

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Richmond Division**

LISA SYKES, individually and as Parent and natural guardian of Wesley Alexander Sykes, a minor child, ET AL.)	
)	
Plaintiffs,)	Case No. 3:07CV660
)	
v.)	
)	
BAYER PHARMACEUTICALS CORPORATION)	
)	
Defendant.)	

**DEFENDANT BAYER HEALTHCARE PHARMACEUTICALS INC.’S,
OPPOSITION TO PLAINTIFFS’ MOTION FOR LEAVE TO FILE
AMENDED COMPLAINT**

Defendant Bayer HealthCare Pharmaceuticals Inc., successor in interest to Bayer Pharmaceuticals Corporation (“Bayer”), opposes the Plaintiffs’ Motion for Leave to Amend the Complaint (“Plaintiffs’ Motion”) and submits the Court should deny it. In support of this Opposition, Bayer states as follows:

I. INTRODUCTION

The Plaintiffs’ Motion should be denied as it seeks a wholesale substitution of the existing complaint. The new Amended Complaint seeks to add new parties and claims previously dismissed by Judge Stengel of the United States District Court for the Eastern District of Pennsylvania. This motion to amend comes nearly two years after

commencement of this action on March 14, 2006, and Plaintiffs offer no sufficient grounds or explanation for this untimely and expansive amendment.

Based upon Bayer's understanding of the Amended Complaint, Plaintiffs seek to assert the following causes of action against Bayer in their Amended Complaint:

1. negligence in failing to warn Plaintiffs' and their health care professionals of the dangers of Thimerosal;
2. negligent or intentional misrepresentation and fraud regarding the safety of Thimerosal;
3. negligence in failing to conduct adequate safety tests to determine whether Thimerosal was safe and nontoxic to humans in the doses administered;
4. inadequate or defective design (negligence and strict liability);
5. negligent infliction of emotional distress; and
6. breach of warranties, express or implied, regarding the safety and suitability of HypRho-D or Thimerosal.

Plaintiffs' only explanation for seeking leave to assert such claims is "so that the claims [in their complaint] are properly made under Virginia law." *See* Plaintiffs' Brief in Support of Motion to Amend Complaint ("Plaintiffs' Brief") at p. 8. As will be discussed in detail below, however, the Court should not grant Plaintiffs' leave to assert such causes of action because:

1. Plaintiffs' failure to warn claims against Bayer have already been properly dismissed on the merits by Judge Stengel and should not be re-litigated (*see* Section II.A);
2. Plaintiffs' negligent or intentional misrepresentation and fraud claims, which merely constitute different legal theories for identical allegations as the failure to warn claims, should also not be re-litigated (*see* Section II.A);
3. Plaintiffs claim that Bayer failed to conduct adequate safety tests fails as a matter of Virginia law (*see* Section II.B);

4. Plaintiffs design defect claims fail as a matter of law (*see* Section II. B); and
5. Plaintiffs, who have not alleged they suffered any bodily injury attributable to Bayer's conduct, cannot maintain a claim for negligent infliction of emotional distress under Virginia law (*see* Section II.C); and
6. Plaintiffs' breach of warranty claims fail as a matter of law (*see* Section II.C).

Plaintiffs also wish to assert new causes of action against two new defendants. *See* Section III. In Plaintiffs' Brief, however, Plaintiffs' failed to offer any specific reason why additional defendants should be added or why the joinder of additional defendants would promote the interests of trial convenience and the expedition of the determination of disputes. To the contrary, Plaintiffs expressly admit in their brief that adding additional defendants would "make this litigation even more protracted" and suggest that claims against the additional defendants could be pursued in other litigation. *See* Plaintiffs' Brief at p. 9-10.

This opposition will first address Plaintiffs' amended claims, and then turn to the amended parties.

II. The Court Should Not Grant Plaintiffs' Leave to Amend.

A. Plaintiffs' Should Not Be Allowed to Re-Introduce Previously Dismissed Claims.

Judge Stengel has already dismissed Plaintiffs' failure to warn or inadequate warning claims, *see* Exhibit A to Plaintiffs' Motion, § A, ¶¶ 40(a)-(c), (e), 44-47, on the basis that federal law preempts them. *See* Opinion (Mar. 28, 2007) at p. 53, 65 attached hereto as Exhibit 1 ("I hold the plaintiffs' failure to warn claims against [Bayer] are

preempted and I dismiss them with prejudice.”)¹ Although “a court has the power to revisit prior decisions of its own or of a coordinate court in any circumstance, . . . as a rule courts should be loathe to do so in the absence of extraordinary circumstances such as where the initial decision was ‘clearly erroneous and would work manifest injustice.’” *See Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 817 (1988) (citation omitted); *see also Hill v. BASF Wyandotte Corp.*, 696 F.2d 287, 290 (4th Cir. 1982) (stating the circumstances when proper for a district judge to treat earlier rulings as binding). Plaintiffs’ Brief fails to offer a single reason why Judge Stengel’s prior rulings should be reconsidered or overturned. Absent a showing by Plaintiffs that his rulings were “clearly erroneous,” Plaintiffs should not be allowed to re-introduce claims previously dismissed by him by way of an amended pleading. *See Christianson*, 486 U.S. at 817.

Neither should Plaintiffs be allowed to plead different legal theories based upon identical allegations in an attempt to re-introduce the previously dismissed claims. Plaintiffs’ Motion attempts to do just that in seeking leave to assert previously unasserted negligent misrepresentation and intentional misrepresentation and fraud claims (against Bayer) that arise out of the identical allegations as the original failure to warn claims. *See Ex. A to Plaintiffs’ Motion*, § A, ¶¶ 49-60.² Plaintiffs’ have already had a full and

¹ Judge Stengel’s Order dismissing Plaintiffs’ failure to warn claims constitutes an adjudication on the merits. *See Fed. R. Civ. P. 41(b)* (“Unless the dismissal order states otherwise, a dismissal under this subdivision (b) and any dismissal not under this rule – except one for lack of jurisdiction, improper venue, or failure to join a party under Rule 19, operates as an adjudication upon the merits.”).

² Plaintiffs’ misrepresentation claims, which allege that Bayer intentionally or negligently concealed the safety, efficacy, risks and dangers of thimerosal from Plaintiffs, essentially mirror the claims brought against SmithKline Beecham Corporation d/b/a GlaxoSmithKline (“GSK”) and Wyeth, Inc., f/k/a American Home Products Corporation

fair opportunity to litigate their failure to warn or inadequate warning claims. They should not have an opportunity to re-introduce such claims now by employing slight variations in legal theory or by engaging in artful pleading.³ Accordingly, Bayer submits this Court should deny Plaintiffs request for leave to amend their complaint to assert claims premised on a failure to warn or inadequate warning theory, including the misrepresentation claims.

B. The Re-Assertion of Previously Asserted Claims Against Bayer Would Be Futile.

As with the failure to warn claims, Plaintiffs similarly seek to reintroduce previously asserted claims of “failure to adequately test” and design defect against Bayer. For the reasons provided in Bayer’s pending Motion for Judgment on the Pleadings

(“Wyeth”) in the prior action. As noted by Judge Stengel, such misrepresentation claims fall under the umbrella of Plaintiffs’ failure to warn claims. *See* Ex. 1 at p. 30.

³ Even if Judge Stengel’s prior decision does not estop Plaintiffs from asserting new misrepresentation and fraud claims, Judge Stengel’s reasoning for dismissing (with prejudice) the misrepresentation claims brought against GSK and Wyeth should apply to the misrepresentation claims asserted against Bayer. In the prior action, Judge Stengel found that the misrepresentation claims brought against Wyeth and GSK were unsupported by specific factual allegations. *See* Ex. 1 at p. 30 (“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.”). Judge Stengel also found that “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.” *Id.*

Just as with the misrepresentation claims asserted against GSK and Wyeth, Plaintiffs provide no specific factual allegations in support of the misrepresentation claims they assert against Bayer in their Amended Complaint. Moreover, because it is undisputed that Bayer also disclosed to the FDA that its product contained a Thimerosal ingredient during the licensing process and because the FDA has taken a consistent position on Thimerosal (“*i.e.*, that there is no causal link between the preservative and neurological injury”), permitting Plaintiffs an opportunity to plead such claims “would be pointless.” *Id.*

(“Bayer’s Motion”), such claims are clearly insufficient and leave to amend should not be granted. *See Johnson v. Oroweat Foods Co.*, 785 F.2d 503, 510 (4th Cir.1986) (stating that leave to amend should be denied where the proposed amendment is “clearly insufficient or frivolous on its face”); *see also Nolte v. Capital One Fin. Corp.*, 390 F.3d 311, 317 (4th Cir.2004) (denying leave to amend the complaint because the “proposed amendment would not have cured the deficiencies of the complaint [and] it would have been futile for the shareholders to have amended it”).

1) Virginia Law Does Not Recognize an Independent Claim for “Failure to Adequately Test.”

Plaintiffs’ claim that Bayer failed to conduct adequate testing on HypRho-D, *see* Ex. A to Plaintiffs’ Motion, § A, ¶ 40(d), fails as a matter of Virginia law. *See* Bayer’s Motion at pp. 13-14. In the products liability context, no Virginia court has ever recognized a claim for “failure to adequately test a product.” *Id.* (citing *Jones v. Ford Motor Co.*, 559 S.E.2d 592 (Va. 2002); *Young v. J.I. Case Co.*, 1994 WL 506403, *9 (E.D. Va. 1991) (Spencer, J.)). Although Virginia law recognizes negligence or breach of warranty claims involving allegedly defective products, to the extent that such claims allege that a defect in manufacture, a defect in design, or an inadequate warning made the product unreasonably dangerous, *see Lust v. Clark Equip. Co., Inc.*, 792 F.2d 436, 438 (4th Cir. 1986), Virginia law outlines no other basis for recovery where an allegedly defective product is at issue. *See* Bayer’s Motion at pp. 13-14. Plaintiffs, therefore, should not be granted leave to assert a claim that does not exist under Virginia law.

2) Plaintiffs’ Design Defect Claims Fail as a Matter of Law.

Plaintiffs’ design defect claims, *see* Ex. A to Plaintiffs’ Motion, § A, ¶ 40(g), § C, ¶¶ 78-81, cannot stand as a matter of law. Plaintiffs’ assert in their Amended Complaint

that Bayer's product, the biologic HypRho-D, was defective and unreasonably dangerous and that Bayer had the ability to manufacture a safer alternative product. *Id.* As noted in Bayer's Motion, Plaintiffs' allegation, that the mere use of Thimerosal in HypRho-D rendered the product "unreasonably dangerous," fails to plead a legally cognizable design defect claim. *See* Bayer's Motion at pp. 15-17. Moreover, Plaintiffs' offer no allegations of an alternative preservative that Bayer should have used instead of Thimerosal – one that was actually available at the relevant times, one that would be allegedly safer and which would "truly provide[] more benefits than risks" – in their Amended Complaint. *See Tunnell v. Ford Motor Co.*, 385 F. Supp. 2d 582, 584-85 (W.D. Va. 2005) ("When evaluating the reasonableness of a design alternative, the overall safety of the product must be considered. It is not sufficient that the alternative design would have reduced or prevented the harm suffered by the plaintiff if it would have introduced into the product other dangers of equal or greater magnitude.") (quoting *Restatement (Third) of Torts: Products Liability* § 2 cmt. f (1997)). As such, Plaintiffs' design defect claims must fail.

Accordingly, leave should not be granted for Plaintiffs to amend their complaint to assert claims premised on a "failure to adequately test" or design defect theory.

C. The Assertion of New Claims Against Bayer Would Be Futile.

Apart from seeking to reintroduce previously dismissed claims and previously asserted claims that fail as a matter of law, Plaintiffs, nearly two years after filing their original Complaint, seek to introduce new claims, including 1) negligent infliction of emotional distress, 2) breach of express warranty of merchantability, 3) breach of implied warranties, and 4) gross negligence, against Bayer in the Amended Complaint. Such

claims, however, are “clearly insufficient” and leave to amend should not be granted. *See Johnson*, 785 F.2d at 510.

Under the facts of this case, Plaintiffs may not recover for negligent infliction of emotional distress. *See Hughes v. Moore*, 197 S.E.2d 214, 219 (Va. 1973). The Virginia Supreme Court has stated that “where conduct is merely negligent, not willful, wanton, or vindictive, and physical impact is lacking, there can be no recovery for emotional disturbance alone.” *Hughes*, 197 S.E.2d at 219. Plaintiffs Lisa and Seth Sykes, who, on the face of the Amended Complaint, appear to be the only Plaintiffs to have suffered “extreme emotional and mental anguish” as a result of their son’s alleged injuries, *see* Ex. A to Plaintiffs’ Motion, ¶ 38, § C, ¶ 77, fail to allege that they have suffered any physical impact as a result of Bayer’s allegedly negligent conduct. As a result, Plaintiffs’ claim for negligent infliction of emotional distress fails as a matter of law.

Similarly, Plaintiffs’ breach of warranty claims cannot stand. At all times relevant, the FDA approved as “safe, effective, and not misbranded” HypRho-D. *See* Bayer’s Motion at p. 6. Thus, Plaintiffs’ allegations that Bayer breached any warranty, express or implied, regarding the safety of its product have no valid legal basis.

Plaintiffs have failed to make any specific allegations that Bayer acted negligently, fraudulently, maliciously or wantonly or that would entitle them to punitive damages. Given the fact that Plaintiffs’ failure to warn or inadequate warning claims have already been dismissed by Judge Stengel and that their “failure to adequately test,” design defect, negligent infliction of emotional distress and warranty claims fail as a matter of law, Plaintiffs cannot maintain a gross negligence claim or recover punitive

damages. Accordingly, Plaintiffs motion for leave to amend their Complaint should be denied.

III. Even if Leave Is Granted for Plaintiffs to Amend Their Complaint, the Claims Asserted Against One of the Previously Unnamed Defendants Should Not Be Joined in This Action.

Plaintiffs, in their Motion for Leave to File Amended Complaint, also seek leave to bring in new defendants and assert new claims against them. Federal Rule of Civil Procedure 20(a) states, in part, that:

“[a]ll persons . . . may be joined in one action as defendants if there is asserted against them jointly, severally, or in the alternative, any right to relief in respect of or arising out of the same transaction, occurrence, or series of transactions or occurrences and if any question of law or fact common to all defendants will arise in the action.”

Fed. R. Civil P. 20(a). Clearly, the claims asserted against Dominion Resources (“Dominion”) should not be joined in this action, as they do not arise out of the same transaction, occurrence, or series of transactions or occurrences. *See id.*; *see also 3M Co. v. Johnson*, 895 So. 2d 151, 158 (Miss. 2005) (finding that a product manufacturer defendant was improperly joined with toxic exposure defendants).

Federal courts have rejected attempts to join parties where the right to relief against each party does not arise out of the same transaction, occurrence or series of transactions or occurrences. For example, in *Wilkinson v. Hamel*, the plaintiff sought leave to amend his complaint to add claims against additional defendants for occurrences that occurred more than four years after the occurrences upon which the plaintiff based the cause of action in his original complaint. 381 F. Supp. 766, 767 (W.D. Va. 1974). The court refused, finding that even if it assumed “that plaintiff’s right to relief against

the additional defendants exist[ed] . . . such right to relief neither arises out of the same occurrence or series of occurrences nor involves a common question of law or fact as required by Rule 20(a).” *Id.* Similarly, federal courts have rejected the joinder of parties where claims against the defendants are only “similar.” *See, e.g., Franconia Assocs. v. United States*, 61 Fed. Cl. 335, 337 n.1 (Fed. Cl. 2004) (citing federal cases disallowing joinder of parties where only “similar” transactions were at issue.).

A plain reading of the Amended Complaint reveals that Plaintiffs’ alleged right to relief against Dominion does not arise out of the same transaction, occurrence, or series of transactions or occurrences that give rise to its alleged right to relief against Bayer. Plaintiffs’ claim against Dominion, *see* Ex. A to Plaintiffs’ Motion, § D, ¶¶ 1-17, involves Dominion’s alleged negligence in operating fossil fuel/coal-burning power plants and Plaintiff’s exposure to industrial mercury through inhalation. On the other hand, Plaintiffs’ claims against Bayer involve Bayer’s use of Thimerosal in HypRho-D and its alleged effect on Plaintiff through *in utero* exposure. Plaintiffs’ claim against Dominion has no effect on the claims asserted against Bayer. The alleged occurrences involve different manners of exposure occurring at different periods of time. Joinder would therefore be improper. *See Wilkinson*, 381 F. Supp. at 767. Moreover, even if the occurrences were found even to be “similar,” Rule 20’s standard has not been satisfied and joinder would be improper. *See Franconia Assocs.*, 61 Fed. Cl. at 337.

To allow Plaintiffs to add Dominion will, as Plaintiffs expressly admit, unduly and unnecessarily complicate this case, which would not serve the purposes, of promoting trial convenience and the expedition of the determination of disputes, behind Rule 20. *See Saval v. BL, Ltd.*, 710 F.2d 1027, 1031 (4th Cir. 1983) (recognizing that

Rule 20 “should be construed in light of its purpose”). Moreover, Bayer should not be put to the needless expense of litigating over air pollution when Plaintiffs have already signaled their willingness to file a separate case to pursue such claims. *See* Plaintiffs’ Brief at pp. 9-10 (“If Plaintiffs are not going to be allowed adequate time to conduct such discovery that is necessary, then Plaintiffs would prefer that their motion to add defendants not be granted, and they will pursue these defendants in other litigation.”). As such, Bayer invites the Court to accept Plaintiffs’ suggestion to bring the claims against the other proposed defendants in a separate proceeding. Bayer sees no need to amend, complicate or delay the Court’s Scheduling Order by adding new defendants. Obtaining service and factoring in additional parties’ discovery could add several months to the existing Scheduling Order. The Court should not grant leave to amend the complaint.

CONCLUSION

WHEREFORE, Bayer respectfully requests this Court to deny Plaintiffs’ Motion for Leave to File Amended Complaint and to strike the Amended Complaint attached as Exhibit A thereto.

Respectfully submitted this 4th day of February, 2008.

**BAYER HEALTHCARE
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CERTIFICATE OF SERVICE

I hereby certify that on the 4th day of February, 2008, I will electronically file the foregoing with the Clerk of Court using the CM/ECF system, which will then send notification of such filing to the following:

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