

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

LISA SYKES and SETH SYKES,	:	CIVIL ACTION
Individually and as Parents and Natural	:	
Guardians of WESLEY ALEXANDER	:	NO.
SYKES, a minor child	:	
	:	
	:	
v.	:	
	:	
GLAXO-SMITHKLINE, individually and as	:	
successor-in-interest to SmithKline Beecham	:	
Corporation;	:	
	:	
WYETH, INC., f/k/a AMERICAN HOME	:	
PRODUCTS CORPORATION, d/b/a WYETH,	:	
INC., WYETH LABORATORIES,	:	
WYETH-AYERST, WYETH-AYERST	:	
LABORATORIES, WYETH LEDERLE,	:	
WYETH LEDERLE VACCINES, and	:	
LEDERLE LABORATORIES; and	:	
	:	
BAYER PHARMACEUTICALS	:	
CORPORATION, f/k/a Bayer Corporation,	:	
Individually and as Successor-In-Interest to	:	
Miles, Inc.	:	

**COMPLAINT AND JURY DEMAND**

**I. INTRODUCTION**

1. Wesley Sykes is a nine year-old boy suffering from neurological and neurodevelopmental injuries as a result of his exposure to dangerous levels of inorganic mercury. The mercury causing his injuries was contained in “thimerosal,” a preservative added both to the vaccines he received during his first three years of life, and to a product (“HypGho-D”) administered to his mother while she was pregnant with Wesley. Plaintiffs assert strict products liability and negligence claims against the vaccine and HypRho-D manufacturers.

## **II. JURISDICTION AND VENUE**

2. Jurisdiction is proper in this personal injury action where there is complete diversity between the parties and plaintiff seeks more than \$75,000 in damages. The jurisdiction of this Court is invoked pursuant to 28 U.S.C. §1332(a).

3. Supplemental Jurisdiction is also proper in the District Court because plaintiffs timely satisfied all material requirements of the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-11 through §300aa-22, to the extent that the federal statute applies to these claims.

## **III. PARTIES**

4. Wesley Sykes was born on January 27, 1996. His parents and guardians are Lisa and Seth Sykes. At all relevant times the Sykes family was residing at 3604 Milbrier Place, Richmond, Virginia 23233, and all of the shots described below were administered to Lisa and Wesley Sykes by health care providers in the state of Virginia.

5. Defendant GlaxoSmithKline (“Glaxo”), formerly doing business as, or as a successor in interest to, SmithKline Beecham Corp., is a vaccine manufacturer. Glaxo is a corporation with its headquarters and principal place of business located at One Franklin Plaza, 200 North 16<sup>th</sup> Street, Philadelphia, Pennsylvania 19105. Glaxo designed, manufactured and distributed the thimerosal-containing Hepatitis B vaccine called “Engerix” that was administered to Wesley Sykes on three different occasions.

6. Defendant Wyeth, formerly known as, or doing business as, and as a successor in interest to American Home Products, Inc., Wyeth Laboratories, Wyeth-Lederle, and Lederle Laboratories, Inc., is a corporation with its headquarters and principal place of business in New Jersey, whose registered agent address for service of process is c/o The Pretnice Hall Corporate

System, 2704 Commerce Drive, Suite B., Harrisburg, Pennsylvania 17107. Wyeth designed, manufactured and distributed the thimerosal-containing DTP, DTaP, and Hib vaccines administered to Wesley Sykes on five different occasions.

7. Defendant Bayer Pharmaceuticals Corporation, is a corporation with its headquarters and principal place of business in Connecticut, whose registered agent address for service of process is c/o C.T. Corporation Systems, 1515 Market Street, Philadelphia, Pennsylvania 19102. Bayer Pharmaceuticals Corporation was formerly known as, or did business as, or is the successor in interest to, Bayer Corp., which in turn was the successor in interest to Miles, Inc. Miles, Inc. was a Connecticut corporation that designed, manufactured and distributed HypRho-D, the thimerosal-containing product administered to plaintiff Lisa Sykes while she was pregnant with Wesley Sykes.

**IV. STATEMENT OF CLAIM**

8. Wesley Sykes received eight intramuscular injections of thimerosal-containing pediatric vaccines as described below:

Date of Shot	Type of Shot/Product Name	Manufacturer	Mercury Content per Shot, in Micrograms
2/9/96	Hepatitis B/Engerix-B	Glaxo	12.5
3/25/96	DTPH/Tetramune	Lederle	25.0
6/10/96	DTPH/Tetramune	Lederle	25.0
7/3/96	DTPH/Tetramune	Lederle	25.0
11/11/96	Hepatitis B/Engerix-B	Glaxo	12.5
7/1/97	DTaP/Acel-Immune	Lederle	25.0
7/1/97	Haemophilus/HibTITER	Lederle	25.0

9. While pregnant with Wesley, Lisa Sykes received an injection of Rh-immune globulin, or HypRho-D, manufactured by defendant Miles, that contained 40 – 60 micrograms of mercury in the form of thimerosal.

10. As a result of his pre- and post-natal exposure to the thimerosal-containing products described above, Wesley Sykes received a cumulative dose of between 202 – 223 micrograms of organic mercury.

11. The form of mercury contained in the thimerosal to which plaintiff was exposed is a known neurotoxin. Each of the thimerosal-containing shots that Wesley Sykes received introduced into his body a dose of toxic mercury in excess of the U.S. Environmental Protection Agency's recommended guidelines for daily mercury exposure, as expressed in micrograms of mercury per kilogram of bodyweight. In addition, Wesley Sykes was exposed to a cumulative dose of mercury via thimerosal that exceeds the U.S. Environmental Protection Agency's recommended guidelines for mercury exposure over time for the period in which he received shots.

12. As a result of the mercury exposure described above, Wesley Sykes suffered neurological injuries, including developmental delays, learning disabilities, social delays and deficits, the impairment of fine motor skills, gastrointestinal illness, immune system dysfunction, and other symptoms of mercury poisoning. Some of his injuries are likely to be permanent.

13. Lisa and Seth Sykes filed a 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-11, *et seq.* The petition for compensation was filed less than three years after the symptoms of Wesley's present injuries first occurred or became manifest, pursuant to 42 U.S.C.

§300aa-16. On November 11, 2002, Mr. and Mrs. 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).

## COUNT I

### **Personal Injury - Strict Products Liability Plaintiffs v. All Defendants**

14. Plaintiffs incorporate by reference paragraphs 1 through 13 of their Complaint as though fully set forth herein at length.

15. Defendants were all in the business of designing, producing and distributing the products used by plaintiff and his mother, and each of the defendants included the mercury-containing ingredient “thimerosal” in the products used by plaintiff and his mother. The products reached plaintiff in substantially the same condition in which they left the defendants’ possession and control.

16. The vaccine products injected into Wesley Sykes and the Rh-immune globulin injected into Lisa Sykes were unreasonably and dangerously defective because they contained dangerous levels of ethyl mercury, a substance known to the defendants to have neurotoxic properties.

17. There existed at all times a safer, practical and feasible alternative to the use of ethyl mercury as a means of preventing the contamination of defendants’ vaccine and HypRho-D products. At all relevant times, the defendants could have packaged their shots in single-dose vials or in single-use, disposable syringes, avoiding completely the need for adding any biocide or fungicide to the products, and completely eliminating the use of ethyl mercury.

18. Thimerosal was not a necessary component of defendants' products, as thimerosal contributed nothing to the immunological properties of the products, the presence or absence of thimerosal did nothing to change the efficacy of the products, and federal law did not require the use of any biocide or preservative in single-dose vials or in single-use, disposable syringes. The dangers of thimerosal use could have been avoided, and essentially the same vaccine and HypRho-D products are on the market today without thimerosal added as a preservative.

19. The defendants failed to warn health care professionals or the individuals to whom their thimerosal-containing shots were administered, of:

- a) The presence of ethyl mercury in the products;
- b) The neurotoxic properties of the ethyl mercury contained in the thimerosal;
- c) The risks of injury arising from exposure to mercury-based compounds such as the thimerosal contained in the defendants' products; or
- d) That there were safer alternatives to the mercury-containing products that he was exposed to.

20. The defendants failed to conduct adequate safety tests to determine whether thimerosal was safe and nontoxic to humans in the doses administered to pregnant women, infants or small children with each individual injection of a thimerosal-containing shot, with each single-day administration of multiple thimerosal-containing shots, or with the cumulative administration of multiple shots during the first 24 months of a child's life, pursuant to the recommended pediatric immunization schedule.

21. The vaccine manufacturer defendants failed to comply in all material respects with the relevant FDA requirements because thimerosal was unsafe and toxic in the doses administered to plaintiff Wesley Sykes.

22. The vaccine manufacturer defendants—Wyeth and Glaxo—intentionally and wrongfully withheld information from the federal Food and Drug Administration and the U.S. Department of Health and Human Services regarding the safety, efficacy, risks and dangers of thimerosal, before, during and after FDA approval of the product license applications for the Wyeth and Glaxo products.

23. The unreasonably dangerous and defective products described were a substantial contributing cause of plaintiff's neurodevelopmental injuries.

**COUNT II**  
**NEGLIGENCE**  
**Plaintiffs v. All Defendants**

24. Plaintiffs incorporate by reference paragraphs 1 through 23 of their Complaint as though fully set forth herein at length.

25. Defendants had a duty to provide plaintiff with reasonably safe products that would not, when used as directed, expose plaintiff to dangerous levels of known neurotoxin.

26. Defendants knew, or reasonably should have known, that they were exposing plaintiff to dangerous levels of a known neurotoxin.

27. Defendants were negligent because they:

- a) Included dangerous levels of a known neurotoxin in products intended for use, in multiple doses over time, by a prenatal and pediatric population including this plaintiff;
- b) Failed to use safer, feasible and practical alternative packaging designs that would have completely eliminated the use of mercury-containing ingredients in the shots used by plaintiff and his mother;

- c) Failed to warn of the presence of toxic ethyl mercury in the products used by plaintiff and his mother;
- d) Failed to conduct adequate safety tests to determine whether thimerosal was safe and nontoxic to humans to in the dose administered to pregnant women, infants or small children with each individual injection of a thimerosal-containing shot, with each single-day administration of multiple thimerosal-containing shots, or with the cumulative administration of multiple shots during the first 24 months of a child's life, pursuant to the recommended pediatric immunization schedule;
- e) Failed to comply in all material respects with the relevant FDA requirements because thimerosal was unsafe and toxic in the doses administered to children such as plaintiff Wesley Sykes;
- f) Intentionally and wrongfully withheld information from the federal Food and Drug Administration and the U.S. Department of Health and Human Services regarding the safety, efficacy, risks and dangers of thimerosal, before, during and after FDA approval of the product license applications for the Wyeth and Glaxo products.

28. It was reasonably foreseeable that children, including this plaintiff, might be injured by the levels of toxic ethyl mercury contained in the vaccines and HypRho-D shots manufactured by the defendants.

29. Defendants' negligence as alleged above were substantial contributing causes of the serious neurodevelopmental injuries suffered by plaintiff, and the negligence was the proximate cause of those injuries.

**PRAYER FOR RELIEF**

30. Plaintiffs incorporate by reference paragraphs 1 through 28 of their Complaint as though fully set forth herein at length.

31. As a result of his injuries, plaintiff has incurred reasonable and necessary medical expenses and will continue to incur medical expenses in the future, all to his economic loss of no less than \$10,000,000. Plaintiff has also suffered a significant impairment in his ability to enjoy life, he faces significant obstacles to performing the tasks and activities of everyday living, and he suffers ongoing physical and mental distress, all to his non-economic loss of no less than \$10,000,000.

WHEREFORE, plaintiff Wesley Sykes, represented by his parents and guardians Lisa and Seth Sykes, seek judgment in their favor against all of the defendants for economic damages of not less than \$10,000,000 and non-economic damages of not less than \$10,000,000, for an award of their costs and expenses, and for any further relief the Court deems just and proper.

**JURY DEMAND**

Plaintiffs request trial by jury.

**ANAPOL, SCHWARTZ, WEISS, COHAN,  
FELDMAN & SMALLEY**

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