

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

<b>LISA SYKES, et al.,</b>	:	
<b>Plaintiffs,</b>	:	<b>CIVIL ACTION</b>
	:	
<b>v.</b>	:	<b>NO. 06-1111</b>
	:	
<b>GLAXO-SMITHKLINE, et al.</b>	:	
<b>Defendants.</b>	:	
	:	

**OPINION**

Stengel, J.

March 28, 2007

**TABLE OF CONTENTS**

I.	Introduction.....	2
II.	Background.....	3
III.	Judgment on the Pleadings v. Summary Judgment.....	8
IV.	Rule 12(c) Judgment on the Pleadings Standard. ....	10
V.	Federal Preemption of State Law Claims.....	11
A.	Preemption in General.....	11
B.	Express Preemption of Defective Design Claims under the Vaccine Act. ....	13
1.	Vaccine Act in General —Congress’s Dual Concern. ....	13
2.	The Parties’ Arguments. ....	16
3.	Section 22(b) — Against the Backdrop of Product Liability Law and Its Legislative History. ....	18
4.	Plaintiffs’ Strict Liability Defective Design Claims against GSK and Wyeth Are Barred. ....	21
5.	Plaintiffs’ Negligent Defective Design Claims Against GSK and Wyeth Are Barred.....	24

C.	Failure to Warn Claims Under the Vaccine Act. . . . .	25
1.	The Vaccine Act’s Modification of State Law Failure to Warn Claims . . . . .	25
2.	Parties’ Arguments. . . . .	26
3.	Direct Warning Claims. . . . .	27
4.	Remaining Failure to Warn Claims. . . . .	27
D.	Conflict Preemption Under the FDCA and FDA Regulations. . . . .	30
1.	Recap of Conflict Preemption. . . . .	31
2.	Overview of Regulatory Process to Obtain Approval from the FDA of a Biological Product. . . . .	32
3.	The FDA’s Preemption Position Regarding Plaintiffs’ Failure to Warn Claims and the Deference to Be Given That Position. . . . .	34
a.	FDA’s Position of Preemption Stated in the Preemption Preamble. . . . .	35
b.	FDA’s Preemption Position as Applied in This Case. . . . .	38
c.	What Deference Should be Given to FDA Position?. . . . .	45
4.	Conclusion. . . . .	53
E.	Plaintiffs’ Remaining Claims Against Bayer. . . . .	54
VI.	Transfer of Venue Motions. . . . .	60
VII.	Conclusion. . . . .	65

**I. INTRODUCTION**

Eleven-year old Wesley Sykes suffers from neurological injuries which his parents believe were caused by products made by the defendants.<sup>1</sup> When Wesley’s mother was pregnant with Wesley she received an injection of an immune globulin<sup>2</sup> and during Wesley’s first three years of life he received injections of various pediatric vaccines.

---

<sup>1</sup>The Complaint alleges Wesley’s neurological injuries include developmental delays, learning disabilities, social delays and deficits, the impairment of motor skills, gastrointestinal illness, and immune system dysfunction.

<sup>2</sup>Federal regulations define an immune globulin as “a sterile solution containing antibodies derived from human plasma.” 21 C.F.R. § 640.100.

These medications have two things in common — they were manufactured by a defendant in this action and they contained the preservative thimerosal.

Thimerosal is an organic compound which is approximately 50% mercury by weight. Wesley's parents, the plaintiffs in this case, claim that the thimerosal-containing products caused Wesley's various injuries. They filed this lawsuit against the manufacturers of the vaccines, SmithKline Beecham Corporation d/b/a GlaxoSmithKline ("GSK") and Wyeth, Inc., f/k/a American Home Products Corporation, and the manufacturer of the immune globulin product, Bayer Pharmaceutical Corporation. The defendants have moved to dismiss the entire state law Complaint based on preemption grounds. The two sources for the preemption of the plaintiffs' state law claims are: (1) the National Childhood Vaccine Injury Compensation Act of 1986 ("Vaccine Act"), 42 U.S.C. § 300aa-1, *et seq.*, and (2) the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. 301, *et seq.*, and the Food and Drug Administration ("FDA") regulations promulgated under that statute. In addition, or in the alternative, the defendants have moved to transfer the case to the Eastern District of Virginia.

## **II. BACKGROUND**

In 1995, Lisa Sykes was pregnant with her son, Wesley. During her pregnancy, Mrs. Sykes received from her physician a dose of Bayer's immune globulin blood product, HypRho-D. Mrs. Sykes's ante-partum shot of HypRho-D contained thimerosal. Wesley Sykes was born on January 27, 1996. Between February 1996 and September 1998

Wesley received the following vaccines: (1) one dose of Wyeth's thimerosal-containing Diphtheria and Tetanus Toxoids and Acellular Pertussis ("DTaP") vaccine (marketed under the trade name ACEL-IMUNE®); (2) one dose of Wyeth's thimerosal-containing Haemophilus influenzae type b ("Hib") vaccine (marketed under the trade name HibTITER®); (3) three doses of Wyeth's thimerosal-containing Diphtheria and Tetanus Toxoids and Pertussis ("DTP")-Hib combination vaccine (marketed under the trade name TETRAMUNE®); and (4) three doses of GSK's thimerosal-containing Hepatitis B vaccine (marketed under the trade name Engerix-B®).<sup>3</sup> According to the Complaint, the ante-partum injection of HypRho-D and the vaccination of Wesley with the defendants' products resulted in neurological and neuro-developmental injuries to Wesley. In particular, the plaintiffs allege that the mercury contained in the thimerosal preservative in each of the products was toxic and led to Wesley's injuries.

The defendants' vaccines and Bayer's immune globulin are "biological products," as that term is defined in FDA regulations. See 21 C.F.R. § 600.3(h). For all biological products containing a preservative, the FDA must be satisfied that the preservative is safe before the product can be marketed:

Any preservative used shall be sufficiently nontoxic so that the amount present in the recommended dose of the product *will not be toxic* to the recipient, and in the combination used it shall not denature the specific substances in the product to result in a decrease below the minimum acceptable potency within the dating period when stored at the recommended temperature. Products in

---

<sup>3</sup>The parties do not dispute that the products administered to Wesley were vaccines under the Vaccine Act. See 42 C.F.R. § 100.3 (Vaccine Injury Table).

multiple-dose containers shall contain a preservative . . . .

21 C.F.R. § 610.15 (emphasis added). Thimerosal has been used as a preservative in a number of biological products since the 1930s to prevent the growth of microbial contaminants. In childhood vaccines, thimerosal has been used to “deter[] microbial and fungal growth, thereby maintaining safety, purity and potency of vaccines” both during and after the manufacturing process. See Ex. 1 to GSK’s Mot. to Take Judicial Notice,<sup>4</sup> U.S. Food and Drug Administration Center for Biologics Evaluation and Research, *Thimerosal in Vaccines* at 2 (updated Nov. 16, 2006), available at <http://www.fda.gov/cber/vaccine/thimerosal.htm>. See also *Owens v. Am. Home Prods. Corp.*, 203 F. Supp. 2d 748, 755 (S.D. Tex. 2002).

The GSK product in question, Engerix-B® vaccine, contained thimerosal as a preservative. It was approved by the FDA for distribution and sale in the United States. The vaccine was distributed with labeling information approved by the FDA. The vaccine’s label disclosed that the vaccine contained “thimerosal (mercury derivative)” as part of the formula, as well as the concentration of the preservative. At all relevant times, the disclosure and description of thimerosal in the label, and the use of thimerosal as an ingredient, could not be changed without FDA approval. See 21 C.F.R. § 601.12 (requiring FDA approval before any changes in the manufacturing methods and labeling of a biological product become effective).

---

<sup>4</sup>I grant GSK’s Motion to Take Judicial Notice of various exhibits in part, to the extent I cite and rely on any exhibit in this opinion. See *infra* Part III; *infra* Order.

All of the Wyeth products administered to Wesley contained thimerosal as a preservative. ACEL-IMUNE®, HibTITER®, and TETRAMUNE® were marketed in multi-dose presentations at the time of Wesley’s vaccination, and the FDA mandates that all childhood vaccines “in multi-dose containers shall contain a preservative.” See 21 C.F.R. § 610.15. The FDA approved Wyeth’s vaccines at issue with thimerosal as an ingredient, and Wyeth complied with federal law and regulations regarding the labeling of the vaccines. In the labels submitted and approved by the FDA, Wyeth disclosed the presence and concentration of thimerosal in the vaccines.

Bayer’s HypRho-D is a prescription biological product that works by suppressing the immune response of Rh negative pregnant women to Rh positive blood cells from the fetus that enter the mother’s circulation. The FDA requires that every immune globulin contain a preservative and Bayer received approval to use thimerosal during the product licensing process of HypRho-D. See 21 C.F.R. § 640.103(a) (“The final product shall be a 16.5[+/-]1.5 percent solution of globulin containing 0.3 molar glycine and a preservative.”). At all relevant times, the licensing, composition, manufacture, testing, and labeling of HypRho-D, including the use of thimerosal in HypRho-D, was regulated and approved by the FDA.

Lisa and Seth Sykes filed a timely petition for compensation on Wesley’s behalf with the National Vaccine Injury Compensation Program (“NVICP”) on October 2, 2000,

pursuant to 42 U.S.C. § 300aa-1, *et seq.*<sup>5</sup> On November 11, 2002, the Sykes filed a notice of withdrawal in the NVICP, and judgment was entered on the withdrawal by the Clerk of the U.S. Court of Federal Claims on January 16, 2003, pursuant to 42 U.S.C. § 300aa-21(b). The Sykes filed an Election to file a civil action on January 24, 2003, pursuant to 42 U.S.C. § 300aa-21(a).

On March 14, 2006, the plaintiffs filed their Complaint with this court, individually and as parents of Wesley Sykes. The plaintiffs assert strict products liability and negligence claims against the vaccine manufacturers, GSK and Wyeth, and the HypRho-D manufacturer, Bayer. The strict products liability claim alleges that the vaccines and HypRho-D were defectively designed and safer alternatives existed. The strict liability and negligence claims both allege that the defendants: (1) failed to warn health care professionals of the dangers of thimerosal and the availability of safer alternatives; (2) failed to conduct adequate safety tests to determine whether thimerosal was safe and

---

<sup>5</sup>The U.S. Court of Appeals for the Federal Circuit recently described the NVICP: Congress established the National Vaccine Injury Compensation Program ("Program") to provide compensation for vaccine-related injuries and deaths. See 42 U.S.C. § 300aa-10. The [Vaccine] Act creates a federal no-fault system for compensating injuries causally connected to vaccines. The Act establishes a claims procedure involving the United States Court of Federal Claims and special masters, see 42 U.S.C. § 300aa-12 . . . . The Act does not entirely preclude traditional tort remedies. However, before an individual may bring an action seeking more than \$ 1,000 in damages in state or federal court, he must first file a petition under the Program. See 42 U.S.C. § 300aa-11(a)(2)(A). The filing of a petition under the Program stays the running of state statutes of limitations. See 42 U.S.C. § 300aa-16(c). The Act then gives a petitioner the choice to accept the judgment obtained under the Program and surrender his tort rights or to reject that judgment and pursue a civil action for damages. See 42 U.S.C. § 300aa-21(a).

Brice v. Secretary of HHS, 240 F.3d 1367, 1368-1369 (Fed. Cir. 2001). The petitioner also has the option to withdraw his petition when the special master or the Federal Claims Court fails to act within a given period. See 42 U.S.C. § 300aa-21(b).

nontoxic to humans in the doses administered; and (3) failed to comply in all material respects with the relevant FDA requirements. In addition, the Sykes allege Wyeth and GSK intentionally and wrongfully withheld information from the FDA and the U.S. Department of Health and Human Services (“HHS”) regarding the safety and risks of thimerosal, before, during, and after FDA approval of the product license application.<sup>6</sup>

By order dated June 19, 2006, discovery was stayed and the defendants were instructed to file motions addressing any federal law preemption issues. GSK filed a motion for summary judgment (Docket No. 39), a motion to take judicial notice of 19 exhibits (Docket No. 40), and a motion to transfer venue (Docket No. 56). Wyeth filed a motion for summary judgment (Docket No. 46) and a motion to transfer venue (Docket No. 57). Bayer filed a motion for judgment on the pleadings (Docket No. 44) and a motion to transfer venue (Docket No. 51). The plaintiffs filed responses to all of the defendants’ motions and counsel presented oral argument on December 18, 2006.

### **III. JUDGMENT ON THE PLEADINGS V. SUMMARY JUDGMENT**

GSK and Wyeth structured their arguments and filings as summary judgment motions. Bayer filed a motion for judgment on the pleadings. All of the defendants

---

<sup>6</sup>The plaintiffs apparently have pleaded certain allegations against the vaccine defendants — failure to comply with the FDA regulations and intentional deception of the FDA — in an attempt to overcome the Vaccine Act’s statutory presumption that the warnings accompanying the defendants’ products were adequate. See infra Part V.C.4. Thus, the Complaint ultimately rests on three possible theories of product liability: design defect, failure to warn, and inadequate testing. But see infra Part V.B.4 (discussing how the only claims allowed under the Vaccine Act against a vaccine manufacturer for a vaccine-related injury are manufacturing defect and failure to warn claims); infra Part V.E. n.32 (discussing how under Pennsylvania law no independent claim for inadequate testing exists, but rather, such an allegation is part of a defective design claim).

attached documents to their motions in support of their arguments.

If the court, in its discretion, considers extrinsic evidence presented by the parties on a Federal Rule of Civil Procedure (“FRCP”) 12(c) motion for judgment on the pleadings, the court must treat the motion as a summary judgment motion. See FED. R. CIV. P. 12(c). In this regard, the court must give all parties notice of such a conversion, and provide them with an opportunity to be heard and present further materials in support of their positions on the motion. Id. Such a "conversion" is *not* required, however, when the court considers documents attached as exhibits to the complaint, documents on which the complaint is based, matters of public record, and materials subject to judicial notice. See Ieradi v. Mylan Labs., Inc., 230 F.3d 594, 600 n.3 (3d Cir. 2000) (“Under Federal Rule of Evidence 201, we may take judicial notice at any stage of the proceeding of a fact not subject to reasonable dispute that is capable of accurate and ready determination by resort to a source whose accuracy cannot be reasonably questioned.”); Pension Benefit Guar. Corp. v. White Consol. Indus., 998 F.2d 1192, 1197 (3d Cir. 1993) (holding a court may consider materials outside the complaint without converting motions to dismiss into summary judgment motions where the materials are public records, which includes “letter decisions of government agencies and published reports of administrative bodies”).

Since I did not rule that the preemption motions would be treated as motions for summary judgment, and with the plaintiffs not having the benefit of discovery or an opportunity to present any pertinent material outside the pleadings, the defendants’

motions on preemption shall be decided as motions for judgment on the pleadings under FRCP 12(c). I will only consider the exhibits of the defendants that fall into one of these categories: matters of public record and materials subject to judicial notice. I will also rely on the facts that the parties do not contest with respect to the defendants' products' FDA approval and label contents. See Docket No. 52, 53, Plaintiffs' Responses to Defendants' Statements of Undisputed Facts. It is worth noting, however, that the hundreds of pages of exhibits have little impact on the decision in this case. As the plaintiff points out: "While GSK and Wyeth have attached extensive exhibits with their motions, these do nothing more than establish that the two manufacturers had FDA approval to market their thimerosal-containing vaccines, and that the FDA approved the labels. These matters are not in dispute." The question for this court is really a matter of law: Given the FDA approvals, are the plaintiffs' state law tort claims preempted by federal law?<sup>7</sup>

#### **IV. RULE 12(C) JUDGMENT ON THE PLEADINGS STANDARD**

"Motions for judgment on the pleadings brought pursuant to Federal Rule of Civil Procedure 12(c) are reviewed under the same standard as motions to dismiss pursuant to Rule 12(b)(6)." Piskanin v. Hammer, No. 04-1321, 2005 U.S. Dist. LEXIS 28135, at \*8 (E.D. Pa. Nov. 14, 2005) (citing Spruill v. Gillis, 372 F.3d 218, 223 n.2 (3d Cir. 2004)).

---

<sup>7</sup>At oral argument, the parties did not agree as to what state's law will apply in this case. The defendants contend that Virginia law applies, and the plaintiffs appear to argue that Pennsylvania law applies. It is not necessary to conduct a choice of law analysis to rule on these preemption motions because federal law determines my conclusion.

When considering a motion to dismiss under Fed. R. Civ. Proc. 12(b)(6), the court must accept the complaint's allegations as true and draw all reasonable inferences in the plaintiff's favor. Zimmerman v. HBO Affiliate Group, 834 F.2d 1163, 1164-65 (3d Cir. 1987). The court, however, "need not accept as true unsupported conclusions and unwarranted inferences." Doug Grant, Inc. v. Greate Bay Casino Corp., 232 F.3d 173, 183-84 (3d Cir. 2000) (citation and internal quotations omitted).

Under Rule 12(b)(6), a defendant may move to dismiss a complaint for "failure to state a claim upon which relief can be granted." The rule is designed to screen out cases where "a complaint states a claim based upon a wrong for which there is clearly no remedy, or a claim which the plaintiff is without right or power to assert and for which no relief could possibly be granted." Port Auth. v. Arcadian Corp., 189 F.3d 305, 311-12 (3d Cir. 1999). Under Rule 12(b)(6), a complaint should not be dismissed for failure to state a claim "unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." Conley v. Gibson, 355 U.S. 41, 45-46 (1957). The issue, therefore, is not whether the plaintiff will ultimately prevail, but whether she is entitled to offer evidence to support her claims. Scheuer v. Rhodes, 416 U.S. 232, 236 (1974); See also Maio v. Aetna, Inc., 221 F.3d 472, 482 (3d Cir. 2000).

## **V. FEDERAL PREEMPTION OF STATE LAW CLAIMS**

### **A. Preemption in General**

Under the Supremacy Clause of the U.S. Constitution, federal law will override

state law in three instances: (1) express preemption, *i.e.*, when Congress expressly preempts state law; (2) field preemption, *i.e.*, when congressional intent to preempt may be inferred from the existence of a pervasive federal regulatory scheme; or (3) conflict preemption, *i.e.*, when state law conflicts with federal law or its purposes and preemption is implied. See English v. General Elec. Co., 496 U.S. 72, 78-79 (1990); Pokorny v. Ford Motor Co., 902 F.2d 1116, 1120 (3d Cir. 1990). Conflict preemption occurs either "where it is impossible for a private party to comply with both state and federal law" (impossibility) or where "under the circumstances of [a] particular case, [the challenged state law] stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" (frustration of purpose). Crosby v. Nat'l Foreign Trade Council, 530 U.S. 363, 372-73 (2000).

Two different preemption issues have been raised in the motions. First, GSK and Wyeth argue that the plaintiffs' defective design and inadequate warning claims against them are expressly preempted under the Vaccine Act. Second, all three defendants argue that the plaintiffs' failure to warn claims are conflict preempted due to the FDA's regulation of their drug labels and the FDA's position on thimerosal. In addition, Bayer raises additional arguments as to why the balance of the claims against it should be dismissed. I will first address the preemption issue under the Vaccine Act and then discuss the preemptory effect of the FDCA and the FDA regulations. Finally, I will turn to Bayer's remaining arguments and determine their merit.

B. Express Preemption of Defective Design Claims under the Vaccine Act

1. Vaccine Act in General —Congress’s Dual Concern

Congress recognized that while most children derived a great benefit from childhood vaccination, "a small but significant number have been gravely injured."

Blackmon v. Am. Home Prods. Corp., 328 F. Supp. 2d 659, 663-66 (S.D. Tex. 2004).

These vaccine-related injuries raised two concerns: “(1) the inconsistency, expense, delay, and unpredictability of the tort system in compensating claims of vaccine-injured children; and (2) the instability and uncertainty of the childhood vaccine market inevitably caused by the risks of tort litigation.” Id. In response, Congress passed the Vaccine Act. With it, Congress hoped to prevent manufacturers from leaving vaccine production or significantly increasing their prices, while at the same time compensate victims of vaccine-related injuries quickly. See Schafer v. Am. Cyanamid Co., 20 F.3d 1, 4 (1st Cir. 1994) (discussing congressional testimony by vaccine manufacturers regarding insurance and litigation costs).

“The Vaccine Act reflects a congressional determination that the disappearance or unavailability of childhood vaccines would cause far greater harm than the inevitable but limited injuries caused by the vaccines themselves. To offset the vicissitudes of the tort system and provide compensation for victims of childhood vaccines, the Vaccine Act established the National Vaccine Program, which provides a unique avenue of recovery for injuries and deaths traceable to vaccinations that works with greater ease and on a faster

timetable than the civil tort system.” Blackmon, 328 F. Supp. 2d at 663-66 (citing Shalala v. Whitecotton, 514 U.S. 268, 269 (1995)). See also Brice v. Secretary of HHS, 240 F.3d 1367, 1368-69 (Fed. Cir. 2001). In effect, the Act "ensures that all children who are injured by vaccines have access to sufficient compensation for their injuries." H.R.Rep. No. 99-908 at 4 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6345. A person alleging a vaccine-related injury can obtain compensation by filing a petition with the Vaccine Court. The petitioner need not prove fault nor causation; he only needs to show that he received the vaccine and then suffered certain symptoms within a defined period. See 42 U.S.C. §§ 300aa-13, 300aa-14. It is worth noting that an alleged defective design claim would be compensated under this no-fault system.

In the event a plaintiff seeking compensation for vaccine-related injuries does not accept the judgment of the Vaccine Court and elects to pursue claims in state or federal court, the Vaccine Act includes certain limitations on state tort claims designed to "free manufacturers from the specter of large, uncertain tort liability, and thereby keep vaccine prices fairly low and keep manufacturers in the market." Schafer v. Am. Cyanamid Co., 20 F.3d 1, 4 (1st Cir. 1994). See also 42 U.S.C. § 300aa-21 (discussing when a petitioner rejects a Vaccine Court’s judgment or withdraw his petition from Vaccine Court). The limitations are stated in 42 U.S.C. § 300aa-22, and convey Congress’s intent to supersede, or preempt, state tort law standards and create legal protections that apply in any civil action brought against a vaccine manufacturer. Therefore, Congress has accomplished

preemption with its enactment of the Vaccine Act by its modification of state tort law. See Brice v. Secretary of HHS, 240 F.3d 1367, 1368-69 (Fed. Cir. 2001) (recognizing that the Vaccine Act modifies state tort law); Schafer, 20 F.3d at 3 (noting that the Vaccine Act “provide[s] certain federal modification of state tort law”). In sum, a vaccine-injured plaintiff who withdraws from the NVICP is limited by the Vaccine Act in the state law claims he can pursue against a vaccine manufacturer.

The pertinent part of the Vaccine Act that modifies state tort law, and is at issue in this case, provides:

- (a) General. 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 . . . if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.
  - (2) For purposes of paragraph (1), a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. §§ 301 *et seq.*] and section 351 of the Public Health Service Act [42 U.S.C. § 262] (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 [fraud or intentional and wrongful withholding of information from the Secretary during any phase of a proceeding for approval of the vaccine or intentional and wrongful withholding of information relating to the safety or efficacy of the vaccine after its approval], 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 . . . 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.

42 U.S.C. § 300aa-22.

As the words of the statute indicate, the Vaccine Act provides that “[s]tate law shall apply to a civil action” for “vaccine-related injury,” except in the following instances, when federal law modifies state law: (1) if a plaintiff’s vaccine-related injury resulted from side effects that were unavoidable even though the vaccine was properly prepared<sup>8</sup> and was accompanied by proper directions and warnings, then the vaccine manufacturer shall not be liable for damages; (2) if the vaccine manufacturer shows it “complied in all material respects” with the applicable FDA and vaccine statutes and regulation, the FDA-approved warnings are presumed adequate and a plaintiff can rebut that presumption only in one of two ways; and (3) no vaccine manufacturer will be liable “solely due to the manufacturer’s failure to provide direct warnings to the injured party. . . .”

## 2. The Parties’ Arguments

The vaccine defendants argue that the plaintiffs' design defect claims against them are barred by § 22(b) of the Vaccine Act.<sup>9</sup> The defendants construe this section of the

---

<sup>8</sup>“Properly prepared” refers to a vaccine made in conformity with its design specifications, *i.e.*, the absence of a manufacturing defect. See Blackmon, 328 F. Supp. 2d at 664.

<sup>9</sup>“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 . . . if the injury or death resulted

Vaccine Act to impose a total bar on design defect claims arising from vaccine-related injuries so long as the vaccine was produced in accordance with FDA-approved specifications. Under the vaccine defendants' view, any vaccine-related injury would be deemed "unavoidable" if the vaccine was properly prepared and accompanied by proper warnings. According to GSK and Wyeth, in order to ensure vaccine manufacturers the protection of the Vaccine Act, Congress entrusted the determination of whether a particular vaccine's design is safe to federal health agencies with the expertise and experience to carry out the mandate, not to juries.<sup>10</sup>

The plaintiffs disagree with the defendants' construction of the Vaccine Act and argue that the Vaccine Act only bars design defect claims if the side effects are determined, on a case-by-case basis, to be "unavoidable." Plaintiffs claim that their defective design claims are permitted because the injuries suffered by Wesley were not unavoidable. They maintain that the injuries could have been avoided if the defendants had used a mercury-free preservative for multi-dose vials of their vaccines, or if they had simply distributed single-dose vials, which do not require a preservative. Under the plaintiffs' view, the express language of the statute envisions three types of civil actions: (1) design defect claims where plaintiffs can show that the adverse side effects were

---

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).

<sup>10</sup>As noted above, the thimerosal-containing formulas for each of the childhood vaccines at issue in this case were subjected to the FDA licensing procedures and received FDA approval for distribution. In other words, the FDA approved the vaccine designs in question.

avoidable; (2) manufacturing defect claims; and (3) failure to warn claims.

Given that both readings of the statute are plausible, and that the plain text of the Vaccine Act does not resolve the proper interpretation, I will look at the legislative history of the Act and any other relevant extrinsic material to decipher Congress's intent in enacting 42 U.S.C. § 300aa-22(b)(1). See Oklahoma v. New Mexico, 501 U.S. 221, 235 n.5 (1991) (“[W]e repeatedly have looked to legislative history and other extrinsic material when required to interpret a statute which is ambiguous.”).

3. Section 22(b) — Against the Backdrop of Product Liability Law and Its Legislative History

The parties in Blackmon v. Am. Home Prods. Corp., 328 F. Supp. 2d 659, 665 (S.D. Tex. 2004), staked the same positions as the plaintiffs and vaccine defendants in this case with respect to the application of the Vaccine Act to defective design claims. The court in Blackmon provided a thorough analysis on why interpreting § 22(b) in the context of product liability law, along with the legislative history of the Vaccine Act, defeats a plaintiff's defective design claims:

Read against the background of products liability law, the language of § 22(b) shows Congress's intent to foreclose all design defect claims against vaccine manufacturers. Texas law recognizes three types of product liability claims: (1) defective design, (2) defective manufacture, and (3) inadequate warning or failure to warn. The drafters of § 22(b) were obviously aware of the different heads of products liability, yet the statute identifies only two: manufacturing defect and failure-to-warn claims. The statute singles out these two claims as the variables that determine whether a claimant may sue the manufacturer for a vaccine-related injury. If the alleged defect that caused the claimants injury does not fall into one of these two enumerated categories, the defect is considered "unavoidable," and the claimant's tort claim is barred.

The origins of § 22(b) reinforce Defendants' construction of the statute. Congress modeled § 22(b) after comment k in § 402A of the Restatement (Second) of Torts. Using the Pasteur rabies vaccine as an example of "products, which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use," the Restatement takes the following view of liability:

“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 reason cannot legally be sold except to physicians . . . .” Restatement (Second) of Torts § 402A cmt. k (1966). Like § 22(b), comment k distinguishes the three heads of products liability--design defect, manufacturing defect, and warning defect--and rejects the notion of defective design in the context of products with certain known and inherent risks that have nonetheless been accepted as a matter of policy given the benefit provided and the grim consequences that would follow if the product were not available. Under comment k, as long as such a product is "properly prepared, and accompanied by proper directions and warning"--that is, as long as it is free from manufacturing and warning defects--the seller will not be held strictly liable for injuries resulting from risks inherent in the product's design.

The legislative history also supports a construction of § 22(b) that would bar all defective design claims under the conditions outlined in the statute. Two passages in the Report of the Committee on Energy and Commerce suggest that Congress intended the National Vaccine Program's compensation system to absorb defective design claims. The report states that the Committee looked to comment k "because it intends that the principle in Comment K regarding 'unavoidably unsafe products ... apply to the vaccines covered in the bill and that such products not be the subject of liability in the tort system." Report of the Committee on Energy and Commerce, H.R. Rep. No. 99-908 at 26, reprinted in 1986 U.S.C.C.A.N. at 6367. The report also contains the following statement: “Given the existence of the compensation system in [the Vaccine Act], the Committee strongly believes that Comment k is appropriate and necessary as the policy for civil actions seeking damages in tort. Vaccine-injured persons will now have an appealing alternative to the tort system. Accordingly, 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.” Id. The last passage indicates

rather clearly the Committee's intent to relegate design defect claims to the compensation system, provided that the injury-producing vaccine was manufactured and distributed according to applicable federal standards.

The Plaintiffs contention that the question whether a side effect was unavoidable must be determined on a case-by-case basis which would permit the jury to decide whether a particular side effect was unavoidable, would provide no protection against design defect claims. A plaintiff could show that an alleged defect was not unavoidable by proving that an alternative design was feasible. Not only is this construction inconsistent with the policy behind the Vaccine Act; it strips the passage of all meaning. If an alleged defect were [sic] truly unavoidable in the broad, literal sense urged by Plaintiffs, a manufacturer could not be subject to liability as a result of that defect. With this meaning, the statute would protect manufacturers from liability only on meritless claims. The Court must presume that Congress intended statutory language to have some effect.

Perhaps more importantly, to permit juries in each state to pass judgment on the design of childhood vaccines could interfere with the federal government's efforts to establish a uniform national standard for childhood vaccines. Congress has established a comprehensive regulatory scheme, administered by the FDA, to control the design and distribution of prescription drugs, including vaccines. See 21 U.S.C. §§ 301-393. Any manufacturer seeking a license to distribute a new vaccine must submit to the FDA a formal Product License Application including information related to the safety, efficacy, labeling, and manufacturing of the specific vaccine. See 42 U.S.C. § 262(a). The FDA licenses each vaccine in accordance with a specific formula and approves specific labeling information. See 21 C.F.R. §§ 601.2, 601.12. After the vaccine is licensed, the manufacturer cannot change the formula or the label without FDA approval. The Vaccine Act delegates questions of vaccine safety to the Secretary of Health and Human Services. Individual challenges to the design of FDA-approved vaccines would undermine the FDA's authority to set standards for childhood vaccines. Case-by-case consideration would also expose manufacturers to inconsistent standards, as juries might hold manufacturers liable for design defects in drugs approved by the FDA. The consequences of case-by-case determination of "unavoidability" lend further support to the conclusion that § 22(b) directs the evaluation of vaccine design exclusively to the FDA.

Blackmon, 328 F. Supp. 2d at 663-66. See also Ferrari v. Am. Home Prods. Corp., No.

02-VS-031404-F, slip op. at 10 (State Ct. of Fulton Cty., Ga. Nov. 30, 2005) (“Congress [did not] leave vaccine design standards open to reexamination under the laws of each state, with the potential for interstate conflict: the Vaccine Act sets one rule, applicable nationwide, that pre-empts design defect claims.”); Militrano v. Lederle Labs., 769 N.Y.S.2d 839, 843 (N.Y. Sup. Ct. 2003), aff’d, 810 N.Y.S.2d 506 (N.Y. App. Div. 2006) (“Congress did not intend that national vaccine policy be determined by the vagaries of a jury’s determination on a case-by-case basis.”). See generally Weiner v. Amer. Honda Motor Co., 718 A.2d 305, 307 (Super. Ct. Pa. 1998) (listing the three types of defective conditions that may give rise to strict liability in Pennsylvania as manufacturing defect, design defect, and failure to warn defect).

4. Plaintiffs’ Strict Liability Defective Design Claims against GSK and Wyeth Are Barred

I agree with the analysis of the Blackmon court and find that the plaintiffs’ defective design claims against GSK and Wyeth, based on a strict liability theory, are barred. First, the purpose of the Vaccine Act would not be served if defective design claims could be tried before juries. A case-by-case determination of whether a vaccine was unavoidably unsafe would defeat the protection the Act was intended to provide vaccine manufacturers. The manufacturers would again be subjected to the unpredictability and expense of the tort system and companies would be dissuaded from remaining or entering the vaccine market.

Second, the structure of the Vaccine Act read as a whole supports this conclusion.

See Pokorny v. Ford Motor Co., 902 F.2d 1116, 1120 (3d Cir. 1990) (citing cases that discuss the court’s role in construing statutes and discussing how a court must give effect to a statute as written and as a whole, not to enforce one section at the expense of another). As counsel for the vaccine defendants correctly pointed out at oral argument, the Vaccine Act set up a National Vaccine Program under the supervision of a Director, a task force, and two commissions. See Mot. Hr’g Tr. at 14-15. See also 42 U.S.C. §§ 300aa-1, 2, 5, 19, 27. These entities and individuals were tasked with the role of researching safer vaccines. Congress established this system to handle any safety concerns with childhood vaccines. For example, under a section of the Vaccine Act entitled “Mandate for Safer Childhood Vaccines,” Congress delegated to the HHS Secretary, and not the jury system, the role of “mak[ing] or assur[ing] 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. § 300aa-27(a)(2). The plaintiffs’ argument would undermine the congressional mandate by replacing the federal agencies’ role with state juries and it would destroy the uniformity Congress intended to establish with the Vaccine Act.

Third, as Blackmon demonstrates, the legislative history of § 22(b) clearly supports the conclusion that Congress intended to protect vaccine manufacturers from liability for defective design claims. Congress struck a compromise between the two interests at risk prior to the Vaccine Act — a person injured by the vaccine and the manufacturers of the

vaccine. See supra Part V.B.1. The no-fault Vaccine Court established under the Act provides an injured party an avenue for relief and Section 22(b) protects vaccine manufacturers from tort liability for making a product in accordance with FDA specifications. If a vaccine-injured person “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.” 1986 U.S.C.C.A.N. at 6367.

Finally, product liability law and comment k to the Restatement (Second) of Torts § 402A<sup>11</sup> aid my holding. The Vaccine Act mirrors this established area of tort law for unavoidably unsafe products and limits the strict liability of vaccine manufacturers for vaccine-related injuries to claims that the vaccine deviated from its FDA-approved design

---

<sup>11</sup>Comment k to Section 402A of the Restatement (Second) of Torts states as follows: Unavoidably unsafe products. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. *The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.*

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

or it was not accompanied by proper warnings (and thereby eliminates strict liability defective design claims).

Here, the plaintiffs do not claim that the vaccine manufacturers deviated from the FDA-approved design for the vaccines. (The improper warnings claims are discussed below.) Accordingly, the plaintiffs' strict liability design defect claims against GSK and Wyeth are preempted by the Vaccine Act and I will dismiss them with prejudice.<sup>12</sup>

5. Plaintiffs' Negligent Defective Design Claims Against GSK and Wyeth Are Barred

In addition, the plaintiffs' defective design claims against the vaccine manufacturers based on negligence are preempted for the same reasons as the strict liability claims. The text of the Vaccine Act that limits a manufacturer's liability is not directed toward any particular cause of action. Section 22(b)(1) states broadly that no manufacturer "shall be liable in a civil action for damages arising from a vaccine-related injury or death." "A civil action for damages" includes a product liability claim based on strict liability as well as negligence. See Blackmon, 328 F. Supp. 2d at 666 ("While comment k is restricted to strict liability claims, § 22(b) is not. Plaintiffs' negligent design defect claims are therefore barred by the Act."). Since the plaintiffs' negligent defective design claims rely on the same factual allegations as the strict liability defective design

---

<sup>12</sup>The plaintiffs' claims that the vaccine products injected into Wesley were defective and that a safer alternative to the vaccines was available are design defect claims. See Compl. ¶¶ 16, 17. In addition, the plaintiffs' claims that the vaccine defendants failed to conduct adequate tests to determine the safety of thimerosal are no more than design defect claims. See Compl. ¶¶ 20, 27(d); infra Part.V.E. n.32. Each of these claims is preempted.

claims, and the vaccines in question were produced in accordance with FDA-approved specifications, I will dismiss the plaintiffs' negligent defective design claims against GSK and Wyeth with prejudice.<sup>13</sup>

C. Failure to Warn Claims Under the Vaccine Act<sup>14</sup>

1. The Vaccine Act's Modification of State Law Failure to Warn Claims

As previously discussed, the Vaccine Act modified a vaccine-injured plaintiff's ability to pursue a product liability failure to warn claim against a vaccine manufacturer. Section 300aa-22(c) expressly prohibits holding a vaccine manufacturer liable because it failed to directly warn a vaccine recipient or his representative of any potential danger from the vaccine. See 42 U.S.C. § 300aa-22(c). As to claims that a manufacturer failed to adequately warn a health care intermediary, Section 22(b)(2) establishes a legal presumption that vaccine warnings are proper and sufficient if the vaccine manufacturer shows that it complied in all material respects with the FDA regulations applicable to the vaccine at issue. A vaccine-injured plaintiff can overcome this presumption by showing that a manufacturer: (1) engaged in fraud or intentional and wrongful withholding of

---

<sup>13</sup>My finding that Congress intended to bar all design defect claims, under any legal theory, is supported by Congress's recognition that "even if the defendant manufacturer may have made as safe a vaccine as anyone reasonably could expect, a court or jury will undoubtedly find it difficult to rule in favor of the 'innocent' manufacturer if the equally 'innocent' child has to bear the risk of loss." H.R. Rep. No. 99-908 at 26, 1986 U.S.C.C.A.N. at 6367.

<sup>14</sup>Because the Vaccine Act permits only manufacturing defect and inadequate warnings claims, the plaintiffs' allegations that the vaccine defendants failed to comply with FDA regulations and intentionally withheld information are only relevant as they pertain to the adequacy of the plaintiffs' failure to warn claims. See supra Part V.B.4.

information during any phase of a proceeding for approval of the vaccine; (2) engaged in intentional and wrongful withholding of information relating to the safety or efficacy of the vaccine *after* its approval; or (3) failed to exercise due care. See 42 U.S.C. § 300aa-22(b)(2).

## 2. Parties' Arguments

The vaccine defendants argue that the plaintiffs' direct warning claims are expressly preempted by section 22(c). As for the remaining warning claims, the vaccine defendants submitted affidavits and supporting documents to establish its compliance with all relevant FDA regulations and to prove they are entitled to the presumption of adequate warnings. GSK and Wyeth then contend that the plaintiffs cannot come forward with any evidence to defeat the presumption. In particular, they point to the FDA's official view, after numerous studies, that there is no proof that the use of thimerosal as a preservative in vaccines causes any harm (other than potential local hypersensitivity reactions). See Ex. 1 to GSK's Mot. to Take Judicial Notice, U.S. Food and Drug Administration Center for Biologics Evaluation and Research, *Thimerosal in Vaccines*.

The plaintiffs counter GSK and Wyeth's arguments by claiming that the motions for summary judgment on the failure to warn claims are premature since no discovery has occurred. The plaintiffs request that the court grant them the right to conduct discovery before determining whether they can successfully rebut the presumption enumerated in § 22(b)(2).

### 3. Direct Warning Claims

The Vaccine Act clearly bars claims based on a vaccine manufacturer's failure to provide warnings to an individual who receives its vaccine. See 42 U.S.C. § 300aa-22(c). Therefore, the plaintiffs' failure to warn claims, inasmuch as they are based on the vaccine defendants' failure to provide direct warnings to the plaintiffs, are dismissed with prejudice.

### 4. Remaining Failure to Warn Claims

The plaintiffs aver in their Complaint that the vaccine manufacturers failed to properly warn health care professionals of thimerosal's danger, failed to comply in all material respects with FDA requirements,<sup>15</sup> and intentionally and wrongfully withheld information from the FDA.<sup>16</sup> GSK and Wyeth attempt to defeat these claims by offering proof via affidavits and supporting documentation of their compliance with all FDA requirements in the licensing and distribution of their vaccines. On a motion for judgment on the pleadings, I cannot consider evidence outside the pleadings without transforming

---

<sup>15</sup>Although the Complaint alleges that the vaccine manufacturers failed to comply in all material respects with the relevant FDA requirements, the plaintiffs appear to concede to the attachment of the § 22(b)(2) presumption in their response brief in opposition to the vaccine defendants' motions. Compare Compl. ¶ 21, with Pls.' Resp. Opp'n Mot. Summ. J. at 5 n.1 ("Plaintiffs do not dispute the facts of FDA approval or licensing . . ."), and id. at 26 ("Plaintiffs have a right to conduct discovery regarding their failure to warn claims to determine if Plaintiffs can rebut the presumption enumerated in § 22(b)(2).").

<sup>16</sup>I understand the last allegation to relate to the plaintiffs' burden to overcome the adequate warning presumption of Section 22(b)(2) and not to constitute an independent claim for relief. See 42 U.S.C. § 300aa-22(b)(2); supra Part V.B. A state law claim based on a vaccine manufacturer's intentional withholding of information from the FDA would be preempted under the Supreme Court's decision in Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341, 348 (2001) (holding that "state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by federal law").

the motion to a motion for summary judgment. And I cannot take judicial notice of the evidence that the vaccine defendants offer to prove that they are entitled to the presumption of section 22(b)(2). Therefore, at this juncture, the question is whether the plaintiffs' failure to warn claims in the Complaint are preempted due to state tort law being modified under the Vaccine Act. The answer is no.

Under the notice pleading requirements of the Federal Rules of Civil Procedure, the plaintiffs have adequately averred facts that the vaccine defendants did not adequately warn medical professionals of the dangers of their product. The Vaccine Act does not preempt failure to warn claims, but rather it creates a presumption if a vaccine manufacturer defendant comes forward with proof of its compliance with federal drug laws and regulations. Whether the vaccine manufacturers in this case have satisfied their burden of production and are entitled to the Act's presumption of "proper direction and warnings" is a question saved for the summary judgment stage. See Blackmon, 328 F. Supp 2d at 666-67 ("Defendants are not entitled to the presumption until they produce evidence of compliance with the FDA regulations."). At that point, the plaintiffs will have had the opportunity to conduct discovery and be better equipped to rebut the presumption (if it does attach). Therefore, the plaintiffs have stated failure to warn claims upon which relief can be granted and the Vaccine Act does not prevent the cause of action.<sup>17</sup>

---

<sup>17</sup>Despite the claims withstanding Vaccine Act preemption, these state law failure to warn claims are conflict preempted by the FDCA and the FDA regulations. See infra Part V.D.

I take note of certain allegations of the plaintiffs that fall under their failure to warn claims. In an attempt to rebut the presumption, the plaintiffs assert in their Complaint that Wyeth and GSK intentionally and wrongfully withheld information from the FDA and the HHS regarding the safety and dangers of thimerosal before, during, and after the FDA approval process of the vaccines at issue. On a motion for judgment on the pleadings, I must accept the plaintiffs' claims as true. However, the plaintiffs' allegations of intentionally withholding information sound in fraud<sup>18</sup> and under Federal Rule of Civil Procedure 9(b), fraud must be pled with particularity. See FED. R. CIV. P. 9(b) (“[I]n all averments of fraud . . . the circumstances constituting fraud . . . shall be stated with particularity.”).

The purpose of the heightened pleading standard for fraud claims is “to give[] defendants notice of the claims against them, provide[] an increased measure of protection for their reputations, and reduce[] the number of frivolous suits brought solely to extract settlements.” In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1418 (3d Cir. 1997). “Boilerplate and conclusory allegations will not suffice. Plaintiffs must accompany their legal theory with factual allegations that make their theoretically viable

---

<sup>18</sup>The elements of a fraud claim in Pennsylvania are: “1) a representation; 2) which is material to the transaction at hand; 3) made falsely, with knowledge of its falsity or recklessness as to whether it is true or false; 4) with the intent of misleading another into relying on it; 5) justifiable reliance on the misrepresentation; and 6) the resulting injury was proximately caused by the reliance.” Viguers v. Philip Morris USA, Inc., 837 A.2d 534, 540 (Pa. Super. Ct. 2003). In addition, concealment of a material fact amounts to actionable fraud if the manufacturer intentionally concealed a material fact to deceive the FDA. See id. See also In re Westinghouse Sec. Litig., 90 F.3d 696, 710 (3d Cir. 1996) (listing the elements of a fraud claim that must be pled with particularity under Fed. R. Civ. P. 9(b)).

claim plausible.” Id.

Here, the plaintiffs’ fraud claims are no more than a recitation of the Vaccine Act language. The Sykes do not support their claims of wrongdoing with specific factual allegations, such as what material information was withheld or when it was withheld or who withheld it. Moreover, the defendants’ disclosure to the FDA of their products’ thimerosal ingredient during the licensing process of the vaccines and the FDA’s continued testing and current position on thimerosal, *i.e.*, that there is no causal link between the preservative and neurological injury, lead to the conclusion that permitting the plaintiffs an opportunity to replead this claim would be pointless. Accordingly, the plaintiffs’ allegations that the vaccine defendants’ intentionally withheld information from the government are dismissed with prejudice.

#### D. Conflict Preemption Under the FDCA and FDA Regulations<sup>19</sup>

Independent of the Vaccine Act preemption, the defendants argue that federal conflict preemption arising out of the FDA’s comprehensive regulation of biological

---

<sup>19</sup>The Vaccine Act and its saving clause do not bar the ordinary working of conflict preemption principles, especially with respect to the labeling regulations under the FDCA . See, e.g., Geier v. Am. Honda Motor Co., Inc., 529 U.S. 861, 869-70 (2000) (holding “the saving clause (like the express pre-emption provision) does not bar the ordinary working of conflict pre-emption principles” because “[n]othing in the language of the saving clause suggests an intent to save state-law tort actions that conflict with federal regulations”); United States v. Locke, 529 U.S. 89 (2000) (declining “to give broad effect to saving clauses where doing so would upset the careful regulatory scheme established by federal law”). The plaintiffs do not contend otherwise.

products' labels bars the plaintiffs' state law failure to warn claims.<sup>20</sup> The plaintiffs' response to the defendants contends: (1) FDA preemption does not apply because Congress has not expressed an intent to bar state law claims; (2) the state law tort remedies complement the FDA regulatory program for prescription drugs and biologics; (3) caselaw supports a position against the conflict preemption sought by the defendants; and (4) the FDA's "Preemption Preamble" is not entitled to any deference.

*1. Recap of Conflict Preemption*

Defendants pursue only "conflict" preemption with their FDA preemption argument. Such a conflict exists where either (1) the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" or (2) it is "impossible for a . . . party to comply with both state and federal law." Geier v. Am. Honda Motor Co., Inc., 529 U.S. 861, 899 (2000); Pokorny, 902 F.2d at 1120; C.E.R. 1988, Inc. v. Aetna Cas. & Sur. Co., 386 F.3d 263, 268 (3d Cir. 2004). In contending that the plaintiffs' claims are impliedly preempted by federal law, the defendants principally assert that allowing state tort liability in this case would thwart the purpose of the FDA's comprehensive federal scheme governing the labeling of prescription products.

Secondarily, the defendants argue that under the facts of this case compliance with state

---

<sup>20</sup>The Complaint alleges that the defendants failed to warn health care professionals and the plaintiffs of the presence of ethylmercury in their products, of the toxicity of ethylmercury, of the risks of injury from exposure to mercury-based compounds, and of the existence of safer alternatives to the mercury-containing products. Only GSK and Bayer raise the FDA preemption issue in their motions and supporting briefs, but Wyeth joined in on GSK and Bayer's FDA preemption argument at oral argument.

law could result in misbranded drugs under federal law and conflict preemption was intended to avoid such situations.

The Supreme Court has urged caution in the application of conflict preemption: "[B]ecause the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly preempt state-law causes of action." C.E.R. 1988, 386 F.3d at 269-70 (quoting Medtronic Inc. v. Lohr, 518 U.S. 470, 485 (1996)). Thus, conflict preemption will be found only if the need for it is clear. Pokorny, 902 F.2d at 1122. "[C]onsideration under the Supremacy Clause starts with the basic assumption that Congress did not intend to displace state law." Bldg. & Constr. Trades Council of Metro. Dist. v. Assoc. Builders & Contractors of Mass./R.I., Inc., 507 U.S. 218, 224 (1993).

## 2. Overview of Regulatory Process to Obtain Approval from the FDA of a Biological Product

A brief overview of the approval process to market and sell vaccines or immune globulins will be helpful in my analysis of the parties' arguments. Virtually all aspects of biological products are governed by regulations promulgated by the FDA pursuant to both the FDCA and the Public Health Services Act, 42 U.S.C. §§ 201 *et seq.* No biological product can be marketed without an FDA-approved license. See 42 U.S.C. § 262(a)(1)(A). Before a product can be approved, the manufacturer must satisfy the FDA that the biologic "is safe, pure, and potent . . . [and that] the facility in which [it] is

manufactured, processed, packed or held meets standards designed to assure that the biologic continues to be safe, pure, and potent . . . .” 42 U.S.C. § 262(a)(2)(C)(I).<sup>21</sup> See 21 C.F.R. § 601.2 (requiring a biologic manufacturer to make a detailed submission to the FDA and demonstrate that its product “meets prescribed requirements of safety, purity, and potency” before a license is issued); id. at § 601.20 (discussing the conditions for issuance of biologic licenses). Any new use or design change of a biologic must be supported with substantial evidence of safety and efficacy and must be reviewed and approved by the FDA. See 21 C.F.R. § 601.12. Any person marketing a biologic product without a FDA license is subject to both civil and criminal penalties. See 42 U.S.C. § 262(d), (f).

Biologics are also subject to detailed labeling requirements which dictate virtually every aspect of a biologic’s label. See 21 U.S.C. §§ 331(a), (b), (k), 352; 42 U.S.C. § 262(b); 21 C.F.R. §§ 606.120-.122, 610.60-.65; 21 C.F.R. §§ 200, 201. The FDA conducts a detailed review and approval process for the information manufacturers must include in package inserts, which are the primary form of labeling for prescription drugs. See 21 C.F.R. §§ 201.56, 201.57. The FDA also approves any warning that must appear on a drug’s label, which alerts a person of any dangerous use. Id.; 21 U.S.C. §§ 352, 355(b). The FDA allows label warnings detailing when a biologic should not be used

---

<sup>21</sup>Because the defendants’ products received FDA-approval at different times, and therefore under different regulatory schemes, the approval process for each product was not identical. However, as spelled out in detail in each of the defendants’ briefs, each of the products at issue was still subject to an extensive, thorough examination by the FDA for its safety and efficacy before being licensed.

(known as “contraindications”) only with respect to “known hazards and not theoretical possibilities” and warnings describing usage risks only if “there is reasonable evidence of an association of a serious hazard.” See 21 C.F.R. §§ 201.56-59. In the case of Bayer’s product, since it was administered to a pregnant woman, its label required word-for-word specific warnings found in the regulations. See 21 C.F.R. § 201.57(f)(6)(c). Finally, once the FDA approves a biologic’s label, it cannot be changed without the FDA’s approval. See 21 C.F.R. § 601.12. Any unapproved changes to the label may render the product “mis-branded” under federal law, subjecting the manufacturer to fines and other penalties.

Each of the defendants’ biologics was at all times fully approved as safe, effective, and not misbranded by the FDA. In addition, Bayer’s product license required the use of thimerosal. See 21 C.F.R. §§ 640.103(a), 610.15, 601.12(a), (b) (requiring a nontoxic preservative for the licensing of an immune globulin). The FDA was aware of the presence of thimerosal in each of the products and the FDA approved the package inserts that disclosed the presence of thimerosal as a “mercury derivative.” The plaintiffs do not dispute these facts.

3. *The FDA’s Preemption Position Regarding Plaintiffs’ Failure to Warn Claims and the Deference to Be Given That Position*

The defendants argue that the FDA’s position on preemption, as articulated in the preamble to the 2006 drug labeling regulations and several amicus briefs, bars the plaintiffs’ failure to warn claims against them. See Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922-97

(Jan. 24, 2006) (effective date June 30, 2006) ("Preemption Preamble"). The defendants contend that this court must afford deference to the FDA's view that its regulations preempt certain state tort claims for inadequate warnings, including the plaintiffs'.<sup>22</sup> The plaintiffs dispute the defendants' claim of deference and argue the Preemption Preamble conflicts with the FDA's earlier position on the preemption of state law.

*a. FDA's Position of Preemption Stated in the Preemption Preamble*

In 2006, the FDA issued its most recent labeling rule. In the preamble to the new rule, the FDA explained the implications of its labeling regulations on product liability claims and "the government's long standing views on preemption." See 71 Fed Reg. 3922, 3934. As the FDA summarized at the outset of its discussion on preemption, "FDA approval of labeling under the act, whether it be in the old or new format, preempts conflicting or contrary State law." Id. The FDA then addressed certain instances when it believes state laws are preempted, with one situation pertinent to this case: "FDA believes that State laws conflict with and stand as an obstacle to achievement of the full objectives and purposes of Federal law when they purport to compel a firm to include in labeling or advertising a statement that FDA has considered and found scientifically unsubstantiated. In such cases, including the statement in labeling or advertising would render the drug

---

<sup>22</sup>The defendants' FDCA preemption arguments mirror the FDA's position in the Preemption Preamble. Therefore, I will first look at the FDA's reasoning. Then, I will determine if under the FDA's view the plaintiffs' failure to warn claims would be preempted. Finally, I will examine how persuasive the FDA's stance is and what deference I should give it.

misbranded under the act (21 U.S.C. § 352(a) and (f)).” Id. at 3935. See also id. at 3936 (“FDA believes that . . . the following claims would be preempted by its regulation of prescription drug labeling: . . . (3) claims that a drug sponsor breached an obligation to warn by failing to include contraindications or warnings that are not supported by evidence that meets the standards set forth in this rule, including § 201.57(c)(5) (requiring that contraindications reflect “[known] hazards and not theoretical possibilities”).

In the Preemption Preamble, the FDA addressed why these state law claims interfere with the federal objectives of drug labeling, and are therefore preempted. First, state law inadequate warning claims can result in manufacturers exaggerating the risks of a vaccine or immune globulin to avoid liability, and, as a result, discourage a biologic’s beneficial use. Second, state law warning claims can lead to overwarning, which also has a negative impact on patient safety and public health. “[L]abeling that includes theoretical hazards not well-grounded in scientific evidence can cause meaningful risk information to ‘lose its significance.’” 71 Fed. Reg. at 3934. A product with too many warnings can result in the significant contraindications and side effects being overshadowed. Third, state law inadequate warning claims undermine the “FDA’s statutorily prescribed role as the expert Federal agency responsible for evaluating and regulating drugs.” Id. Under the state tort systems, lay juries get to second-guess the FDA’s careful assessment of the benefits versus the risks of a specific drug to the general public and drive manufacturers to propose “defensive labeling” to avoid state liability.

Therefore, “FDA interprets the act to establish both a ‘floor’ and a ‘ceiling,’ such that additional disclosures of risk information can expose a manufacturer to liability under the act if the additional statement is unsubstantiated or otherwise false or misleading.” Id.

In addition, the FDA detailed in the Preemption Preamble the role it plays in approving and updating a drug label:

FDA is the expert Federal public health agency charged by Congress with ensuring that drugs are safe and effective, and that their labeling adequately informs users of the risks and benefits of the product and is truthful and not misleading. Under the act and FDA regulations, the agency makes approval decisions based . . . on a comprehensive scientific evaluation of the product's risks and benefits under the conditions of use prescribed, recommended, or suggested in the labeling (21 U.S.C. 355(d)). . . . The centerpiece of risk management for prescription drugs generally is the labeling which reflects thorough FDA review of the pertinent scientific evidence and communicates to health care practitioners the agency's formal, authoritative conclusions regarding the conditions under which the product can be used safely and effectively. FDA carefully controls the content of labeling for a prescription drug, because such labeling is FDA's principal tool for educating health care professionals about the risks and benefits of the approved product to help ensure safe and effective use. FDA continuously works to evaluate the latest available scientific information to monitor the safety of products and to incorporate information into the product's labeling when appropriate.

Id. In the realm of vaccines, the FDA has issued a guidance paper detailing its continued, active involvement in the review of vaccine labels to ensure their accuracy. See Ex. 2 to GSK’s Mot. to Take Judicial Notice, *Guidance for Industry: FDA Review of Vaccine Labeling Requirements for Warnings, Use Instructions, and Precautionary Information* (September 2004) (“FDA continues to engage in an ongoing, case-by-case review of all vaccine labeling and routinely requires revision of labeling that is found too inadequate to

warn health care providers of the risk associated with the use of a particular vaccine.”). Finally, the FDA rejected the idea that drug manufacturers have “latitude under FDA regulations to revise labeling by adding or strengthening warning statements” without FDA approval. 71 Fed. Reg. at 3934. This belief had been the basis for many courts to overrule preemption claims, but in reality, “the determination of whether labeling revisions are necessary is, in the end, squarely and solely FDA’s under the act.” *Id.* at 3934.

*b. FDA’s Preemption Position as Applied in This Case*

In this case, based on the FDA’s position on preemption in the preamble and its articulation of the objectives of the federal labeling scheme, the plaintiffs’ failure to warn claims against the defendants would be preempted for the following reasons: (1) the defendants’ products’ labels disclosed the use of thimerosal and its mercury content; (2) the FDA considered the use of thimerosal as a preservative in each of the defendants’ products as nontoxic; (3) the FDA has considered and dismissed any risk associated with the use of thimerosal in vaccines or biologics; and (4) Bayer’s product label contained a warning that covered the plaintiffs’ concerns.

As a result of its active role in assessing the adequacy of vaccine labels, the FDA issued a statement regarding its 1999 “comprehensive review” of the use of thimerosal in childhood vaccines: “[There is n]o evidence of harm from the use of thimerosal as a vaccine preservative, other than local hypersensitivity reactions.” Ex. 1 to GSK’s Mot. to

Take Judicial Notice, U.S. Food and Drug Administration Center for Biologics Evaluation and Research, *Thimerosal in Vaccines* at 5.<sup>23</sup> Although this statement by the FDA was issued after Wesley received his vaccines, it is reasonable for this court to conclude that the FDA would have reached the same conclusion in 1996, when less information was available and fewer studies existed discussing a connection between thimerosal and neurological injury. If GSK and Wyeth sought to add a warning to their products regarding thimerosal's "danger," the FDA would have rejected it as scientifically unsubstantiated and deemed it misbranded. See FDA's Amicus Brief at 11-12, Perry v. Novartis Pharma. Corp., No. 05-5350, 2006 U.S. Dist. LEXIS 75319 (E.D. Pa. Oct. 16, 2006) ("Perry Amicus") (stating that federal preemption bars any claim that a drug manufacturer should have warned of a causal link between a product and certain malignancies in 2001 when in 2006 the "FDA's determination was that available scientific evidence has not established the existence of a causal relationship" and, "therefore, no causal relationship had been established before that time and, had defendants attempted to claim such a relationship in their labeling, the drug would have been deemed misbranded by FDA"). Moreover, if GSK and Wyeth attempted to warn of the alleged toxicity of thimerosal, their labels would have been "false or misleading" and

---

<sup>23</sup>And while the FDA discussed the results of other studies conducted by governmental and/or health organizations regarding the link between thimerosal and neuro-developmental disorders, the evidence only showed a "weak association" and "favors rejection of a causal-relationship." These results are far from "reasonable evidence of an association of a serious hazard" nor do they show "known hazards and not theoretical possibilities," as required under the FDA labeling scheme. See 21 C.F.R. §§ 201.56-59.

thus “misbranded.” See 21 C.F.R. § 610.15 (requiring a manufacturer to use a “sufficiently nontoxic” preservative which means the FDA approved thimerosal as a nontoxic ingredient for the vaccines at issue); 21 U.S.C. § 352 (defining a drug as “misbranded” if its label is “false or misleading”). And as the FDA stated in an amicus brief in a recent preemption case in this Circuit, “[a] court must ask whether the warning sought by the plaintiff would have rendered the drug misbranded in the agency’s judgment at the relevant time, or if any new warnings proposed to be added to the warning label would have been rejected by the agency as unsubstantiated.” Perry\_Amicus at 11. See also Perry Amicus at 2 (“[S]tate tort law is preempted if it imposes liability for a company’s failure to provide a warning that FDA has rejected, or would reject, as scientifically unsubstantiated . . . .”); Colacicco, 432 F. Supp. 2d at 527 (discussing the FDA’s submitted amicus brief in which it stated that “public policy requires that warnings be scientifically substantiated”).

In the case of Bayer’s immune globulin HypRho-D, which required as an ingredient a nontoxic preservative, see 21 C.F.R. §§ 640.103(a), 610.15, the FDA package insert disclosed the presence of mercury in thimerosal and warned that HypRho-D “should be given with caution . . . to patients who are known to have had an allergic response to thimerosal” and it is “not known whether [Hyp-Rho-D] can cause fetal harm when administered to a pregnant women [and] should be given to a pregnant woman only if clearly needed.” If Bayer had inserted a warning about the alleged toxicity of

thimerosal, it would have been directly contrary to the FDA's decision concerning the nontoxic characteristic of that preservative. See 21 C.F.R. § 610.15; 21 U.S.C. § 352. And if Bayer added the plaintiffs' additional warnings about the alleged risks of injury resulting from thimerosal, the label content would not have been substantiated by "reasonable evidence of an association of a serious hazard with a drug." See id. at § 201.57(d), (e); Perry Amicus at 11-12.<sup>24</sup> In any event, the HypRho-D label reflected a warning that encompassed the plaintiffs' concerns. In the FDA's expert view, HypRho-D was to be administered in dire situations because the danger of the product to the fetus was unknown, meaning the product could cause neurological injury to the fetus. Therefore, under the FDA's current position, the plaintiffs' state law failure to warn claims against the vaccine defendants and Bayer would be preempted because they allege the "drug sponsor breached an obligation to warn by failing to include contraindications or warnings that are not supported by evidence that meets the standards set forth in" the federal regulations, and they compel the inclusion of "a statement that FDA has

---

<sup>24</sup>The FDA, in the context of a thimerosal-containing influenza vaccine being administered to a pregnant woman, has stated that any risk associated with thimerosal is "theoretical" and is outweighed by the benefit of the biologic paired with thimerosal. See FDA, Center for Biologics Evaluation and Research, Thimerosal in Vaccines Frequently Asked Questions, *available at* <http://www.fda.gov/cber/vaccine/thimfaq.htm#q12> ("Because pregnant women are at increased risk for influenza-related complications and because a substantial safety margin has been incorporated into the health guidance values for organic mercury exposure, the benefits of thimerosal-reduced influenza vaccine or thimerosal-preserved containing influenza vaccine outweighs the theoretical risk, if any, of thimerosal.") (last updated Sept. 29, 2006). It is a fair assumption that the FDA would have labeled the risk of thimerosal in an immune globulin injection as "theoretical." Therefore, much like the vaccines, the state law warning claims against Bayer would be preempted because they impose liability for a manufacturer's failure to provide a warning that the FDA would reject.

considered and found scientifically unsubstantiated.”<sup>25</sup>

In addition, for all three defendants the FDA approved the products’ labels and fulfilled its statutory role as “the expert federal agency responsible for evaluating and regulating drugs.” The plaintiffs now attempt to hold the manufacturers liable for disclosure failures involving unsubstantiated risk information that the FDA has considered and rejected. But the FDA’s view under these circumstances is both the “floor” and the “ceiling” and to subject the defendants to liability would upset the careful benefit-risk balance that FDA has struck in approving a product for market. To allow the plaintiffs’ warnings would lead to the very result the FDA wants to avoid, *i.e.*, overwarning, exaggeration, and defensive labeling. It would “undermine FDA’s authority to protect the public health through enforcement of the prohibition against false and misleading labeling of drug products in the Federal Food, Drug and Cosmetic Act.” FDA’s Amicus Brief at 1, Colacicco, 432 F. Supp. 2d 514 (“Colacicco Amicus”).

The plaintiffs argue that the defendants could unilaterally strengthen their products’ labels and thereby abide by both federal and state standards. The regulations and the Preemption Preamble hold otherwise. First, in the Preemption Preamble, the FDA

---

<sup>25</sup>The plaintiffs’ failure to warn claims also allege that the defendants failed to warn of safer alternatives to the thimerosal containing products administered to Sykes. This claim is also preempted insofar as it only restates the claim that the defendants should have warned of what allegedly made their products unsafe. In any event, the defendants’ products’ labels informed an individual of the existence of thimerosal and its mercury content, which the plaintiffs consider the ingredient that made the products not as safe as alternative products. For the defendants to include language that the thimerosal made the product less safe than a non-thimerosal biologic would be false and misleading for the reasons already discussed.

specifically addressed and dismissed this notion. “A manufacturer may, under FDA regulations, strengthen a labeling warning, but in practice manufacturers typically consult with FDA before doing so to avoid implementing labeling changes with which the agency ultimately might disagree (and that therefore might subject the manufacturer to enforcement action).” Second, a manufacturer of biologics is subject to additional regulations that are above and beyond those of regular prescription drugs and, at the relevant time, a biologic labeling change was not effective unless approved. See 21 C.F.R. § 600.2 et. seq.; 21 C.F.R. § 601.12(b) (1996) (“Proposed changes in manufacturing methods and labeling may not become effective until notification of acceptance is received from the Director, Center for Biologics Evaluation and Research.”).

Finally, my finding that the FDA would consider the plaintiffs’ warning claims preempted is supported by various amicus briefs the FDA has filed in federal court (several of which I have already cited).<sup>26</sup> Two amicus briefs were filed in this district. First, in Colacicco, the FDA determined that the plaintiff’s state law claims were preempted because it had previously considered the warning the plaintiff sought and found no reliable scientific evidence to support an association between the drug and the adverse consequence. The FDA framed the operative question in a preemption analysis as

---

<sup>26</sup> “[T]he Supreme Court has explicitly stated that *amicus* briefs are an appropriate form to express preemptive intent, which, pursuant to Chevron, Medtronic, Geier, we must afford significant deference.” Colacicco, 432 F. Supp. 2d at 529. See also infra Part V.D.3.c

“whether a tort suit would ‘stand[]as an obstacle to the accomplishment and execution’ of the objectives of federal law.” Colacicco Amicus at 15 (citing Hines v. Davidowitz, 312 U.S. 52, 67 (1941)). The FDA then answered that question by finding the plaintiff’s state law tort action would be an obstacle: “Given FDA’s repeated determinations [of the inappropriateness of the warning], it would stymie the regulatory scheme established by Congress to hold as a matter of state law that the defendants are liable for failing to provide such an inappropriate warning. Judicial imposition of liability for failure to warn would interfere with FDA’s ability to protect the public from unsubstantiated warnings that would deter appropriate uses of a drug and diminish the impact of valid warnings.” Id. at 16. In this case, the Colacicco amicus brief supports the preemption of the failure to warn of the toxicity of thimerosal claims. When the FDA approved the defendants’ products it had determined that thimerosal was an appropriate preservative because it was “sufficiently nontoxic.” See 21 C.F.R. § 610.15.

In Colacicco, the FDA determined that there was an inadequate scientific basis for the disputed warning *prior* to the drug being prescribed to the plaintiff. In the Perry Amicus the FDA addressed the circumstance where its determination of a lack of a connection between a drug and a certain adverse health consequence was made *after* the plaintiff took the drug in question. In Perry, the plaintiff was prescribed the drug at issue in April 2003. As of January 2006, “FDA’s determination was that available scientific evidence has not established the existence of a causal relationship” between the drug and

the plaintiff's injury. Perry Amicus at 12. Thus, the FDA concluded that "a claim that the defendants should have warned that [the drug caused the plaintiff's injury] would be barred under the doctrine of federal conflict preemption, because it conflicts with FDA's determination, as of January 2006, that causation has not yet been established." Id. at 2. In this case, the FDA's view articulated in the Perry Amicus preempts the plaintiffs' failure to warn claims involving the risk of injury from thimerosal. To this day and after numerous studies, the FDA believes no causal relationship exists between thimerosal in biologics and neurological injuries in the recipient of the product. See Perry Amicus at 11-12 (discussing how the FDA took a proactive role in the determination of any risk from the drug in question after it became aware of "adverse event reports involving the drug" and concluded that scientific evidence did not support the risk and a label could not state otherwise).

For all the reasons stated, the plaintiffs' failure to warn claims against the defendants would be preempted under the FDA's view of conflict preemption.

*c. What Deference Should be Given to FDA Position?*

It appears clear that the FDA would hold that the FDCA and its corresponding regulations impliedly preempt the plaintiffs' state law tort claims arising out of the manufacturers' alleged failure to warn of the dangers associated with the use of their products. The next step in this analysis is to determine the weight to give the FDA's statements. Under Supreme Court precedent, an agency's interpretation of the statute and

regulations it administers is entitled to deference when Congress has not made its intent known. See Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 844 (1984) (holding that it has been "long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer"). However, a court's deference to a federal agency is not absolute. The question, according to the Third Circuit, is "whether the agency's answer is based on a permissible construction of the statute." NLRB v. N.J. Bell Tel. Co., 936 F.2d 144, 147 (3d Cir. 1991). If the agency's stance is "rational and consistent with the statute," I am not free to replace the agency's interpretation with my preference. In addition, I must review the consistency with which the agency has applied its particular interpretation. Id. But see id. n.5. (noting that a federal agency is "free to change course provided the new direction is within the [agency's] power and also constitutes a reasoned approach").

In the context of preemption, the Supreme Court has held that the FDA's position on the preemptive scope of its regulatory authority "is dispositive" as long as Congress does not clearly express its intent or other developments do not occur that reveal a change in the agency's position. See Hillsborough County v. Automated Med. Labs. Inc., 471 U.S. 707, 714 (1985). Further, the Court has stated that such preemptive intent may properly be communicated in amicus briefs as well as in "regulations, preambles, interpretive statements and responses to comments." Id., 471 U.S. at 718.

More recently, the Supreme Court has confronted the question of whether a federal agency's regulations preempted state tort law claims and it has given considerable weight to the agency's preemption position because "Congress has delegated to [the agency] authority to implement the statute; the subject matter is technical; and the relevant history and background are complex and extensive. The agency is likely to have a thorough understanding of its own regulation and its objectives and is 'uniquely qualified' to comprehend the likely impact of state requirements." See Geier, 529 U.S. at 883. In Medtronic v. Lohr, 518 U.S. 470 (1996), Justice Breyer noted that the Court had "previously suggested that, in the absence of a clear congressional command as to pre-emption, courts may infer that the relevant administrative agency possesses a degree of leeway to determine which rules, regulations, or other administrative actions will have pre-emptive effect." Id. at 505 (Breyer, J., concurring in part). See also id. at 505-06 ("The FDA can translate [its special understanding of whether (or the extent to which) state requirements may interfere with federal objectives] into particularized pre-emptive intentions accompanying its various rules and regulations. It can communicate those intentions, for example, through statements in regulations, preambles, interpretive statements, and responses to comments."), quoted in Horn v. Thoratec Corporation, 376 F.3d 163, 170 n.12 (3d Cir. 2004).

In Colacicco, Judge Baylson discussed the Third Circuit's position regarding the deference to be afforded the FDA's view on preemption:

The Third Circuit has not rendered an opinion as to the level of deference that should be afforded to the FDA's position on whether the FDCA impliedly preempts state failure-to-warn claims. However, the Third Circuit considered whether to defer to the FDA's position on express preemption in the 2004 case Horn v. Thoratec Corp., 376 F.3d 163, 171 (3d Cir. 2004). Horn held that the plaintiff's state law claims against a heart valve manufacturer were preempted by the express preemption provision of the M[edical Devices Amendment]. In coming to this conclusion, the court stated that the Supreme Court's decision in Medtronic required it to afford deference to the FDA's position that the claims were preempted. Moreover, it held that this was the case even though this stance was a change from the FDA's prior position. Id. (noting "we cannot agree [with Plaintiff] that the FDA's position is entitled to no deference or 'near indifference' simply because it represents a departure from its prior position."). The court noted that the Supreme Court in Chevron held that a "revised interpretation by an agency is [still] entitled to deference because an initial agency interpretation is not instantly carved in stone," and that an agency may change its position "so long as it can justify its change with reasoned analysis." Id. Horn held that it was "fully persuaded" that the FDA adequately justified its change in position on preemption. Importantly, while the facts of Horn involved the express preemption provision of the MDA, to which there is no corollary part in the prescription labeling provisions of the FDCA, the Horn court broadly announced a policy of affording deference to the FDA's position on preemption, and did not narrow the holding only to cases involving express preemption.

Colacicco, 432 F. Supp. 2d at 526.

Here, the plaintiffs are correct to point out that the FDA's position on the preemption of state law failure to warn claims has not been the model of consistency. Compare 71 Fed Reg. 3922, 3934-36 ("Preemption Preamble"), with 65 Fed. Reg. 81082, 81103 (Dec. 22, 2000) (stating in its initial Notice of Proposed Rulemaking in the Federal Register, setting forth its intent to revise its regulations pertaining to prescription drug labeling, that the "FDA has determined that this proposed rule does not contain policies

that have federalism implications or that preempt State law”). But see 71 Fed. Reg. at 3934 (calling the position stated in the Preemption Preamble “the government’s long standing views on preemption”). However, as Chevron, Horn, and Colacicco explain, inconsistency does not translate into dismissal of the FDA’s position. As a federal court in California accurately stated, “the Supreme Court has recognized that an agency’s view of the preemptive effect of its regulations may change over time as the agency gains more experience with the interrelationship between its regulations and state laws.” In re Bextra & Celebrex Marketing Sales Practices & Prod. Liab. Litig. (“Celebrex”), No: CV-05-1699CRB, MDL 1699, 2006 WL 2374742, at \*8 (N.D. Cal. Aug. 16, 2006).

Moreover, to the extent there was a change, the government has provided a reasoned analysis in the Preemption Preamble as to why certain state law tort claims are now preempted. See Horn, 376 F.3d at 179 (requiring deference to the FDA’s position on preemption even where the position changed “so long as it can justify its change with reasoned analysis”). For example, in the Preemption Preamble, the FDA analyzed many cases that found state law was not preempted and explained how those holdings conflicted with the objectives of its comprehensive labeling scheme and therefore, in such circumstances, preemption was warranted. The FDA responded to the development of caselaw and this view of the preemptive effect of its regulations is not “plainly erroneous or inconsistent with the regulation[s].” Auer v. Robbins, 519 U.S. 452, 461 (1997).

Further, as Colacicco noted, since 2000 the FDA has been very consistent in its

preemption position. In the Preemption Preamble and in various amicus briefs, the FDA “set forth detailed analyses of its position that the Supremacy Clause bars state tort liability specifically for failure to include a warning on a drug label that is in conflict with or contrary to the warnings approved by the FDA.” Colacicco, 432 F. Supp. 2d at 531-32 (citing other FDA amicus briefs in which the FDA communicated the same preemption position it did in the preamble).

Finally, the 2000 statement in the Federal Register referred generally to the regulations and did not address the situation in this case — where the plaintiffs’ proposed warnings would have misbranded the biologics or were found scientifically unsubstantiated by the FDA. And as the FDA has made clear, its position only preempts state labeling laws to the extent they conflict with or are contrary to FDA approved labels. See Perry Amicus at 11 (“FDA has not attempted to ‘occupy the field’ of prescription drug labeling, and state tort liability for failure to warn does not necessarily prevent FDA from carrying out its regulatory goals. . . . [Preemption only occurs when] the imposition of state tort liability on a drug manufacturer for failure to warn would conflict with FDA’s regulatory authority or interfere with the accomplishment of federal objectives.”).<sup>27</sup>

---

<sup>27</sup>It is worth noting two other objections to the FDA’s Preemption Preamble position. First, the plaintiffs argue that the FDA’s position is not persuasive because the FDA failed to involve the states in the rule-making process before issuing its preemption decision. See Jackson v. Pfizer, 432 F. Supp. 2d 964, 968 n.3 (D. Neb. 2006) (“The FDA failed to comply with its requirements to communicate with the states and to allow the states an opportunity to participate in the proceedings prior to a preemption decision.” (citing Executive Order 13132)). The FDA sufficiently disposed of this argument in its Colacicco Amicus: “Neither the Administrative Procedure Act nor Executive Order 13,132 requires FDA to provide notice of and an opportunity to comment on responses to public comments about a proposed rule, setting forth the agency’s view of principles of implied conflict preemption in a preamble that is not

The plaintiffs relies heavily on the holding in Mazur v. Merck & Co., 742 F. Supp. 239, 247 (E.D. Pa. 1990), that “FDA regulations are generally minimal standards of conduct unless Congress intended to preempt common law, which Congress has not done in this area.” Mazur was decided before the FDA issued the Preemption Preamble or filed its recent amicus briefs. In fact, the FDA cited to Mazur in the Preemption Preamble and explained why that case’s misunderstanding of the FDCA must not be followed: “Given the comprehensiveness of FDA regulation of drug safety, effectiveness, and labeling under the act, additional requirements for the disclosure of risk information are not necessarily more protective of patients.” 71 Fed. Reg. at 3934-35. In a case like this one, the FDA regulations and its approved label establishes both the “floor” and “ceiling” and to require the additional disclosure of unsubstantiated or false information exposes the manufacturer to liability under the FDCA.

In addition, the plaintiffs cite to several 2006 federal district court pharmaceutical cases decided after the promulgation of the Preemption Preamble in which the courts do

---

part of the codified final rule. Nevertheless, in adopting the final rule in 2006, FDA did consult with a number of organizations representing the interests of state and local governments about the potential interaction between FDA drug labeling requirements and state law.” Colacicco Amicus at 19 n.8 (citing 71 Fed. Reg. 3922, 3969 (2006)). See also Celebrex, 2006 WL 2374742, at \*7 (stating that any administrative failure to consult with the states “does not mean that this Court cannot consider the FDA’s view of how certain state laws stand as an obstacle to the accomplishment of the objectives of Federal law”). Second, questions have been raised in other courts as to the 2006 Preemption Preamble applying retroactively. We adopt the reasoning and holding in Colacicco that the Preemption Preamble is an interpretative rule that “has no prohibited retroactive effect.” Colacicco, 432 F. Supp. 2d at 532-35 (finding significant that the FDA described the Preemption Preamble as “merely clarifying its ‘longstanding views on preemption’”). And even if the Preemption Preamble did not apply retroactively, the FDA has expressed its view on preemption in several amicus briefs that would lead to the same conclusion in this case — the plaintiffs’ failure to warn claims are preempted.

not preempt conflicting state law warning claims, despite the FDA's position in the preamble and contrary to Colacicco.<sup>28</sup> However, some of the cases do not even mention the Preemption Preamble, the cases that do mention the Preemption Preamble dismiss it with little or no analysis, none of the cases are binding authority, and none of the cases rely on an amicus brief produced by the FDA. See, e.g., Jackson v. Pfizer, Inc., 432 F. Supp. 2d 964 (D. Neb. 2006) (dismissing any deference to the Preemption Preamble in one sentence (“The recent notice issued by the FDA claiming preemption is not persuasive.”) and a footnote (“The FDA failed to comply with its requirements to communicate with the states . . . prior to a preemption decision.”)); Laisure-Radke v. Par Pharmaceutical, 426 F. Supp. 2d 1163, 1169 (W.D. Wash. 2006) (citing to previous Order it issued on defendants’ motion for summary judgment on preemption grounds, Laisure-Radke, 2006 U.S. Dist. LEXIS 78804 (W.D. Wash. Apr. 4, 2006), which states the defendants’ argument relies on the Preemption Preamble but does not discuss the preamble or the deference it should be afforded in any detail); Peters v. Astrazeneca LP, 417 F. Supp. 2d 1051, 1056-57 (W.D. Wis. 2006) (no mention of Preemption Preamble).<sup>29</sup> In short, none of the cases cited by the plaintiffs are persuasive and none

---

<sup>28</sup>The plaintiffs also cite to several cases decided before the Preemption Preamble was issued in January 2006. Those courts did not have the benefit of the FDA's clear articulation of its preemption position that this court relies on.

<sup>29</sup>I also mention two cases in this district. The plaintiffs rely on Mingus v. Wyeth, MDL No. 1203, No. 04-23744 (E.D. Pa. Apr. 21, 2006), to argue that the opinions in this district are conflicting regarding the FDA preemption argument. However, Mingus involved a defective design claim and a negligence claim based on the defendant manufacturer's post-FDA approval duties. The case did not involve a failure to warn claim and the case does not consider the FDA's Preemption Preamble.

provide a detailed analysis (similar to Judge Baylson's in Colacicco) of the deference due to the FDA's preemption position.

For all the reasons cited, it is clear that the FDA's position is entitled to significant deference, Geier, 529 U.S. at 883; Chevron, 467 U.S. at 844; Hillsborough County, 471 U.S. at 714; Horn, 376 F.3d at 180; Colacicco, 432 F. Supp. 2d at 536 (holding that the Colacicco Amicus and Preemption Preamble are “dispositive to our determination that Plaintiff's claims are preempted”), and I find its position persuasive.

#### 4. Conclusion

The failure to warn claims seek to hold the defendants' liable for failing to include labeling that was not scientifically supported and would have been false and misleading under federal law. The defendants could not have altered the labeling without FDA approval; the additional labeling would have posed a threat to the federal regulatory objectives of the FDA. The FDA's position supports the defendants' arguments in this case and that position must be given its fair weight. Accordingly, the defendants have defeated the presumption against preemption. I hold the plaintiffs' failure to warn claims against the three defendants are preempted and I dismiss them with prejudice.

---

Therefore, it does not conflict with Colacicco. Second, in Perry, the court acknowledged the Preemption Preamble and an amicus brief filed by the FDA, but it did think any deference to the FDA's preemption position was warranted. See Perry v. Novartis Pharma. Corp., 2006 U.S. Dist. LEXIS 75319, at \*12-15. In support of its position, the Perry court cites a footnote in a recent Second Circuit opinion. The Perry court did not consider Horn and it did not discuss Supreme Court precedent that defers to a federal agency's interpretation of its regulations' “objectives and its conclusion . . . that a tort suit . . . would stand as an obstacle to the accomplishment and execution of those objectives.” Geier, 529 U.S. at 883. This is especially true in the technical, complex field of biologics. See id.

E. Plaintiffs' Remaining Claims Against Bayer

Since I have found that the plaintiffs' failure to warn claims are preempted, all claims against the vaccine manufacturers, Glaxo and Wyeth, have been dismissed. See supra Part V.C. n.14.<sup>30</sup> The remaining claims are against Bayer and they are design defect

---

<sup>30</sup>Since I have dismissed all claims against GSK on preemption grounds, I do not need to address GSK's primary jurisdiction argument.

claims<sup>31</sup> and inadequate testing claims<sup>32</sup> under both strict liability and negligence.<sup>33</sup>

---

<sup>31</sup>The strict product liability claim alleges that HypRho-D was unreasonably and dangerously defective because it contained ethylmercury and that there existed a safer alternative to the use of thimerosal as the preservative in the product. In Pennsylvania, the “safer alternative” averment is a factor a court considers in its evaluation of whether a product is unreasonably dangerous in a strict liability defective design claim. See Weiner v. American Honda Motor Co., 718 A.2d 305, 307-08 (Pa. Super. Ct. 1998) (“The threshold inquiry in all products liability cases is whether there is a defect which rendered the product unreasonably dangerous. . . . In Azzarello v. Black Bros. Co., Inc., 480 Pa. 547, 391 A.2d 1020 (1978), our Supreme Court held that the question of whether a product is ‘unreasonably dangerous’ is a question of law to be decided by the trial court, the resolution of which depends upon considerations of social policy, including weighing factors such as ‘the gravity of the danger posed by the challenged design; the likelihood that such danger would occur; the mechanical feasibility of a safer design; and the adverse consequences to the product and to the consumer that would result from a safer design.’ (internal citations omitted)). However, in this case, because it deals with a prescription drug whose warning labels have already been determined to be adequate as a matter of law, Pennsylvania law would not allow the plaintiffs’ strict liability defective design claim to go forward. See Davenport v. Medtronic, Inc., 302 F. Supp. 2d 419, 441-42 (E.D. Pa. 2004) (“Pennsylvania has adopted Section 402A of the Restatement (Second) of Torts . . . [and] Comment k of Section 402A, . . . entitled ‘Unavoidably Unsafe Products,’ [which] alters the strict liability rule on certain products. Comment k ‘denies application of strict liability to products such as prescription drugs, which, although dangerous in that they are not without medical risks, are not deemed defective and unreasonably dangerous when marketed with proper warnings.’” (quoting Hahn v. Richter, 673 A.2d 888, 889-90 (Pa. 1996))). Cf. Morgen Industries, Inc. v. Vaughan, 252 Va. 60, 471 S.E. 2d 489 (1996) (“In order to recover under either a negligence or a breach of implied warranty theory for the manufacture of an unreasonably dangerous product, a plaintiff must show (1) that the goods were unreasonably dangerous either for the use to which they would ordinarily be put or for some other reasonably foreseeable purpose, and (2) that the unreasonably dangerous condition existed when the goods left the manufacturer's hands. . . . The issue whether a product is unreasonably dangerous is a question of fact.”); Dreisonstok v. Volkswagenwerk, A. G., 489 F.2d 1066, 1073 (4th Cir. 1974) (applying Virginia law in a negligent defective design case and stating “if an article can be made safer and the hazard of harm may be mitigated ‘by an alternate design or device at no substantial increase in price’, then the manufacturer has a duty to adopt such a design”).

<sup>32</sup>I note that under Pennsylvania law an inadequate testing claim does not support an independent claim for relief in strict product liability, see Weiner v. American Honda Motor Co., 718 A.2d 305, 307 (Pa. Super. Ct. 1998) (“The Restatement (Second) of Torts § 402A, adopted as the law of this Commonwealth in Webb v. Zern, 422 Pa. 424, 220 A.2d 853 (1966), governs all claims of products liability . . . . Success on such a claim requires the plaintiff to prove that (1) the product was defective, and (2) the defect was the proximate cause of the harm. There are three types of defective conditions which may give rise to strict liability: manufacturing defect, design defect, and failure to warn defect.” (internal citations omitted)), or under a negligence theory. See Viguers v. Philip Morris USA, Inc., 837 A.2d 534, 541 (Pa. Super. Ct. 2003) (holding “‘negligent failure to test’ is not a viable cause of action recognized by our courts, and we have found no ‘duty to test’ that would be the basis of such a claim”); Oddi v. Ford Motor Co., 234 F.3d 136, 143-44 (3d Cir. 2000) (holding that plaintiff’s negligent failure to test claim is nothing more than a products liability case based on negligence and the plaintiff must establish a defect in order to recover); Shires v. Celotex Corp., 1988 WL 1001970, \*2 (E.D. Pa. Mar. 30,

The plaintiffs attempt to hold Bayer liable because its immune globulin product was designed to include the preservative thimerosal when safer, feasible alternative preservatives were available. In addition, the plaintiffs contend that the FDA approval process establishes only the minimum standard for a drug manufacturer and state law can impose additional testing requirements without interfering with the FDA regulatory program.

In a two paragraph argument in its initial memorandum, Bayer contends that the plaintiffs' attempt to hold them liable for an "alternative packaging design" claim should be preempted. Bayer argues this claim fails as a matter of law because the FDA regulations required the use of a preservative in its product and the FDA approved thimerosal as a safe and effective preservative. In its reply brief, Bayer argues that the plaintiffs' alternative packaging design claim is actually "a private claim to enforce FDA regulations or a 'fraud on the agency' claim – neither of which can be maintained."<sup>34</sup> As

---

1988) (noting that the duty to test would appear logically subsumed within plaintiff's defective design or defective manufacture claims).

<sup>33</sup>At this point in the case, where only the issue of preemption has been briefed, I will not address whether the remaining strict liability claims or the negligence claims are viable. Since the parties do not agree as what state's law applies in this case and I am granting Bayer's motion to transfer venue, I will let the new court determine the choice of law and the legal sufficiency of the remaining claims under that law.

<sup>34</sup>These arguments of Bayer do not have merit. In the Complaint, the plaintiffs are arguing that Bayer could have made a better, safer product if it had not used thimerosal and if it conducted better safety tests. Although the plaintiffs do assert that the mercury found in HypRho-D was toxic contrary to the FDA's judgment, the crux of their claim focuses on the duty a manufacturer owes to its consumer, as opposed to any duty owed to a federal agency. See Buckman, 531 U.S. at 352-53. In other words, the plaintiffs' defective design claims are based on traditional state tort law principles.

for the testing claims, Bayer argues that the claims are conflict preempted because it is the FDA's role to mandate what level of testing is required for a biologic to be released into the market. It believes that the reasoning this court applied to preempt the failure to warn claims should apply to the inadequate testing claims.<sup>35</sup> I disagree.

On the Bayer motion, I am asked to determine whether the remaining claims are conflict preempted under the FDCA, as implemented by the FDA.<sup>36</sup> Starting with the presumption against preemption, I conclude that Bayer fails to overcome the presumption by showing clear evidence that the defective design and testing claims present a direct conflict with federal law. Bayer does not point to a statute similar to the Vaccine Act, with its language, its purpose, and extensive legislative history, to support a congressional intent to preempt design defect claims against manufacturers of immune globulin. Bayer does not have the support of a FDA statement or amicus brief that articulates an agency position of preemption in the circumstances before me. (The Preemption Preamble dealt only with drug labeling, not drug design.) At oral argument Bayer relied on the overwhelming extent that the FDA regulates biologics to support its preemption claim. See Mot. Hr'g Tr. at 34-37 (“[W]hen it comes to biologics and specifically when it comes

---

<sup>35</sup>Bayer also argues in its reply brief that plaintiffs' “failure to comply with FDA regulations” claim against it should be dismissed. That claim is against the vaccine manufacturers and not against Bayer. See Compl. ¶¶ 21.

<sup>36</sup>Conflict preemption occurs where either (1) the state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress” or (2) it is “impossible for a . . . party to comply with both state and federal law.” Geier, 529 U.S. at 899.

to immune globulins there is a very comprehensive and thorough separate regulatory scheme that the FDA has set out for defining what a biologic is . . . because . . . the product is defined by the process and the process is defined by the FDA.”). But the Supreme Court has made clear that the detail of a federal agency’s regulations, in particular the FDA’s, is not a sufficient basis for a court to find preemption of state law.

As the Court noted in Hillsborough County v. Automated Medical Laboratories, Inc.:

We are even more reluctant to infer pre-emption from the comprehensiveness of regulations than from the comprehensiveness of statutes. As a result of their specialized functions, agencies normally deal with problems in far more detail than does Congress. To infer pre-emption whenever an agency deals with a problem comprehensively is virtually tantamount to saying that whenever a federal agency decides to step into a field, its regulations will be exclusive. Such a rule, of course, would be inconsistent with the federal-state balance embodied in our Supremacy Clause jurisprudence.

Moreover, because agencies normally address problems in a detailed manner and can speak through a variety of means, including regulations, preambles, interpretive statements, and responses to comments, we can expect that they will make their intentions clear if they intend for their regulations to be exclusive. Thus, if an agency does not speak to the question of pre-emption, we will pause before saying that the mere volume and complexity of its regulations indicate that the agency did in fact intend to pre-empt. Given the presumption that state and local regulation related to matters of health and safety can normally coexist with federal regulations, we will seldom infer, solely from the comprehensiveness of federal regulations, an intent to pre-empt in its entirety a field related to health and safety.

471 U.S. at 717-18.

In addition, it is (and was) not impossible for Bayer to comply with both the FDA regulations and any state law requirement regarding the design of its product. I

understand that the FDA regulations require the pairing of an immune globulin with a preservative and, more specifically, Bayer's license for HypRho-D required the thimerosal preservative. See 21 C.F.R. 640.103(a). However, Bayer's license is not etched in stone and thimerosal is not the only preservative available to immune globulin manufacturers. And, if under a state tort law claim a judge or a jury determines that a biologic is defectively designed, a manufacturer can reevaluate its product and perhaps alter the composition of its product. Of course, the manufacturer will have to seek FDA approval of any newly constructed product, but the existence of that state law verdict compliments the federal regulations in an important way. It ensures that the safest product possible is on the market. Accordingly, Bayer fails to sufficiently demonstrate that a state law tort claim based on a FDA-approved biologic's alleged defective design is preempted.

As for the inadequate testing claim, it is not impossible for a drug manufacturer to adhere to federal law while at the same time conduct additional tests to determine the safety of its product as required by state law. Bayer could have performed additional tests in addition to the safety testing requirements of the FDA. The FDA does not limit the amount of testing a drug manufacturer can perform on its products prior to its submission of its product license application. The FDA's testing requirements are the "floor." In addition, this claim is not similar to the failure to warn claims because additional testing would not result in a misbranded drug. Additional testing could result in a safer drug and that is how state tort law is intended to complement the FDA regulations.

Therefore, the remaining state law claims against Bayer do not stand as an obstacle to the accomplishment of the FDA’s objectives of ensuring that drugs are safe and effective.<sup>37</sup> Nothing in the FDCA or the FDA regulations or any FDA communication prevents the plaintiffs from holding Bayer liable for failing to use a different “design” or failing to take additional testing measures. Therefore, no conflict exists and the plaintiffs’ remaining claims against Bayer are not preempted. See Compl. ¶¶ 16, 17, 20, 27(a), (b), (d).

## **VI. TRANSFER OF VENUE MOTIONS**

Since I have dismissed all claims against defendants GSK and Wyeth, their transfer of venue motions are moot. Bayer’s motion for transfer of venue, however, does remain and for the reasons stated below, I will grant the motion and transfer this case to the Eastern District of Virginia.

Under 28 U.S.C. § 1404, “a district court may transfer any civil action to any other district or division where it might have been brought” for “the convenience of the parties and witnesses and the interests of justice.” The parties do not dispute that the plaintiffs

---

<sup>37</sup>It is important to note how the defective design claims are different from the failure to warn claims in this respect. To allow the state inadequate warning claims to proceed in this case would result in misbranded drugs and drugs with labels that overstate or misstate a risk. The product would be the same, but its label would disturb the careful benefit-risk balance the FDA had already considered and continues to consider after licensing. A new label dictated by a state jury would disrupt the FDA’s clearly stated objective to ensure that the drugs on the market “are safe and effective, and their labeling adequately informs users of the risks and benefits of the product and is truthful and not misleading.” 71 Fed. Reg. at 3934. On the other hand, defective design claims under state law may result in better products — products that the FDA has not considered and products that assist the FDA in their goal. Therefore, no conflict exists.

could have commenced this action in the Eastern District of Virginia, *i.e.*, venue would be proper there.<sup>38</sup> Therefore, the remaining issue is whether the convenience of the parties and witnesses and the interest of justice justify transferring this case to the Eastern District of Virginia.

“While there is no definitive formula or list of factors” for courts to consider when determining whether to transfer an action, courts typically look to various private interests and public interests in their analysis. See Jumara v. State Farm Ins. Co., 55 F.3d 873, 879 (3d Cir. 1995). The *private interests* include: “plaintiff’s forum preference; the defendant’s preference; whether the claim arose elsewhere; the convenience of the parties as indicated by their relative physical and financial condition; and the convenience of the witnesses -- but only to the extent that the witnesses may actually be unavailable for trial in one of the fora” and the relative access to the sources of proof. Id. (internal citations omitted). The *public interests* include: “the enforceability of the judgment; practical considerations that could make the trial easy, expeditious, or inexpensive; the relative administrative difficulty in the two fora resulting from court congestion; the local interest in deciding local controversies at home; the public policies of the fora; and the familiarity of the trial judge with the applicable state law in diversity cases.” Id. (internal citations omitted).

---

<sup>38</sup>Where subject matter jurisdiction is based on diversity of citizenship, as in this case, venue is proper in any district where a defendant corporation is subject to personal jurisdiction at the time the action is commenced. See 28 U.S.C. § 1391(a), (c). It is not in dispute that Bayer would have been subject to personal jurisdiction in the Eastern District of Virginia.

The private factors weigh heavily in favor of a transfer to the Eastern District of Virginia. The Eastern District of Virginia is Bayer's preferred forum. The Eastern District of Virginia is convenient to the plaintiffs, who reside in Richmond, Virginia. In addition, the underlying facts giving rise to Wesley's injuries, *i.e.*, Wesley's mother's injection with HypRho-D, all took place in Virginia, not in Pennsylvania. Moreover, the alleged wrongful conduct of Bayer — the design, development, and testing of its immune globulin product — occurred outside of Pennsylvania. See Ex. A to Bayer Mot. Transfer Venue (an affidavit from Bayer's Vice President of Regulatory Affairs that states all developing, licensing, processing, manufacturing, marketing, and distribution of Bayer's Rho(D) product took place in California, North Carolina, and Connecticut). See generally Miller v. Atkins Nutritional, Inc., No. 04-5775, 2005 U.S. Dist. LEXIS 3250, at \*9 (E.D. Pa. Mar. 3, 2005) (granting defendant's transfer motion to Eastern District of New York because plaintiff agreed to jurisdiction, operative facts occurred there, defendants resided there, and New York law applied); Zeevi v. Am. Home Products Corp., No. 99-20277, 2002 U.S. Dist. LEXIS 1095, at \*7 (E.D. Pa. Jan. 24, 2002) (transferring case because the operative facts of the case outweighed the plaintiff's chosen forum). Also, not one of Wesley's treating physicians is within the subpoena power of this court, but most of them are located in the Eastern District of Virginia. See id. (transferring a strict product liability prescription drug case to a district where the plaintiff resides, the alleged injuries were sustained, and the plaintiff's treating physicians, "who are essential to the litigation," are

more conveniently called to testify); Dinterman v. Nationwide, 26 F. Supp. 2d 747, 750 (E.D. Pa. 1998) (noting that the subpoena power of the transferor court did not extend far enough to reach certain key witnesses under Fed. R. Civ. P. 45(b)(2)). It is much easier for a Virginia federal court to require the production of documents or the testimony of a corporate representative from Bayer, then it would be for me to compel the testimony of any non-party witness located in Virginia. In addition, a multi-national corporation is better equipped financially to travel to and litigate a case in a distant forum. The financial demands on the Sykes to continue this case in this court would be significant. Finally, although “the plaintiff’s choice of venue should not be lightly disturbed,” see Jumara, 55 F.3d at 879, a plaintiff’s choice is given less deference when he or she does not reside in the chosen venue and even further discounted when the events allegedly giving rise to the injury did not arise in the chosen forum. See Zeevi, 2002 U.S. Dist. LEXIS 1095, at \*5. Here, the plaintiffs have no connection whatsoever to the Eastern District of Pennsylvania and defendant Bayer’s action that allegedly gave rise to Wesley’s injuries did not occur in this district. Therefore, the plaintiffs’ forum preference is not entitled to its usual deference.

As for the public factors, they too weigh in favor of granting Bayer’s motion and transferring the remaining claims to the Eastern District of Virginia.<sup>39</sup> First, the citizens of

---

<sup>39</sup>The “choice of law” factor does not favor either side because the parties could not agree at oral argument that Virginia law governs the balance of the case. In any event, if the transferee court’s choice of law analysis determines that Pennsylvania law applies, I have provided guidance to that court on Pennsylvania law in the footnotes throughout this opinion.

Virginia have a greater interest in deciding this case in Virginia — the plaintiffs’ home state and the location of the events relating to Wesley’s alleged injuries. Second, the Eastern District of Virginia would be an easier, quicker forum than this district. Based on the location of most of the non-party witnesses and the non-corporate plaintiffs, it would be more convenient and less expensive to travel within Virginia.

The plaintiffs’ arguments in opposition to the transfer do not alter the balance of the factors. First, the plaintiffs rely on filings in a Pennsylvania state court case to prove that the defendants have substantial activity in this district.<sup>40</sup> For Bayer, the plaintiffs cite to Bayer’s website which states that Bayer’s United States headquarters is in Pittsburgh, Pennsylvania and that Bayer has a manufacturing facility for its Consumer Care Division in Lebanon County, Pennsylvania. Neither of those locations are located in the Eastern District of Pennsylvania. In addition, the distance between Pittsburgh (the only Bayer location in Pennsylvania with any relevance to this case) and Philadelphia is only forty miles less than the distance between Pittsburgh and Richmond. Second, the plaintiffs incorrectly state Bayer’s position in its reliance on the Jumara case. Bayer did not rely on Jumara for the proposition that a plaintiff’s choice of forum is entitled to less deference in a case like this. Rather, Bayer cited to several persuasive Eastern District of Pennsylvania cases to support its argument of less deference. Finally, the plaintiffs’ judicial economy

---

<sup>40</sup>The plaintiffs rely heavily on the fact that GSK has its principal place of business in Philadelphia, Pennsylvania. Since all the claims against GSK have been dismissed on preemption grounds, GSK’s relationship to this district carries little weight in my transfer of venue analysis.

argument does not save the remainder of this case from being transferred. At this point, the only submissions to this court involve federal preemption. No discovery has taken place and the substance of the state law claims have not been examined. My holding merely removes the claims that should not have been brought under federal law. The Eastern District of Virginia will be the first court to examine the merits of the state tort claims.

Accordingly, with the majority of the private and public factors favoring the Eastern District of Virginia, and with this district being inconvenient for both parties and most of the witnesses, in the interest of justice I will transfer the plaintiffs' remaining claims against Bayer to the Eastern District of Virginia.

## **VII. CONCLUSION**

For the reasons discussed above, all claims against vaccine defendants GSK and Wyeth are dismissed with prejudice. In addition, all failure to warn claims against defendant Bayer are dismissed with prejudice. The remaining claims against Bayer, defective design and inadequate testing claims, are transferred to the Eastern District of Virginia. An appropriate Order follows.

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

<b>LISA SYKES, et al.,</b>	:	
<b>Plaintiffs,</b>	:	<b>CIVIL ACTION</b>
	:	
<b>v.</b>	:	<b>NO. 06-1111</b>
	:	
<b>GLAXO-SMITHKLINE, et al.</b>	:	
<b>Defendants.</b>	:	
	:	

**ORDER**

**AND NOW**, this 28th day of March, 2007, upon consideration of all outstanding motions filed by the defendants, all responses thereto, and oral argument, it is hereby

**ORDERED:**

- 1.) Defendants GlaxoSmithKline and Wyeth's Motions for Summary Judgment (Docket No. 39 and 46) are **GRANTED**. All claims against GSK and Wyeth are preempted and dismissed for the reasons set forth in the preceding opinion.
- 2.) Defendant Bayer's Motion for Judgment on the Pleadings (Docket No. 44) is **GRANTED in part**. All failure to warn claims against Bayer are preempted and dismissed with prejudice.
- 3.) Defendant GlaxoSmithKline's Motion to Take Judicial Notice of Certain

Exhibits (Docket No. 40 and 41) is **GRANTED in part**, to the extent I reference any of the exhibits in the preceding opinion.

- 4.) Defendants GlaxoSmithKline and Wyeth's Motions to Transfer Venue (Docket No. 56 and 57) are **DENIED** as moot.
- 5.) Defendant Bayer's Motion to Transfer Venue (Docket No. 51) is **GRANTED**. The Clerk of Court shall transfer the plaintiffs' remaining case against Bayer to the United States District Court for the Eastern District of Virginia.
- 6.) The Clerk of Court shall transfer all original documents in the file to the United States District Court for the Eastern District of Virginia.
- 7.) The Clerk of Court shall mark this case as **CLOSED** for statistical purposes.

BY THE COURT:

/s/ Lawrence F. Stengel  
LAWRENCE F. STENGEL, J.