given to infants and children. Because of the particular toxicity of mercury, the FDA recommends limited human exposure to mercury and warns that such exposure may be harmful to the developing nervous systems of young children and unborn fetuses. While the scientific community continues to debate the link between exposure to ethyl mercury and neurological and neurodevelopmental disorders, the National Institutes of Health ("NIH") and other organizations have conducted studies that suggest a connection between toxins such as ethyl mercury and damage to developing brains.

[1] Specifically, Appellants claim that Minor Appellant was injected with sixteen vaccines containing thimerosal, including: two haemophilus influenza type b vaccines, a diptheria, tetanus, and pertussis vaccine, a diphtheria, two tetanus and acellular pertussis vaccines, and two hepatitis B vaccines. Appellants' Substitute Brief on Rehearing *En Banc* at 18.

See H.R. REP. 110-231 at 137-138. Therefore, since 2001, the FDA has not licensed any new vaccines for children that contain thimerosal as a preservative.[2] Also since 2001, vaccines that the Center for Disease Control ("CDC") routinely recommends for children under the age of six have either been free of thimerosal or contained only trace amounts of the preservative. Multi-dose formulations of influenza vaccine are the only exceptions where thimerosal continues to appear in more sizeable amounts in vaccines that may be routinely administered to children.

In 2001, pursuant to the requirements of the National Vaccine Injury Compensation Program ("VICP"), Minor Appellant filed a petition against the Secretary of Health and Human Services ("HHS") in the Court of Federal Claims alleging vaccine-related injuries. The National Childhood Vaccine Injury Act of 1986 ("Vaccine Act"), 42 U.S.C.A. § 300aa-1 *et seq.*, created a no-fault compensation system as a statutory remedy for children suffering from vaccine-related injuries. Under the VICP, injured vaccine recipients may recover damages without showing "causation of injury and without a demonstration that a manufacturer was negligent or that a vaccine was defective." H.R. REP. No. 99-908 at 12-13, 1986 U.S.C.C.A.N. 6344, 6353. The VICP entertains two distinct types of claims, table claims and causation-in-fact claims. For table claims, the Vaccine Act does not require claimants

[2] Center for Disease Control, ***Questions and Answers about Thimerosal***, available at www.cdc.gov/h1n1flu/vaccination/thimerosal_qa.htm (last visited on June 7, 2010).

to prove causation. Rather, the Act affords claimants a presumption of causation if claimants are able to demonstrate that they received a vaccination listed in the Vaccine Table and suffered certain symptoms within a specified period of time. ***See*** 42 U.S.C.A. §§ 300aa-11(c)(1)(C)(ii)(I), 300aa-14. For an injury that does not appear on the Vaccine Table, claimants need to prove causation-in-fact. ***See*** 42 U.S.C.A. §§ 300aa-11(c)(1)(C)(ii)(I), 300aa-13(a)(1)(A). Minor Appellant's claim was not covered under any of the enumerated bases listed on the Vaccine Table. ***See*** 42 C.F.R. § 100.3(a). Pursuant to his statutory rights, Minor Appellant withdrew his petition on December 23, 2002 and filed suit against Vaccine Defendants in Pennsylvania State Court. ***See*** 42 U.S.C.A. §§ 300aa-11(a)(2)(A)(ii), 300aa-16.

Specifically, on May 29, 2003, in their own right and as parents and natural guardians of Minor Appellant, Jacqueline and Howard Wright ("Appellants") instituted a products liability action against the vaccine manufacturers.[3] An amended complaint was filed on August 13, 2003, and a second amended complaint was filed on December 9, 2003.

Appellants contended that their son's "neurological damage, including but not limited to developmental and speech delays" was "a result of the mercury in the thimerosal-containing vaccinations and the measles-mumps-

[3] Originally, Appellants also brought this action against Eli Lilly and Company, Bayer Corporation, Ortho-Clinical Diagnostics, Inc., and Johnson & Johnson Consumer Companies, Inc. The actions against Bayer, Ortho-Clinical, and Johnson & Johnson, however, were voluntarily discontinued whereas the action against Eli Lilly was dismissed by stipulation.

rubella ("MMR") vaccine that Jared Wright received as an infant." Complaint ¶ 23. Specifically, Appellants alleged that their son suffers from either Autism or Pervasive Developmental Disorder–Not Otherwise Specified, which is a condition within Autism Spectrum Disorder. Trial Court Opinion, 8/27/08, at 3. Vaccine Defendants manufactured the thimerosal-containing vaccines, which were administered to Minor Appellant.

In their complaint, Appellants claimed that Vaccine Defendants were negligent for two reasons: (1) for including thimerosal as a preservative in the vaccine designs; and (2) for failing to warn Appellants, the consuming public, and the medical community about the purported hazards stemming from the use of thimerosal.[4] ***See*** Complaint ¶ 25-27, 39. In their answer, Vaccine Defendants denied the material allegations of the Complaint. On July 2, 2007, Vaccine Defendants moved for summary judgment. They argued (1) that the Vaccine Act preempted Appellants' claims and (2) that Appellants failed to overcome the Vaccine Defendants' presumption of proper warnings.[5]

[4] On July 2, 2007, Merck filed a separate motion for summary judgment. Trial Court Opinion, 8/27/08, at 1. In an order entered on December 31, 2007, the trial court granted summary judgment in favor of Merck. No appeal has been taken from this order as to Merck alone, and Merck is not a party to this appeal as to the MMR claim.

[5] The Vaccine Defendants attached affidavits and exhibits to their motions, which showed (1) that the FDA approved and licensed the vaccines at issue, and (2) that FDA-approved package inserts accompanied those vaccines. Moreover, each of the Vaccine Defendants' package inserts expressly stated that the vaccine formula included thimerosal and that thimerosal was a mercury derivative; the package inserts also specified the particular concentration of thimerosal present in each vaccine.

On December 31, 2007, the trial court granted Vaccine Defendants' motion for summary judgment. The trial court found that "Plaintiffs' design defect claim and failure to warn claims against the Vaccine Defendants are preempted by the Vaccine Act" and "failed to raise any genuine issues of material fact to overcome the presumptions of proper warnings to which the Vaccine Defendants were entitled to under the Vaccine Act." Trial Court Opinion, 8/27/08, at 1.

Appellants filed a timely appeal on January 29, 2008, and on November 9, 2009, this Court reversed the trial court's order in a memorandum opinion. Subsequently, Appellees sought rehearing *en banc*, which was granted on January 22, 2010.

In their Substituted Brief on Reargument *En Banc*, Appellants raise the following four issues for our review.

> 1. Section 22(b)(1) of the National Childhood Vaccine Injury Act of 1986 ["Vaccine Act" or "the Act"] expressly preempts certain design defect claims against vaccine manufacturers "if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." 42 U.S.C. § 300aa-22(b)(1).
>
>   The question involved here then is whether the trial court made an error of law and/or abused its discretion when it held Section 22(b)(1) preempts ***all*** vaccine design defect claims, whether the side effects of a vaccine or its preservative were unavoidable or not?
>
> 2. Whether the trial court made an error of law and/or abused its discretion when it granted summary

> judgment against the Wrights on Appellees' express preemption defense under Section 22(b)(1) and dismissed their design defect claims without requiring that Appellees first show that the side effects of the preservative thimerosal were unavoidable?
>
> 3. Section 22(b)(2) of the Act applies a rebuttable presumption that vaccine warnings are adequate only "for purposes of Section 22(b)(1)," which addresses design defect claims.
>
> The question involved here is whether the trial court made an error of law and/or abused its discretion when it applied Section 22(b)(2)'s rebuttable presumption of adequate warnings to Appellants' failure-to-warn claims, which are viable and independent, and held that Appellants were required to, but had not, overcome that presumption?
>
> 4. Whether the trial court made an error of law and/or abused its discretion when it failed to apply Section 22(e)'s express preemption clause to preempt expressly Pennsylvania law that Appellees contend bars Appellants' failure-to-warn claims?

Appellants' Substituted Brief on Reargument *En Banc* at 3-4 (emphasis in original).

When reviewing a trial court's grant of summary judgment, our standard and scope of review is as follows.

> Our review on an appeal from the grant of a motion for summary judgment is well-settled. A reviewing court may disturb the order of the trial court only where it is established that the court committed an error of law or abused its discretion. As with all questions of law, our review is plenary.
>
> In evaluating the trial court's decision to enter summary judgment, we focus on the legal standard articulated in the summary judgment rule. The rule

> states that where there is no genuine issue of material fact and the moving party is entitled to relief as a matter of law, summary judgment may be entered. Where the non-moving party bears the burden of proof on an issue, he may not merely rely on his pleadings or answers in order to survive summary judgment. Failure of a non-moving party to adduce sufficient evidence on an issue essential to his case and on which it bears the burden of proof establishes the entitlement of the moving party to judgment as a matter of law. Lastly, we will view the record in the light most favorable to the non-moving party, and all doubts as to the existence of a genuine issue of material fact must be resolved against the moving party.

Evans v. Sodexho, 946 A.2d 733, 737-738 (Pa. Super. 2008), *quoting* ***Murphy v. Duquesne Univ. of the Holy Ghost***, 777 A.2d 418, 429 (Pa. 2001) (internal citations and quotation marks omitted). Here, the question of whether the Vaccine Act preempts Appellants' state law tort claims is a question of law. Because "we are not bound by the trial court's conclusions of law, but may reach our own conclusions," we shall conduct our review *de novo*. ***Rohrer v. Pope***, 918 A.2d 122, 126 (Pa. Super. 2007) (internal citations omitted).

I.

We begin our review by considering Appellants' two design defect issues in conjunction.[6] Taken together, these issues raise two separate but

[6] Appellants suggest that § 300aa-22(b)(1) treats thimerosal claims differently from other design defect claims. Appellants' Substitute Brief on Rehearing *En Banc* at 58-62. Based on our analysis, we find this argument unpersuasive. Congress used broad language to draft § 300aa-22(b)(1), applying the subsection to civil claims where the injury or death is

interrelated questions: (1) whether § 300aa-22(b)(1) of the Vaccine Act preempts all design defect claims against vaccine manufacturers; or (2) whether § 300aa-22(b)(1) requires a preliminary showing that the side effects, which caused the vaccine-related injury, were in fact unavoidable. Both questions address the preemptive scope of § 300aa-22(b)(1) of the Vaccine Act. While Appellants acknowledge that § 300aa-22(b)(1) preempts some design defect claims leveled against vaccine manufacturers, they contend that Congress never intended to preempt all such claims with the enactment of the Vaccine Act. The Vaccine Defendants, however, argue that § 300aa-22(b)(1) spreads its preemptive net more broadly, limiting prospective plaintiffs' tort remedies to claims of either improper manufacturing or improper packaging. In order to review these issues, we must begin our discussion by setting forth (1) the doctrine of preemption and (2) the current landscape under the Vaccine Act.

A. The Preemption Doctrine

The United States Supreme Court "ha[s] long recognized that state laws that conflict with federal law are without effect." ***Altria Group Inc. v. Good***, 129 S.Ct. 538, 543 (2008) (citation and internal quotation omitted); ***see*** U.S. CONST. art. VI, cl. 2. While conflicts between federal and state law

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"vaccine-related[.]" 42 U.S.C.A. § 300aa-22(b)(1); ***See also Cheskiewicz v. Aventis***

are not easy to discern, federal law may supersede state law in three delineated fashions: express preemption, implied conflict preemption, and field preemption. ***See Hillsborough County, Fla., v. Automated Med. Labs., Inc.***, 471 U.S. 707, 713 (1985); ***see also Dooner v. DiDonato***, 971 A.2d 1187 (Pa. 2009).

First, Congress may enact a statute that expressly preempts state law through the language contained therein. ***Lorillard Tobacco Co. v. Reilly***, 533 U.S. 525, 541 (2001). Our review of an express preemption clause "must in the first instance focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent." ***Sprietsma v. Mercury Marine***, 537 U.S. 51, 62-63 (2002) (citation and quotation omitted). Though the statutory language may clearly indicate that Congress intended to preempt "at least some state law," we must "identify the domain expressly pre-empted by that language." ***Medtronic, Inc. v. Lohr***, 518 U.S. 470, 484 (1996) (internal quotation omitted). "Our inquiry into the scope of a statute's pre-emptive effect is guided by the rule that '[t]he purpose of Congress is the ultimate touchstone in every pre-emption case.'" ***Altria Group***, ***supra*** at 543, *quoting* ***Medtronic, Inc.***, ***supra*** at 485. Moreover, "[i]f a federal law contains an express pre-emption clause, it does not immediately end the inquiry because the question of the substance

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Pasteur, Inc., 843 A.2d 1258, 1265-1266 (Pa. Super. 2004).

and scope of Congress' displacement of state law still remains." ***Altria Group, Inc.***, ***supra*** at 543.

Second, implied conflict preemption may arise in either of two separate fashions: (1) when a private party cannot adhere simultaneously to both state and federal requirements; or (2) when state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." ***Hines v. Davidowitz***, 312 U.S. 52, 67 (1941); ***English v. Gen. Elec. Co.***, 496 U.S. 72, 78-79 (1990). "[I]mplied preemption may exist even in the face of an express preemption clause." ***Bruesewitz v. Wyeth Inc.***, 561 F.3d 233, 239 (3d Cir. 2009), *cert. granted* 130 S.Ct. 1734 (2010). While an express preemption clause suggests that Congress never intended the scope of preemption to reach beyond the plain language of that clause, the existence of an express preemption clause "does not […] entirely foreclose[] any possibility of implied pre-emption." ***Freightliner Corp. v. Myrick***, 514 U.S. 280, 288 (1995).

Third, field preemption arises when Congress creates a comprehensive scheme of federal regulation that occupies a specified field and leaves "no room for [supplementary] state regulation" within that field. ***United States v. Locke***, 529 U.S. 89, 111 (2000); ***see also Lorillard Tobacco Co.***, ***supra*** at 541. Moreover, we also may infer the existence of field preemption when Congress legislates within a field wherein "the federal

interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject." ***English***, ***supra*** at 79.

While preemption jurisprudence delineates the different ways in which federal law may supersede state law, we begin any consideration of these issues by applying the presumption against preemption. ***See Cipollone v. Liggett Group, Inc.***, 505 U.S. 504, 516 (1992). We must "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." ***Medtronic, Inc.***, ***supra*** at 485 (internal citation and quotation omitted); ***Bates v. Dow Agrosciences***, 544 U.S. 431, 449 (2005). Importantly, this assumption also applies to questions concerning the scope of a federal statute's preemptive reach. ***Medtronic, Inc.***, ***supra*** at 485; ***see also Cipollone***, ***supra*** at 518, 523 (using the presumption against preemption to support a narrow interpretation of an express preemption command).

Moreover, when confronted with two equally "plausible" interpretations of the same statutory text, courts "have a duty to accept the reading that disfavors pre-emption." ***Bates***, ***supra*** at 449. This duty applies "even in the event of an express preemption clause." ***Bruesewitz***, ***supra*** at 240, *citing* ***Riegel v. Medtronic Inc.***, 552 U.S. 312, 334-335 (2008). The presumption against preemption, however, may be overcome. ***See Crosby v. Nat'l Foreign Trade Council***, 530 U.S. 363, 374 n. 8 (2000) (noting

that the presumption against preemption may be overcome where state law "presents a sufficient obstacle to the full accomplishment of Congress's objectives under the federal [enactment] to find it preempted").

B. The Vaccine Act – Generally

In the wake of concerns stemming from "a small but significant number" of accounts reporting that children had been gravely injured by routine childhood vaccinations, Congress enacted the Vaccine Act in 1986. ***Blackmon v. Am. Home Prods. Corp.***, 328 F.Supp.2d 659, 663-666 (S.D. Tex. 2004). By passing the Act, Congress sought "to prevent [vaccine] manufacturers from leaving vaccine production or significantly increasing their prices" as well as to "compensate victims of vaccine-related injuries quickly." ***Sykes v. Glaxo-SmithKline***, 484 F.Supp.2d 289, 297 (E.D. Pa. 2007).

To deal with these dilemmas, the Vaccine Act established the National Vaccine Program that provides those suffering from vaccine-related injuries with an alternative statutory method of recovery. ***Id.***; ***see also*** H.R. REP. 99-908 at 26 (1986). Under the Act, injured parties must initially pursue their claim by filing a petition with the Vaccine Court as part of a no-fault compensation system. 42 U.S.C.A. §§ 300aa-11(a)(2)(A), 300aa-13(a)(1)(A, B). The Act does not require the petitioner to prove fault or causation so long as the petitioner can demonstrate that he received a

particular vaccine and subsequently suffered certain enumerated symptoms within a defined period. 42 U.S.C.A. §§ 300aa-13, 300aa-14. This system was designed to be less burdensome and to produce faster results than the traditional civil tort system. ***Sykes***, ***supra*** at 297. Nevertheless, if the injured party is dissatisfied with the judgment of the Vaccine Court, the injured party may decide to pursue a traditional tort action. ***Id.***; ***see*** 42 U.S.C.A. § 300aa-11. The Act, however, imposes certain limitations upon an injured party's subsequent civil tort suit. ***See*** 42 U.S.C.A. §§ 300aa-11(a)(2)(A)(ii), 300aa-16, 300aa-21 (referring to when a petitioner either rejects the judgment of the Vaccine Court or withdraws his petition from the Vaccine Court).

The Act also modifies state tort law, thereby preempting it in at least certain instances. ***See*** 42 U.S.C.A. § 300aa-22. "Part B of the Vaccine Act establishes the circumstances under which individuals who have rejected the judgment of the Vaccine Court may subsequently file suit in state or federal court." ***Bruesewitz***, ***supra*** at 241. Section 300aa-22 provides as follows.

> **(a)** General rule
>
> Except as provided in subsections (b), (c), and (e) of this section State law shall apply to a civil action brought for damages for a vaccine-related injury or death.
>
> **(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.A. § 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).

(c) Direct warnings

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, solely due to the manufacturer's failure to provide direct warnings to the injured party (or the injured party's legal representative) of the potential dangers resulting from the administration of the vaccine manufactured by the manufacturer.

(d) Construction

> The standards of responsibility prescribed by this section are not to be construed as authorizing a person who brought a civil action for damages against a vaccine manufacturer for a vaccine-related injury or death in which damages were denied or which was dismissed with prejudice to bring a new civil action against such manufacturer for such injury or death.
>
> **(e)** Preemption
>
> No State may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this part.

42 U.S.C.A. § 300aa-22.

The Third Circuit Court of Appeals correctly observed that "Section 22(a) of the Vaccine Act establishes a general rule permitting states to regulate vaccines subject to several exceptions set forth in subsections (b), (c), and (e)." ***Bruesewitz***, ***supra*** at 242. Specifically, as the plain language of the statute indicates, the Vaccine Act "displace[s] state law in several enumerated instances, including as provided for in subsection [22(b)]," which immunizes vaccine manufacturers from liability "for claims arising from 'unavoidable' injuries and deaths related to vaccine administration, thereby prohibiting states from regulating in this area." ***Id.*** at 243. Thus, § 300aa-22(a) and § 300aa-22(b)(1) of the Vaccine Act contain express preemption clauses. Nevertheless, while the "language conveys a clear intent to override state law civil action claims in particular,

defined circumstances," ***Bruesewitz***, ***supra*** at 242, the scope of Congress' intent to override such claims remains unresolved.

The preemptive scope of § 300aa-22(b)(1) is an issue of first impression for this Court, and few other courts have had the opportunity to consider the question involved. Recently, in ***Bruesewitz***, ***supra***[7] at 251, the Third Circuit held that § 300aa-22(b)(1) preempts all design defect claims without a case-by-case inquiry to determine whether the injury-causing vaccine side effects were unavoidable. The Third Circuit determined that preempting all design defect claims represented Congress' clear and manifest intent regarding § 300aa-22(b)(1). ***Id.*** at 247-249, 251. In ***Ferrari v. American Home Products Corp.***, 668 S.E.2d 236, 242 (Ga. 2008), however, the Georgia Supreme Court considered the same issue but reached the opposite conclusion. Rather than holding that Congress intended § 300aa-22(b)(1) to serve as an outright bar to all design defect claims, the ***Ferrari*** Court determined that Congress expressed a clear and manifest intent to distinguish between avoidable and unavoidable side effects. ***Id.*** at 242. As such, the ***Ferrari*** Court held that the statute requires courts to draw this distinction on a case-by-case basis. ***Id.*** at 242-243. Upon reviewing the court decisions that have previously considered the preemptive scope of § 300aa-22(b)(1), we conclude that those decisions

[7] As reflected in the full citation, the United States Supreme Court has granted certiorari in ***Bruesewitz***, ***supra***. Thus, we are mindful that the Supreme Court may address the issue before us.

have tended to either overemphasize or underemphasize critical components involved in the analysis. We note that none of these decisions is binding upon this Court and, while we are free to find the precedent of the Third Circuit or any other federal appeals court or district court persuasive, Pennsylvania appellate courts "are not obligated to follow the decisions of the Third Circuit on issues of federal law." ***Hall v. Pennsylvania Bd. of Probation and Parole***, 851 A.2d 859, 865 (Pa. 2004). Although the opinions of these courts have been informative, we determine that none entirely encapsulates the intent of Congress. As such, the reasoning of this Court does not solely rely upon any of these.

C. The Preemptive Scope of § 300aa-22(b)(1)

In the case before us, Appellants claim that the trial court erred by determining that the Vaccine Act preempts all design defect claims regardless of whether or not the claims arise from avoidable side effects. Appellants' Substitute Brief on Rehearing *En Banc* at 23. According to Appellants, not only does the Vaccine Act lack any express language banning all design defect claims, but § 300aa-22(b)(1) explicitly makes vaccine manufacturers' immunity from tort liability conditional. ***Id.*** at 30. Appellants contend that vaccine manufacturers only enjoy immunity when injuries result from side effects that were unavoidable. ***Id.*** Thus, by inference, the Act does not preempt such claims arising from injuries caused

by avoidable side effects. Moreover, if Congress had sought to preempt all design defect claims, Appellants reason, it would have included clearer language and omitted any conditional words or phrases. ***Id.*** at 30-31. The legislative history, Appellants argue, is ambiguous and lacks the necessary clear and manifest intent to preempt. ***Id.*** at 36. Therefore, based upon the statute's structure, language, and legislative history, Appellants maintain that the Act defers to civil courts to determine unavoidability on a case-by-case basis. ***Id.*** at 28.

Conversely, in urging this Court to accept the trial court's grant of summary judgment, Vaccine Defendants allege that the language of § 300aa-22(b)(1) deems routinely administered childhood vaccinations "unavoidably unsafe" and, thus, categorically preempts all design defect claims arising from vaccine-related injuries. Substitute Brief of Vaccine Defendants on Reargument *En Banc* at 19, 24. The Vaccine Defendants argue that forcing courts to conduct case-by-case inquiries would frustrate the purpose and structure of the statute and fail to give effect to the clear wording of § 300aa-22(b)(1) as well as the legislative history. ***Id.*** at 19, 27-29. Specifically, the Vaccine Defendants contend that the statutory structure and the legislative history indicate that Congress sought to eliminate the vast majority of costly civil suits, only allowing claims for defective manufacturing and failure-to-warn. ***Id.*** at 31. Vaccine Defendants, therefore, claim that construing the Act to preempt all design

defect claims is the only reading that bestows meaning upon every word in the statute and effectuates Congressional intent. ***Id.*** at 19.

All parties agree that the Vaccine Act preempts certain claims. The point in controversy concerns the scope and reach of § 300aa-22(b)(1)'s express preemption provision. We must determine whether the Act provides vaccine manufacturers with blanket immunity against all design defect claims or whether the Act conditions the immunity of vaccine manufacturers upon a case-by-case inquiry to discern if the pertinent vaccine-related injury resulted from unavoidable side effects. If the statute authorizes courts to judge the unavoidability of injury-causing side effects, then § 300aa-22(b)(1) only preempts some design defect claims. Those design defect claims that arise from avoidable side effects, according to a court's independent inquiry, would not be subject to preemption. However, if the Vaccine Act bars courts from conducting such case-by-case inquiries, then § 300aa-22(b)(1) would preempt all design defect claims without independent consideration as to whether the injury-causing side effects were unavoidable. Essentially, any vaccine-related injury would be considered unavoidable so long as the vaccine complied with all pertinent regulations and was manufactured properly. Therefore, the issues raised by Appellants require this Court to "identify the domain expressly preempted by the language" of § 300aa-22(b)(1) of the Vaccine Act. ***Medtronic Inc.***, ***supra*** at 484.

We note initially that, under the Vaccine Act, Congress addressed the safety of vaccines, which is indisputably an issue of health and safety. "Throughout our history the several States have exercised their police powers to protect the health and safety of their citizens. Because these are 'primarily, and historically, [...] matter[s] of local concern,' the 'States traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons[.]'" ***Medtronic Inc.***, ***supra*** at 475 (citations omitted). Because the Vaccine Act legislates in an "area[] of traditional state regulation," this Court shall "assume that [the Vaccine Act] has not supplanted state law unless Congress has made such an intention 'clear and manifest.'" ***Bates***, ***supra*** at 449.

As we begin our analysis aimed at defining the scope of § 300aa-22(b)(1), the Vaccine Act's express preemption clause, we reiterate that "[t]he purpose of Congress is the ultimate touchstone" of our inquiry. ***Altria Group, Inc.***, ***supra*** at 543 (internal quotation and citation omitted); ***see also Cipollone***, ***supra*** at 516. We must discern:

> Congress' intent, of course, primarily [] from the language of the pre-emption statute and the statutory framework surrounding it. Also relevant, however, is the structure and purpose of the statute as a whole, as revealed not only in the text, but through the reviewing court's reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law.

Medtronic, Inc., ***supra*** at 486 (internal quotation and citations omitted). Moreover, "we must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy." ***Bruesewitz***, ***supra*** at 243, *quoting* ***Pilot Life Ins. Co. v. Dedeaux***, 481 U.S. 41, 51 (1987). The presumption against preemption does not prevent us from considering a statute's purpose, structure, and regulatory scheme. ***See Cipollone***, ***supra*** at 518-519.

A "well-established principl[e] of statutory interpretation" proclaims that, if possible, statutes should normally be construed "in a manner that gives effect to all of their provisions." ***United States ex rel. Eisenstein v. City of New York***, 129 S.Ct. 2230, 2234-2235 (2009); ***see also Mac's Shell Service, Inc. v. Shell Oil Products Co. LLC***, 130 S.Ct. 1251, 1261 (2010). Nevertheless, as with any cannon of statutory construction, this principle may be countered "by some maxim pointing in a different direction." ***Circuit City Stores, Inc. v. Adam****s*, 532 U.S. 105, 115 (2001). Though courts are to give effect to each word included within the statutory text, courts are also permitted to reject words "as surplusage if inadvertently inserted or if repugnant to the rest of the statute[.]" ***Chickasaw Nation v. U.S.***, 534 U.S. 84, 85 (2001) (internal citation and quotation omitted). Additionally, "a single word must not be read in isolation but instead defined by reference to its statutory context." ***Ali v. Federal Bureau of Prisons***, 552 U.S. 214, 234 (2008). "[T]he meaning of statutory language, plain or

not, depends on context[.]" ***King v. St. Vincent's Hospital****,* 502 U.S. 215, 221 (1991).

Furthermore, we may "consider legislative history to resolve ambiguity in the scope of an express preemption provision." ***Bruesewitz***, ***supra*** at 244; ***see also BedRoc Ltd., LLC v. United States***, 541 U.S. 176, 187 n.8 (2004). In order to define the scope and reach of an express preemption clause, the United States Supreme Court has considered previous incarnations of the relevant provision as well as "the circumstances in which the current [statutory] language was adopted." ***Lorillard Tobacco Co.***, ***supra*** at 542-544 (citing reports from the United States Surgeon General, the House of Representatives, and Senate floor debates). "Legislative history, of course, refers to the pre-enactment statements of those who drafted or voted for a law; it is considered persuasive by some, not because they reflect the general understanding of the disputed terms, but because the legislators who heard or read those statements presumably voted with that understanding." ***District of Columbia v. Heller***, 128 S.Ct. 2783, 2805 (2008).

As a tool of statutory interpretation, however, we note that legislative history may paint a "murky, ambiguous, and contradictory" portrait of the events that transpired prior to the enactment of the legislation. ***Exxon Mobile Corp. v. Allapattah Servs., Inc.***, 545 U.S. 546, 568 (2005). In particular, the consideration of legislative history "may give unrepresentative

committee members—or, worse yet, unelected staffers and lobbyists—both the power and the incentive to attempt strategic manipulations of legislative history to secure results they were unable to achieve through the statutory text." ***Id.*** Therefore, in utilizing legislative history as an interpretative tool, we must proceed with caution.

Thus, to resolve the issue before us, we begin by examining the language of the Vaccine Act. Then, if necessary, we may consider the Act's structure and purpose as well as its legislative history to assist us in discerning the intent of Congress.

1. Language

We first consider the plain language of the statute. In pertinent part, the relevant subsection states the following.

> (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.

42 U.S.C.A. § 300aa-22(b)(1). This subsection immunizes vaccine manufacturers from all forms of civil liability stemming from vaccine-related injuries unless the side effects that caused those injuries could have been avoided. By conditioning this protection upon the unavoidability of the vaccine's side effects, Congress drew a distinction between claims arising

from avoidable side effects and those arising from unavoidable side effects. The Act, however, offers no categorical definition of the term "unavoidable." According to ***Merriam Webster's Collegiate Dictionary*** 1360 (11th ed. 2003), "unavoidable" means "not avoidable" or "inevitable." In looking solely at the text of the subsection, however, this definition proves unenlightening. Although the definition conveys the meaning of the word "unavoidable," it fails to provide the tools needed to determine the types of side effects that the statute categorizes as "unavoidable."

Furthermore, the text surrounding the word "unavoidable" contains grammatical ambiguity that further contributes to the imprecise meaning of the provision. Section 300aa-22(b)(1) contains two subordinate clauses that qualify the grant of immunity to vaccine manufacturers. The first clause (hereinafter "if" clause) conditions immunity upon "if the injury or death resulted from side effects that were unavoidable[.]" 42 U.S.C.A. § 300aa-22(b)(1). Following immediately thereafter, the second clause (hereinafter "even though" clause) qualifies the initial clause by providing; "even though the vaccine was properly prepared and was accompanied by proper directions and warnings." ***Id.*** Together, these two clauses fail to provide a context that would allow us to give clear meaning to the word "unavoidable." As a result, the language of § 300aa-22(b)(1) leads us to two plausible interpretations of this express preemption provision.

First, the "even though" clause may indicate, as Vaccine Defendants contend, that the Act deems side effects to be avoidable **only** if those side effects could have been avoided through either proper manufacturing or proper warnings. ***See*** Substitute Brief of Vaccine Defendants on Reargument *En Banc* at 20-21. Neither party disputes that either defective warnings or defective manufacturing would render vaccine side effects avoidable. The Act never immunizes manufacturers from liability for claims of defective manufacturing or defective warnings where the manufacturer failed to comply with all applicable regulations.[8] Likewise, the Act expressly allows warning claims despite regulatory compliance if plaintiffs successfully rebut the statutory presumption of proper warnings.[9] ***See*** 42 U.S.C.A. § 300aa-22(b)(2).

We, however, are not persuaded that § 300aa-22(b)(1) limits vaccine manufacturers' civil liability exposure to warning claims and manufacturing claims. The language of the provision never evidences an intent to define

[8] Section 300aa-22(a) only preempts existing state law as indicated under subsections (b), (c), and (e). Except in instances when those three subsections are applicable, existing state law governs. None of the pertinent subsections bars claims where vaccine manufacturers have either failed to produce a vaccine in accordance with the FDA-approved specifications or failed to appropriately label the vaccine. Therefore, in such situations, state law applies normally without regard to the Vaccine Act.

[9] Section 300aa-22(b)(2) gives plaintiffs the opportunity to overcome the presumption of proper warnings despite vaccine manufacturers' regulatory compliance either (1) by demonstrating that manufacturers intentionally and wrongfully withheld information from regulatory agencies either during or after the vaccine approval process; or (2) by presenting clear and convincing evidence that the vaccine manufacturer failed to exercise due care despite regulatory compliance. 42 U.S.C.A. § 300aa-22(b)(2).

avoidable side effects solely in terms of these two legal theories. Based upon the express language of the statute, we recognize either defective warnings or defective manufacturing may serve as the basis for alleging that certain vaccine side effects were avoidable. From this fact alone, however, we cannot draw the conclusion that improper warnings and improper manufacturing are the **only** bases upon which to categorize side effects as avoidable.

If Congress intended to limit plaintiffs' available claims to defective manufacturing and failure-to-warn, then it could have accomplished that goal more easily by excluding the "if" clause. Eliminating any possibility of defective design claims would give the term "unavoidable" little meaning apart from regulatory compliance. Without defective design claims, § 300aa-22(b)(1) would expose vaccine manufacturers to liability in **only** three instances: (1) where vaccine manufacturers fail to comply with applicable regulations regarding directions and warnings; (2) where vaccine manufacturers fail to produce vaccines in accordance with the approved manufacturing specifications; and (3) where plaintiffs overcome the presumption of proper warnings under § 300aa-22(b)(2). As such, the "if" clause virtually collapses underneath the weight of the "even though" clause. Because Congress' inclusion of the "if" clause "is evidence of its intent," we must strive never to create an "amputated version" of the Vaccine Act with our construction. ***Bates***, ***supra*** at 449; ***see also United States ex rel.***

Eisenstein, ***supra*** at 2234-2235; ***Mac's Shell Service, Inc***, ***surpa*** at 1261. We emphasize that the statutory context connotes the significance of the "if" clause; thus, we observe that it cannot be disregarded as surplus language. ***See Chickasaw Nation***, ***supra*** at 85.

The second plausible interpretation of § 300aa-22(b)(1) supports Appellants' position. Whereas the former interpretation essentially makes the "if" clause superfluous language, this interpretation minimizes the significance of the "even though" clause. We observe, however, that § 300aa-22(b)(1) uses the conjunction "even though" to introduce a clause that concedes a point. This conjunction "make[s] light of the concession" by "indicat[ing] that what follows may be true but that it has no bearing on the point at issue." Bergen Evans & Cornelia Evans, ***Dictionary of Contemporary American Usage*** 511 (9th ed. 1957). In proper grammatical context, this interpretation reads the language of the "even though" clause as merely presuming that unavoidable side effects are unavoidable despite the existence of proper warnings and proper manufacturing. Rather than defining the term "unavoidable," the conjunction "even though" signals that unavoidability and proper warnings and manufacturing are two distinct concepts. While this reading concedes that some avoidable side effects may be avoided by proper warnings or proper manufacturing, it rejects the notion that either proper warnings or proper manufacturing are sufficient to cure all avoidable side effects. By

never identifying specifically what renders side effects "unavoidable" in the first instance, we recognize this reading strongly implies that Congress intended courts to determine the nature of vaccine side effects on a case-by-case basis.

After careful review of § 300aa-22(b)(1)'s language, however, we conclude that the statutory text fails to resolve the question regarding the subsection's preemptive scope. Neither interpretation of § 300aa-22(b)(1) directly conflicts with, nor garners strong support from, the express language of the Vaccine Act. We recognize that Vaccine Defendants offer a plausible reading of § 300aa-22(b)(1). Their interpretation, however, is no more plausible than the alternative interpretation supporting Appellants' argument. Nonetheless, as using the conjunction "even though" signifies intent to be dismissive of the clause that follows, we note that the Appellants' interpretation seems to place the appropriate weight upon each of § 300aa-22(b)(1)'s two respective clauses. Conversely, Vaccine Defendants draw a conclusion that appears unwarranted based upon the statutory text because they conflate two possible bases for avoidable side effects with the only possible bases for avoidable side effects. Our review of the statutory text has yet to reveal an explicit delineation of every possible cause of avoidable vaccine side effects under the Vaccine Act. We, nevertheless, conclude that each construction struggles to bestow meaning

upon every part of § 300aa-22(b)(1). ***See United States ex rel. Eisenstein***, ***supra*** at 2234-2235; ***Mac's Shell Service, Inc***, ***surpa*** 1261.

As such, the language of § 300aa-22(b)(1) alone fails to reveal the clear and manifest intent of Congress. Rather than solely focusing our attention upon "a single sentence or member of a sentence" and consequently reading other words out of the statute, we must "look to the provisions of the whole law, and to its object and policy" in order to construe the Act and to identify the scope of preemption. ***See Dedeaux***, ***supra*** at 51.

2. Structure and Purpose

Next, we turn our attention to the Act's structure and purpose in order to discern Congressional intent. Our review only reinforces the ambiguity discovered during our discussion of the Act's plain language.

Looking at § 300aa-22 as a whole, we observe that "Subsection 22(a) displaces state law only as defined in Subsections (b), (c), and (e)." ***Bruesewitz***, ***supra*** at 245. We also note that Subsection (e) preempts state law that would ban civil actions which are otherwise "not barred by [the Vaccine Act]." ***Id.***, *quoting* 42 U.S.C.A. § 300aa-22(e). When read in conjunction with Subsections (b) and (c), we recognize that the language of Subsection (e) implies "that other parts of § 300aa-22 are designed to not only limit liability but bar some claims entirely." ***Id.*** Conducting a similar

examination in ***Bruesewitz***, ***supra*** at 245-247, the Third Circuit Court of Appeals used these structural observations to conclude that the structure and purpose of the Vaccine Act clearly indicate Congress' intent for Subsections (b) and (c) to serve as "an outright bar to [at least] some claims." ***Id.*** In particular, the Third Circuit determined that § 300aa-22(b) evidences a clear and manifest intent to "exempt manufacturers from liability for some design defect claims" without resorting to a case-by-case determination.[10] ***Id.*** at 245-246. The Third Circuit reasoned that determining whether side effects are "unavoidable" on a case-by-case basis "is contrary to the structure of the [Vaccine] Act because [such an inquiry] does not bar any design defect claims" as "every design defect claim [would be] subject to evaluation by a court." ***Id.*** at 246.

In the matter before us, when it examined the Act as a whole, the trial court found that a case-by-case inquiry to determine whether side effects were "unavoidable" would defeat the Vaccine Act's purpose. Trial Court Opinion, 8/27/08, at 16. The trial court reasoned that the Act was designed to protect vaccine manufacturers against "the instability and uncertainty of the childhood vaccine market," which arose from "the risk of tort litigation."

[10] According to the Third Circuit, the structure of the Act represented a clear and manifest intent to preempt all strict liability design defect claims without a case-by-case consideration. Regarding negligent design defect claims, however, the Third Circuit found that neither the Act's structure nor its purpose provided clear guidance. From our review, we see no basis upon which to draw this distinction between claims. A distinction between negligent and strict liability design defect claims appears nowhere in the statute's language, nor is the distinction manifest in its structure or purpose.

Id. Therefore, the trial court concluded that a case-by-case inquiry would once again thrust upon manufacturers the unpredictability and expense of tort litigation, consequently enticing manufacturers to leave the market. ***Id.*** at 17; ***see also Sykes***, ***supra*** at 301-302. In support of its finding, the trial court cited the "comprehensive statutory scheme" under which the Vaccine Act operates. Trial Court Opinion, 8/27/08, at 18. Specifically, the trial court found that Congress crafted the structure of this "comprehensive statutory scheme" to eliminate state law tort claims because (1) it creates an alternative statutory remedy for injured parties and (2) it entrusts the safety of vaccines to the FDA approval process. ***Id.***; ***see*** 21 U.S.C.A. §§ 301-393.

As the trial court correctly noted, the Vaccine Act exists within a "comprehensive statutory scheme." Forged by a highly sophisticated set of regulations that are administered by expert agencies and bureaucrats, we further note that this scheme contains numerous mechanisms designed to address issues of vaccine safety. The scheme is premised upon the FDA's oversight and approval of the design and distribution of prescription drugs. ***See*** 21 U.S.C.A. §§ 301-393; 42 U.S.C.A. § 262(a); 21 C.F.R. §§ 601.2, 601.12. In addition, the Vaccine Act specifically charges the Secretary of HHS with "promot[ing] the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on December 22, 1987, and promot[ing] the refinement of such vaccines[.]"

42 U.S.C.A. § 300aa-27(a)(1). The Act also directs the Secretary to "make or assure improvements in, […], the licensing, manufacturing, processing, testing, labeling, warning, […], and research on vaccines, in order to reduce the risks of adverse reactions to vaccines." 42 U.S.C.A. § 300aa-27(a)(2).

In accordance with the trial court's reasoning, the Vaccine Defendants contend that this regulatory structure has "left no role for juries in 50 disparate state tort regimes to second-guess the safety of a vaccine's approved design." Substitute Brief of Vaccine Defendants on Reargument *En Banc* at 30. The Vaccine Defendants further claim that this statutory scheme evidences Congress' intent to completely delegate the issue of vaccine safety to bureaucrats like the Secretary of HHS. ***Id.*** at 29. Although we acknowledge the Vaccine Act's structure may suggest that a case-by-case analysis would "expose manufacturers to inconsistent standards" and "undermine the congressional mandate by replacing the federal agencies' role with state juries[,]" ***Sykes***, ***supra*** at 301-302, we are not persuaded that the Act's structure compels this supposition. Rather, our review has revealed other structural elements included in the Act that favor requiring case-by-case inquiries to determine whether a particular vaccine's side effects are "unavoidable."

We conclude that, although the structure of § 300aa-22 may suggest that Subsection 22(b) stands as "an outright bar to [at least] some claims," ***Bruesewitz***, ***supra*** at 245, the inverse of this proposition is equally true.

First, Subsection 22(e) prevents any state from "establish[ing] or enforce[ing] a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death" so long as the Vaccine Act does not preempt such a suit. 42 U.S.C.A. § 300aa-22(e). While Subsection (e) may imply that the Vaccine Act bars some state tort claims, it expressly preserves other such claims. Subsection 22(e) weakens any argument alleging that Subsection 22(b)(1) entirely preempts all design defect claims because "Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate" the tension between the claims preserved by Subsection 22(e) and federal law. ***Wyeth v. Levine***, 129 S.Ct. 1187, 1200 (2009) (internal quotation and citation omitted). "If Congress thought state-law suits posed an obstacle to its objectives, it surely would [not] have enacted" Subsection 22(e). ***Id.***

Second, the structure of the Act as a whole indicates that some of the claims preserved by Subsection 22(e) are likely design defect claims. For example, after petitioners have exhausted their administrative remedies, the Act separates civil trials concerning vaccine-related injuries or deaths into three distinct stages: liability, general damages, and punitive damages. ***See*** 42 U.S.C.A. § 300aa-23. Section 300aa-23(d) sets forth the rules governing the punitive damage stage of the trial, which necessarily occurs only after liability has been established and general damages have been determined.

Section 300aa-23(d) exempts vaccine manufacturers from being "held liable for punitive damages" if the manufacturer demonstrates that "it complied, in all material respects" with all the applicable requirements of the Public Health Service Act and the Federal Food, Drug and Cosmetic Act pertinent to vaccine safety. ***See*** 42 U.S.C.A. § 300aa-23(d). Specifically, § 300aa-23(d) provides the following:

> **(d)** Punitive damages
>
> > **(1)** If sought by the plaintiff, the third stage of such an action shall be held to determine the amount of punitive damages a vaccine manufacturer found to be liable under section 300aa-22 of this title shall be required to pay.
> >
> > **(2)** If in such an action the manufacturer shows that it complied, in all material respects, with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 et seq.] and this chapter applicable to the vaccine and related to the vaccine injury or death with respect to which the action was brought, the manufacturer shall not be held liable for punitive damages unless the manufacturer engaged in--
> >
> > > **(A)** fraud or intentional and wrongful withholding of information from the Secretary during any phase of a proceeding for approval of the vaccine under section 262 of this title,
> > >
> > > **(B)** intentional and wrongful withholding of information relating to the safety or efficacy of the vaccine after its approval, or
> > >
> > > **(C)** other criminal or illegal activity relating to the safety and effectiveness of vaccines, which activity related to the vaccine-related injury or death for which the civil action was brought.

42 U.S.C.A. § 300aa-23(d). Under § 300aa-23(d), so long as a vaccine manufacturer complies with the regulatory requirements, the statute generally bars punitive damages.[11]

Because punitive damages are determined in the final stage of the trial, after liability has been established, § 300aa-23(d) strongly implies that vaccine defendants may be found liable in the first stage of the trial for reasons other than warning defects or manufacturing defects. As defective design is the only other products liability tort claim, we reason that § 300aa-23(d) denotes that Congress anticipated future plaintiffs would file actions alleging defective design. Section 300aa-23(d) caps punitive damages where a vaccine manufacturer is found liable yet the vaccine was manufactured and labeled in compliance with regulatory specifications. If the statute completely barred all design defect claims, § 300aa-23(d)'s cap on punitive damages would only protect manufacturers found liable for failure-to-warn pursuant to § 300aa-22(b)(2)(B). ***See*** 42 U.S.C.A. § 300aa-22(b)(2)(B) (providing that plaintiffs may overcome a vaccine manufacturer's presumption of proper directions and warnings "by clear and convincing evidence that the manufacturer failed to exercise due care

[11] Where they have complied with the pertinent regulations, vaccine manufacturers may only be held liable for punitive damages if they wrongfully withhold information relevant to vaccine safety or efficacy, either during or after the approval process, or if they engage in other forms of criminal or illegal activity relating to the safety and effectiveness of vaccines. ***See*** 42 U.S.C.A. § 300aa-23(d)(2)(A)-(C). Therefore, aside from overtly illegal activity, punitive damages are essentially only possible in two situations: (1) where plaintiff overcomes the presumption of proper directions and warnings under § 300aa-22(b)(2)(A);

notwithstanding its compliance with [the applicable regulatory scheme]"). No other type of manufacturing defect or warning defect could form the basis for liability. Regulatory compliance rules out a manufacturing defect, and Subsections 22(b) and 22(c) bar nearly all failure to warn claims. ***See*** 42 U.S.C.A. § 300aa-22(b)-(c). Therefore, in addition to claims of defective manufacturing and warning, the text of § 300aa-23(d) suggests that the Act preserves the state tort claim of design defect. Otherwise, the Act would only bar the possibility of punitive damages in a situation that may rarely occur.[12] Thus, when read in light of § 300aa-23(d), it is unlikely § 300aa-22(b)(1) preempts all design defect claims.

In addition, the relationship between Subsections 22(b)(1) and 22(b)(2) detracts further from the contention that the Act bars all design defect claims outright. Subsection 22(b)(2) indicates that all warning claims must satisfy Subsection 22(b)(1) because the presumption of proper warnings under Subsection 22(b)(2) only applies "[f]or purposes of paragraph (1)[.]" 42 U.S.C.A. § 300aa-22(b)(2). Therefore, the Act's

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and (2) where a vaccine defendant simply fails to comply with the pertinent regulatory scheme.

[12] For § 300aa-22(b)(2)(B) to apply, plaintiffs must show by clear and convincing evidence that a vaccine manufacturer "failed to exercise due care" when it did not alert the public of a particular threat presented by the vaccine that does not appear on the approved directions or warnings. ***See*** 42 U.S.C.A. § 300aa-22(b)(2)(B). Nevertheless, this failure to exercise due care cannot rise to an intentional or fraudulent withholding of information either before, during or after the approval process. ***See*** 42 U.S.C.A. § 300aa-23(d)(2)(A)-(B). Thus, despite the language of § 300aa-22(b)(2)(B), the standard may be quite narrow. A vaccine defendant would be required to have sufficient knowledge of the threat to demand action, but the vaccine defendant's failure to disclose such a threat to the pertinent regulatory agencies must fall short of intentional or fraudulent conduct.

structure does not restrict the reach of Subsection 22(b)(1) to design defect claims only. The relationship between these subsections shows that Subsection 22(b)(1) draws a distinction between avoidable and unavoidable vaccine side effects, not between types of products liability claims. Defective manufacturing, defective warnings, or defective design would each render vaccine side effects avoidable. Any other conclusion would lead to an absurd result, wherein the Act's presumption of proper warnings would never apply to claims for failure-to-warn.

Although we recognize that the conditional language of Subsection 22(b)(1) "does not foreclose the preemption of some claims," ***Bruesewitz***, ***supra*** at 246, the structure of Subsections 22(b)(1) and 22(b)(2) would seem to require a case-by-case determination, at least, for warning claims. The Act only allows warning claims so long as the plaintiff overcomes Subsection 22(b)(2)'s presumption of proper warnings. ***See*** 42 U.S.C.A. § 300aa-22(b)(2). To determine whether plaintiffs satisfy this burden, however, courts must conduct an inquiry on a case-by-case basis. As the statute expressly permits case-by-case inquires under Subsection 22(b)(1) for warning claims, we can discern no reason why the Act would treat design defect claims differently or how a case-by-case inquiry of design defect claims would frustrate the purpose of Subsection 22(b)(1), yet the same form of inquiry into warning claims does not have a disruptive effect.

Furthermore, any concern that a case-by-case inquiry would frustrate the Act's purpose of creating a stable and predictable childhood vaccine market is belied by the other meaningful protections that vaccine manufacturers enjoy under the Vaccine Act aside from the express preemption provision in § 300aa-22(b)(1). Though short of "virtually complete immunity from suit[,]" other provisions of the Vaccine Act insulate vaccine manufacturers from the hazards associated with tort litigation. ***See*** Appellants' Substitute Brief on Rehearing *En Banc* at 53. Specifically, the National Vaccine Injury Compensation Program (VICP) and the aforementioned cap on punitive damages are critical components of the Vaccine Act's structure, which is designed to protect the nation's vaccine supply. Inclusion of these two components suggests that Congress intended to remedy the vaccine crisis without virtually exempting vaccine manufacturers from civil liability. Thus, as Appellants maintain, the Act's structure does not indicate that nearly full immunity from tort liability "is the only means to preserve the vaccine supply." ***Id.***

The VICP has been instrumental in tempering large jury verdicts against vaccine manufacturers and, thus, stabilizing the vaccine market.[13] Acting as a prophylactic, the VICP discourages claimants from ever filing civil suits against vaccine manufacturers. The VICP diverts vaccine claims into a

[13] ***See*** Rob Henson, Inoculated Against Recovery: A Comparative Analysis of Vaccine Injury Compensation in the United States and Great Britain, 15 Tulsa J. Comp. & Int'l L. 61, 88 (2007); ***See also*** Derry Ridgway, No-Fault Vaccine Insurance: Lessons from the National Vaccine Injury Compensation Program, 24 J. Health Pol. Pol'y & L. 59, 76 (1999).

no-fault compensation program, requiring claimants to file their claims against the government in the United States Court of Federal Claims. ***See*** 42 U.S.C.A. § 300aa-11(b)(1)(A); 42 U.S.C.A. § 300aa-14(a). Since the program began, over 13,000 petitions have been filed with the VICP and 2,428 claims have been compensated as of April 22, 2010.[14] Because petitioners may not file a civil suit against vaccine manufacturers until they have exhausted their administrative remedies under the VICP, the VICP relieves vaccine manufacturers from dealing with a flood of claims in the civil tort system. ***See*** 42 U.S.C.A. § 300aa-11(a)(2)(A). Moreover, the VICP offers petitioners lessened burdens of proof than they would face in the civil tort system, making the prospect of civil tort litigation far less attractive to many petitioners.[15] Thus, even without barring civil tort claims, "the VICP has succeeded in reducing the number of lawsuits brought under the tort system."[16]

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[14] ***See*** U.S. Department of Health & Human Services, Health Resources and Services Administration, National Vaccine Injury Compensation Program, http://www.hrsa.gov/vaccinecompensation/statistics_report.htm (last visited on April 28, 2010).

[15] Whitney S. Waldenberg and Sarah E. Wallace, When Silence Is Silent: Examining Compensation of Vaccine-Related Injuries When Scientific Evidence of Causation Is Inconclusive, 42 Wake Forest L. Rev. 303, 310 (2007) (observing that by rejecting VICP awards "claimants will not benefit from any of the [Vaccine] Act's lessened burdens of proof and will instead be subject to the more stringent traditional civil standards of causation").

[16] Lainie Rutkow; Brad Maggy; Joanna Zablotsky; and Thomas R. Oliver, Balancing Consumer and Industrial Interests in Public Health: The National Vaccine Injury Compensation Program and Its Influence During the Last Two Decades, 111 Penn St. L. Rev. 681, 718 (2007); ***see also*** Jaclyn Shoshana Levine, The National Vaccine Injury Compensation Program: Can It Still Protect an Essential Technology, 4 B.U. J. Sci. & Tech. L. 9, 12 (1998) (observing that "[o]nly a relatively small number of petitioners to the

In addition, the time limitations on filing claims with the VICP further inhibit the ability of claimants to bring civil actions against vaccine manufacturers. Congress structured the Vaccine Act to impose a three-year statute of limitations on filing claims with the VICP. 42 U.S.C.A. § 300aa-16(a). This statute of limitations makes no allowances for incidents where parents of claimants fail to discover the causal link between the vaccine and the victim's injury until after the limitation period has expired.[17] The limitation period is, in effect, a statute of repose because any failure to comply with its express provision operates as a complete time bar. Thus, the statute of limitations shields the government from potentially unending liability by barring claimants from filing petitions more than three years after the date of the vaccine administration. ***Id.*** With § 300aa-11(a)(2)(B), the Act specifically directs any civil court to dismiss a tort claim regarding vaccine-related injuries filed against a vaccine manufacturer unless the plaintiff exhausted all remedies under the VICP. ***See*** 42 U.S.C.A. § 300aa-11(a)(2)(A)-(B). Consequently, claimants barred from filing with the VICP are also prevented from ever pursuing a civil tort claim. As the three-year limitation period denies claimants the opportunity to seek compensation

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Compensation Program elect to preserve their rights to civil remedies by rejecting VICP awards").

[17] ***See*** Waldenberg, ***supra*** at 310-311.

under the VICP, vaccine manufacturers enjoy yet another structural mechanism that substantially limits their exposure to civil liability.[18]

Our review of the Vaccine Act's structure reveals Congressional intent, in part, focused upon limiting vaccine manufacturers' exposure to civil actions. Passed in response to a volatile vaccine market caused by an inundation of tort claims, the Act created mechanisms like the VICP process designed to divert claims away from the tort system. However, the Act also capped punitive damages, suggesting that Congress anticipated the continued presence of civil litigation against vaccine manufacturers. ***See*** 42 U.S.C.A. § 300aa-23(d). The need for these types of protections would be greatly reduced if the Act outright preempted all design defect claims. Thus, as Subsection 22(e) indicates, Congress recognized the importance of preserving access to the civil tort system despite the need to reduce the number of tort claims. ***See*** 42 U.S.C.A. § 300aa-22(e) (preserving civil actions against vaccine manufacturers for vaccine-related injuries or deaths so long as the Vaccine Act does not bar such action); ***see also*** 42 U.S.C.A. §§ 300aa-11(a)(2)(A)-(B), 300aa-16. As such, we conclude that the Act's entire structure is premised upon reducing civil litigation, not barring it.

Therefore, while § 300aa-22(b)(1) expressly preempts some claims, the Act's structure fails to demonstrate any clear and manifest intent that

[18] ***See*** Henson, ***supra*** at 92; ***see also*** Leonard D. Pertnoy, A Child's View of Recover Under the National Childhood Vaccine Act or "He Who Hesitates is Lost," 59 Mont. L. Rev. 275, 297 (1998).

§ 300aa-22(b)(1) acts as a complete bar to all design defect claims. To the contrary, Congress' explicit preservation of state tort claims under § 300aa-22(e) "is powerful evidence that Congress did not intend FDA [and HHS] oversight to be the exclusive means of ensuring [the] safety and effectiveness" of vaccine designs. ***Levine***, ***supra*** at 1200. Considering the Act's cap on punitive damages as well as the protection vaccine manufacturers glean from the VICP process, we are far from convinced that either the Act's structure or its purpose indicate that courts should deem all vaccine side effects "unavoidable" as a matter of law. Rather, if all design defect claims were simply barred outright, the significance of many of the Act's structural elements would be diminished. The overall structure of the Act is designed to mitigate the continued effect of tort litigation upon vaccine manufacturers and the vaccine supply. As no provision of the Act targets design defects for disparate treatment, we see no reason why design defect claims ought to be treated differently from other claims. Nevertheless, we remain unable to discern the clear and manifest intent of Congress regarding § 300aa-22(b)(1) As such, we now enlist the aid of legislative history to assist us in our search for the Congressional intent underlying § 300aa-22(b)(1).

3. Legislative History

As we begin our consideration of the Vaccine Act's legislative history, we note that "the authoritative source for finding the Legislature's intent lies in the Committee Reports on the bill[.]" ***Garcia v. United States***, 469 U.S. 70, 76 (1984). Committee Reports "represen[t] the considered and collective understanding of those Congressmen involved in drafting and studying proposed legislation." ***Zuber v. Allen***, 396 U.S. 168, 186 (1969). Moreover, the United States Supreme Court has "eschewed reliance on the passing comments of one Member" as well as "casual statements from the floor debates." ***Garcia***, ***supra*** at 76. Courts "should not go beyond Committee [R]eports" because statements made during floor debates are "not always distinguished for candor or accuracy." ***Schwegmann Bros. v. Calvert Distillers Corp.***, 341 U.S. 384, 395-396 (1951) (Jackson, J., concurring). Courts would "substitute [themselves] for the Congress in one of its important functions" by using floor statements "as a basis for making up [their] minds what law Congress intended to enact." ***Id.***

We acknowledge that the parties dispute precisely which Committee Reports constitute the Vaccine Act's legislative history. In 1986, the House Committee on Energy and Commerce issued a report (hereinafter "1986 Report") that reflects the views of the committee that guided the Vaccine Act through the legislative process. The Energy and Commerce Committee published the 1986 Report contemporaneously with the passage of the

legislation. As such, consideration of the 1986 Report is uncontroversial. The parties, however, dispute whether a 1987 report from the House Committee on the Budget (hereinafter "1987 Report") should also be included in the legislative history of the Vaccine Act. The 1987 Report derives from legislation that enacted certain amendments to the Vaccine Act. Specifically, with this 1987 legislation, Congress provided funding for the compensation program created by the Vaccine Act. Because the 1987 Report post-dates the original legislation, the Vaccine Defendants categorize the 1987 Report as subsequent legislative history that "is not entitled to consideration, much less reliance[.]" Substitute Brief of Vaccine Defendants on Reargument *En Banc* at 28. As such, Vaccine Defendants contend that this Court may only consider the 1986 Report. Conversely, Appellants argue that the legislation passed in 1986 would never have gone into effect without the amendments passed in 1987. Appellants' Substitute Brief on Rehearing *En Banc* at 41-42. Thus, according to Appellants, the 1987 Report is a component of the Vaccine Act's authoritative legislative history and should be treated by this Court as such. We shall address the significance of each Committee Report respectively.

The 1986 Report reveals that Congress recognized the various competing interests involved with the issue of childhood vaccinations. The Report observed that vaccines have "been one of the most spectacularly effective public health initiatives this country has ever undertaken" by

preventing numerous deaths and substantially reducing the effects of disease. H.R. REP. 99-908 at 4, 1986 U.S.C.C.A.N. at 6345. Acknowledging that "[t]here is no 'perfect' or reaction-free childhood vaccine on the market," however, the Report conceded that "[a] relatively small number of children who receive immunizations each year have serious reactions to them." ***Id.*** at 6, 1986 U.S.C.C.A.N. at 6347. Nevertheless, the Report notes that for those injured by vaccines "the opportunities for redress and restitution [in the tort system] are limited, time-consuming, expensive, and often unanswered." ***Id.*** Furthermore, the Report warned that the tort claims of this "small but significant number [of children who] have been gravely injured" by vaccines threaten the Nation's vaccine supply. ***Id.*** at 4, 1986 U.S.C.C.A.N. at 6345. According to the Report, the increase in tort litigation against vaccine manufacturers was, at least partly, responsible for the rising vaccine prices, the flight of some manufacturers from the vaccine market, and the decrease in the incidents of immunization. ***Id.*** Thus, these conditions precipitated the Energy and Commerce Committee's reevaluation of federal vaccine regulatory policy. ***Id.*** at 5, 1986 U.S.C.C.A.N. at 6346.

As the Vaccine Act reflects, Congress adopted the position that "it is safer [for children] to take the required [vaccine] shots than to risk the health consequences of contracting the diseases immunizations are designed to prevent." ***Id.*** at 6, 1986 U.S.C.C.A.N. at 6347. The 1986 Report explains

that Congress drafted the Vaccine Act to primarily address "two overriding concerns."

> (a) the inadequacy—from both the perspective of vaccine-injured persons as well as vaccine manufacturers—of the current approach to compensating those who have been damaged by a vaccine; and (b) the instability and unpredictability of the childhood vaccine market.

Id. at 7, 1986 U.S.C.C.A.N. at 6348. The 1986 Report indicates that Congress recognized the need to stabilize the vaccine market by preventing any further withdrawals from other manufacturers because "the withdrawal of even a single manufacturer would present the very real possibility of vaccine shortages, and, in turn, increasing numbers of unimmunized children, and, perhaps, a resurgence of preventable diseases." ***Id.*** According to the Report, vaccine manufacturers feared the time and expense of litigation as well as "the availability of affordable product liability insurance that [] cover[s] losses related to vaccine injury cases." ***Id.*** at 6, 1986 U.S.C.C.A.N. at 6347. Thus, as the Report demonstrates, the Vaccine Act created a statutory compensation program for victims injured by vaccines in order to address the explosion of litigation aimed at vaccine manufacturers. ***Id.*** at 7, 1986 U.S.C.C.A.N. at 6348. In addition to being "fair, simple, and easy to administer," the Report states that "the Committee believe[d] that once this system is in place and manufacturers have a better sense of their potential litigation obligations, a more stable childhood vaccine market will evolve." ***Id.***

Although the Vaccine Act designed this compensation program to reduce the cost and frequency of litigation for vaccine manufacturers, the 1986 Report denotes that Congress never minimized the program's role in compensating victims injured by vaccines. When the compensation program yields an unsatisfactory outcome for a claimant, the Report evidences Congress' intent to preserve a claimant's civil remedies in those rare instances. The Report states, "[i]f, however, after compensation proceedings are complete, a vaccine-injured person elects to reject the system's findings and award and go on to court, he or she is free to do so." ***Id.*** at 12, 1986 U.S.C.C.A.N. at 6353. As the Report details, however, Congress deemed that it "is appropriate in light of the availability of a comprehensive and fair compensation system" to place certain limitations on civil actions against vaccine manufacturers for vaccine-related injuries. ***Id.*** at 25, 1986 U.S.C.C.A.N. at 6367.

In addressing the specific limitations that the Vaccine Act imposes upon tort litigation, the 1986 Report specifically discusses § 300aa-22. According to the 1986 Report, the standards set forth in § 300aa-22 "will [in some cases] be the same or similar to existing State law [but] in others, the standards will change most State laws." ***Id*** at 25, 1986 U.S.C.C.A.N. at 6366. The standards referenced by this Report include the express preemption clause in § 300aa-22(b)(1). Regarding § 300aa-22(b), the Report unequivocally declares that it "sets forth the principle contained in

Comment k of Section 402A of the Restatement of Torts (Second)." ***Id.*** The Report reveals that Congress understood the principle of Comment k to immunize unavoidably unsafe products from tort liability.[19] ***Id.*** at 26, 1986 U.S.C.C.A.N. at 6367. The Report defined unavoidably unsafe products as "those products which in the present state of human skill and knowledge cannot be made safe[.]" ***Id.*** The Report further explained that the Energy and Commerce Committee employed Comment k in drafting the Act because the Committee "intend[ed] that the principle in Comment K regarding

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[19] In Restatement (Second) of Torts § 402A, Comment k provides the following.

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

RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1966).

'unavoidably unsafe' products […] apply to the vaccines covered in the [Vaccine Act] and that such products not be the subject of liability in the tort system." ***Id.***

In a majority of states, we note that Comment k does not outright bar all design defect claims against FDA-approved drugs. As the Third Circuit aptly observed, however, "the current state of affairs with regard to the interpretation of Comment k tells us little about what Congress knew in 1986 when it passed the Vaccine Act." ***Bruesewitz***, ***supra*** at 247, n.9. Moreover, in 1986, there was no consensus on either the proper interpretation of Comment k or the proper policy approach to design defect claims against prescription drug manufacturers. ***Id.*** Therefore, the murky understanding of Comment k in 1986 alone obscures Congressional intent. We cannot conclude that Congress expressed any clear or manifest intent by invoking the principle of Comment k because Congress invoked this principle at a time when there was no consensus regarding its meaning.

By incorporating this principle from Comment k, the 1986 Report indicates that under the Vaccine Act "a vaccine manufacturer should not be liable for injuries or deaths resulting from unavoidable side effects even [though] the vaccine was properly prepared and accompanied by proper directions and warnings." H.R. REP. 99-908 at 25-26, 1986 U.S.C.C.A.N. at 6366-6367. As such, Vaccine Defendants contend that the Act deems all childhood vaccines specified in § 300aa-14 unavoidably unsafe as a matter

of law. Substitute Brief of Vaccine Defendants on Reargument *En Banc* at 27. We, however, discern no such clear and manifest intent from the 1986 Report.

The 1986 Report definitively states that § 300aa-22(b) reflects the principle regarding unavoidably unsafe products found in Comment k. This principle, however, only addresses the tort liability consequences for a product once that product has been determined to be unavoidably unsafe. This principle does not specify how to determine whether a product is unavoidably unsafe in the first instance. Neither party disputes that the Act bars design defect claims against vaccine manufacturers once the vaccine's side effects have been determined to be unavoidably unsafe. The critical question that neither the statutory language nor the 1986 Report directly address is whether the Act considers all vaccines to be unavoidably unsafe as a matter of law. The products that the 1986 Report indicates should "not be the subject of liability in the tort system" are unavoidably unsafe products, not necessarily all vaccines covered by this Act. ***Id.*** at 26, 1986 U.S.C.C.A.N. at 6367. Despite Vaccine Defendants' argument, we have uncovered no incontrovertible evidence from the 1986 Report that Congress ever intended to categorize all vaccines covered by this Act as unavoidably unsafe.[20]

[20] Additionally, we concede there is insufficient basis to determine that "the objectives extolled by the [1986] Report would be undermined if design defect claims were permitted under the [Vaccine Act]." ***Contra Bruesewitz***, ***supra*** at 249. The Act incorporates the principle of Comment k. As such, a case-by-case approach to determine whether a vaccine

Vaccine Defendants point to other language in the 1986 Report, which they argue clarifies Congressional intent and supports their position regarding § 300aa-22(b)(1). Specifically, Vaccine Defendants cite a paragraph in which the Report refers to the difficulties in applying Comment k to the typical vaccine injury case. The Energy and Commerce Committee observed that such cases "almost invariably [concern] a young child, often badly injured or killed, and free from wrongdoing[.]" H.R. REP. 99-908 at 26, 1986 U.S.C.C.A.N. at 6367. As such, the Committee recognized that vaccine injury cases "present the hardest case[s] for the application of Comment K." ***Id.***

> [E]ven if the defendant manufacturer may have made as safe a vaccine as anyone reasonably could expect, a court or jury undoubtedly will find it difficult to rule in favor of the 'innocent' manufacturer if the equally 'innocent' child has to bear the risk of loss with no other possibility of recompense.

Id. According to Vaccine Defendants, this excerpt from the 1986 Report indicates that Congress was apprehensive in allowing a jury to consider

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is unavoidably unsafe does not necessarily frustrate the Act's objectives because a case-by-case approach has not frustrated the purpose of Comment k in a majority of jurisdictions. Although a case-by-case approach would not eliminate civil litigation against vaccine manufacturers, this was never the express intent of Congress. A case-by-case approach, combined with the Act's other protections like the statutory compensation system and the cap on punitive damages, would continue to reduce civil litigation against manufacturers and, thus, add stability and predictability to the childhood vaccine market. ***See*** H.R. REP. 99-908 at 7, 1986 U.S.C.C.A.N. at 6348. While the Act acknowledges that vaccine manufacturers should not be expected to pursue safe alternatives without regard to cost, the 1986 Report states clearly that "maintain[ing] safe and reliable childhood vaccination programs" is of critical importance. ***Id.*** The Act charges HHS with ensuring vaccine safety, but this does not demonstrate Congressional intent to exempt vaccine manufacturers from their responsibility regarding vaccine safety.

questions of vaccine safety. Substitute Brief of Vaccine Defendants on Reargument *En Banc* at 27. Their argument implies Congress feared that juries and courts would simply award child plaintiffs sizeable verdicts rather than apply Comment k in an appropriate fashion. Although we acknowledge that this excerpt may recognize such a fear, our review of the 1986 Report reveals that the Committee included this excerpt for broader reasons than Vaccine Defendants suggest.

The Committee detailed the dilemma associated with Comment k in order to illustrate the difficulties that vaccine plaintiffs face in civil court, not solely to reiterate the vulnerability of vaccine manufacturers. As indicated by the paragraph that immediately follows this discussion, the Committee used Comment k's application to demonstrate the need for victims to have "another, better, alternative" to the civil tort system. H.R. REP. 99-908 at 26, 1986 U.S.C.C.A.N. at 6367. The inadequacy of tort remedies for vaccine victims was one of the principle concerns that spurred Congress to enact the Vaccine Act. Congress recognized that, due to Comment k, civil courts had proven to be inhospitable environments for vaccine plaintiffs. Because Comment k places a high burden upon plaintiffs, the tort system left many victims injured by vaccines uncompensated. Thus, after documenting the hurdles that Comment k imposes upon plaintiffs, the 1986 Report proceeds to state explicitly how the Act's compensation system is designed to create a more suitable forum for vaccine claimants. The Committee highlights that

the compensation program allows victims to recover "even if the manufacturer has made as safe a vaccine as possible[,]" which is a scenario wherein Comment k would bar recovery in civil court. ***Id.*** In addition, Congress emphasizes that petitioners may recover from the compensation program "because they suffered harm from the vaccine—even a 'safe' one—not because they demonstrated wrongdoing on the part of the manufacturer." ***Id.*** Thus, rather than expressing concern over the ramifications of allowing juries to consider questions of vaccine safety, the Report discusses Comment k predominantly to bolster support for the Act's compensation program. The 1986 Report's discussion of Comment k hardly demonstrates clear and manifest intent to bar all design defect claims. To the contrary, the discussion implies that Comment k prevented many plaintiffs from prevailing; yet plaintiffs continued to file suit because no viable alternative to the tort system existed.

Moreover, the 1986 Report **never** stated "in precise and certain terms that its reference to comment k and the language of 22(b) results in immunity for liability for all design defects." ***Contra Bruesewitz***, ***supra*** at 248. The Report advises vaccine claimants:

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

H.R. REP. 99-908 at 26, 1986 U.S.C.C.A.N. at 6367. By specifically using the word "should," the 1986 Report indicates that Congress intended to make a recommendation to potential claimants rather than impose a mandate upon them. Congress created a statutory compensation program as "an appealing alternative to the tort system" for victims injured by vaccines because it believed that the tort system provided an inadequate remedy. This sentence merely reflects Congress' recommendation for claimants to use the compensation system that it explicitly created in order to compensate victims injured by vaccines. From this isolated sentence, we discern no clear or manifest intent to completely foreclose an avenue of recovery for claimants. Rather, the 1986 Report made this recommendation largely because Congress anticipated that claimants would find recompense more easily under the compensation program's reduced burden of proof. Where a vaccine was improperly manufactured or improperly warned, the Report does not recommend that claimants use the compensation program because such claims have better prospects for success in the tort system than design defect claims. By definition, if a product is improperly warned or improperly manufactured, then Comment k cannot apply because such a product cannot be categorized as unavoidably unsafe. Importantly, this recommendation does not intimate that all vaccines are unavoidably unsafe unless improperly warned or improperly manufactured. This recommendation merely acknowledges that, where a vaccine enjoys proper warnings and proper

manufacturing, plaintiffs must show that the vaccine's hazards were avoidable in order to prevail in civil court. As the Vaccine Act created a compensation program intended to allow claimants to recover more easily, we determine that this statement reveals nothing more than Congress' desire for claimants to use the program.

As we turn to the 1987 Report, we must first determine whether we may consider it for the purpose of discerning Congressional intent with regard to the Vaccine Act. Although it explicitly refers to the Vaccine Act's intent, the 1987 Report was published about one year after Congress had enacted the Vaccine Act in 1986. The question, then, is whether the Report can provide any insight into the intent of the enacting Congress. Beginning with the premise that "legislators who hear[] or read [the pre-enactment] statements [of their colleagues] presumably vote[] with that understanding[,]" the Supreme Court of the United States has defined "'[p]ostenactment legislative history' [as] a deprecatory contradiction in terms [which] refers to statements of those who drafted or voted for the law that are made after its enactment and hence could have no effect on the congressional vote." ***Heller***, ***supra*** at 2805; ***see also Sullivan v. Finkelstein***, 496 U.S. 617, 631 (1990) (Scalia, J., concurring in part). Nevertheless, the Supreme Court has also determined "while the views of subsequent Congresses cannot override the unmistakable intent of the enacting one, such views are entitled to significant weight, and particularly

so when the precise intent of the enacting Congress is obscure." ***Seatrain Shipbuilding Corp. v. Shell Oil Co.***, 444 U.S. 572, 596 (1980) (internal citations omitted); ***see also NLRB v. Bell Aerospace Co.***, 416 U.S. 267, 275 (1974); ***Red Lion Broadcasting Co. v. F.C.C.***, 395 U.S. 367, 380-381 (1969). The problem with enlisting the aid of post-enactment legislative history, according to Justice Scalia, is that it will be "used to smuggle into judicial consideration legislators' expressions *not* of what a bill currently under consideration means […] but of what a law *previously enacted* means." ***Sullivan***, ***supra*** at 631 (Scalia, J., concurring in part) (emphasis in original). Although Justice Scalia believes that subsequent legislative history "should not be taken seriously," he explained one scenario where such material would be instructive to a statutory analysis.

> In some situations, of course, the expression of a legislator relating to a previously enacted statute may bear upon the meaning of a provision in a bill under consideration-which provision, if passed, may in turn affect judicial interpretation of the previously enacted statute, since statutes *in pari materia* should be interpreted harmoniously.

Id. at 632. Justice Scalia realized, however, that this type of post-enactment history "would be useful, if at all, not because it was subsequent legislative history of the earlier statute, but because it was plain old legislative history of the later one." ***Id.***

As the Third Circuit acknowledged, Congress amended the Vaccine Act in 1987 in order "to fund the [Vaccine Act's] compensation program."

Bruesewitz, ***supra*** at 249. The Vaccine Act as passed in 1986 "did not include a source of payment for [the compensation program] and made the compensation program and accompanying tort reforms contingent on the enactment of a tax to provide funding for the compensation." H.R. REP. 100-391 at 690, 1987 U.S.C.C.A.N. 2313-1, 2313-364. The 1987 Report explains that the 1987 amendments to the Vaccine Act were necessary to enable "a complete system of vaccine compensation [to] take effect[.]" ***Id.*** at 691, 1987 U.S.C.C.A.N. 2313-1, 2313–365. After careful review, we determine that the context giving rise to the 1987 Report allows us to consider the Report in our examination of the Vaccine Act's legislative history.

The 1987 amendments to the Vaccine Act present the exact scenario that Justice Scalia used in order to illustrate an occasion in which courts may appropriately consider post-enactment history. Without funding, or with insufficient funding, the entire Vaccine Act—including the limits on vaccine manufacturers' liability exposure—would either be rendered a nullity or courts would be forced to give effect to the remaining parts of the statute in isolation. Because the 1987 amendments impacted the legal effect of the Vaccine Act as a whole, those amendments essentially determined whether the Vaccine Act ever became operative. As such, "the expression of [the 1987 Committee Report] relating to [the] previously enacted [1986 version of the Vaccine Act] may [have] [borne] upon" Congress' ultimate decision to

pass the 1987 amendments and provide funding for the Act's programs. ***See Sullivan***, ***supra*** at 632 (Scalia, J., concurring in part). If legislative history is relevant "because the legislators who heard or read [the] statements [of their colleagues] presumably voted with that understanding[,]" ***Heller***, ***supra*** at 2805, then any statements pertaining to the Vaccine Act's operation made in the 1987 Report are relevant to our analysis as they would be indicative of Congress' intent at the time it passed legislation making the Vaccine Act's component parts, including § 300aa-22(b)(1), operative.

We conclude that the 1986 Vaccine Act and the 1987 amendments to that Act exist *in pari materia*. Therefore, "since statutes *in pari materia* should be interpreted harmoniously[,]" we may consider the history of the 1987 legislation that amended the Vaccine Act. ***See Sullivan***, ***supra*** at 632 (Scalia, J., concurring in part). We should not ignore Congress' intent when it passed the amendments that made the Act operative. Moreover, we conclude that the 1987 Report "[is] entitled to significant weight" because "the precise intent of the enacting Congress is obscure"; we have been unable to discern "the unmistakable intent of the enacting [Congress]" from any other source. ***See Seatrain Shipbuilding Corp.***, ***supra*** at 596.

Vaccine Defendants dispute that any relevant connection exists between the funding amendments passed in 1987 and the initial legislation passed in 1986. They claim that "[t]he funding of the [Vaccine] Act via the

1987 amendments did not concern in any way the Section 22 limitations on liability of vaccine manufacturers in civil actions and so do not provide any guidance on the intent of the enacted law." Substitute Brief of Vaccine Defendants on Reargument *En Banc* at 28. However, the 1986 Report, which the Vaccine Defendants rely upon, directly contradicts this reasoning. The 1986 Report states, "[t]he Committee believes that the establishment of these standards of responsibility [under § 300aa-22] is appropriate in light of the availability of a comprehensive and fair compensation system." H.R. REP. No. 99-908 at 25, 1986 U.S.C.C.A.N. at 6366. Without the 1987 amendments, as Appellants emphasize, this "comprehensive and fair compensation system" would be unfunded and rendered a nullity. Thus, Vaccine Defendants are incorrect in asserting that the 1987 amendments and the limitations on vaccine manufacturers' liability are unrelated. To the contrary, the protections enjoyed by vaccine manufacturers were contingent upon the passage of the 1987 amendments. As the excerpt from the 1986 Report indicates, Congress only intended to give vaccine manufacturers liability protections so long as claimants could turn to an alternative compensation system. The Vaccine Act does not demonstrate Congress' intent to simply immunize vaccine manufacturers from liability without providing any recourse for those injured by vaccines.

Now, we turn to the substance of the 1987 Report. The Report directly addresses the issue before us. The 1987 Report expresses clear and unequivocal intent to preserve tort remedies for vaccine claimants.[21]

> It is important to note that both at the time of original enactment and in passing this legislation, the Committee acted with the understanding that tort remedies were and are available. Without this understanding, such provisions of the Act as those allowing rejection of compensation, trifurcation of trial, and limitation of punitive damages would be meaningless.

H.R. REP. 100-391 at 691, 1987 U.S.C.C.A.N. at 2313–365. Furthermore, emphasizing that "[i]t [was] not the Committee's intention to preclude court actions under applicable law[,]" the 1987 Report attempted to clarify the intent of Congress when it incorporated the principle of Comment k into §300aa-22(b).[22] ***Id.***

> [T]he codification of Comment (k) of The Restatement (Second) of Torts was not intended to decide as a matter of law the circumstances in which a vaccine should be deemed unavoidably unsafe. The

[21] The 1987 Report uses the term "Committee" equivocally, leaving it uncertain as to whether the word references the Energy and Commerce Committee or the Budget Committee. The context of the 1987 Report seems to suggest that the parts pertinent to the Vaccine Act refer to the Energy and Commerce Committee, the Committee that originally guided the legislation in 1986. For example, the 1987 Report includes a statement from the Acting Director of the Congressional Budget Office directed to the Chairman of the Energy and Commerce Committee. H.R. REP. 100-391 at 692, 1987 U.S.C.C.A.N. at 2313–366. However, because the 1986 legislation and the 1987 amendments exist *in pari materia*, the precise Committee referenced is not determinative.

[22] The 1987 Report states, "[a]n Amendment to establish as part of this compensation system that a manufacturer's failure to develop [a] safer vaccine was not grounds for liability was rejected by the Committee during its original consideration of the [Vaccine] Act." H.R. REP. 100-391 at 691, 1987 U.S.C.C.A.N. at 2313–365. Although the Energy and Commerce Committee conducted a mark-up hearing to consider proposed amendments to the Vaccine Act, there is no record available to confirm that the Committee rejected an amendment regarding design defect claims. ***See Bruesewitz***, ***supra*** at 250, n. 12.

> 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. According to this excerpt from the 1987 Report, Congress did not intend for § 300aa-22(b)(1) to deem all vaccines unavoidably unsafe as a matter of law. Rather, the 1987 Report explicitly indicates that the Act defers to the case-by-case determinations of courts as to whether vaccine side effects are unavoidable. Nevertheless, we cannot agree with Appellants that the 1987 Report unequivocally evidences Congressional intent. ***See*** Appellants' Substitute Brief on Rehearing *En Banc* at 39. While these excerpts from the 1987 Report are compelling, they only reveal that Congress' intent is anything but clear and manifest. The 1987 Report could easily be reconciled with the 1986 Report, but that is not the pertinent inquiry. The question is whether we are able to glean the clear and manifest intent of Congress from these sources. From our review, we have discerned that the 1986 Report is at best equivocal as to Congressional intent regarding § 300aa-22(b) and its incorporation of the principle of Comment k. Although the 1987 Report appears to offer definitive evidence of Congress' intent, the 1987 Report, when read it in tandem with the 1986 Report, ultimately leaves more lingering questions than it answers. Therefore, after considering all the relevant legislative history, we have been unable to discover the clear and manifest intent of Congress.

D. Conclusion

Our discussion of the Vaccine Act has examined every aspect of the statute's language, structure, purpose, and history. Nevertheless, we have been unable to discern the clear and manifest intent of Congress regarding § 300aa-22(b)(1). As we noted at the beginning of our analysis, we must "start with the assumption that the historic police powers of the States were not to be superseded by [a] Federal Act unless that was the clear and manifest purpose of Congress." ***Medtronic, Inc.***, ***supra*** at 485 (internal citation and quotation omitted). We reiterate that this presumption against preemption applies with equal force to questions pertaining to a federal statute's preemptive scope. ***Id.***; ***see also Cipollone***, ***supra*** at 518, 523.

Although we must concede Vaccine Defendants have presented a plausible interpretation of § 300aa-22(b)(1) that declares all vaccine side effects unavoidable as a matter of law, our review has revealed that this interpretation of § 300aa-22(b)(1) does not stand alone as the only plausible interpretation of this provision. To the contrary, our review intimates that Congress intended courts to conduct case-by-case inquiries into the nature of vaccine side effects. At each level of our analysis, we have been struck by the extraordinary measures that the Act takes in order to ensure plaintiffs retain a defined avenue to the civil tort system. If Congress desired to bar outright all design defect claims as a matter of law, there were far more straightforward methods that Congress could have employed to realize that

intent. Because Congress utilized conditional language in its grant of immunity to vaccine manufacturers, in order to conclude that Congress clearly and manifestly intended § 300aa-22(b)(1) as a complete bar to any type of claim, we would be forced to exceed the bounds of this Court's customary judicial restraint. If anything with regard to this statute is clear and manifest, it must be Congress' aversion to imposing unyielding rules that fail to account for individual circumstances.

Because we have been confronted by two "plausible" interpretations of § 300aa-22(b)(1), we "have a duty to accept the reading that disfavors pre-emption." ***Bates***, ***supra*** at 449. As such, we hold that § 300aa-22(b)(1) does not serve as an outright bar to any design defect claim. Rather, § 300aa-22(b)(1) requires courts to conduct a case-by-case inquiry in order to determine whether a particular vaccine's side effects are unavoidable. Before ruling that § 300aa-22(b)(1) preempts Appellants' design defect claim, the trial court must first conduct an inquiry to determine whether the injury-causing side effects were unavoidable. Therefore, the trial court erred in granting summary judgment in favor of Vaccine Defendants regarding the design defect claim.

II.

In their third issue, Appellants argue the trial court erred by granting summary judgment on Appellants' failure-to-warn claim. Appellants'

Substitute Brief on Rehearing *En Banc* at 63. Specifically, Appellants contend that the trial court erred in applying § 300aa-22(b)(1) to their independent failure-to-warn claim. ***Id.*** at 64. According to Appellants, § 300aa-22(b)(1) only applies to design defect claims. ***Id.*** Because the presumption of proper warnings under § 300aa-22(b)(2) is only "[f]or the purposes of paragraph (1)," Appellants contend that it too only applies to design defect claims. ***Id.***, *quoting* 42 U.S.C.A. § 300aa-22(b)(2). As such, Appellants conclude that the trial court misapplied the presumption of proper warnings to their failure-to-warn claim, and they argue that the presumption pursuant to § 300aa-22(b)(2) should not bar them from proceeding with their claim. ***Id.***

Appellants averred, in their complaint, that the Vaccine Defendants failed to warn the "medical community" that vaccines containing thimerosal "could and would result in mercury poisoning as a result of the underlying toxicity of the unidentified mercury injected into the vaccine product."[23] ***See*** Complaint ¶¶ 25-27, 39. In granting the motion for summary judgment, the trial court determined that Vaccine Defendants were entitled to the presumption of proper warnings under § 300aa-22(b)(2) of the Vaccine Act. As such, the trial court correctly shifted the burden to Appellants to offer

[23] We note that, in their complaint, Appellants also alleged that Vaccine Defendants failed to warn the "consuming public" of the dangers associated with thimerosal. ¶¶ 25-27, 39. The trial court determined, and Appellants conceded, that § 300aa-22(c) barred their failure-to-warn claim as it relates to consumers generally and Appellants in particular. Trial Court Opinion, 8/27/08, at 20; ***see also*** 42 U.S.C.A. § 300aa-22(c). To the extent that this remains an issue, we agree with the trial court's conclusion.

evidence sufficient to overcome that presumption. ***See*** 42 U.S.C.A. §§ 300aa-22(b)(2), 300aa-23(d). In ruling that Appellants were unable to satisfy that burden, the trial court concluded, "[Appellants] failed to raise any genuine issues of material fact to overcome the presumption of proper warnings to which the Vaccine Defendants were entitled under the Vaccine Act."[24] Trial Court Opinion, 8/27/08, at 21. After careful review, we conclude that the trial court did not commit any error of law or abuse its discretion when it granted summary judgment. It applied the Vaccine Act properly to Appellants' failure-to-warn claim.

The presumption under § 300aa-22(b)(2) applies "to claims that a manufacturer failed to adequately warn a health care intermediary[.]" ***Sykes***, ***supra*** at 304. Section 300aa-22(b)(2) presumes that a vaccine is "accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all [FDA regulations and regulations pursuant to the Public Health and Safety Act]" that apply to the vaccine at issue and relate to the vaccine-related injury or death underlying the civil cause of action. 42 U.S.C.A. § 300aa-22(b)(2). "[O]nce the manufacturer establishes that it complied with federal law, the burden shifts

[24] The trial court also granted the motion for summary judgment because it found that "[Appellants] failed to distinguish their failure to warn claim[] from their design defect claim." Trial Court Opinion, 8/27/08, at 21. Our analysis of Appellants' design defect claim concluded that the Act requires courts to conduct case-by-case reviews of all design defect claims to determine whether the pertinent vaccine side effects were unavoidable. As such, we ruled that the Act does not serve as an outright bar to any design defect claim. Thus, we need not determine whether there is a distinction between Appellants' design defect claim and Appellants' failure-to-warn claim.

to the plaintiff to establish that" one of the two statutory bases for overcoming the presumption has been satisfied. ***Bruesewitz***, ***supra*** at 252. To overcome the presumption under § 300aa-22(b)(2), a plaintiff must demonstrate one of the following.

> (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).

42 U.S.C.A. § 300aa-22(b)(2)(A)-(B). Section 300aa-22(b)(2)(A) requires plaintiffs to demonstrate that vaccine manufacturers either: (A) fraudulently or intentionally and wrongfully withheld information from the government "during any phase of a proceeding for approval of the vaccine"; or (B) intentionally and wrongfully withheld "information relating to the safety or efficacy of the vaccine after its approval[.]" 42. U.S.C.A. § 300aa-23(d)(A)-(B).

First, we reject Appellants' claim that the presumption pursuant to § 300aa-22(b)(2) does not apply to their failure-to-warn claim. Although the presumption under § 300aa-22(b)(2) only applies "[f]or purposes of [Subsection 22(b)(1)]," no language in the Act limits the reach of § 300aa-22(b)(1) to design defect claims as Appellants suggest. ***See*** 42 U.S.C.A. § 300aa-22(b). Rather, the language of § 300aa-22(b)(1) merely

immunizes manufacturers from civil liability resulting from unavoidable vaccine side effects. In conditioning vaccine manufacturers' immunity, § 300aa-22(b)(1) draws a distinction between avoidable and unavoidable side effects. Section 300aa-22(b)(1), however, never distinguishes between different types of claims. As such, we see nothing that precludes this subsection's application to all variety of vaccine claims—including claims for failure-to-warn. Therefore, because Appellants must satisfy § 300aa-22(b)(1) in order to prevail on their warning claim, we conclude that § 300aa-22(b)(2) also applies to their claim.[25]

Second, we agree with the trial court's determination that Vaccine Defendants demonstrated their compliance with all pertinent regulations and, therefore, they are entitled to the presumption pursuant to § 300aa-22(b)(2). The trial court recounted, "[t]he affidavits and supporting documentation of Lori A. Easterday (Aventis), Dr. Jack D. Love (Wyeth), and Louis Washington (Merck) offered by the Vaccine Defendants showed they each materially satisfied the relevant FDA regulations in connection with the licensing and approval of the vaccines at issue." Trial Court Opinion, 8/27/08, at 22-23. Specifically, the Vaccine Defendants provided evidence

[25] Importantly, from our review, we conclude that Congress established the presumption under § 300aa-22(b)(2) to apply to failure-to-warn claims. The presumption was designed to limit the available warning claims to "only those significant failures to warn or [to] provide directions that clearly pertain to vaccine safety and that clearly arise from substantial wrongdoing on the part of the manufacturer[.]" H.R. Rep. 99-908 at 26, 1986 U.S.C.C.A.N. at 6367. Of course, the intent of Congress may only be realized if warning claims are also required to satisfy § 300aa-22(b)(1) because the presumption only applies for purposes of that subsection.

demonstrating that the vaccines administered to Minor Appellant were licensed and accompanied by the FDA-approved package inserts.[26] ***Id.*** at 23. Moreover, neither Appellants nor the trial court identified any evidence that suggested Vaccine Defendants had failed to comply with the applicable regulations in some material respect. ***Id.*** As such, we conclude that Vaccine Defendants are entitled to the presumption of proper warnings under § 300aa-22(b)(2). Unless Appellants can overcome this presumption, it will bar Appellants' failure-to-warn claim. With the presumption in place, Appellants' failure-to-warn claim will not be able to survive § 300aa-22(b)(1). Although demonstrating that the vaccine at issue was accompanied by inadequate warnings is sufficient to render side effects avoidable for purposes of § 300aa-22(b)(1), Appellants would be barred from making such a demonstration unless they first overcome the presumption of proper warnings.

Finally, we conclude that the trial court correctly found that Appellants offered no evidence sufficient to overcome the presumption of proper warnings. The evidence proffered by Appellants is heavy with innuendo but light on substance. For instance, Appellants point to animal studies evidencing the toxicity of thimerosal. ***See*** Trial Court Opinion, 8/27/08, at 24. From these studies, Appellants suggest that the Vaccine Defendants

[26] We note that each of the Vaccine Defendants' package inserts expressly stated that the vaccine formula included thimerosal and that thimerosal was a mercury derivative; the package inserts also specified the particular concentration of thimerosal present in each vaccine.

acted improperly for failing to conduct further research regarding the effects of thimerosal on human subjects. Although further research may have been appropriate, this evidence alone is insufficient to meet Appellants' burden of proof. Likewise, Appellants use the common knowledge of mercury's high level of toxicity as evidence that the FDA-approved warnings were inadequate to alert of the potential hazards associated with thimerosal. ***Id.*** Citing warnings that highlight the risk of mercury contact with exposed skin or eyes, Appellants infer that such warnings are equally needed on labels of vaccines where thimerosal is used as a preservative. While we make no determination as to the truth of that inference, we emphasize that mere inferences are insufficient substitutes for the evidence needed to overcome the presumption under § 300aa-22(b)(2). The only substantial evidence that Appellants offered to the trial court was the anecdotal reports of adverse events correlating with vaccine administrations.[27] ***Id.*** at 25. Vaccine Defendants, however, were the entities responsible for these reports. As such, the reports hardly demonstrate any effort to withhold information from the regulatory apparatus. Moreover, though additional research may have been appropriate based upon these anecdotal reports, Appellants offer no evidence that Vaccine Defendants ever acted improperly. Furthermore, Appellants fail to cite in their brief any evidence of record that

[27] The Act established a reporting system called the Vaccine Adverse Event Reports ("VAERS"), which requires vaccine manufacturers to report adverse events that may be correlated with the administration of their vaccines.

would contradict the trial court's conclusion, and we have discovered no such evidence during our review.

Therefore, our review of the record has revealed that Appellants failed to establish any basis upon which the presumption could have been overcome. ***See*** 42 U.S.C.A. §§ 300aa-22(b)(2), 300aa-23(d). As the trial court aptly found, Appellants failed to show either (1) Vaccine Defendants intentionally and wrongfully withheld information during or after the vaccine approval process or (2) Vaccine Defendants failed to exercise due care. ***See*** Trial Court Opinion, 8/27/08, at 24; ***see also*** 42 U.S.C.A. §§ 300aa-22(b)(2), 300aa-23(d). Thus, because all vaccine warnings at issue were presumed proper pursuant to § 300aa-22(b)(2), the Vaccine Act bars Appellants' failure-to-warn claim. As such, we conclude that the trial court did not commit an error of law or abuse its discretion by granting summary judgment in favor of Vaccine Defendants regarding the failure-to-warn claim.

III.

In their final issue, Appellants allege that the trial court erred in failing to apply § 300aa-22(e) in order to preserve their claims from state law barriers. Appellants' Substitute Brief on Rehearing *En Banc* at 67. Appellants argue that Congress intended for § 300aa-22(e) "to preempt, among other things, state laws that immunized vaccine manufacturers from design defect or other claims under their own interpretations of Comment

k." ***Id.*** at 68. Because the trial court never had occasion to reach this issue, we shall not consider the merits of Appellants' argument.

Conclusion

We hold that § 300aa-22(b)(1) of the Vaccine Act expressly preempts all design defect claims that arise from unavoidable vaccine side effects, and before granting summary judgment, the trial court was required to conduct a case-by-case inquiry to determine the nature of the vaccine side effects presented in this case. Therefore, regarding Appellants' design defect claim, we reverse the trial court's order granting summary judgment in favor of Vaccine Defendants.

As to Appellants' failure-to-warn claim, we hold that Vaccine Defendants are entitled to the presumption of proper warnings under § 300aa-22(b)(2), and that Appellants failed to rebut this presumption. Accordingly, we affirm the trial court's order granting summary judgment in favor of Vaccine Defendants on this issue.

Order affirmed in part and reversed in part. Case remanded. Jurisdiction relinquished.

Judge Gantman concurs in the result.

Judge Shogan files a Concurring and Dissenting Opinion.

JACQUELINE WRIGHT AND HOWARD WRIGHT, PARENTS AND NATURAL GUARDIANS OF JARED WRIGHT, A MINOR CHILD AND IN THEIR OWN RIGHT,	:	IN THE SUPERIOR COURT OF PENNSYLVANIA
Appellants	:	
v.	:	
AVENTIS PASTEUR, INC., MERCK & CO., INC., AMERICAN HOME PRODUCTS D/B/A WYETH, WYETH LABORATORIES, WYETH-AYERST, WYETH-AYERST LABORATORIES, WYETH LEDERLE, WYETH LEDERLE VACCINES, AND LEDERLE LABORATORIES, C/O CT CORPORATION SYSTEMS,	:	
Appellees	:	No. 336 EDA 2008

Appeal from the Order entered December 31, 2007,
in the Court of Common Pleas, Philadelphia County,
Civil Division, at No. 003861 May Term 2003.

BEFORE: FORD ELLIOTT, P.J., STEVENS, GANTMAN, PANELLA, DONOHUE, SHOGAN, ALLEN, LAZARUS, and MUNDY, JJ.

CONCURRING AND DISSENTING OPINION BY SHOGAN, J.:

Although the Majority has provided a thorough discussion of statutory interpretation and the law of preemption, I discern no basis on which to disturb the trial court's entry of summary judgment in favor of Vaccine

Defendants on both the failure-to-warn and design defect claims. Accordingly, I concur in part and dissent in part.

Plaintiffs filed a complaint in state court, alleging that Vaccine Defendants were negligent in designing the vaccines to include thimerosal, and that Vaccine Defendants failed to warn of the dangers of using thimerosal. Second Amended Complaint, 12/9/03, at ¶¶ 25-27, 39. The National Childhood Vaccine Injury Act of 1986 ("Vaccine Act"), 42 U.S.C.A. §§ 300aa-1 *et seq.*, provides for the preemption of state design defect claims and affords a presumption of proper warning to vaccine manufacturers. 42 U.S.C.A. § 300-22(b). The question before the trial court with regards to the design defect claim was the scope of preemption.[1] Plaintiffs advocated a case-by-case determination by a trial court of whether the vaccine design was defective, *i.e.*, whether a safer alternative to thimerosal should have been used, before vaccine manufacturers would be able to obtain the protections of Section 22(b). Vaccine Defendants argued that the Vaccine Act preempts all design defect claims, without use of a case-by-case determination of whether a particular vaccine is unavoidably unsafe.

[1] Vaccine Defendants contended that the failure-to-warn claim was also preempted by the Vaccine Act. I agree with the trial court that Plaintiffs failed to distinguish that claim, as to the injured party, from their design defect claim. ***See*** Trial Court Opinion, 8/27/08, at 19-22.

Citing the language of Section 22(b), the Federal Drug Administration's ("FDA") licensing process, federal cases favoring preemption in this context, and legislative intent, the trial court concluded that Congress intended to preempt design defect claims without a preliminary showing that thimerosal-containing vaccines were unavoidably unsafe. Trial Court Opinion, 8/27/08, at 19. Considering, *inter alia,* subsequent legislative history, the Majority concludes that the trial court erred and holds that Section 22(b)(1) requires a trial court to conduct a case-by-case inquiry to determine if a vaccine's side effects are unavoidable before deciding whether a design defect claim is preempted. I cannot agree.

The first part of Section 22(b)(1) speaks plainly and broadly, while the second part is conditional:

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

42 U.S.C.A. § 300aa-22(b)(1). Determining whether side effects are unavoidable, whether the vaccine was properly prepared, and whether proper warnings were provided is the function of the FDA. As the trial court observed, the FDA regulates the formation (including ingredients and preservatives), the production, and the labeling of vaccines. Trial Court Opinion, 8/27/08, at 4 n.6 (citing 21 U.S.C.A. §§ 301 *et seq.*; 21 C.F.R.

§ 610.15). The FDA's licensing process requires demonstration that a product is "safe, pure, and potent." ***Id.*** at 5 n.6 (citing 42 U.S.C.A. § 262(a)(2)(C)).[2] Thus, as the trial court opined, use of a case-by-case approach is unnecessary because "[a]n FDA-approved design includes the side-effects of that vaccine, and is, therefore, by statutory definition, the unavoidably safe product subject to . . . immunity." Trial Court Opinion, 8/27/08, at 18 (citation omitted).[3]

Federal decisions favoring preemption in this context further support the trial court's decision. ***See***, ***e.g.***, ***Bruesewitz v. Wyeth, Inc.***, 561 F.3d 233 (3d Cir. 2009), *cert. granted*, ___ U.S. ___, 130 S.Ct. 1734 (2010) (holding that Vaccine Act preempts design defect claims without a

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[2] Notably, the FDA "has concluded that no ill effects 'other than minor local reactions at the site of injection' have been established for thimerosal in childhood vaccines." FDA, *Thimerosal in Vaccines*, at 3 (August 18, 2008).

[3] Section 22(b)(1) is an express preemption provision. Since ***Wyeth v. Levine***, ___ U.S. ___, 129 S.Ct. 1187 (2009), dealt with implied preemption, it is of limited relevance in our analysis. In fact, the issue in ***Levine*** of whether federal labeling law preempted the plaintiffs' inadequate labeling claim is directly addressed by Section 22(b)(2), which provides that:

> 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.A. §§ 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.

42 U.S.C.A. § 300aa-22(b)(2).

determination of whether the vaccine is unavoidably unsafe);[4] ***Sykes v. Glaxo-SmithKline***, 484 F. Supp.2d 289 (E.D. Pa. 2006) (same); ***Blackmon v. American Home Prods. Corp.***, 328 F. Supp.2d 659 (S.D. Tx. 2004) (holding that Vaccine Act totally bars design defect and failure-to-warn claims); ***see also Militrano v. Lederle Labs***., 26 A.D.3d 475, 810 N.Y.S.2d 506 (App. Div. 2d Dept. 2006) (holding that Vaccine Act preempts state law design defect claims and provides presumption of proper warning). Even the Georgia state decision, cited by the Majority as adopting a case-by-case approach, recognized the reasonableness of interpreting the statute as preempting all design defect claims. ***See Ferrari v. American Home Prods. Corp.***, 650 S.E.2d 585, 286 Ga. App. 305 (Ga. Ct. App. 2007) (agreeing with previous court rulings regarding congressional intent to preempt all design defect claims).

Finally, the legislative history of the Vaccine Act favors preemption of all design defect claims and, hence, supports the trial court's ruling.[5] In

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[4] The United States Supreme Court heard oral argument in the ***Bruesewitz*** case on October 12, 2010.

[5] In examining legislative intent, I respectfully disagree with the Majority that we should consider "subsequent legislative history" in this case. In my opinion, the expressions of the legislature relating to the 1987 funding amendments to the Vaccine Act do not fall within the scenario described by Justice Scalia in his concurring opinion in the social security disability case, ***Sullivan v. Finkelstein***, 496 U.S. 617, 632 (1990) (Scalia, J., concurring in part) ("[T]he expression of a legislator relating to a previously enacted statute . . . would be useful, if at all, not because it was subsequent

concluding that "the basic presumption against preemption does not accord with Congress' intent in enacting the Vaccine Act," the trial court observed:

> [c]oncerns which led to the Vaccine Act legislation included the inadequacy—from both the injured persons and the vaccine manufacturers perspective—of the tort system in compensating vaccine-injured children and the instability and uncertainty of the childhood vaccine market inevitably caused by the risk of tort litigation. *See* H.R. Rep. No. 99-908 at 7. . . With case-by-case determination, vaccine manufacturers "would again be subjected to the unpredictability and expense of the tort system and companies would be dissuaded from remaining [in] or entering the vaccine market." *Sykes*, 484 F. Supp. 2d at 302. Such an approach "would do nothing to protect vaccine manufacturers from suit from design defects, since such an inquiry would require a fact finder to consider the manufacturer's design against a purported safer alternative." *Bruesewitz*, 508 F. Supp. 2d at 445.

Trial Court Opinion, 8/27/08, at 16-17.

The trial court found further support for preemption in H.R. Rep. No. 99-908, as follows:[6]

> Given the existence of the compensation system [provided for in the Vaccine Act], the Committee strongly believes that Comment k is appropriate and necessary. . . Vaccine-injured persons will now have an appealing alternative to the tort system. Accordingly, **if they cannot demonstrate** under

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legislative history of the earlier statute, but because it was plain old legislative history of the later one."). Consideration of subsequent legislative history of an earlier statute can be construed simply as a form of revisionist history.

[6] "Preemption is a question of Congressional intent," and "[t]he best source for divining that intent is the committee reports on the bill." ***Militrano***, 810 N.Y.S.2d at 508 (citing ***California Federal Sav. & Loan Assn. v. Guerra***, 479 U.S. 272, 280 (1987); ***Garcia v. United States***, 469 U.S. 70, 76 (1984)).

> applicable law **either [1] *that a vaccine was improperly prepared* or [2] *that it was accompanied by improper directions or inadequate warnings* [they] should pursue recompense in the compensation system, not the tort system.**

Id. at 17 (quoting H.R.Rep. No. 99-908 at 26) (emphasis and bracketed material in original).

Finally, the trial court found Section 22 to be even broader than Comment k and rejected Plaintiffs' position that the court should adopt a case-by-case approach based on Comment k. ***Id.*** at 18. I am constrained to agree. ***See Blackmon***, 328 F. Supp.2d at 666 ("[Section 22(b)'s] phrase 'a civil action for damages' encompasses products liability claims based on negligence as well as those based on strict liability. While comment k is restricted to strict liability claims, § 22(b) is not.").

Plaintiffs raised design defect and failure-to-warn claims. As discussed in the trial court's very thorough and well-reasoned opinion, the statutory language, FDA functions, federal case law, and legislative intent support the trial court's conclusions that the Vaccine Act preempts the design defect claim and that Vaccine Defendants were entitled to the presumption of proper warning. Therefore, I do not consider the trial court's entry of summary judgment in favor of Vaccine Defendants on both claims an abuse of discretion or an error of law.