3-27-2009

Bruesewitz v. Wyeth Inc

PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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No. 07-3794

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RUSSELL BRUESEWITZ; ROBALEE BRUESEWITZ,
parents and natural guardians of Hannah Bruesewitz,
a minor child and in their own right,

Appellants

v.

WYETH INC.
f/k/a
WYETH LABORATORIES, WYETH-AYERST
LABORATORIES,
WYETH LEDERLE, WYETH LEDERLE VACCINES,
AND
LEDERLE LABORATORIES

_____

On Appeal from the United States District Court
for the Eastern District of Pennsylvania
District Court No. 05-cv-05994
District Judge: The Honorable Michael M. Baylson

_____

Argued September 11, 2008

Before: McKEE, SMITH, and WEIS, *Circuit Judges*

(Filed: March 27, 2009)

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OPINION

SMITH, *Circuit Judge.*

This appeal presents three questions related to the National Childhood Vaccine Injury Act: (1) whether the Act preempts all design defect claims against the manufacturer of a vaccine; (2) whether the plaintiffs demonstrated that the manufacturer failed to adequately warn the plaintiffs of the risks associated with the vaccine; and (3) whether the plaintiffs provided sufficient evidence of a manufacturing defect to survive the defendant's motion for summary judgment. The District Court held that the Act preempted all design defect claims and concluded that the plaintiffs failed to provide sufficient evidence to support the other two claims. For the reasons that follow, we will affirm.

I.

A.

Historically, the states have possessed "great latitude

under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet" of their citizens. *Metro. Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756 (1985). This has been true with regard to drugs, as the Supreme Court has declared it "well settled that the State has broad police powers in regulating the administration of drugs by the health professions." *Whalen v. Roe*, 429 U.S. 589, 603 (1977). And the police powers extend to immunization, as state and local authorities have responded to illnesses like smallpox and sought to inoculate members of the populous. Center for Biologics Evaluation and Research, Food and Drug Administration, *Science and the Regulation of Biological Products: From a Rich History to a Challenging Future* 8 (2002). Despite calls in the late nineteenth-century for the federal regulation of vaccines to promote uniform safety regulations, Congress did not act until 1902, when thirteen children died after being vaccinated with contaminated diptheria antitoxin. *Id.* at 12. Over the past century, however, the federal government has taken a predominate role in approving, regulating, and promoting vaccines—from the passage of the Biologics Control Act in 1902, Pub. L. No. 57-244, which authorized a federal agency to issue regulations related to vaccines, to the Public Health Service Act, Pub. L. No. 78-410, which required federal authorities to license vaccines and vaccine manufacturers, to the Emergency Supplemental Appropriations Act for Recovery from and Response to Terrorist Attacks on the United States, Pub. L. No. 107-9, which appropriated money for the acquisition of a sufficient quantity of the smallpox vaccine to inoculate the

country.

The National Childhood Vaccine Injury Act ("Vaccine Act") is one such effort. P.L. 99-660, Title III, 100 Stat. 3743, 3756–3784 (codified at 42 U.S.C. § 300aa-1 *et seq*.). Enacted in 1986, the Vaccine Act established a national vaccine program to "achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines." 42 U.S.C. § 300aa-1. It sought to accomplish this primarily through the creation of the National Vaccine Injury Compensation Program ("NVICP") for claims against drug manufacturers for vaccine-related injuries and deaths. 42 U.S.C. § 300aa-10 *et seq*.

The NVICP has two parts. Part A creates a mandatory forum for the administration of claims—it requires a petitioner seeking compensation, including the injured party's legal representative, to file a petition in the "Vaccine Court," which is part of the United States Court of Federal Claims. *Id.* at § 300aa-11. The petitioner is entitled to receive compensation if: (1) the affected person received a vaccine covered by the Vaccine Act; (2) the affected person suffered a "Table injury";[1]

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[1] The Vaccine Act created the "Vaccine Injury Table." 42 U.S.C. § 300aa-14. It sets forth the "vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration" of vaccines for which individuals may seek compensation. *Id.*

and (3) it cannot be shown by a preponderance of the evidence that the injuries or death were not caused by the vaccine. *Id.* at §§ 300aa-11, 300aa-13. Alternatively, a petitioner who suffers a non-Table injury may still obtain compensation by proving affirmatively that the vaccine caused the injury. *See Grant v. Sec'y of HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Part B of the NVICP permits a petitioner, after the Vaccine Court has issued a final judgment, to either accept or reject that judgment. 42 U.S.C. § 300aa-21 *et seq*. If the petitioner rejects the judgment, she may pursue certain limited claims in state or federal court.[2] 42 U.S.C. § 300aa-21.

B.

Hannah Bruesewitz was born on October 20, 1991. At the time, the federal Advisory Committee on Immunization Practices recommended that children receive five doses of the diphtheria-pertussis-tetanus ("DPT") vaccine during the course of their childhood, one dose at each of the following ages: (1) 2 months; (2) 4 months; (3) 6 months; (4) 15-18 months; and (5) 4-6 years. Hannah received her first three shots of the DPT vaccine according to this schedule. After the third DPT shot, marketed under the trade name TRI-IMMUNOL and administered on April 1, 1992, she suffered a series of seizures.

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[2] The party also has the option of appealing the Court of Federal Claims' judgment to the United States Court of Appeals for the Federal Circuit. 42 U.S.C. § 300aa-12(f).

Doctors subsequently diagnosed Hannah as having residual seizure disorder and developmental delay. Hannah, who is now seventeen, will likely require some medical care related to that condition for the remainder of her life.

Defendant Wyeth, Inc. and its predecessors[3] ("Wyeth") manufactured TRI-IMMUNOL until 1998. Approved in 1948, this vaccine contains the "whole-cell" pertussis vaccine—it is prepared using whole, inactivated pertussis bacterial cells. Although the whole-cell vaccine effectively reduced pertussis infections and deaths associated with these infections, it was also linked to a variety of adverse events. This led to interest in and efforts to develop a safer, acellular pertussis vaccine.

In December 1991, the Food and Drug Administration ("FDA") approved the defendant's application for an alternate DPT vaccine, which was known as ACEL-IMUNE. ACEL-IMUNE contains an acellular pertussis component. While the acellular vaccine contains parts of pertussis bacterial cells, because it does not contain a complete cell, it has less endotoxin

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[3] The National Health Institute first issued a product license for TRI-IMMUNOL in 1948 to American Cyanamid Company ("Cyanamid"). Lederle Laboratories, an unincorporated division of Cyanamid, produced TRI-IMMUNOL. In 1994, American Home Products Corporation ("AHPC") acquired Cyanamid. In March 2002, AHPC changed its name to Wyeth.

and is less likely to cause adverse events.[4] The FDA initially approved ACEL-IMUNE, however, for administration as the fourth and/or fifth DPT dose in the series of five. The FDA did not approve an acellular pertussis vaccine for the first three shots in the series until July 1996 when it approved the license of Connaught Laboratories, Inc. Defendant's ACEL-IMUNE did not receive approval for these same doses until December 1996.

Nonetheless, at the time of vaccination in April 1992, Hannah's doctor administered the TRI-IMMUNOL vaccine because there were no acellular pertussis vaccines commercially available for the third dose. Hannah's particular vaccine came from a lot that generated sixty-five reports of adverse reactions with the FDA and Centers for Disease Control and Prevention, including thirty-nine emergency room visits, six hospitalizations, and two deaths. Hannah's physician later

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[4] The acellular pertussis vaccine contains pertussis toxin and other bacterial components. These components, however, are less reactive and cause fewer adverse events because they have been detoxified using chemical or genetic techniques. Centers for Disease Control and Prevention, Pertussis Vaccination: Acellular Pertussis Vaccine for the Fourth and Fifth Doses of the DPT Series; Update to Supplementary ACIP Stat Recommendations of the Advisory Committee on Immunization Practices, October 9, 1992, http://www.cdc.gov/mmwr/preview/mmwrhtml/00048610.htm.

indicated, as part of this litigation, that she would not have immunized Hannah had she known of the adverse event reports associated with this lot of the vaccine.

In 1998, Wyeth voluntarily discontinued manufacturing TRI-IMMUNOL.

C.

Hannah's parents ("plaintiffs") filed a petition in the Vaccine Court in April 1995, alleging that Hannah suffered an on-Table residual seizure disorder and encephalopathy.[5] *Bruesewitz v. Sec'y of Dep't of HHS*, No. 95-0266V, 2002 WL 31965744, at *1 n.1 (Fed. Cl. Dec. 20, 2002). The Court held a hearing in July 2002 and concluded in December of that year that Hannah's injuries were non-Table injuries and that the petitioners had not proven causation in fact. *Id.* at *13–17. Accordingly, it dismissed the claim with prejudice. *Id.* at *17. Hannah's parents rejected the Court's judgment on February 14,

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[5] Effective March 10, 1995, approximately one month before the plaintiffs filed their petition with the Vaccine Court, new regulations deleted residual seizure disorder as a Table injury for DPT vaccine. *Bruesewitz v. Sec'y of Dep't of HHS*, No. 95-0266V, 2002 WL 31965744, at *1 n.1 (Fed. Cl. Dec. 20, 2002); *see also* National Vaccine Injury Compensation Program Revision of the Vaccine Injury Table, 60 Fed. Reg. 7678, 7689–91 (Feb. 8, 1995).

2003.

Having exhausted their administrative remedies, the plaintiffs filed a Complaint in the Philadelphia Court of Common Pleas in October 2005. The complaint sought recovery on four claims: (I) negligent failure to produce a safer vaccine; (II) negligent failure to warn; (III) strict liability for design defect; and (IV) strict liability for manufacturing defect. Wyeth removed the action on the basis of diversity to the Eastern District of Pennsylvania and filed a motion for summary judgment. The District Court denied the motion without prejudice because the parties had not engaged in discovery. Following completion of discovery, Wyeth again moved for summary judgment on all four counts.

Although the District Court did not accept all of Wyeth's theories, it granted summary judgment in Wyeth's favor on all counts on August 24, 2007. The District Court concluded that Section 22(b)(1) of the Vaccine Act, 42 U.S.C. § 300aa-22(b)(1), preempts all design defect claims arising from a vaccine-related injury or death and dismissed Counts I and III on that basis. Regarding Count II, which alleged negligent failure to warn, the District Court concluded that the plaintiffs had not rebutted the statutory presumption created by Section 22(b)(2) of the Vaccine Act, 42 U.S.C. § 300aa-22(b)(2), that Wyeth's FDA-compliant warnings were proper. As to Count IV, which alleged that the particular lot from which Hannah's dose originated was especially prone to adverse reactions due to a

manufacturing defect, the District Court concluded that the plaintiffs had failed to present sufficient evidence that the lot was defective or that it caused Hannah's injuries.

The District Court's ruling on the first and third claims warrants further examination. Both counts alleged a design defect—Count I alleged that Hannah's vaccine was negligently designed because the defendant knew of a safer alternative and failed to produce it, while Count III alleged strict liability design defect. The District Court ruled that both claims were preempted by the Vaccine Act. It rested this decision on four points. First, it stated that a case-by-case consideration of whether a vaccine was unavoidably safe would not protect vaccine manufacturers from suit. Second, it reasoned that Congress passed the Vaccine Act to "provide an umbrella under which manufacturers would improve the safety of their products while remaining immune from design defect claims." Third, the Court found that Congress achieved an appropriate balance by offsetting the effect of the preemption of design defect claims with creation of a compensation program for individuals injured by vaccines. Finally, it concluded that the Vaccine Act preempts both strict liability and negligent design defect claims against FDA-approved vaccines. Accordingly, it dismissed plaintiffs' first and third claims.

The plaintiffs appealed. Their appeal presents this Court with three questions: (1) does § 300aa-22(b)(1) act as a complete bar to design defect claims; (2) have the plaintiffs in

this case met their burden under § 22(b)(2) of the Vaccine Act to show that defendants failed to provide an adequate warning of the alleged dangers of the vaccine; and (3) have the plaintiffs provided sufficient evidence of a manufacturing defect to survive the defendant's motion for summary judgment.

II.

The District Court had jurisdiction under 28 U.S.C. §§ 1332 and 1441, and we have appellate jurisdiction under 28 U.S.C. § 1291. Our review of a District Court's grant of summary judgment is plenary, and we apply the same standard as the District Court to determine whether summary judgment was appropriate. *Norfolk S. Ry. Co. v. Basell USA Inc.*, 512 F.3d 86, 91 (3d Cir. 2008). A grant of summary judgment is appropriate "if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). In making this determination, we must view the facts in the light most favorable to the nonmoving party and draw all inferences in that party's favor. *Norfolk*, 512 F.3d at 91.

III.

Preemption doctrine is rooted in the Supremacy Clause of the United States Constitution. Article VI declares that the laws of the United States "shall be the supreme Law of the

Land; . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. "Under the Supremacy Clause, federal law may supersede state law in several different ways." *Hillsborough County, Fla., v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713 (1985). Over the years, the Supreme Court has recognized three types of preemption: express preemption, implied conflict preemption, and field preemption. *Id.*

A federal enactment expressly preempts state law if it contains language so requiring. *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 541 (2001). Thus, when construing an express preemption clause, a reviewing court must necessarily begin by examining the "plain wording of the clause," as this "necessarily contains the best evidence of Congress' pre-emptive intent." *Sprietsma v. Mercury Marine*, 537 U.S. 51, 62–63 (2002) (quoting *CSX Transp. v. Easterwood*, 507 U.S. 658, 664 (1993)). Though the language of the provision offers a starting point, courts are often called upon to "identify the domain expressly pre-empted by that language." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 484 (1996) (internal quotation marks and citations omitted). This, in turn, is guided by two principles. *Id.* at 485. First, "Congressional purpose is the 'ultimate touchstone' of our inquiry." *Lorillard Tobacco Co.*, 533 U.S. at 541 (quoting *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992)); *see also Altria Group, Inc. v. Good*, 129 S. Ct. 538, 543 (2008) ("If a federal law contains an express pre-emption clause, it does not immediately end the inquiry because the

question of the substance and scope of Congress' displacement of state law still remains."). Second, courts must operate under the "assumption that the historic police powers of the States [a]re not to be superseded by the Federal Act unless that [is] the clear and manifest purpose of Congress." *Cal. Div. of Labor Standards Enforcement v. Dillingham Constr., N.A., Inc.*, 519 U.S. 316, 325 (1997).

Implied conflict preemption arises when state law conflicts with a federal statute in one of two situations. First, it arises when it is "impossible for a private party to comply with both state and federal requirements." *English v. General Elec. Co.*, 496 U.S. 72, 78–79 (1990). It is also present 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). Furthermore, implied preemption may exist even in the face of an express preemption clause. As the Supreme Court observed in *Freightliner Corp. v. Myrick*, 514 U.S. 280, 288 (1995), "Congress' enactment of a provision defining the preemptive reach of a statute implies that matters beyond that reach are not pre-empted," but that "does not mean that the express clause entirely forecloses any possibility of implied pre-emption."

When confronting arguments that a law stands as an obstacle to Congressional objectives, a court must use its judgment: "What is a sufficient obstacle is a matter of judgment, to be informed by examining the federal statute as a whole and

identifying its purpose and intended effects." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 373 (2000). In fact, we must look to "'the entire scheme of the statute'" and determine "'[i]f the purpose of the [federal] act cannot otherwise be accomplished—if its operation with its chosen field [would] be frustrated and its provisions be refused their natural effect.'" *Id.* (quoting *Savage v. Jones*, 225 U.S. 501, 533 (1912)). Once again, this requires an examination of the "'whole law, and to its object and policy.'" *Gade v. Nat'l Solid Wastes Mgmt. Assn.*, 505 U.S. 88, 98 (1992) (quoting *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 51 (1987)).

Field preemption arises by implication when state law occupies a "field reserved for federal regulation." *United States v. Locke*, 529 U.S. 89, 111 (2000). This occurs when "Congress [] left no room for state regulation of these matters." *Id.*; *see also Lorillard Tobacco Co.*, 533 U.S. at 541. It may also be inferred when "an Act of Congress 'touch[es] a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.'" *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). Nonetheless, because field preemption typically arises in areas traditionally regulated by states under their police powers, "congressional intent to supersede state laws must be 'clear and manifest.'" *Id.* (citation omitted).

Yet despite the development of the foregoing preemption

jurisprudence, courts must begin their analysis of these questions by applying a presumption against preemption. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992). "In areas of traditional state regulation, we assume that a federal statute has not supplanted state law unless Congress has made such an intention 'clear and manifest.'" *Bates v. Dow AgroSciences*, 544 U.S. 431, 449 (2005). When faced with two equally plausible readings of statutory text, we "have a duty to accept the reading that disfavors preemption." *Id; see also Altria Group, Inc.*, 129 S. Ct. at 543; *Cipollone*, 505 U.S. at 518. This is true even in the event of an express preemption clause. *Riegel v. Medtronic, Inc.*, 128 S.Ct. 999, 1014 (2008) (quoting *Bates,* 544 U.S. at 449). That issues of health and safety have traditionally fallen within the province of state regulation is beyond refute. That safety of vaccines is an issue of health and safety is equally clear. *See, e.g.*, *Medtronic, Inc.*, 518 U.S. at 485. Nonetheless, in the face of clear evidence, the presumption against preemption can be overcome. *See Crosby*, 530 U.S. at 374 n.8. ("Assuming, *arguendo*, that some presumption against preemption is appropriate, we conclude, based on our analysis below, that the state Act presents a sufficient obstacle to the full accomplishment of Congress's objectives under the federal Act to find it preempted.").

We must decide here whether the plaintiffs' design defect claims are preempted. As we have noted, the District Court reasoned that four points counseled in favor of finding that both claims were preempted by the Vaccine Act: (1) if the Vaccine

Act permitted case-by-case consideration of design defect claims, the Act would do little to protect manufacturers from suit; (2) Congress intended the Vaccine Act to encourage vaccine improvements while providing immunity for design defect claims; (3) Congress achieved a balance between manufacturers and patients by creating the compensation system to offset design defect immunity; and (4) the Vaccine Act is broader than comment k of the Restatement (Second) of Torts § 402A such that the Act encompasses both strict liability and negligence claims. At the same time, the District Court did not explicitly lay out a framework for coming to these conclusions, nor did it state whether they were predicated on express, implied, or field preemption grounds.

Plaintiffs now seek to turn such ambiguity to their advantage by arguing that the District Court's decision was "based on some kind of implied or field preemption" when the defendant's motion for summary judgment raised only express preemption. This, they maintain, violated "well-settled summary judgment principles."[6] Accordingly, we must consider

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[6] The plaintiffs argue that the District Court's decision violates the principle that a "district court may not grant summary judgment *sua sponte* on grounds not requested by the moving party." *John Deere Co. v. Am. Nat'l Bank*, 809 F.2d 1190, 1192 (5th Cir. 1987). This Court has previously remanded a claim because the District Court granted summary judgment on a ground not offered in the moving party's motion.

four questions related to the preemption of the design defect claim: (1) whether § 300aa-22(b) constitutes an express preemption provision; (2) whether we may use traditional tools of statutory interpretation, including legislative history, when construing such a provision; (3) whether this provision preempts plaintiffs' design defect claims; and (4) whether the District Court's decision is consistent with this analysis.

A.

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. Section 300aa-22, entitled "Standards of Responsibility," sets forth both a general rule and several exceptions to that rule. It states:

Brobst v. Columbus Servs. Intern., 761 F.2d 148, 159 (3d Cir. 1985). For the reasons that follow, we need not decide this issue. We note, however, that our ruling in *Brobst* was predicated on a district court's obligation to provide notice to the parties before ruling on a particular issue. In this case, the plaintiffs argued in their response to the motion for summary judgment about the propriety of ruling on implied preemption grounds, thereby indicating that they were on notice that the District Court may have been considering implied preemption at that time and furthermore that they had an opportunity to respond on this issue.

(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. § 300aa-22.

We are guided by two cases interpreting language similar to that which appears in § 300aa-22. In *Lorillard Tobacco Co.*, the Supreme Court interpreted the Federal Cigarette Labeling and Advertising Act, which stated that "'[n]o statement relating to smoking and health other than the statement required by section 1333 of this title, shall be required on any cigarette package.'" 533 U.S. at 541 (quoting 15 U.S.C. § 1334). This language is analogous to subsection 22(b)(1) of the Vaccine Act, which states that "[n]o vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death . . . if the injury or death resulted from side effects that were unavoidable." In both provisions, without using language such as "no state shall" or "state law is preempted," Congress has set forth an area in which state law may not operate. In *CSX Transportation, Inc.*, the Supreme Court construed the following provision: "A state may adopt or continue in force any law . . . until such time as the Secretary has adopted a rule . . . covering the subject matter of such State requirement. A state may adopt or continue in force an additional or more stringent law . . . when not incompatible with any Federal law. . . ." 507 U.S. at 662 & n.2 (quoting 45 U.S.C. § 434 (repealed 1994)). Similarly, 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).

In both *Lorillard Tobacco Co.* and *CSX Transportation, Inc.*, the Supreme Court characterized the language at issue as an express preemption provision. In the former case, the Court declared that "Congress unequivocally preclude[d] the requirement of any additional statements on cigarette packages beyond those provided in § 1333." *Lorillard Tobacco Co.*, 533 U.S. at 542. In the latter case, the Court characterized the quoted language as containing "express saving and preemption clauses." *CSX Transp., Inc.*, 505 U.S. at 662. Accordingly, we conclude that § 22(a) and § 22(b)(1) of the Vaccine Act also contain express preemption clauses.

Our conclusion is consistent with prior jurisprudence from this Court, stating that express preemption "arises when there is an explicit statutory command that state law be displaced." *St. Thomas-St. John Hotel & Tourism Ass'n, Inc. v. Gov't of the U.S., V.I.*, 218 F.3d 232, 238 (3d Cir. 2000). Section 22(a) clearly states Congress's intent to displace state law in several enumerated instances, including as provided for in subsection (b). Subsection (b) then declares that manufacturers are immune from liability for claims arising from "unavoidable" injuries and deaths related to vaccine administration, thereby prohibiting states from regulating in this area. The scope of a preemption provision stating that "no state shall pass laws with the following exceptions" may well be broader than a provision stating "state law applies with the following exceptions." Yet the breadth of a provision does not alter the import of the underlying language, and here that language conveys a clear intent to override state law civil action claims in particular, defined circumstances.

Yet we must still determine the scope and reach of the express preemption provision. The plaintiffs here concede that the statute "expressly precludes only those state tort claims involving vaccines with side effects first shown to be 'unavoidable,'" but they argue that avoidability must first be determined "on a case-by-basis" as part of a court's examination of a design defect claim. In response, Wyeth argues that this language "preempts all claims arising from allegations of design defect." Accordingly, "we must [] 'identify the domain expressly pre-empted' by [the] language" of the Vaccine Act. *Medtronic Inc.*, 518 U.S. at 484.

B.

Again, we are mindful that courts seeking to identify the scope of an express preemption provision are compelled to consider "Congressional purpose [] the 'ultimate touchstone' of our inquiry." *Lorillard Tobacco Co.*, 533 U.S. at 541 (quoting *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992)). The Supreme Court has declared on numerous occasions that reviewing courts have several tools to aid them in their interpretation of congressional purpose. Courts may be guided by 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.*, 518 U.S. at 486 (internal quotation marks and citations omitted); *see also Gade*, 505 U.S. at 98 ("Our ultimate task in any pre-emption case is to determine whether state regulation is consistent with the structure and purpose of the statute as a whole.");

Ingersoll-Rand Co. v. McClendon, 498 U.S. 133, 138 (1990) ("To discern Congress' intent we examine the explicit statutory language and the structure and purpose of the statute."). Beyond structure and purpose, the Court has also stated "that '[i]n expounding a statute, 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.'" *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 51 (1987) (quoting *Kelly v. Robinson*, 479 U.S. 36, 43 (1986).

The above analysis, allowing courts to consider a statute's purpose, structure, and regulatory scheme, applies even in light of the presumption against preemption. The Court's preemption discussion in *Cipollone* is particularly instructive on this point. In that case, the Court considered a statute stating that "[n]o statement relating to smoking and health shall be required in the advertising of [properly labeled] cigarettes." *Cipollone*, 505 U.S. at 518 (internal quotations and emphasis omitted). The Court reaffirmed the presumption against preemption. *Id.* at 516. It also noted the existence of an express preemption clause, *id.* at 517, which it construed using several tools of statutory construction, *id.* at 519. The Court noted the Act's explicit "statement of purpose," and it read this against a "backdrop of regulatory activity." *Id.* It also considered the "regulatory context," namely the factors that served as "the catalyst for the passage" of the statute. *Id.* The Court stated that this backdrop and context supported a narrow reading of the preemption clause. *Id.* at 518–19. In dissent, Justice Scalia criticized the majority and argued for a broader interpretation of the provision, predicated on the statute's use of the phrase "no statement." *Id.* at 549–50 (Scalia, J., dissenting). The majority

rejected Justice Scalia's interpretation because it "relie[d] solely on an interpretation of those two words, artificially severed from both textual and legislative context." *Id.* at 519 n.16.

We have recognized that legislative history is not without its shortcomings as a tool of interpretation. "As a point of fact, there can be multiple legislative intents because hundreds of men and women must vote in favor of a bill in order for it to become a law." *Morgan v. Gay*, 466 F.3d 276, 278 (3d Cir. 2006); *see also Exxon Mobil Corp. v. Allapattah Servs., Inc.*, 545 U.S. 546, 568 (2005) (noting that "legislative history is itself often murky, ambiguous, and contradictory," and that it "may give unrepresentative committee members—or, worse yet, unelected staffers and lobbyists—both the power and the incentive to . . . secure results they were unable to achieve through the statutory text"). Yet, resort to legislative history is appropriate "when necessary to interpret ambiguous statutory text." *BedRoc Ltd., LLC v. United States*, 541 U.S. 176, 187 n.8 (2004) (plurality opinion). Although this Court has declined to employ legislative history if a statute is clear on its face, we have allowed recourse to legislative history in the face of ambiguity. *See, e.g.*, *In re Mehta*, 310 F.3d 308, 311 (3d Cir. 2002) ("We look to the text of a statute to determine congressional intent, and look to legislative history only if the text is ambiguous."); *United States v. Gregg*, 226 F.3d 253, 257 (3d Cir. 2000) ("To determine a law's plain meaning, we begin with the language of the statute. If the language of the statute expresses Congress's intent with sufficient precision, the inquiry ends there . . . Where the statutory language does not express Congress's intent unequivocally, a court traditionally refers to the legislative history . . . .").

It is, therefore, appropriate to consider legislative history to resolve ambiguity in the scope of an express preemption provision. In *Cipollone*, as part of the discussion of the regulatory context of the statute at issue, the Court cited language from a House of Representatives' report that was issued during Congress's consideration of the legislation. *Cipollone*, 505 U.S. at 519. Similarly, in *Lorillard Tobacco Co.*, the Court stated that its task was to "identify the domain expressly pre-empted," 533 U.S. at 541, and that this was aided "by considering the predecessor pre-emption provision and the circumstances in which the current language was adopted." *Id.* at 542. It went on to cite reports from the United States Surgeon General, the House of Representatives, and the Senate in the course of its discussion. *Id.* at 542–44.

We cannot resolve from statutory text alone the scope of the express preemption provision before us. Accordingly, we will look at the language, structure, and purpose of the Vaccine Act to ascertain whether it preempts all design defect claims, and we will resort—as we must—to legislative history to aid our interpretation.

C.

We are left to construe the scope of preemption created by the phrase "if the injury or death resulted from side effects that were unavoidable . . . ." § 300aa-22(b). The phrase hinges on the word "unavoidable," yet the term is not defined in the Vaccine Act. Nor does the surrounding language answer questions such as whether all design defect claims are preempted or whether state courts may determine avoidability on

a case-by-case basis. According to the *Oxford English Dictionary*, "unavoidable" means "[n]ot avoidable; that [which] cannot be avoided or escaped; inevitable." (2d ed. 1989). By itself, this succinct definition is unhelpful. Yet, the structure of the provision as a whole provides necessary context, and we can conceive of two possible interpretations of this language.

1.

The first construction would result in the preemption of some design defect claims. Subsection (a) expressly preempts state law to the degree indicated in subsection (b). Subsection (b), in turn, primarily relates to design defect claims, as evidenced by the use of a subordinate clause introduced by "even though" to reference claims that might arise from a manufacturing defect or warning defect. That structure makes it clear that we must consider design defects in the first instance. Clearly, then, subsection (a) and (b) work in concert to preempt state law and exempt manufacturers from liability for some design defect claims.

Section 300aa–22, taken as a whole, further clarifies Congress's intent with regard to design defect claims. Subsection (a) displaces state law only as defined in subsections (b), (c), and (e). Subsections (b) and (c) employ identical introductory language, stating that "[n]o vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine . . . ." Subsection (e) prohibits states from foreclosing civil actions that are otherwise "not barred by this part," thereby stating that other parts of § 300aa-22 are

designed to not only limit liability but bar some claims entirely. Thus, by reading these three provisions together, it becomes clear that Congress intended that subsections (b) and (c) should be an outright bar to some claims.

In a case presenting design defect claims similar to those in the present case, the Georgia Supreme Court reached a different conclusion regarding the meaning of § 22(b). *Am. Home Prods. Corp v. Ferrari*, 669 S.E.2d 236 (Ga. 2008). It focused on the clause "if the injury or death resulted from side effects that were unavoidable." That Court first noted that this language is conditional and implies that some vaccine-related injuries and deaths may be avoided. *Id.* at 240. The *Ferrari* Court also reasoned that reading the preemption provision to exclude all design defect claims would render the clause superfluous. *Id.* at 240. That Court concluded that if Congress intended to preempt all design defect claims, it could have achieved that result by omitting the "unavoidable" clause such that the provision would prevent liability "if the vaccine was properly prepared and was accompanied by proper directions and warnings." *Id.*

We do not consider the *Ferrari* Court's reading to be compelling. First, while we recognize that the language is conditional, such a reading does not foreclose the preemption of some claims. Furthermore, it is always possible to construct through hindsight an alternate structure for a statute with alternative wording that would render it more clear. For instance, subpart (b)(1) notes that manufacturers may not be liable for unavoidable side effects caused by a vaccine that was "properly prepared and was accompanied by proper directions

and warnings," and subpart (b)(2) sets limits on this. In subpart 22(b)(2), the statute declares that vaccines issued in accordance with federal labeling requirements are presumed to have proper directions and warnings *unless* one of the following applies: (1) the manufacturer engaged in conduct that would subject it to punitive damages under § 300aa-23 of the Vaccine Act, or (2) there is clear and convincing evidence that the manufacturer failed to exercise due care. § 300aa-22(b)(2). If, as plaintiffs claim, Congress intended to carve out from subsection 22(b) a mechanism to enable states to determine what side effects could have been avoided through an alternate design, Congress could have done so in the manner used in subpart (b)(2) to preserve some warning defect claims against vaccines that meet federal labeling requirements.

More importantly, we think the *Ferrari* Court's construction is contrary to the structure of the Act because it does not bar any design defect claims. If we interpret the Vaccine Act to allow case-by-case analysis of whether particular vaccine side effects are avoidable, every design defect claim is subject to evaluation by a court. Furthermore, in 1986 when Congress enacted the Vaccine Act, several courts had already barred strict liability design defect claims against prescription drug manufacturers under state law.[7] The *Ferrari* Court's construction of § 300aa-22 could create an awkward dichotomy in the case law of these states—their courts would be required

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[7] *See, e.g.*, *Davis v. Wyeth Labs., Inc.*, 399 F.2d 121, 128 (9th Cir. 1968); *Lewis v. Baker*, 413 P.2d 400, 404 (Or. 1966) (overruled in part on other grounds).

to engage in case-by-case analysis of all strict liability and negligent design defect claims brought under the Vaccine Act, while barring strict liability design defect claims against prescription drug manufacturers. As discussed above, Congress could not have intended such a result, as § 300aa-22 makes clear that Congress intended to preempt and bar certain claims.

Though there are two possible interpretations of subsection (b), we conclude that a "clear and manifest" expression of congressional intent supports the first interpretation.[8] Our construction, however, does not indicate

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[8] In *Wyeth v. Levine*, __ S. Ct. __, No. 06-1249, 2009 WL 529172, at *1 (2009), the Supreme Court examined whether federal law preempted state tort claims alleging that a drug manufacturer failed to adequately warn of the dangers associated with a drug. *Id.* at *1. Though we recognize that the Supreme Court concluded that state tort law claims were not preempted in that case, *id.* at 13, Levine is readily distinguishable on several grounds. First, the Court explicitly noted the absence of an express preemption provision and found Congress's silence, "coupled with its certain awareness of the prevalence of state tort litigation, [] powerful evidence." *Id.* at 10. In this case, however, Congress included an express preemption provision that was prompted, as evidenced by the Committee Report, by the prevalence of state tort litigation. Second, it recognized that, under federal law, a drug manufacturer could strengthen a drug's label without preapproval from the FDA. *Id.* at 7. This stands in contrast to the FDA's far-more extensive control and oversight of the

whether subsection (b) preempts all design defect claims or only strict liability design defect claims.

2.

There is no language in the statute indicating whether the Vaccine Act preempts only strict liability design defect claims or also those based in negligence, and the structure and purpose of the Act are of little assistance in resolving that question. As a result, there remains some inherent ambiguity in the statute, and we must resort to legislative history to resolve that ambiguity. The parties in this case cite to different congressional reports to support their claims. Each argument will be addressed in turn.

a.

Wyeth cites to a report ("Commerce Report") from the House Committee on Energy and Commerce ("Energy and Commerce Committee"), which had jurisdiction over the Vaccine Act and guided the legislation through passage. H.R. Rep. No. 99-108 (1986). The Commerce Report declared that childhood vaccinations have been "one of the most spectacularly effective public health initiatives this country has ever undertaken," preventing countless deaths and saving billions of dollars. *Id.* at 4. The Report stated, however, that "the Nation's ability to maintain this level of success has come into question" as a result of tort claims by individuals gravely injured by

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approval of a drug's design and alteration.

vaccines. *Id.* This, in turn, caused an increase in the cost of vaccines, the withdrawal of some manufacturers from the market, and a decreased rate of immunization. *Id.* The Report noted that these conditions prompted the Energy and Commerce Committee to reevaluate the federal regulation of vaccines. *Id.* at 5.

Though the Committee was concerned with compensating individuals injured by vaccines, it also sought to reduce the cost of such claims in order to safeguard the development and availability of such vaccines. It noted that there was "no 'perfect' or reaction-free childhood vaccine on the market" and that a small number of children suffered serious reactions. *Id.* at 6. It then stated that "despite these possibilities . . . it is safer to take the required shots than to risk the health consequences of contracting the diseases . . . ." *Id.* The Committee expressed concern that 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.* at 7. The Report demonstrates that the Vaccine Act was motivated in great measure by Congress's belief that an alternate compensation system would reduce awards and create a stable, predictable basis for estimating liability: "[T]he Committee believes 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.*

Importantly, the Commerce Report specifically addressed § 300aa-22, the section at issue here. First, it noted that some

provisions of the Vaccine Act would "change most State laws" related to vaccine injuries and deaths. Yet, it deemed this an appropriate change "in light of the availability of a comprehensive and fair compensation system." *Id.* at 25. Then, the Commerce Report stated that the Vaccine Act reflected the *principle* of Restatement (Second) of Torts § 402A comment k,[9]

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[9] The Georgia Supreme Court took this reference to mean that Congress intended to preserve some design defect claims and permit case-by-case consideration of whether a vaccine is unavoidably harmful. *See Ferrari*, 668 S.E.2d at 239–40. Specifically, the *Ferrari* Court pointed to the fact that a majority of courts have interpreted comment k as permitting a case-by-case analysis of whether a vaccine's side effects are avoidable. *Id.* at 239. It then drew on the Vaccine Act's legislative history to support its conclusion that Congress interpreted comment k in the same manner as those other courts. *Id.* at 240.

Though we acknowledge that a majority of states permit some design defect claims under comment k, we disagree with the Georgia Supreme Court on the relevance of this fact. First, it discounts that courts in a significant minority of states have held that comment k preempts all strict liability design defect claims against FDA-approved drugs. Second, 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. As one court has noted, "in 1986 courts had not yet reached a consensus on the meaning of Comment k, or the proper treatment of prescription drugs in design defect legislation. Thus, while some courts concluded that a case-by-case analysis was necessary . . . others concluded that

which states that sellers of certain products, including vaccines, should not be strictly liable for harm caused by their products when it is not possible to make these products entirely safe.[10] *Id.*

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prescription drug manufacturers were generally not liable for design defect claims." *Militrano v. Lederle Labs.* 769 N.Y.S.2d 839, 844–45 (N.Y. Sup. Ct. 2003). Finally, we note that regardless of state court consideration of comment k, we believe Congress made it clear what it intended when it invoked comment k.

[10] Comment k states the following:

> 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. . . . An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to both 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 seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls

at 25–26. The Report described the type of vaccine cases in which comment k would have import—cases in which innocent children would be "badly injured or killed" by a vaccine, but in which a jury would likely impose liability on the manufacturer "even if the defendant manufacturer *may* have made as safe a vaccine as anyone reasonably could expect." H.R. Rep. 99–908 at 26 (emphasis added). Finally, it 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, whether liability rests on theories of strict liability or negligence: "[i]f [injured individuals] 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." *Id.*

In our view, the Commerce Report supports the conclusion that the Vaccine Act preempts all design defect claims, including those based in negligence. First, the Committee Report repeatedly stressed the importance of vaccine development and availability. Second, it expressed serious

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> 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).

concern over the withdrawal of even a single vaccine manufacturer from the marketplace. Third, though it described a regime that sought to compensate individuals, the Commerce Report emphasized that the new system would reduce and stabilize litigation costs while also enabling manufacturers to estimate the costs associated with compensation. Finally, it explicitly stated that injured individuals could only seek redress in the state tort system for certain manufacturing defect and warning claims.

Each of the objectives extolled by the Commerce Report would be undermined if design defect claims were permitted under the statute. The plaintiffs' construction of the statute would permit state courts to determine on a case-by-case basis whether a vaccine manufacturer could have conceivably created a safer vaccine. This would undoubtedly increase the costs and risks associated with litigation and would undermine a manufacturer's efforts to estimate and control costs. It would also effectively impose an affirmative obligation on vaccine manufacturers to pursue, regardless of cost, the countless avenues through which they could develop a safer vaccine. These were the very problems which led to instability in the vaccine market and which caused Congress to intervene through the passage of the Vaccine Act.

b.

Unfortunately, our review of legislative history does not end here. Rather than rely on the Commerce Report, the plaintiffs respond that other language in the legislative history strongly favors their position that design defect claims are not

preempted. The Vaccine Act, which Congress passed in 1986, did not initially "include a source of payment for such compensation 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. No. 100-391(I), at 690 (1987). In 1987, Congress passed legislation to fund the compensation program. On October 26, 1987, as part of this funding legislation, the House Committee on the Budget ("Budget Committee") issued its own report ("Budget Report") which stated the following:

> It is not the Committee's intention to preclude court actions under applicable law. The Committee's intent at the time of considering the Act and in these amendments was and is to leave otherwise applicable law unaffected, except as expressly altered by the Act and the amendments. An amendment to establish as part of this compensation system that a manufacturer's failure to develop safer vaccine was not grounds for liability was rejected by the Committee during its original consideration of the Act. Further, the codification of Comment (k) of The Restatement (Second) of Torts was not intended to decide as a matter of law the circumstances in which a vaccine should be deemed unavoidably unsafe. The Committee stresses that there should be no misunderstanding that the Act undertook to decide as a matter of law whether vaccines were unavoidably unsafe or not. This question is left to the courts to determine in accordance with

applicable law.

Id. at 691.

According to the plaintiffs, this language demonstrates that Congress considered and rejected an amendment that would have explicitly preempted all design defect claims. This argument is premised on the well-settled notion that "[f]ew principles of statutory construction are more compelling than the proposition that Congress does not intend *sub silentio* to enact statutory language that it has earlier discarded in favor of other language." *INS v. Cardoza-Fonseca*, 480 U.S. 421, 442–443 (1987) (internal quotation marks and citation omitted). Additionally, plaintiffs claim that the Budget Report evidences Congress's intent to permit courts to determine on a case-by-case basis whether a vaccine's side effects were "unavoidable."

The problems with the Budget Report, however, are three-fold. First, the Budget Report repeatedly uses the term "the Committee," but it is unclear whether this refers to the Budget Committee or the Energy and Commerce Committee. While the Budget Committee did not play a role in the drafting or passage of the Vaccine Act, the Energy and Commerce Committee had jurisdiction over the bill and held several hearings on childhood vaccines and the proposed legislation. A subcommittee of the Energy and Commerce Committee also held a hearing, known as a "mark-up" hearing, on the Vaccine Act in September 1986 during which time it considered

amendments to the legislation.[11] Because the Budget Committee did not consider amendments to the Vaccine Act, we will presume that references in the Budget Report to "the Committee" refer to the Energy and Commerce Committee. Second, though the Energy and Commerce Committee conducted a mark-up hearing to consider proposed amendments, no record is available to confirm that the Energy and Commerce Committee considered and rejected an amendment related to design defects at that time.[12] Third, "the views of a subsequent Congress form a hazardous basis for inferring the intent of an earlier one." *United States v. Price*, 361 U.S. 304, 313 (1960). That danger is amply present here, where the subsequent report was not issued by the committee with jurisdiction over the legislation, but by a committee which played no role in passage of the Vaccine Act. *See United States v. United Mine Workers of Am.*, 330 U.S. 258, 281–82 (1947). Without more, we have no basis to conclude that the Budget Report is an accurate

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[11] Information pertaining to Congressional passage of the Vaccine Act, including the dates of the markup hearing and Committee consideration, can be found on the Library of Congress's website for legislative information. Library of Congress, THOMAS, S.1744 (P.L. 99-660): All Congressional Actions with Amendments, http://thomas.loc.gov/cgi-bin/bdquery/z?d099:SN01744:@@@S|TOM:/bss/d099query.html.

[12] The Energy and Commerce Committee retains a transcript of this hearing, but this transcript was not available to us.

reflection of what transpired before the Energy and Commerce Committee, or for that matter, the motivations underlying Congress's enactment of the Vaccine Act in 1986.

For these reasons, and despite plaintiffs urging, we refuse to view the relevant legislative history as containing "dueling" committee reports.

3.

Even if Congress did not intend to prohibit all design defect claims against vaccine manufacturers, the legislative history indicates that it intended to preempt the specific claim at issue here. In the days prior to passage of the Vaccine Act, the Energy and Commerce Committee issued a report containing "background information on the various issues concerning childhood vaccines . . . ." ("Background Report"). Staff of H. Comm. on Energy & Commerce, 99th Cong., *Childhood Immunizations*, at III (1986). This report stated that the pertussis vaccine "is considered the most reactive of all the commonly used vaccines and has been the one of most concern in debates over adverse effects of vaccines." *Id.* at 24. It recounted the risks and side effects associated with the pertussis vaccine, including neurological problems and even death, and the efforts of parent groups to raise awareness of these serious consequences. *Id.* at 24–29. The Background Report also stated that "research is proceeding on the effort to develop an acellular vaccine that would cause fewer side effects." *Id.* at 38. Namely, it explained that researchers were attempting to isolate the reactive components of the pertussis bacterial cell so that these components could be excluded from the vaccine. *Id.* at 24.

The Background Report also explained that Japan had used such a vaccine, but it indicated that the safety and efficacy of this vaccine had not been reported. *Id.* It then warned that "conducting clinical trials to test any new pertussis vaccine will pose major logistic, legal, and ethical problems." *Id.*

The Commerce Report on the Vaccine Act also contained numerous references to the DPT vaccine. H.R. Rep. 99-908. It noted the "serious—and sometimes deadly—consequences" of vaccines and that this was "particularly true with regard to the pertussis" component of the DPT vaccine. *Id.* at 6. Before warning of the ramifications of the withdrawal of "even a single manufacturer," the Report also highlighted the increasing number of lawsuits related to the DPT vaccine and recognized that there were only two manufacturers of the DPT vaccine at that time. *Id.* at 6–7.

Whereas the plaintiffs contend that Wyeth and its predecessors knew "for more than 25 years that the acellular vaccine was less reactogenic and, therefore, safer for the children who receive it" and seek to establish liability by virtue of that knowledge, the two reports discussed immediately above, taken together, establish that Congress intended to preempt such claims. The Background Report indicates that Congress was well aware of the state of the art concerning development of an acellular DPT vaccine. It also evidences that Congress believed there were hurdles before such a vaccine could undergo clinical testing in the United States. The Commerce Report stresses the particular problems faced by DPT vaccine manufacturers, including the high number of lawsuits and existence of only two producers. The Commerce Report then concludes that the

"withdrawal of even a single manufacturer would present the very real possibility of vaccine shortages . . . [and] a resurgence of preventable diseases" and that the vaccine market will stabilize once "manufacturers have a better sense of their potential litigation obligations." *Id.* at 7. This evidence indicates that Congress weighed the various concerns related to the pertussis vaccine and concluded that DPT manufacturers should be shielded from liability for injuries arising from the whole-cell pertussis vaccine.

4.

As we stated at the beginning of this part, "Congressional purpose is the 'ultimate touchstone' of our inquiry." *Lorillard Tobacco Co.*, 533 U.S. at 541 (quoting *Cipollone*, 505 U.S. at 516). Section 22(a) and 22(b)(1) of the Vaccine Act contain express preemption clauses. Further, the structure and purpose of § 300aa-22 of the Act make clear that Congress intended to preempt some design defect claims. The legislative history identifies the scope of this preemption, which encompasses both strict liability and negligent design defect claims.

D.

The District Court did not clearly explain the basis of its summary judgment decision. It neither discussed the three types of preemption nor mentioned that the motion for summary judgment raised only express preemption. Nevertheless, the District Court decision is consistent with an express preemption analysis, and we take it to have intended application of that doctrine. The four points discussed in the District Court's

opinion were grounded in the purpose of the Vaccine Act. As discussed in Part III.B above, such an analysis is permitted when construing an express preemption clause. Furthermore, in response to the motion for summary judgment, the plaintiffs cited to the Vaccine Act's legislative history and purpose to support their argument that design defect claims were not preempted. As a result, we reject plaintiffs' argument that the District Court's decision was based on implied or field preemption grounds or that it violated well-settled principles of summary judgment.

IV.

Plaintiffs also allege that Wyeth is liable for failing to warn Hannah's doctor, Jane M. Breck, M.D., that the vaccine administered to Hannah came from a lot of TRI-IMMUNOL associated with at least two deaths and more than thirty injuries prior to April 1992. Dr. Breck testified that had she known that the vaccine came from this lot, she would not have administered the dose. Although § 22(c) of the Vaccine Act expressly preempts failure-to-warn claims based on "the manufacturer's failure to provide direct warnings to the injured party (or the injured party's legal representative)," 42 U.S.C. § 300aa-22(c), nothing in the Vaccine Act expressly bars claims based on failure to warn "doctors and other medical intermediaries."[13]

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[13] The parties disagree as to whether Section 22(b)(2) is a preemption clause. Though Wyeth classified it as such, the District Court expressly held that the failure-to-warn claim was not preempted. We need not reach this issue, however, for the

As discussed above, § 22(b)(1) states that manufacturers shall not be liable for injuries caused by "side effects that were unavoidable even though the vaccine . . . was accompanied by proper directions and warnings." Section 22(b)(2) states that proper directions and warnings will be presumed when the manufacturer "complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act . . . and section 262 of this title . . . ." Nevertheless, the Vaccine Act provides two circumstances in which this presumption can be overridden: (1) when the manufacturer engages in conduct that would subject it to punitive damages under the Vaccine Act; and (2) when the manufacturer "failed to exercise due care." 42 U.S.C. § 300aa-22(b)(2)(A)-(B). As the District Court correctly noted, this creates a shifting burden—once the manufacturer establishes that it complied with federal law, the burden shifts to the plaintiff to establish that either § 22(b)(2)(A) or § 22(b)(2)(B) has been met.

The District Court dismissed this claim on the ground that Wyeth was entitled to the statutory presumption of proper warning and that the plaintiffs had failed to rebut the presumption. Noting that Wyeth had presented uncontested evidence that TRI-IMMUNOL and its warnings had been approved by the FDA, the District Court found that Wyeth was entitled to § 22(b)(2)'s presumption of proper warning. Next, the District Court noted that the Amended Complaint did not allege fraud or wrongful withholding of information within the

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reasons set forth in this section.

meaning of § 22(b)(2)(A).[14] Thus, the only relevant question was whether plaintiffs had presented clear and convincing evidence that Wyeth had not exercised due care.

Plaintiffs presented a report of the Vaccine Adverse Event Reporting System ("VAERS")[15] confirming that the lot of TRI-IMMUNOL that included the dose administered to Hannah Bruesewitz was associated with two deaths and more than thirty injuries. They also presented the affidavit of Dr. Donald H. Marks, who claimed that such a lot is sometimes called a "hot lot." Dr. Marks relied on a 1984 memorandum by an epidemiologist at the Department of Health and Human Services ("HHS") regarding the "Investigation of Potential Hot Lots," which said that "potential hot fill lots of DTP vaccine" are "fill lots that exceeded a threshold of 2 deaths or 2 convulsions or

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[14] The District Court acknowledged that the original Complaint alleged that Wyeth had committed fraud or wrongful withholding of information, but the Amended Complaint failed to do so. Nevertheless, even if the Amended Complaint had repeated this allegation, the District Court suggested that it would not have survived application of Fed. R. Civ. P. 9(b), which requires that allegations of fraud be pled with particularity.

[15] As the District Court explained, "VAERS is a database created, pursuant to the Vaccine Act, by the FDA and the Centers for Disease Control and Prevention to receive reports about adverse events which may be associated with vaccines."

10 total reports." The District Court, however, found it significant that this memorandum identified such lots merely as "potential" hot lots.

The memorandum also stated that "[i]n order to proceed with an investigation by which we could differentiate reporting bias from a higher rate of reactivity in specific fill lots we needed information on the number of doses distributed and which percent went to the public sector." Thus, in order to differentiate between a "hot lot" and a "potential hot lot," investigators must know not only the total number of incidents but also the rate at which the incidents occurred. Because the "[p]laintiffs have produced no evidence from which a trier of fact could infer that the dose in question originated" in such a lot, the District Court concluded that the plaintiffs had not proven that Wyeth failed to exercise due care by distributing doses from this lot.

Before this Court, the plaintiffs argue that the District Court's reasoning is flawed on two grounds: (1) Wyeth is not entitled to a presumption of proper warning unless the side effects of the vaccine are first shown to be unavoidable; because they allege a safer vaccine design was available, they argue that § 22(b)(2) should not apply; and (2) Dr. Mark's opinion raises an issue of fact as to whether Hannah's dose came from a "hot lot." We dismiss both arguments. The first argument must be dismissed for the reasons discussed in Part III—the Vaccine Act preempts design defect claims premised on the notion that the manufacturer could have created a safer vaccine. The second requires more discussion.

As stated above, a court may not grant summary judgment so long as there exists a genuine issue of material fact. Fed. R. Civ. P. 56(c); *Kaucher v. County of Bucks*, 455 F.3d 418, 423 (3d Cir. 2006). To determine whether a factual dispute is genuine, "the court's function is not to weigh the evidence or to determine the truth of the matter, but only to determine whether the evidence of record is such that a reasonable jury could return a verdict for the nonmoving party." *Orsatti v. N.J. State Police*, 71 F.3d 480, 482 (3d Cir. 1995); *see also Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The "mere existence of a scintilla of evidence" in support of the nonmoving party's claim is insufficent. *Anderson*, 477 U.S. at 252. We will resolve all doubts and draw all reasonable inferences in favor of the nonmoving party. *Conoshenti v. Pub. Serv. Elec. & Gas Co.*, 364 F.3d 135, 140 (3d Cir. 2004).

Dr. Marks identified the HHS memorandum as the basis on which he drew his conclusions: "This memorandum provides what I understood to be the official definition of a 'Hot Lot'."[16]

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[16] Dr. Marks also approvingly cited to an older document from the Food and Drug Administration. This document states:

> In analyzing patterns of adverse event reporting, the FDA considers more than just the number of reports for a lot. More reports will be received for a large lot than a small one, simply because vaccine from the large lot will be given to more children. Some lots contain as many as 700,000

As the District Court correctly noted, the memorandum clearly states that the incident statistics, cited above, only establish "potential hot lots." It further states that investigators must identify the number of doses administered to determine whether a particular vaccine lot qualifies as a "hot lot."[17] Because

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> doses, while others as few as 20,000 doses. Similarly, more reports will be received for a lot that has been in use for a long time than a lot in use for a short time. Even among lots of similar size and time in use, some lots will receive more reports than others simply due to change. The FDA continually looks for lots that have received more serious reports tha[n] should be expected on the basis of such factors as size, time in use, and chance variation.

Pub. Health Serv., Dep't of Health & Human Servs., *Vaccine Adverse Event Reporting System (VAERS)* 2.

[17] Other authorities support this. For instance, according to the Centers for Disease Control and Prevention:

> Vaccine lots are not the same. The sizes of vaccine lots might vary from several hundred thousand doses to several million, and some are in distribution much longer than others. Naturally a larger lot or one that is in distribution longer will be associated with more adverse events, simply by chance. Also, more coincidental deaths are

plaintiffs have not offered any evidence on this point, Dr. Marks' assertions and conclusions are unsupported by the very memorandum upon which he relies.

The plaintiffs also contend that the sheer number of adverse events associated with this vaccine lot is sufficient to establish "some evidence of a serious health problem no [matter] how many doses, circumscribed by the concept of a batch, it contains." While this may be true, the plaintiffs' burden is not to produce "some evidence"—a mere scintilla—but evidence sufficient for a reasonable jury to find in their favor. The HHS memorandum states that investigators cannot conclude whether a vaccine lot is a "hot lot" without evidence on the number of doses administered. Thus, even drawing all inferences and

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> associated with vaccines given in infancy than later in childhood, since the background death rates for children are highest during the first year of life. So knowing that lot A has been associated with x number of adverse events while lot B has been associated with y number would not necessarily say anything about the relative safety of the two lots, even if the vaccine *did* cause the events.

Centers for Disease Control and Prevention, Some Common Misconceptions About Vaccination and How to Respond to Them, http://www.cdc.gov/vaccines/vac-gen/6mishome.htm#Therearehot.

doubts in favor of the plaintiffs, there is insufficient evidence on which a jury could conclude that Hannah's vaccine came from a "hot lot." Accordingly, the District Court did not err in granting summary judgment on the failure to warn claim.

V.

In their Amended Complaint, the plaintiffs alleged that Wyeth's "manufacturing process and inadequate quality control resulted in recurrent problems with maintaining the appropriate balance between neuron-toxins and endo-toxins in the pertussis vaccine." Plaintiffs also assert, as they do before this Court, that they have a "classic manufacturing defect claim here: that the vaccine lot used on Hannah Bruesewitz was tainted such that it was associated with two deaths and more than 66 injuries, a number and percentage far in excess of that for other lots." Under Pennsylvania law, a plaintiff alleging a manufacturing defect based on a strict liability theory must show that: (1) "the product was defective;" (2) "the defect was a proximate cause of the plaintiff's injuries;" and (3) the defect causing the injury existed at the time the product left the seller's hands." *Berkebile v. Brantly Helicopter Corp.*, 337 A.2d 893, 898 (Pa. 1975).

The District Court held that plaintiffs had failed to provide enough evidence of a manufacturing defect to meet their burden for purposes of summary judgment. With regard to the first claim, related to the balance of neuro- and endo-toxins, the District Court concluded that "Plaintiffs have offered absolutely no evidence to support this allegation . . . ." Moreover, the District Court noted this claim was directly refuted by Wyeth, which offered undisputed evidence that its pertussis vaccine did

not contain a neuro-toxin component and was not known to have a neuro-toxic effect.

The District Court also considered the plaintiffs' second argument, which was essentially the same as the "hot lot" theory discussed above. The plaintiffs argued to the District Court that a "hot lot" can serve as circumstantial evidence of a manufacturing defect. The District Court noted that this theory is known as the "malfunction theory:"

> The malfunction theory permits a plaintiff to prove a defect in a product with evidence of the occurrence of a malfunction and with evidence eliminating abnormal use or reasonable, secondary causes for the malfunction. The plaintiff is relieved from demonstrating precisely the defect yet it permits the trier-of-fact to infer one existed from evidence of the malfunction, of the absence of abnormal use and of the absence of reasonable secondary causes.

Bruesewitz v. Wyeth, 508 F. Supp.2d 430, 450 (E.D. Pa. 2007) (quoting *Barnish v. KWI Bldg. Co.*, 916 A.2d 642, 646 (Pa. Super. Ct. 2007)).

As the District Court recognized, this theory has not been applied to allegedly defective vaccines. Nevertheless, we need not determine if and how this theory of liability would apply in this case. Both before the District Court and this Court, the plaintiffs predicated their argument for a manufacturing defect on the fact that Hannah's vaccine came from a "hot lot." For the

reasons stated in Part IV, after drawing all reasonable inferences in favor of the plaintiffs, we agree with the District Court's conclusion that the plaintiffs have not provided evidence from which a jury could conclude that Hannah was administered a vaccine from a "hot lot." Because plaintiffs sole arguments to this Court on the manufacturing defect issue require a finding of a "hot lot," we will also affirm the District Court's judgment on this claim.

VI.

We hold that the plaintiffs design defect claims are expressly preempted by the Vaccine Act. We also conclude that the plaintiffs have failed to establish either a manufacturing defect or a warning defect claim under the Vaccine Act. For the reasons discussed above, we will affirm the District Court's grant of summary judgment in favor of Wyeth.