

**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 PHARMACEUTICALS CORPORATION'S
MEMORANDUM OF LAW IN SUPPORT OF ITS
MOTION FOR JUDGMENT ON THE PLEADINGS**

TABLE OF CONTENTS

INTRODUCTION.....	1
A. Brief Summary of the Issue & Bayer’s Position	1
B. Plaintiffs’ Claims	3
C. FDA Regulatory Requirements Govern All Aspects of the Production & Sale of HypRho-D	3
1. FDA licensing regulations	5
2. FDA regulations governing new uses of licensed biologics.....	6
3. FDA regulation of the composition of immune globulins.....	7
4. FDA regulation of labels and warnings.....	7
5. FDA regulation of the labeling of thimerosal in HypRho-D.....	8
6. FDA regulations concerning continuous testing.....	9
D. Summary History of Bayer’s Immune Globulin “HypRho-D”	10
ARGUMENT	12
I. Plaintiff’s Strict Liability Claims Fail Because Virginia Does Not Recognize Strict Liability Claims in Products Liability Actions.	13
II. Virginia Does Not Recognize a Claim of Failure to Conduct Adequate Safety Tests.....	13
III. Plaintiffs’ Claim Concerning An Alleged Failure To Use Alternative Packaging Design Is Inapplicable To Bayer, And Nonetheless Fails as a Matter of Law.	14
A. As presented in Plaintiffs’ Complaint, the “design defect” claim fails on its face.....	14
B. Plaintiffs’ newly-asserted (but not yet pleaded) theory of “design defect” would also fail.	15
CONCLUSION.....	17

COMES NOW Bayer Pharmaceuticals Corporation (“Bayer”) and moves this Court, pursuant to Rule 12(c) of the Federal Rules of Civil Procedure, to enter judgment as a matter of law in favor of Bayer on all of the Plaintiffs’ claims. Judgment in Bayer’s favor is warranted on the pleadings now before the Court. In support of this motion, Bayer states as follows:

INTRODUCTION

Judge Stengel of the Eastern District of Pennsylvania transferred this case to this Court on motion of Bayer. Prior to the transfer, Judge Stengel granted Bayer’s Motion for Judgment on the Pleadings in part and dismissed Plaintiffs’ state law failure to warn claims. *Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289 (E.D. Pa. 2007). Judge Stengel held that Plaintiffs’ failure to warn claims were preempted under federal law because such claims second-guessed and interfered with the FDA’s determination that Bayer’s warnings on HypRho-D, the product at issue, were proper and beneficial to the public. *Sykes*, 484 F. Supp. 2d at 306-18. Plaintiffs’ remaining state law claims against Bayer allege (1) failure to adequately test, and (2) design defect under both strict liability and negligence. *Id.* at 23. Judge Stengel explained in his opinion that these remaining claims would have also been dismissed had Pennsylvania law applied, but he did not presume to apply Virginia law. *Id.* at 23 nn. 31 & 32. These claims are now likewise due to be dismissed, as those claims are without merit under Virginia law.

A. Brief Summary of the Issue & Bayer’s Position

As detailed further below, Plaintiffs allege state law claims against Bayer’s immune globulin blood product, HypRho-D, which Mrs. Sykes received from her physician while pregnant in order to protect her unborn child from developing a serious and potentially life-threatening condition called Hemolytic Disease of the Newborn. Plaintiffs allege Mrs. Sykes’

ante-partum shot was HypRho-D, which contained an anti-bacterial preservative known as thimerosal.¹

At all times relevant to this action, the U.S. Food & Drug Administration's ("FDA's") applicable regulations had *mandated* the inclusion of an anti-bacterial preservative in the single shot formulation of HypRho-D received by Mrs. Sykes. 21 C.F.R. § 640.103(a) (mandating the inclusion of a preservative in all final single and multiple dose formulations of immune globulins).² Bayer's 1971 license for *post*-partum administration of HypRho-D to Rh negative mothers required thimerosal to be the preservative. In 1981, the modification to Bayer's HypRho-D license for ante-partum administration also required thimerosal to be the preservative to satisfy 21 C.F.R. § 640.103(a).

Mrs. Sykes received her shot in 1995. To process HypRho-D *without* a preservative at that time – which is what Plaintiffs' Complaint alleges Bayer should have done - would have violated FDA's regulations. To process HypRho-D *without* using thimerosal at that time would have violated Bayer's license from the FDA.

¹ Bayer accepts plaintiffs' allegations solely for purposes of this Motion for Judgment on the Pleadings.

² In this brief, Bayer cites to a number of federal regulations and official FDA statements and documents. The Court can take judicial notice of these materials. *See, e.g., Flath v. Bombardier, Inc.*, No. 99-2519, 2000 WL 930406, at *3 (4th Cir. July 10, 2000) (unpublished) ("Courts may take judicial notice, in their discretion, of facts that are 'not subject to reasonable dispute in that [they are] either (1) generally known within the territorial jurisdiction of the trial court or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned.'") (quoting Fed. R. Evid. 201). In any event, none of the information in any of those materials will be disputed. This Court may consider materials outside the pleadings without converting motions on the pleadings into summary judgment motions where the materials consist of matters such as "official public records pertinent to the plaintiffs' claims." *Gasner v. County of Dinwiddie*, 162 F.R.D. 280, 282 (E.D. Va. 1995) (citing *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1197 (3d Cir. 1993) (allowing citation to "decisions of government agencies and published reports of administrative bodies" on motions for judgment on the pleadings without converting such a motion to one for summary judgment)).

B. Plaintiffs' Claims

Plaintiffs filed their Complaint (“Compl.”) on March 14, 2006. The Complaint asserts strict products liability and negligence claims against the defendants arising out of alleged injuries suffered by minor Sykes. (Compl. ¶ 1). Against Bayer, Plaintiffs alleged failure to warn, failure to conduct adequate safety tests and failure to use alternative packaging (design defect).³ (*Id.* ¶¶ 19-21, 27). Plaintiffs allege that minor Sykes’ received “serious neurodevelopmental injuries” from his exposure⁴ to the ethylmercury contained in thimerosal, the preservative in the vaccines he received during his first three years of life and the single dose of immune globulin produced by Bayer, HypRho-D, that was administered to Mrs. Sykes while she was pregnant. (Compl. ¶¶ 1, 9). Bayer filed its Answer and Affirmative Defenses on April 13, 2006.

The essence of the Plaintiffs’ remaining claims appears to be that Bayer should not have used thimerosal, a preservative that was widely used -- and universally approved as safe by the FDA and its predecessor agencies -- since 1930. Contrary to the Plaintiffs’ allegations, federal law required the use of a preservative in HypRho-D. 21 C.F.R. § 640.103(a).

C. FDA Regulatory Requirements Govern All Aspects of the Production & Sale of HypRho-D

HypRho-D is a prescription biological that works by suppressing the immune response of Rh negative women to Rh positive blood cells. Rho(D) Immune Globulin (Human), USP - HypRho-D Full Dose Package Insert (Rev. October 1995), attached as Exhibit A to Bayer’s Motion for Judgment on the Pleadings. Its use is indicated whenever it is known or suspected that fetal red blood cells have entered the circulation of an Rh negative mother, unless the fetus

³ Plaintiffs also made claims alleging a wrongful withholding of information from the FDA during the approval process. (Compl. ¶ 22, 27(f)). However, these claims were made against only defendants Wyeth, Inc., and Glaxo-Smithkline. *Id.* In any event, these claims appear to be “fraud on the agency” claims prohibited under the United States Supreme Court’s decision in *Buckman Co. v. Plaintiffs’ Legal Committee*, 531 U.S. 341 (2001).

⁴ Plaintiffs do **not** claim Mrs. Sykes had any allergic response to HypRho-D.

or the biological father is shown conclusively to be Rh negative. Rho(D) Immune Globulin (Human), USP - HypRho-D Full Dose Package Insert (Rev. October 1995). Without HypRho-D, the children of an Rh negative mother have a risk of serious injury or death from Hemolytic Disease of the Newborn.

Prior to the ante-partum administration of HypRho-D to Mrs. Sykes, HypRho-D was subjected to comprehensive regulation by the FDA. Like all immune globulins,⁵ HypRho-D is what is known as a “biologic.” See 42 U.S.C. § 262(i); 21 C.F.R. § 600.3(h). Virtually all aspects of biologics are governed by regulations promulgated by the FDA pursuant to both the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq. (“FDCA”), and the Public Health Services Act, 42 U.S.C. §§ 201 et seq. (“PHSA”). See, e.g., 21 C.F.R. §§ 600-680 (citing both the FDCA and the PHSA as providing regulatory authority); *U.S. v. Najarian*, 915 F. Supp. 1460, 1471-72 (D. Minn. 1996); *Walls v. Armour Pharm. Co.*, 832 F. Supp. 1467, 1482 (M.D. Fla. 1993). Federal law mandates every aspect of immune globulin production, from the proper name and definition to the manufacturing, testing, and labeling of the final product. The final immune globulin product does not leave the manufacturer, nor may it be administered to a patient, until the immune globulin satisfies all of the requirements promulgated by federal law.

No biologic can be marketed without an FDA-issued license. 42 U.S.C. § 262(a)(1)(A). Any person marketing an immune globulin without such a license is subject to both civil and criminal penalties. *Id.* at § 262(d)(2) & (f). At all times, the licensing, composition, manufacture, testing, labeling, storage, and release for sale of HypRho-D -- and, most

⁵ Federal regulations define an immune globulin as “a sterile solution containing antibodies derived from human plasma.” 21 C.F.R. § 640.100. That solution contains the immunoglobulins (i.e., antibodies) to protect against disease-causing infectious agents. Immune globulins are sometimes referred to as gamma globulins or immune serum globulins.

importantly, Bayer's use of thimerosal in HypRho-D -- was regulated in almost every detail, and approved by, the FDA.

1. FDA licensing regulations

The ability to license a biologic for marketing in the United States is solely in the hands of the FDA. 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)(I & II); *see* 21 U.S.C. § 393(b)(1); 21 C.F.R. § 601.2 (requiring, in order to obtain a product license, a manufacturer of a biologic to submit detailed information "which demonstrate[s] that the manufactured product meets prescribed requirements of safety, purity, and potency"); *id.* at § 601.20 (conditions for issuance of biologics licenses).

Federal regulatory responsibility for licensing biologics was transferred from the NIH to the FDA in 1972. Biologics approved prior to that transfer (such as HypRho-D) underwent a rigorous examination by independent panels of experts in order to determine whether the biologic would continue to enjoy its original approval. *See* 21 C.F.R. §§ 601.25-.26; 65 Fed. Reg. 31003, 31003 (May 15, 2000) (summarizing procedure). Those panels were "charged with preparing a report to the agency that (1) [e]valuated the safety and effectiveness of the biological product; (2) reviewed the labeling of the biological product; and (3) advised the FDA on which biological products under review were safe, effective, and not misbranded." 65 Fed. Reg. at 31003; *see* 21 C.F.R. § 601.25. The panels then classified the biologic into one of three categories.⁶ After reviewing the panel's findings and recommendations, the FDA published a

⁶ Category I biologics were those "determined by the panel to be safe and effective and not misbranded." 21 C.F.R. § 601.25(e)(1). Category II biologics were those determined to be

proposed order containing, among other things, its opinion of the proper categorization and seeking public comments. *Id.* at § 601.25(f). After reviewing any public comments, the FDA published a final determination on the biologic’s approval. *Id.* at § 601.25(g). As discussed below, the FDA approval of HypRho-D was made according to the very process outlined in these regulations, and HypRho-D was determined to be a Category I biologic: “Safe and effective and not misbranded.”

2. *FDA regulations governing new uses of licensed biologics*

Any new use, or “indication,” for a biologic must be supported with substantial evidence of safety and efficacy as well as ultimately reviewed and approved by the FDA. The process of obtaining such approval includes an exhaustive and detailed examination of every aspect of the proposed change. *See* 21 C.F.R. § 601.12 (listing regulations governing “each change in the product, production process, quality controls, equipment, facilities, responsible personnel, or labeling established in the approved license application(s)”). Specifically, the FDA regulations provide:

Before distributing a product made using a change, an applicant must assess the effects of the change and demonstrate through appropriate validation and/or other clinical and/or nonclinical laboratory studies the lack of adverse effect of the change on the identity, strength, quality, purity, or potency of the product as they may relate to the safety or effectiveness of the product.

21 C.F.R. § 601.12(a)(2). Bayer’s immune globulin HypRho-D -- and, most relevant to this case, its subsequent use as a ante-partum biologic -- was at all times fully approved as “safe, effective, and not misbranded” by the FDA.

“unsafe or ineffective, or to be misbranded,” and Category III biologics were those on which the panel required more information. *Id.* at § 601.25(e)(2)&(3).

3. FDA regulation of the composition of immune globulins

The FDA also has promulgated detailed regulations to insure the continual safety, purity and potency of approved biologics. These regulations govern virtually every aspect of the biologic, including the composition, manufacturing process, bulk storage, lot determination, warning labels, and sterilization and heating. *See* 21 C.F.R. §§ 600-680. Most relevant to this case, however, is the FDA's requirement that every immune globulin contain a preservative. 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.*") (emphasis added). Before the FDA will allow a biologic containing a preservative to be marketed, the FDA must be satisfied that the preservative is safe:

All ingredients used in a licensed product, and any diluents provided as an aid in the administration of the product, shall meet generally accepted standards of purity and quality. *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 room temperature. ...*

21 C.F.R. § 610.15 (emphasis added). Thus, the safety of the preservative at issue in this case was the subject of specific FDA review, oversight, and approval. After that initial approval of a preservative, a manufacturer may *not* change the FDA-approved formulation or preservative without permission from FDA. 21 C.F.R. § 601.12(a)(2), (b).

4. FDA regulation of labels and warnings

Like drugs, biologics are also subject to detailed labeling requirements which dictate virtually every aspect of the 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. As the FDA explained earlier this year, "[t]he 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." *Requirements on Content & Format of Labeling for Human Prescription Drug and Biological Products*, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006). Most relevant to this case is the warning, which, like the rest of the labeling, must be approved by the FDA and which must provide adequate warning of any use dangerous to health. *See, e.g.*, 21 U.S.C. §§ 352, 355(b)(1)(F); 21 C.F.R. §§ 201.56-59 (particularly § 201.57(e)&(f)). If a biologic is used during pregnancy, it must contain -- word-for-word -- specific warnings found in the regulations. 21 C.F.R. § 201.57(f)(6)(c). Warnings of dangers or situations where a biologic should not be used are allowed by the FDA only if "there is reasonable evidence of an association of a serious hazard," (*Id.* at § 201.57(e)) and only with respect to "[k]nown hazards and not theoretical possibilities." *Id.* at § 201.57(d). Once a biologic's labeling is approved, it cannot be changed without FDA approval. 21 C.F.R. § 601.12. *See also Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 537 (E.D. Pa. 2006) (acknowledging the FDA's position that the FDA must approve *all* label changes).

5. *FDA regulation of the labeling of thimerosal in HypRho-D*

Disclosure of the details regarding the FDA-approved preservative also is highly regulated by the FDA. 21 C.F.R. § 610.61(e) (biologic's label must list "[t]he preservative used and its concentration"). Here, the FDA-approved package insert in effect when minor Sykes' mother was administered HypRho-D advised physicians that it contained "80-120µg/mL thimerosal (a mercury derivative), as measured by mercury assay," and warned that HypRho-D "should be given with caution ... to patients who are known to have had an allergic response to thimerosal." Rho(D) Immune Globulin (Human), USP - HypRho-D Full Dose Package Insert (Rev. October 1995), Exhibit A. This was the information the FDA required Bayer to supply

about thimerosal. Further, the FDA-mandated Pregnancy Category C warning advised physicians that it is “not known whether [HypRho-D] can cause fetal harm when administered to a pregnant women” and therefore it “should be given to a pregnant woman only if clearly needed.” Rho(D) Immune Globulin (Human), USP - HypRho-D Full Dose Package Insert (Rev. October 1995), Exhibit A; 21 C.F.R. § 201.57(c) (requiring verbatim warning). A manufacturer may not include a warning on its label unless there is “reasonable evidence of an association of a serious hazard with a drug.” 21 C.F.R. § 201.57(e).

6. FDA regulations concerning continuous testing

Biologics are also subject to rigorous, mandatory testing, both in the initial approval process and on a continual basis afterward on each and every lot of the biologic. For example, before any biologic can be released for sale, each lot must be tested to ensure safety, potency and purity. *See* 21 C.F.R. § 610.1 (“No lot of any licensed product shall be released by the manufacturer prior to the completion of tests for conformity with standards applicable to such product.”); *see also id.* § 610.2. Various tests must be performed to insure the potency (21 C.F.R. § 610.10), general safety (*id.* § 610.11), purity (*id.* § 610.13), and identity (*id.* § 610.14) of the biologic, and any modifications to any test method or manufacturing process must be approved by the FDA after a showing that that modification will ensure the “safety, purity, potency, and effectiveness of the biological product” (*id.* § 610.9). In addition, after each lot is tested and found acceptable by the manufacturer, a sample of all test results as well as test samples from the lot are sent to the FDA for its review and further testing, as deemed necessary. A lot can be released only when a final release letter has been received from the FDA indicating approval of its review and test results. (*id.* § 610.2(a)).

Beyond these extensive regulations governing production, processing and labeling of the biologic, every manufacturer must consent to allow inspections, at “all reasonable hours ... [of]

any establishment for the propagation or manufacture and preparation of any biological product,” 42 U.S.C. § 262(a)(2)(C)(ii); § 262(c); 21 C.F.R. §§ 600.20-22 (detailing establishment inspections), and those establishments must meet exacting quality standards, 21 C.F.R. §§ 600.10-15; 606.3-.171. The manufacturer must also report adverse post-marketing experiences with the product or face revocation of the product license. 21 C.F.R. §§ 600.80-90.

D. Summary History of Bayer’s Immune Globulin “HypRho-D”

In 1968, Bayer (then known as Cutter Laboratories) first sought a product license for HypRho(D) for use as a post-partum immune globulin, that is, for administration to mothers with Rh negative blood within 72 hours of delivery. *See* Bayer (Cutter) Application for Product License for a Derivative Obtained from Blood, October 24, 1968, attached as Exhibit B. In order to comply with applicable regulations requiring the inclusion of a preservative in the final formulation of HypRho(D), Bayer proposed using thimerosal. In 1971, when Bayer’s product license was granted, Bayer’s use of thimerosal in HypRho(D) received the full approval of the NIH -- the precursor regulatory body to the FDA. *See* NIH, Product License for HypRho(D), issued on June 11, 1971, attached as Exhibit C, and FDA Transmittal Form dated December 9, 1981, and the November 5, 1981 Application for Amending Package Insert, attached as Exhibit D. At that time, thimerosal had at least a 40-year history as a preservative in biologics, much of that use regulated by various federal agencies. *See* FDA, Center for Biologics Evaluation and Research, Thimerosal in Vaccines Frequently Asked Questions, *available at* <http://www.fda.gov/cber/vaccine/thimfaq.htm>, attached as Exhibit E, and Memorandum of Sam T. Gibson, Director of the FDA’s Bureau of Biologics, on the Use of Thimerosal in Biologics Production, dated February 27, 1976, attached as Exhibit F.

Bayer’s product license for HypRho(D) was granted before regulatory responsibility was transferred from the NIH to the FDA, and thus HypRho(D) was subject to review by an expert

panel as discussed above. In 1980, the panel recommended that HypRho(D) be placed into Category I, after determining HypRho(D) to be safe, effective and not misbranded. FDA, Biological Products, Blood & Blood Derivatives, 50 Fed. Reg. 52602, 52674 (Dec. 24, 1985); *see also* 45 Fed. Reg. 77134 (November 21, 1980) (notice of publication of panel report). In 1985, the FDA published its findings that “Rho immune globulin is a highly effective product with few serious side effects.” 50 Fed. Reg. at 52674. Accordingly, the FDA gave its final approval of HypRho(D) as a safe, effective and properly branded biologic. *Id.*⁷

In 1981, Bayer received the FDA’s approval to market HypRho(D) for ante-partum use. This new indication called for an injection of HypRho(D) to be given to the mother at 28 weeks of pregnancy. Ante-partum use had been shown to reduce the possibility of Hemolytic Disease of the Newborn, beyond the level of reduction achieved by the post-partum dose licensed in

⁷ In approving Rho immune globulins as safe and effective, the panel noted no problem with the use of thimerosal, only that there may be some local irritation. 50 Fed. Reg. at 52674 (“Localized reaction at the site of intramuscular injection is probably the most frequent side effect.”). This was consistent with the FDA’s expert panel report on a related biologic, immune serum globulins (“ISGs”), which also used thimerosal. In accepting the panel’s endorsement of ISGs in 1980, the FDA indicated no safety concern about the use of thimerosal with regard to mercury intake, only a concern about certain local skin irritations. 45 Fed. Reg. 25652, 25756 (April 15, 1980) (stating that “[t]he desirability of replacing thimerosal as a preservative in biologicals is of major concern primarily with intradermally inoculated skin test products and where thimerosal-induced skin reactions may interfere with an accurate diagnostic reading. *However, there is no evidence that thimerosal affects either the safety or the effectiveness of ISG, and reactions to thimerosal have presented little if any problem.*”) (emphasis added). The FDA’s evaluation of the safety of biologics containing thimerosal in 1980 was consistent with the previously cited study [Exhibit F] performed by the FDA itself in 1976, summarized on the FDA official website:

FDA had previously reviewed thimerosal use in biological products, including vaccines, in 1976. This review evaluated exposure to thimerosal from biological products using the 1974 American Academy of Pediatrics “Red Book” immunization schedule and concluded that, with the exception of long term immune globulin replacement therapy [not at issue with the one-time-use HypRho(D) as alleged here], “no dangerous quantity of mercury is likely to be received from biologic products in a lifetime.”

The FDA website is Exhibit E.

1971. In this action, Plaintiffs allege injury only from ante-partum use of HypRho(D). (Compl. ¶¶ 28-30).

Given that Bayer's product license for HypRho(D) from the FDA required the use of thimerosal, it would have been impermissible to produce HypRho(D) without including thimerosal. *See, e.g.*, 42 U.S.C. §§ 262(a)(1)(A), (d)(2) & (f); 21 C.F.R. § 601.12; 21 C.F.R. § 640.103(a). In accord with a larger processing change designed to further enhance the viral safety of all of Bayer's intramuscularly administered immune globulins, including HypRho(D), in 1996 Bayer sought and obtained a waiver from requiring the inclusion of thimerosal in the final formulation of each immune globulin. *See* FDA, Center for Biologics Evaluation and Research, Thimerosal in Plasma-Derived Products, *available at* <http://www.fda.gov/CBER/blood/mercplasma.htm>. Absent this waiver, Bayer could not have removed thimerosal.

ARGUMENT

Bayer's Motion for Judgment on the Pleadings, filed pursuant to Rule 12(c), Fed. R. Civ. P., should be granted. When ruling on such a motion the Court must view the facts stated in the pleadings and draw reasonable inferences from those facts in the light most favorable to the plaintiff. *See, e.g., Sun-Lite Glazing Contractors, Inc. v. J.E. Berkowitz, L.P.*, 37 F. App'x. 677, 679 (4th Cir. June 20, 2002) (unpublished). Dismissal under Rule 12(c) is appropriate here because Plaintiffs "can prove no set of facts in support of its claim that would entitle [them] to relief." *Id.*

I. Plaintiff's Strict Liability Claims Fail Because Virginia Does Not Recognize Strict Liability Claims in Products Liability Actions.

In Count One of her Complaint, ¶¶ 14-23, Sykes alleges claims sounding in strict liability. These claims should be summarily dismissed because, as this Court has correctly noted, “it is beyond question that Virginia does not recognize a cause of action for strict liability in tort.” *St. Jarre v. Heidelberger Druckmaschinen A.G.*, 816 F. Supp. 424, 427 (E.D. Va. 1994); *see Sensenbrenner v. Rust, Orling & Neale, Architects, Inc.*, 236 Va. 419, 424 n.4, 374 S.E.2d 55, 57 n.4 (1988) (“Virginia law has not adopted § 402A of the Restatement (Second) of Torts and does not permit tort recovery on a strict-liability theory in products-liability cases.”). Regardless of the product at issue, Virginia allows only claims that are based on a theory of negligence or on breach of warranty. *Abbot v. American Cyanamid Co.*, 844 F.2d 1108, 1114 (4th Cir. 1988) (applying Virginia law to a claim for neurological injuries related to DTP vaccine, and stating that “[u]nder Virginia law, recoveries for personal injuries caused by defective products can be made as breach of an implied warranty of merchantability or under a tort theory of negligent design.”). Therefore, Plaintiffs’ strict liability claims must be dismissed.

II. Virginia Does Not Recognize a Claim of Failure to Conduct Adequate Safety Tests.

Plaintiffs’ claims that Bayer failed to conduct adequate testing on HypRho-D, *see* Compl. ¶¶ 20, 27(d), fail as a matter of Virginia law. In the products liability context, no Virginia court has ever recognized a claim for “failure to adequately test a product.”⁸ Instead, Virginia law

⁸ *Cf. Jones v. Ford Motor Co.*, 559 S.E.2d 592 (Va. 2002) (refusing to address whether Virginia law provides a claim for failing to adequately test because plaintiff failed to plead such a claim in her motion for judgment); *Young v. J.I. Case Co.*, 1994 WL 506403, *9 (E.D. Va. 1991) (Spencer, J.):

On the issue of negligent testing and inspection, defendant contends that although some courts appear to recognize an independent claim for failure to test and inspect, the law of Virginia does not necessarily impose such a requirement. Of course, plaintiff claims otherwise. Nonetheless, plaintiff fails to demonstrate that

recognizes negligence or breach of warranty claims involving allegedly defective products only to the extent that they allege that a defect in manufacture, a defect in design, or an inadequate warning has made the product unreasonably dangerous. *Lust v. Clark Equip. Co., Inc.*, 792 F.2d 436, 438 (4th Cir. 1986). Virginia case law outlines no other basis for recovery where an allegedly defective product is at issue.

III. Plaintiffs’ Claim Concerning An Alleged Failure To Use Alternative Packaging Design Is Inapplicable To Bayer, And Nonetheless Fails as a Matter of Law.

A. As presented in Plaintiffs’ Complaint, the “design defect” claim fails on its face.

Plaintiffs’ claim alleging “design defect,” (Compl. ¶ 17, 18, 27(b)), fails as a matter of law. In their Complaint, Plaintiffs allege (1) that HypRho-D is defectively designed because it failed to use single-dose shots rather than multi-dose shots, and (2) that single-dose biologics were not required to contain any preservative. Specifically, Plaintiffs allege:

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, and federal law did not require the use of any biocide or preservative in single-dose vials or in single-use, disposable syringes. . . .

...

27. Defendants were negligent because they:

...

defendant did not use reasonable care in its testing and inspection of the trencher. As a result, defendant’s motion for summary judgment will be granted and judgment entered in favor of defendant on plaintiff’s claim of negligent testing and inspection.

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....

Compl. ¶¶ 17, 18, 27(b).

This claim is meritless for two reasons. First Bayer's biologic, HypRho-D, was undisputedly *always* administered in single doses. And, as the Plaintiffs have conceded in their briefing to the Eastern District of Pennsylvania, the FDA required the use of a preservative in *all* biologics -- even single-dose biologics. *See* Plaintiffs' Response Opposing Bayer Pharmaceuticals' Motion for Judgment on the Pleadings at 13; *see also* 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.*") (emphasis added).

B. Plaintiffs' newly-asserted (but not yet pleaded) theory of "design defect" would also fail.

Plaintiffs' design defect claim is something of a moving target. Although they have not amended their Complaint, Plaintiffs' "design defect" claim appears to have morphed after these fatal defects were brought to light in Bayer's Motion for Judgment on the Pleadings in the Pennsylvania court. In their response to that motion, Plaintiffs argued that "[w]hile 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." Plaintiffs' Response Opposing Bayer Pharmaceuticals' Motion for Judgment on the Pleadings at 13 (emphasis in original). Apparently, Plaintiffs' "design defect" contention is now that the use of thimerosal *at all* rendered HypRho-D "toxic" and therefore defective, as Plaintiffs went on in their Response to correctly note that the FDA mandated that preservatives used be "non-toxic." *Id.*; *see* 21 C.F.R. § 610.15 ("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....").

This new claim -- which still does not appear in the Plaintiffs' Complaint -- cannot stand. *See, e.g., Bessinger v. Food Lion, Inc.*, 305 F. Supp. 2d 574, 581 (D.S.C. 2003) ("It is ... well-settled that a complaint cannot be amended by the plaintiff's briefs in opposition to a motion to dismiss."). To prevail in this claim were it to be alleged here, Plaintiffs' have the burden of proving that the use of thimerosal in HypRho-D rendered that biologic unreasonably dangerous. *See, e.g., Logan v. Montgomery Ward & Co.*, 216 Va. 425, 428, 219 S.E.2d 685, 687 (1975). However, producers of biologics (such as Bayer) have a duty to produce biologics that meet prevailing safety standards at the time the biologic is made. *See Sexton v. Bell Helmets, Inc.*, 926 F.2d 331, 336-37 (4th Cir. 1991). The undisputed facts in this case overwhelmingly show that Bayer did just that. Those undisputed facts are: 1) the FDA required a preservative, 2) that preservative had to be "sufficiently nontoxic," 3) thimerosal widely used as a preservative -- and approved by the FDA and its predecessor agencies as safe -- since the 1930's, 4) the FDA *continues* to believe that thimerosal is safe for use by pregnant women⁹; and 5) the FDA specifically (but not surprisingly) approved Bayer's use of thimerosal as the preservative in HypRho-D. *See Alevromagiros v. Hechinger Co.*, 993 F.2d 417, 420 (4th Cir. 1993) ("In determining what constitutes an unreasonably dangerous defect, a court will consider safety standards promulgated by the government or the relevant industry, as well as the reasonable expectations of consumers.") (interpreting Virginia law).

And, in the 20 months since filing their Complaint, the Plaintiffs have not even *mentioned* 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." *Tunnell v. Ford Motor Co.*, 385 F. Supp. 2d

⁹ On its official website, the FDA states that it is safe for pregnant women to receive an influenza vaccine that contains thimerosal. *See* <http://www.fda.gov/cber/vaccine/thimfaq.htm#q12>.

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)). Of course, Plaintiffs must make such a showing to proceed with their case. Given the undisputed facts above, that will be virtually impossible.

Even under this new “design defect” claim, given the undisputed facts in this case Plaintiffs simply cannot show that the mere use of thimerosal in HypRho-D rendered that biologic “unreasonably dangerous.” Accordingly, Plaintiffs’ design defect claim should be dismissed.

CONCLUSION

WHEREFORE, pursuant to Federal Rule of Civil Procedure 12(c), Bayer respectfully requests this Court to enter an Order granting judgment in its favor on all of the Plaintiffs’ claims.

Respectfully submitted this 3rd day of January, 2008.

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CERTIFICATE OF SERVICE

I hereby certify that on the 3rd day of January, 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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