

# Exhibit A

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF OREGON

LISA SYKES and SETH SYKES, Individually  
and as Parents and Natural Guardians of  
WESLEY ALEXANDER SYKES, a minor  
child,

Plaintiff(s),

v.

Civil Action

Case No. 06-CV-1111

**PLAINTIFFS' RESPONSE OPPOSING  
BAYER PHARMACEUTICALS'  
MOTION FOR JUDGMENT ON THE  
PLEADINGS**

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.

Defendant(s).

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## I. INTRODUCTION

Bayer's motion raises the purely legal questions of whether the FDA regulatory process for biologic products preempts plaintiffs' claims as a matter of law. While Bayer's thimerosal-containing HypRho-D product was licensed by the FDA, and the product label was FDA-approved, that does not as a matter of law preempt plaintiffs claims. Congress did not intend that the federal regulatory program for biologics would displace tort claims under state law; in fact, the FDA regulatory scheme and the civil justice system are complementary processes to promote drug safety and public health.

Congress has purposely declined to preempt civil lawsuits involving failure-to-warn claims against drug companies; the weight of judicial decisions historically rejects FDA preemption arguments; and nothing about the FDA's recent "Preemption Preamble"<sup>1</sup> changes the analysis—this Court is not required to defer to the FDA's gratuitous attempt to override Congressional intent and the tort law of the states.

## II. POINTS AND AUTHORITIES

### A. Plaintiffs' Claims are not Preempted Because Congress has Not Expressed an Intention to Prohibit Drug Product Liability Lawsuits, and the FDA Cannot "Interpret Away" Substantive State Tort Law.

#### 1. Overview of Preemption Law.

The Supreme Court has identified three types of preemption: express preemption, field preemption, and conflict preemption. *English v. General Elec. Co.*, 496 U.S. 72, 78-79 (1990). Express preemption exists when Congress clearly states its intent to preempt state law. *Id.* at 78. Field preemption arises where congress has intended the federal government to occupy an entire field of regulation exclusively, leaving no room for states to supplement federal law. *Id.* at 79. Conflict preemption displaces state law to the extent that it actually conflicts with federal law. *Id.*

Bayer does not argue that express or field preemption applies here, because Congress

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<sup>1</sup> *Requirements on Content and Format of Labeling for Human Prescription Drug and Biologic Products* (21 C.F.R. parts 201, 314 and 601), 71 Fed. Reg. 3922, 3933-36 (Jan. 24, 2006).

neither explicitly intended for the Food, Drug and Cosmetic Act (“FDCA”) to displace state tort law, nor has Congress expressed any intent for the FDCA to govern drug safety exclusively. Therefore, conflict preemption is Bayer’s sole allegation in this case.<sup>2</sup>

Conflict preemption, which may be “direct” or “indirect,” applies only if it is impossible for a private party to comply with both state and federal requirements. Indirect conflict occurs only where state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” *Id.* (citations omitted). Neither conflict exists in this case. Given the Constitution’s respect for state sovereignty, there is a strong presumption that Congress does not cavalierly preempt state law causes of action. *Bates v. Dow Agrosciences, LLC*, 544 U.S. 431, 449 (2005). As the Supreme Court has emphasized, “[I]n areas of traditional state regulation, we assume that a federal statute has not supplanted state law unless Congress has made such an intention ‘clear and manifest.’” *Id.* (citations omitted) In other words, a court should presume that the state’s historic police powers are not to be superseded by a federal act unless it was the clear and manifest purpose of Congress to do so. *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995).

The presumption against preemption is especially strong if it would effectively deny plaintiffs a remedy, which is precisely what Bayer wants to do. The Supreme Court has emphasized that a preemptive federal regulatory scheme that would leave injured citizens without any federal or state recourse runs counter to the fundamental principles of justice. *Sprietsma v. Mercury Marine*, 537 U.S. 51, 64 (2002) (noting that it would be irrational for Congress to preempt common law claims that provide an important remedy for compensating accident victims); *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984). As the Supreme Court recently noted:

The long history of tort litigation against manufacturers of poisonous substances adds force to the basic presumption against preemption. If Congress had intended to deprive injured

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<sup>2</sup> See, Bayer’s Motion at pp. 13-14.

parties of a long available form of compensation, it surely would have expressed that intent more clearly.

554 U.S. 431, at 449.

Thus, courts should be extremely reluctant to imply “clear evidence” of the intent to immunize an entire industry from liability, even a highly regulated one. *Ohler v. Purdue Pharma, L.P.*, CV-01-3061, 2002 WL 88945 at \*14 (E.D. La. Jan. 22, 2002). Such intent can be ascribed only under the most compelling circumstances. *English v. General Elec. Co.*, 496 U.S. 72, 87-90 (1990). Because the displacement of the state law protecting the health and safety of their citizens is not favored, a party seeking preemption of state law bears a heavy burden of proof.

In the context of FDA preemption, one court has noted, “Congress knows how to enact FDA legislation that contains a preemption clause. Thus, the absence of any such clause with respect to prescription drugs demonstrates an implied intent not to preempt cases, such as this.” *Cartwright v. Pfizer*, 369 F. Supp. 2d. 876, 885 (E.D. Tex. 2005).

Defendant also contends that gratuitous commentary the FDA recently inserted in its introduction to new labeling rules automatically immunizes the entire pharmaceutical industry against liability in cases arising from state tort law, regardless of what Congress intended.<sup>3</sup> The effect is to deprive plaintiffs in this litigation of all legal recourse, since the FDCA does not provide remedies for damages to injured parties. This Court should deny the motion, because there is no evidence that Congress so intended.

**2. Courts have Consistently Denied Preemption Involving Prescription Drug Cases, Holding that FDA Prescription Drug Labeling Requirements are Minimum Standards.**

The issue of whether FDA approval is a shield to liability in failure to warn cases has been addressed in the Eastern District of Pennsylvania before, in a vaccine injury case, in which Judge Ditter soundly rejected the vaccine maker’s attempt to argue that regulation of vaccine

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<sup>3</sup> Bayer Motion at p. 14-18.

labels under the FDCA and the Vaccine Act preempted the tort claims of a vaccine-injured child. Addressing arguments very similar to those raised by defendants in this case involving a vaccine additive, Judge Ditter held that:

. . . mere compliance with an FDA suggestion, or for that matter, rule or order, does not mean that state tort law becomes irrelevant. First, compliance with an FDA regulation may establish that the manufacturer met the appropriate minimum standards of due care, but compliance does not absolve the manufacturer of all liability. Manufacturers must meet state safety requirements, whether codified or embodied in the common law, in addition to satisfying the initial FDA requirements.

*Mazur v. Merck & Co.*, 742 F. Supp. 239, 247 (E.D. Pa. 1990) (internal citation omitted). The opinion further notes that the state tort system is “intended to supplement federal regulation by providing a vehicle for compensation of vaccine-related injuries.” *Id.*

Judge Ditter’s conclusion is consistent with opinions in other jurisdictions. *See, e.g., Hill v. Searle Laboratories*, 884 F.2d 1064, 1068 (8<sup>th</sup> Cir. 1989) (“FDA regulations are generally minimal standards of conduct unless Congress intended to preempt common law, which Congress has not done in this area.”); *Wells v. Ortho Pharmaceutical Corp.*, 788 F.2d 741, 746 (11<sup>th</sup> Cir. 1986) (“An FDA determination that a warning is not necessary may be sufficient for federal regulatory purposes but still not be sufficient for state tort law purposes.”); *Brochu v. Ortho Pharms. Corp.*, 642 F.2d 652, 658 (1<sup>st</sup> Cir. 1981) (FDA approval of a drug label is not conclusive in a common law failure to warn action); *Kociemba v. Searle & Co.*, 680 F. Supp. 1293, 1299 (D. Minn. 1988); *Motus v. Pfizer, Inc.*, 127 F. Supp. 2d 1085, 1092 (C.D. Cal. 2000), *rev’d on other grounds*, 358 F.3d 659 (9<sup>th</sup> Cir. 2004).<sup>4</sup>

In addition, manufacturers such as Bayer are not locked into a particular drug label or

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<sup>4</sup> The FDA preemption defense has recently received judicial attention in a number of cases involving anti-depressant drugs in district courts around the country, and has been the case with pharmaceutical cases generally, the overwhelming weight of authority in recent these cases holds that state law warning claims are not preempted by the FDA’s regulation of the product. *See, e.g., Laisure Radke v. Par Pharmaceutical, Inc.*, 426 F. Supp.2d 1163, 1169 (W.D. Wash. 2006); *Witezak v. Pfizer*, 377 F.Supp.2d 726, 728-30 (D. Minn. 2005); *Cartwright v. Pfizer*, 369 F. Supp.2d 876, 881 (E.D. Tex. 2005); *Peters v. Astrazeneca, LP*, 417 F. Supp.2d 1051, 1055 (W.D. Wis. 2006); *McNellis v. Pfizer*, CV-05-5500, 2005 WL 3752269 \*10 (D. N.J. December 29, 2005).

warning. In fact, FDA regulations allow manufacturers to change label language if supported by research (largely provided by the manufacturers), and manufacturers can make changes and later ask for FDA approval. *Jackson v. Pfizer, Inc.*, 432 F.Supp.2d 964, 965 (D. Neb. May 31, 2006) (citing 21 C.F.R. §314.70(c)(6)(ii)(A)). This ability of manufacturers to seek changes to the product labels—including changes in response to a jury finding that the existing warnings are inadequate—shows that a manufacturer “could meet both federal and state law requirements,” obviating any conflict. *Mazur*, 742 F.Supp. at 248 (citing 21 C.F.R. §601.12).

The poor record of the “FDA preemption defense” in the case law is to be expected given Congress’ treatment of preemption in the regulation of pharmaceuticals. Long before federal law regulated drugs, states provided redress to people harmed by drugs and other products through their laws and tort systems, and Congress recognized the states’ traditional role in protecting the health and safety of their citizens. When Congress enacted the Food, Drug & Cosmetic Act (FDCA) of 1938, it rejected the creation of a federal private right of action for damages caused by unsafe products because this cause of action already existed under state common law.<sup>5</sup> Similarly, when Congress amended the FDCA in 1962, Congress again made clear that it did not intend to invalidate state law, by establishing an extremely high burden on anyone attempting to argue that a state law conflicted with the federal regulations:

Nothing in the amendments made by this Act to the Federal Food, Drug and Cosmetic Act shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provisions of state law.

Pub.L. No. 87-781, 76 Stat. 780, 793 (1962). Given this, it is not surprising that *no* appellate court has found that Congress intended the FDCA to preempt common law tort claims. Bayer falls far short of meeting its burden of showing that Pennsylvania law is in “direct and positive conflict” with the FDA’s regulatory program, and Glaxo thus cannot overcome the extremely

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<sup>5</sup> Adler & Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 Mo. L. Rev. 895, 924 & n. 130 (1995).

strong presumption against preemption.

3. **The Recent FDA “Preemption Preamble” is Neither Binding nor Persuasive, and Should be Given no Deference.**

Bayer tries to exploit the FDA’s recent opinion language about preemption in the recent new drug label rules (71 Fed.Reg. 3933-35 (Jan. 24, 2006)), and apparently hopes that this will turn the judicial tide on the issue—that through administrative fiat the FDA might provide liability protection where the Congress and the judiciary have not. Bayer’s enthusiasm is premature and misplaced.

First, the “Preemption Preamble” is entitled to little deference because it contradicts the FDA’s official position, articulated until 2001, that the agency’s proposed changes to the label rules would not conflict with or preempt existing state law. In 1988, the FDA stated in a regulatory preamble addressing medication guides that agency regulations establish the minimal standards necessary; state tort law did not conflict with the agency’s regulations. 63 Fed.Reg. 66378-01, 66384 (Dec. 1, 1988). In 2000, the FDA said the proposed label rule changes would:

Establish minimum graphical requirements for labeling. This proposal would also eliminate certain unnecessary statements on prescription drug labels and move other, less important information to labeling. Because enforcement of these labeling provisions is a Federal responsibility, there should be little, if any, impact from this rule, if finalized, on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of Government. *In addition, this rule does not preempt State law.*

65 Fed.Reg. 81082, 81103 (2000) (emphasis added). An agency’s interpretation of its regulations is not given its usual deference when the interpretation “contradicts the agency’s own previous construction” of the regulation, if courts have relied on the previous construction as authoritative. *Norfolk Southern Railway Co. v. Shanklin*, 529 U.S. 344, 356 (2000). Here, the FDA’s apparent flip-flop on the preemption issue obliges the Court to discount any deference that might have been due to the FDA opinion. While an agency reversal of position may be

granted some deference if the agency provides a compelling reason explaining the change, Bayer points to no such persuasive rationale proffered by the FDA. The sudden “about face” by the agency is therefore entitled to very little judicial deference.

In addition, the FDA position is not persuasive because in adding this language, the FDA failed to comply with its own requirements to: 1) involve the states in the rule-making proceedings prior to a preemption decision; 2) keep regulatory preemption to a minimum level; 3) consult with state officials to minimize the conflict between agency decisions and state law; and 4) provide state and local officials with notice and an opportunity to participate in the rule-making process. 432 F. Supp.2d at 968, fn.3 (internal citations omitted).

A number of District Courts have decided FDA preemption issues in the months since the agency promulgated the rule in January 2006 (it became effective in June 2006) and, as was the case before January 2006, the current of judicial opinion has run against the FDA’s interpretation and against the manufacturers’ attempts to use the preamble to make a liability shield. *Jackson*, 432 F. Supp.2d at 964; *Laisure\_Radke*, 426 F. Supp.2d at 1169; *Peters*, 417 F. Supp.2d at 1055. In the Eastern District of Arkansas, Judge Wilson simply adopted by reference in its entirety Judge Bataillon’s *Jackson v. Pfizer, Inc.* opinion in an order denying Wyeth’s preemption motion in the hormone therapy Multi-District Litigation, finding that Judge Bataillon’s holding was “mules and bicycles;” that is, directly on point. (Attached as Exhibit A). At least one state court trial judge has also considered and rejected the preamble preemption argument, in an unpublished opinion. *Coutu v. Tracy*, Case No. C.A. PC-00-3720 (Sup. Ct. R.I., May 11, 2006) (Attached as Exhibit B).

While one judge in this District has ruled with the distinct minority of courts on the issue of FDA preemption, as discussed in Bayer’s motion, *Colacicco v. Apotex, Inc.*, \_\_\_ F.Supp.2d \_\_\_, CV-05-5500, 2006 WL 1443357 (E.D. Pa. May 25, 2006) (Attached as Exhibit C), that decision is not the definitive word even in this District. Chief Judge Harvey Bartle III rejected Wyeth’s FDA preemption arguments in a diet drug case, allowing plaintiff’s design defect claim to proceed. *Mingus v. Wyeth, et al.*, MDL Docket No. 1203, Case No. CV04-23744

(April 21, 2006), at p. 7. Given the conflicting District Court opinions in this District, and the overwhelming weight of judicial authority rejecting the FDA preemption argument (with or without the preamble language at issue), this Court should also reject Bayer's argument and deny its motion.

**B. Plaintiffs' Claim that Bayer Negligently Failed to Adequately Test the Thimerosal used in its Product is Not Preempted.**

As one of their specifications supporting their design defect and negligence claims, plaintiffs properly allege that Bayer should have conducted more and better testing of the thimerosal in its products so that a safer product would be marketed, and so that proper warnings could be given. Bayer's failure to conduct adequate testing is but one of several reasons that a potentially toxic product was approved by the FDA and marketed. Just as FDA licensing and label approval does not, as a matter of law, preempt plaintiffs' claims altogether, the FDA approval process does not, as a matter of law, establish the standard of care under state law. FDA approval does not foreclose a factual finding that Bayer could and should reasonably have conducted additional product testing, because the FDA approval process establishes minimum standards, not maximum standards. *Hill*, 884 F.2d at 1068 ("FDA regulations are generally minimal standards of conduct unless Congress intended to preempt common law, which Congress has not done in this area.").

Nothing about the states' imposition of additional or heightened standards of care for product design or labeling conflicts with the FDA regulatory program; it is entirely possible for a manufacturer such as Bayer to comply with both minimal FDA standards and higher standards established under state law. *Mazur*, 742 F. Supp. at 247. The complementary role of the tort system thus advances the important public policy goal of allowing the states to exercise their traditional role of protecting the public health of their citizens. *Id.*

Plaintiffs' allegations that Bayer failed to adequately test their thimerosal-containing products are not preempted by the mere fact that the FDA approved the product and its label, and Bayer's motion should therefore be denied.

**C. Plaintiffs' "Alternative Packaging" Claims are not Preempted.**

Plaintiffs allege that Bayer could have used a safer alternative product design by packaging the biologic without the use of thimerosal. While the FDA required the use of *some* preservative in Bayer's single-dose presentations of the product, the FDA did not specifically require thimerosal as the *only* preservative option. In fact, the FDA mandate to use preservatives in biologics also required that any preservative used must be non-toxic in the dose administered. The toxicity of thimerosal is one of the fundamental fact questions in this case, and neither the FDA requirement for a preservative, nor the FDA approval of thimerosal for a this product for a period of time establishes that thimerosal was in fact non-toxic.

Whether safer alternative preservatives were available to Bayer at the time it manufactured and marketed the HypRho-D product is a question of fact for resolution after discovery. It is not a question that can be answered as a matter of law in, and Bayer's motions should therefore be denied.

**D. Plaintiffs are not Suing to Enforce FDA Regulations**

Plaintiffs claim that Bayer's thimerosal-containing products were unsafe, that Bayer knew or should have known that the thimerosal used in its product was unsafe, and that Bayer failed to warn of the dangers of thimerosal. These claims against Bayer rely in part on allegations that Bayer, while completing and submitting its paperwork for FDA approval, did not pass on to the FDA material and relevant information about the safety and efficacy of thimerosal. Plaintiffs do not dispute that Bayer submitted material to the FDA in order to obtain product licenses and label approval. Plaintiffs contend that the information was inadequate, incomplete, or inaccurate, based on the toxicity of thimerosal and the availability of safer ways to package FDA-compliant biologics.

Bayer mischaracterizes the claims as a private action to enforce FDA regulations. That is not the case, the claims are not preempted by the FDA's regulatory program, and the motion should be denied.

**III. CONCLUSION**

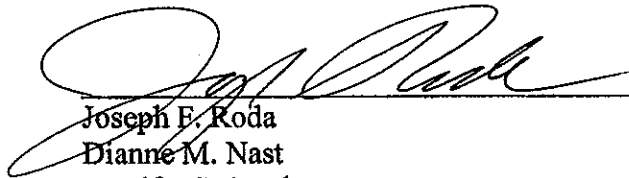
Plaintiffs claims against Bayer are not preempted by the FDA's regulation of biologic products, and Bayer's motion should therefore be denied.

DATED this 14<sup>th</sup> day of August, 2006.

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