

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF
VIRGINIA RICHMOND DIVISION

LISA SYKES, et
al.,

Plaintiffs

,

CORPORATION,

v.

Defendant.

BAYER
PHARMACEUTICALS

Action No. 3:07-CV-660

MEMORANDUM
OPINION

THIS MATTER is before the Court on a Motion for Judgment on the Pleadings (Docket No. 90) by Bayer Pharmaceuticals Corporation and a Motion for Leave to File Amended Complaint (Docket No. 96) by Lisa and Seth Sykes, on behalf of their son, Wesley Sykes. For the reasons stated below, Bayer's Motion shall be GRANTED and Sykes' Motion shall be GRANTED IN PART AND DENIED IN PART.

In 1995, Lisa received an injection of HypRho-D while she was pregnant with Wesley to prevent him from developing hemolytic disease of the newborn. HypRho-D, which is manufactured by Bayer, is an immune globulin, a “sterile solution containing antibodies derived from human plasma,” 21 C.F.R. § 640.100, that suppresses the immune response of a Rh-negative pregnant woman to Rh-positive blood cells from her fetus that enter her circulation. Immune globulins are a type of “biological product” that is regulated by the Food and Drug Administration. See *id.* § 600.3(h). The FDA requires HypRho-D,

like other immune globulins, to contain a preservative that, in the amount added to a recommended dose of the product, is not toxic. *Id.* § 610.15. Bayer’s license for HypRho-D requires it to use thimerosal, a preservative that has been used to prevent the growth of microbes and fungi in vaccines for children since the 1930s. Thimerosal contains ethylmercury – by weight, about 50%. The Sykes allege that Wesley suffered serious neurological injuries and other symptoms of mercury poisoning because he was exposed to the mercury contained in the injection of HypRho-D that his mother received.

The Sykes sued Bayer, and two manufacturers of vaccines that Wesley received as an infant, in the Eastern District of Pennsylvania. Judge Lawrence Stengel granted

summary judgment in favor of the vaccine manufacturers, ruling that the Sykes' claims against them were pre-empted by the National Vaccine Injury Compensation Act. See *Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289 (E.D. Pa. 2007). He also dismissed the Sykes' claim that Bayer failed to warn them about the risk of taking HypRho-D, ruling that it was pre-empted by federal law and regulations. *Id.* at 318. Judge Stengel did not resolve the Sykes' other claims against Bayer, transferring them to this Court. Those claims are that (1) Bayer is strictly liable for failing (a) to package HypRho-D in a single-dose vial, which allegedly would have obviated the use of thimerosal, and (b) to test whether thimerosal is safe; and (2) Bayer negligently designed and failed to test its product. Bayer asks the Court for judgment in its favor on those claims, and the Sykes ask the Court to allow them to amend their Complaint to add a variety of other claims against Bayer, manufacturers of

thimerosal, and Dominion Electric, which allegedly released mercury into the air in Richmond.

A motion for judgment on the pleadings under Federal Rule of Civil Procedure 12(c) is governed by the same standard that applies to a motion to dismiss for failing to state a claim under Rule 12(b)(6). *Burbach Broad. Co. v. Elkins Radio Corp.*, 278 F.3d 401, 405–06 (4th Cir. 2002). A motion to dismiss for failure to state a claim upon which relief can be granted challenges the legal sufficiency of a claim, not the facts supporting it. *Conley v. Gibson*, 355 U.S. 41, 45–46 (1957); see *Goodman v. Praxair, Inc.*, 494 F.3d 458, 464 (4th Cir. 2007). Thus, in ruling on a Rule 12(b)(6) motion, a court must regard as true all of the factual allegations in the complaint, *Erickson v. Pardus*, 127 S.Ct. 2197, 2200 (2007), as well as any facts that could be proved that are consistent with those allegations, *Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984), and view those facts in the light most favorable to the plaintiff, *Christopher v. Harbury*, 536 U.S. 403, 406 (2002).¹ The court may grant a Rule 12(b)(6) motion only if it “appears beyond doubt” that the party bringing the claim cannot prove any facts that would entitle it to relief. *Conley*, 355 U.S. at 46; accord *Franks v. Ross*, 313 F.3d 184, 192 (4th Cir. 2002). But, the court does not have to accept legal conclusions that are couched as factual allegations. *Bell Atl. Corp. v. Twombly*, 127 S.Ct. 1555, 1564 (2007).

¹ This principle is rarely applied literally. See *Car Carriers, Inc. v. Ford Motor Co.*, 745 F.2d 1101, 1106 (7th Cir. 1984) (stating that, in practice, a complaint must allege, directly or indirectly, facts that are relevant to all of the elements of “some viable legal theory”).

Thus, at this stage of these proceedings, the Court must decide whether the Sykes are entitled to offer evidence to support their claims, not whether they will ultimately prevail. See *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974), abrogated on other grounds by *Harlow v. Fitzgerald*, 457 U.S. 800 (1982). In doing so, the Court may consider “official public records” that are relevant to the Sykes’ claims without converting Bayer’s motion to one for summary judgment. See *Gasner v. County of Dinwiddie*, 162 F.R.D. 280, 282 (E.D. Va. 1995); see also *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 127 S.Ct. 2499, 2509 (2007) (holding that a court, in deciding a Rule 12(b)(6) motion, may consider a document that is incorporated by reference into the complaint).

III

First, the Sykes claim that Bayer is strictly liable for Wesley’s injuries. In general, however, courts applying Virginia law² have not applied the doctrine of strict liability in product liability cases. See *Sensenbrenner v. Rust, Orling & Neale, Architects, Inc.*, 374 S.E.2d 55, 57 n.4 (Va. 1988) (“Virginia ... does not permit tort recovery on a strict-liability theory in products-liability cases.”); *St. Jarre v. Heidelberger Druckmaschinen A.G.*, 816 F. Supp. 424, 427 (E.D. Va. 1993) (Payne, J.) (stating that “it is beyond question that Virginia

does not recognize a cause of action for strict liability in tort”). Only in cases that involve abnormally dangerous activities does Virginia impose strict liability. See *Richmond*,

²The Court has diversity jurisdiction over this suit. See 28 U.S.C. § 1332. Thus, the Court applies Virginia law, including its choice-of-law rules. *Klaxon Co. v. Stentor Elec. Mfg. Co.*, 313 U.S. 487, 496 (1941); *Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 79 (1938). In Virginia, tort claims are governed by the law of the place where the alleged wrong occurred. See *Dreher v. Budget Rent-A-Car System, Inc.*, 634 S.E.2d 324, 327 (Va. 2006). The Sykes allege that Lisa received HypRho-D in Virginia.⁴

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Fredericksburg & Potomac R. Co. v. Davis Indus., Inc., 787 F. Supp. 572, 575 (E.D. Va. 1992) (Ellis, J.) (emphasizing that only activities, not substances, can be “abnormally dangerous”). Thus, the Sykes’ strict-liability claim for injuries allegedly caused by HypRho-D, a substance, fails as a matter of law.

Second, the Sykes claim that Bayer acted negligently by failing to package HypRho-D in a single-dose vial, alleging that changing the design of the product’s packaging would have eliminated the need to use a preservative. But, the FDA requires that every immune globulin “shall be a 16.5 ± 1.5 percent solution of globulin containing 0.3 molar glycine and a preservative.” 21 C.F.R. § 640.103(a) (emphasis added). The Sykes acknowledge that “the FDA required the use of some preservative in Bayer’s single-dose presentation of [HypRho-D].” Pl.’s Resp. Opp. Bayer’s Mot. J. Pleadings at 13. Since a premise of the

Sykes' design-defect claim – that Bayer could have avoided using a preservative by packaging HypRho-D differently – is false, the claim, as it is stated in the Sykes' Complaint,³ fails

Third, the Sykes argue that Bayer failed to conduct testing on HypRho-D to determine whether the mercury in thimerosal, in the quantity contained in a recommended dose of the HypRho-D, was dangerous. But, the Virginia Supreme Court has stated that a product may be “unreasonably dangerous” in three ways, “if it is defective in assembly or

³ The Sykes argue in their response to Bayer's Motion for Judgment on the Pleadings that Bayer should have used a different preservative, not that Bayer should have changed the way that HypRho-D is packaged. But, a party may not amend its complaint in a brief opposing a motion to dismiss. See *Car Carriers, Inc. v. Ford Motor Co.*, 745 F.2d 1101, 1107 (7th Cir. 1984) (stating that this principle is “axiomatic”).

manufacture, unreasonably dangerous in design, or unaccompanied by adequate warnings concerning its hazardous properties.” *Morgen Indus., Inc. v. Vaughan*, 471 S.E.2d 489, 492 (Va. 1996). By implication, any other type of product-liability claim cannot succeed.⁴

While the Sykes' claim might be regarded as a species of manufacturing-defect claim,⁵ their allegation that Bayer failed to test HypRho-D generally – not that it failed to test

a particular dose or batch of its product – differentiates their claim from a typical manufacturing-defect claim. See, e.g., *Matthews v. Ford Motor Co.*, 479 F.2d 399 (4th Cir. 1973) (applying Virginia law). See generally Restatement (Third) of Torts: Product Liability § 2(a) (1997) (stating that a product “contains a manufacturing defect when the product departs from its intended design”); Spahn, Gary J., et al., *Va. Prac. Prods. Liab.* § 4:1 (2007) (stating that a manufacturing defect is a “fail[ure] to conform to [its] intended design). Since the Sykes have not alleged that Lisa received an injection of HypRho-D that

⁴ Although the Virginia Supreme Court has decided at least three cases that involved a “failure to test” or “failure to inspect” claim, it has never explicitly recognized either of those claims. See *Jones v. Ford Motor Co.*, 559 S.E.2d 592, 604, 606 (Va. 2002); *Locke v. Johns-Manville Corp.*, 275 S.E.2d 900, 903–04 (Va. 1981); *Robey v. Richmond Coca-Cola Bottling Works*, 64 S.E.2d 723, 727 (Va. 1951). See also *Evans v. Mentor Corp.*, 2005 WL 1667661, *1 (E.D. Va. 2005) (Jones, J.) (ruling that the plaintiff failed to offer evidence that the product at issue was defective, without addressing the plaintiff’s “failure to test” claim).

⁵ See Restatement (Second) of Torts § 395 cmt. f (1965) (describing the manufacturing process as including (1) “the adoption of a formula or plan which, if properly followed, will produce an article safe for the use for which it is sold”; (2) “the selection of material and parts to be incorporated in the finished article”; (3) “the making of such inspections and tests during the course of manufacture and after the article is completed as the manufacturer should recognize as reasonably necessary to secure the production of a safe article”). Applying that standard, the Sykes’ claim could be construed as alleging that Bayer negligently adopted a plan for producing HypRho-D, selected material for the product, and/or failed to test it as it was being manufactured and after it was completed.

was not made as Bayer intended, the Court cannot regard the Sykes' "failure to test" claim as a manufacturing-defect claim. Thus, since Virginia recognizes only three ways in which a product may be unreasonably dangerous (and the Sykes' "failure to test" claim cannot plausibly be classified as a design-defect or failure-to-warn claim), this claim cannot succeed. Accordingly, since each of the claims in the Sykes' Complaint fails as a matter of law, Bayer's Motion for Judgment on the Pleadings shall be GRANTED.

IV

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The Sykes want to amend their Complaint to add claims against Bayer for failure to warn, failure to test, negligent design,⁶ negligent misrepresentation, intentional misrepresentation, fraud, negligent infliction of emotional distress, breach of express warranty of merchantability, breach of implied warranty of merchantability, gross negligence, and punitive damages. They also want to join as defendants another division of Bayer; Eli Lilly and Company ("Lilly"), which allegedly manufactured thimerosal in Virginia; other manufacturers of thimerosal; and Dominion Resources, Inc. ("Dominion"), which allegedly "is responsible for emitting tons of mercury into the air in the Richmond area each year." Pl.'s Proposed Am. Compl. at 4.

A

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Since Bayer has responded to the Sykes' Complaint and has not consented in writing to the Sykes' request to amend their Complaint, the Sykes may amend their

⁶The Sykes want to add a claim for "inadequate design or formulation." The Court regards this cause of action as a design-defect claim.

Complaint only with the Court's permission, which it must grant "freely" if "justice so requires." Fed. R. Civ. P. 15(a). That rule reflects the federal policy of "resolving cases on their merits instead of disposing of them on technicalities." *Sciolino v. City of Newport News, Va.*, 480 F.3d 642, 651 (4th Cir. 2007). But, the Court may deny the Sykes the opportunity to amend their Complaint in ways that would be futile. See *Foman v. Davis*, 372 U.S. 178, 182 (1962); *Laber v. Harvey*, 438 F.3d 404, 426 (4th Cir. 2006) (en banc). Attempting to add a claim that would fail as a matter of law is futile. *Glaser v. Enzo Biochem, Inc.*, 126 F. App'x 593, 602 (4th Cir. 2005). Accordingly, most of the Sykes' requests to amend their Complaint will be denied.

First, the Sykes' proposed Amended Complaint contains a claim for failure to warn. The Sykes pled a similar claim against Bayer before the Eastern District of Pennsylvania, but Judge Stengel ruled that the claim was pre-empted by federal law. *Sykes v. Glaxo-*

SmithKline, 484 F. Supp. 2d 289, 318 (E.D. Pa. 2007). The Court may review a decision that it – or a “coordinate court” – made previously, but it should do so only if the decision was “clearly erroneous.” *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 817 (1988). The Sykes do not offer any compelling reason why Judge Stengel’s conclusion was clearly erroneous. Thus, the Court will not review that ruling, and adding another “failure to warn” claim would be futile.

Second, the Sykes want to add a “failure to test” claim that is similar to the Sykes’ claim in their Complaint that Bayer negligently did not evaluate the safety of using thimerosal in HypRho-D. Since the Court will dismiss the Sykes’ original “failure to test”

claim, for the reasons stated in this Memorandum Opinion, adding a similar claim would be futile

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Third, the Sykes want to add a claim for negligent misrepresentation. In Virginia, negligently making a false representation is called “constructive fraud.” See *Prospect Dev. Co. v. Bershader*, 515 S.E.2d 291, 297 (Va. 1999). Constructive fraud must be pled specifically. *Mortarino v. Consultant Eng’g Servs.*, 467 S.E.2d 778, 782 (Va. 1996)

(rejecting a claim for constructive fraud because the plaintiff “failed to plead, with the requisite degree of particularity, facts which support all the elements of [the] cause of action”). The Sykes’ claim for negligent misrepresentation is based on general, conclusory allegations, however. They do not explain when, where, or how Bayer engaged in negligent misrepresentation. Since the Sykes fail to allege specific facts that support this claim, it would fail as a matter of law, and they may not add it to their Complaint.

Fourth, the Sykes want to add claims for fraud and intentional misrepresentation. In Virginia, intentionally making a false representation is an element of a claim for “actual fraud.” See *Davis v. Marshall Homes, Inc.*, 576 S.E.2d 504, 506 (Va. 2003); *Hitachi Credit Am. Corp. v. Signet Bank*, 166 F.3d 614, 628 (4th Cir. 1999). Thus, the Court will treat these two claims together. A party alleging fraud “must state with particularity the circumstances constituting fraud.” Fed. R. Civ. P. 9(b); see *United States ex rel. Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908, 921 (4th Cir. 2003) (explaining that, under Rule 9(b), a defendant must be notified of its allegedly fraudulent conduct so that it may defend itself); cf. *Alsop v. Catlett*, 34 S.E. 48, 50 (Va. 1899) (ruling that a party

claiming fraud “must show specifically in what the fraud consists”). Like the Sykes’ claim

for negligent misrepresentation, however, their claims for fraud are not based on any specific allegations of fact. Since these claims do not comply with the requirement of Federal Rule of Civil Procedure 9(b), adding them would be futile.

Fifth, the Sykes want to add a claim for negligent infliction of emotional distress. In Virginia, a claim of negligent infliction of emotional distress cannot succeed if a party does not “plead with specificity that [it] incurred a physical injury which was the natural result of fright or shock proximately caused by the defendant[’s] alleged negligence.” *Delk v. Columbia/HCA Healthcare Corp.*, 523 S.E.2d 826, 834 (Va. 2000); see *Hughes v. Moore*, 197 S.E.2d 214, 220 (Va. 1973) (holding that a party claiming negligent infliction of emotional distress cannot recover “for emotional disturbance alone”). Here, neither Lisa nor Seth Sykes have specifically alleged that they were physically injured by any emotional distress that was caused by Bayer’s conduct. Since this claim would fail as a matter of law, adding it would be futile.

Next, the Sykes want to add a claim for gross negligence. Gross negligence is behavior that shows “indifference to another and an utter disregard of prudence that amounts to a complete neglect of the safety of [that] person”; it is “a degree of negligence [that] would shock fair[-]minded men.” *Cowan v. Hospice Support Care, Inc.*, 603 S.E.2d 916, 918 (Va. 2004). Intentional conduct does not constitute gross negligence. *Gedrich v. Fairfax County Dept. of Family Servs.*, 282 F. Supp. 2d 439, 475, 476 (E.D. Va. 2003).

Whether conduct constitutes gross negligence is generally a question of fact, not of law, but

a party claiming gross negligence must plead facts that, if true, show that the defendant was grossly negligent. *Id.* at 474–75. The Sykes’ allegations that Bayer was grossly negligent because it willfully, wantonly, recklessly, and heedlessly disregarded Wesley’s safety are conclusory, and the Court is not required to regard them as true. See *Bell Atl. Corp.*, 127 S.Ct. at 1964. While the Sykes allege that Bayer intentionally concealed the risks posed by HypRho-D, those allegations do not support a claim of gross negligence. And, none of the Sykes’ allegations of negligence suggest that Bayer acted in a grossly negligent way, utterly disregarding Wesley’s safety. Thus, since none of the allegations in the Sykes’ proposed Amended Complaint support a claim of gross negligence, adding this claim would be futile.

Next, the Sykes want to seek punitive damages. Virginia does not favor imposing punitive damages, which may “be awarded only in cases of the most egregious conduct.” *Owens-Corning Fiberglas Corp. v. Watson*, 413 S.E.2d 630, 639 (Va. 1992). A defendant’s conduct must be malicious, reckless, or so negligent that it “evinces a conscious disregard of the rights of others.” *Simbeck, Inc. v. Dodd Sisk Whitlock Corp.*, 508 S.E.2d 601, 604 (Va. 1999). The Sykes allege that Bayer is liable for punitive damages because its conduct

was fraudulent, malicious, and willful or wanton. However, that allegation is conclusory, and the Sykes do not allege any facts that support that characterization of Bayer's conduct. Thus, it would be futile to add this claim.

On the other hand, the Sykes also ask the Court to allow them to add a claim for negligent design. While the Court will dismiss the Sykes' original design-defect claim, since it rests on a factual allegation that the Sykes acknowledge is not true, as explained in this

Memorandum Opinion, the Court concludes that a different design-defect claim, one with a different factual basis, would not necessarily fail as a matter of law. Thus, adding a different design-defect claim would not be futile; nor would doing so prejudice Bayer or evince bad faith by the Sykes. See *Foman*, 372 U.S. at 182; *Laber*, 438 F.3d at 426. Thus, the Sykes shall be allowed to amend their Complaint accordingly.

Finally, the Sykes want to add claims for breach of express warranty of merchantability and breach of implied warranty of merchantability. The Court concludes that adding those claims would not be futile, prejudicial, or in bad faith. So, the Sykes will be allowed to amend their Complaint to add those claims.

The Sykes also want to add as defendants another division of Bayer; Lilly, which allegedly manufactured thimerosal in Virginia; other manufacturers of thimerosal; and Dominion. The Sykes argue that their request to add other defendants is permitted by Federal Rule of Civil Procedure 20, which provides:

Persons ... may be joined in one action as defendants if: (A) any right to relief is asserted against them jointly, severally, or in the alternative with respect to or arising out of the same transaction, occurrence, or series of transactions or occurrences; and (B) any question of law or fact common to all defendants will arise in the action.

Fed. R. Civ. P. 20(a)(2). Under Rule 20, “reasonably related claims” may be tried together. *Saval v. BL Ltd.*, 710 F.2d 1027, 1031 (4th Cir. 1983). But, Rule 20 does not authorize a plaintiff to add claims “against different parties [that] present[] entirely different factual and legal issues.” *Lovelace v. Lee*, 2007 WL 3069660, slip op. at *1 (W.D. Va. Oct. 21, 2007) (citation omitted). And, a court may “deny joinder if it determines that the addition of the

party under Rule 20 will not foster the objectives of the rule, but will result in prejudice, expense, or delay.” *Aleman v. Chugach Support Servs., Inc.*, 485 F.3d 206, 218 n.5 (4th Cir. 2007) (identifying the purposes of Rule 20 as promoting convenience and expediting the resolution of disputes). Usually, a plaintiff will join defendants under Rule 20 in its initial complaint, “rather than waiting to do so later.” *Rosmer v. Pfizer Inc.*, 272 F.3d 243,

246 (4th Cir. 2001) (denying rehearing en banc).

The Sykes' claims against Bayer Biological Products, allegedly the division of Bayer that was responsible for producing Bayer's immune globulin products, are reasonably related to their claims against Bayer and involve common questions of law and fact. Thus, the Sykes may join Bayer Biological Products to the suit. But, the Sykes' claims against Lilly and unidentified manufacturers of thimerosal, involving allegations about the development, manufacture, sale, and licensing of thimerosal, are not reasonably related to the Sykes' claims about a specific use of thimerosal by Bayer. Allowing the Sykes to add manufacturers of thimerosal – some of which the Sykes have not yet identified – will delay the resolution of this suit, prejudicing Bayer, which has spent nearly two years defending itself already. For the same reason, allowing the Sykes to join Dominion would not promote the aims of Rule 20. The Sykes' allegations that Dominion released mercury into the air in Richmond are not related in any way to their claims about the risks posed by mercury in HypRho-D, and may not involve any common questions of law or fact. Moreover, allowing the Sykes to join Dominion would significantly expand the scope of discovery in this suit, prolonging the case and prejudicing Bayer.

15^V. For the reasons stated above, all of the claims in the Sykes' Complaint, as they are currently stated, shall be DISMISSED and the Sykes shall be allowed to amend their Complaint to plead a claim for design defect, breach of express warranty of merchantability, and breach of implied warranty of merchantability against Bayer.

It shall be SO ORDERED.

ENTERED this 12th day of February 2008

/s/ James R. Spencer Chief United States District Judge