IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

DEBRA JAVENS,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 18-1030-RGA-SRF
	)	
GE HEALTHCARE INC. and GENERAL ELECTRIC COMPANY,	)	
	)	
	)	
Defendants.	)	

REPORT AND RECOMMENDATION

I. INTRODUCTION

Presently before the court in this products liability action is the motion for judgment on the pleadings pursuant to Rule 12(c) of the Federal Rules of Civil Procedure, filed by defendants GE Healthcare Inc. and General Electric Company (together, "Defendants").[1] (D.I. 45) For the following reasons, I recommend that the court GRANT Defendants' motion for judgment on the pleadings.

II. BACKGROUND[2]

On May 3, 2018, plaintiff Debra Javens ("Plaintiff") filed this products liability action in the District of Massachusetts, alleging causes of action for: (1) strict liability for failure to warn, and (2) negligent failure to warn and negligent design and manufacturing of Defendants'

[1] The briefing for the pending motion is as follows: Defendants' opening brief (D.I. 46), Plaintiff's answering brief (D.I. 48), Defendants' reply brief (D.I. 49), and Defendants' notices of supplemental authority (D.I. 54; D.I. 55).

[2] The facts in this section are based upon allegations in the complaint, which the court accepts as true for the purposes of the present motion for judgment on the pleadings. *See Umland v. Planco Fin. Servs.*, 542 F.3d 59, 64 (3d Cir. 2008). The court has not considered matters outside the pleadings in its Report and Recommendation. Therefore, Plaintiff's request to convert the motion for judgment on the pleadings to a motion for summary judgment based on Defendants' reliance on matters outside the pleadings is moot. (D.I. 48 at 18)

gadolinium-based contrast agent, Omniscan. (D.I. 1) Pursuant to the parties' stipulation, the case was transferred to this court on July 12, 2018. (D.I. 13; D.I. 15-17) On October 19, 2018, Defendants filed their answer and affirmative defenses, including the affirmative defense of federal preemption. (D.I. 23 at ¶ 14) Defendants subsequently filed the pending motion for judgment on the pleadings on November 15, 2019. (D.I. 45)

Plaintiff alleges that she had normal kidney function until she underwent multiple magnetic resonance angiographies ("MRAs") and/or magnetic resonance imaging scans ("MRIs"). (D.I. 1 at ¶ 10) At the time of the procedures, Plaintiff was injected with a gadolinium-based contrast agent ("GBCA") called Omniscan,[3] which is manufactured and sold by Defendants. (*Id.* at ¶¶ 1, 10) Thereafter, Plaintiff developed Gadolinium Deposition Disease ("GDD"), exhibiting symptoms including cognitive impairment, burning skin sensation, heart palpitations, and pain throughout her body. (*Id.* at ¶ 10) According to Plaintiff, these symptoms are consistent with the toxic effects of retained gadolinium, which is a highly toxic heavy metal that does not occur naturally in the human body. (*Id.* at ¶¶ 11, 13)

Plaintiff's complaint outlines a substantial amount of clinical data allegedly establishing a connection between GBCAs and the deposition and long-term retention of toxic gadolinium in organ tissues. (*Id.* at ¶¶ 14, 24, 27-40, 43) The FDA issued a public safety alert in July 2015 in response to a 2014 study by the Mayo Clinic which found gadolinium deposits in the brains of deceased individuals who had normal renal function and had received multiple injections of GBCAs in the years prior to their deaths. (*Id.* at ¶¶ 39, 41) In September 2017, the FDA's medical advisory committee voted in favor of adding a warning on GBCA labels that gadolinium

[3] A gadolinium-based contrast agent is injected intravenously to enhance the imaging in a diagnostic study such as an MRI. (D.I. 1 at ¶¶ 2, 10)

may be retained in some organs, even in patients with normal kidney function. (*Id.* at ¶ 42) Although Defendants corrected their label in 2012 to include contraindications for use in people with kidney disease or injury, the label does not contain a warning regarding the possibility of gadolinium retention in people with normal renal function. (*Id.* at ¶ 44)

III. LEGAL STANDARD

Under Federal Rule of Civil Procedure 12(c), "[a]fter the pleadings are closed – but early enough not to delay trial – a party may move for judgment on the pleadings." Fed. R. Civ. P. 12(c). When deciding a Rule 12(c) motion for judgment on the pleadings based on an allegation that the plaintiff has failed to state a claim, the motion is analyzed under the same standards that apply to a Rule 12(b)(6) motion. *Revell v. Port Auth.*, 598 F.3d 128, 134 (3d Cir. 2010), *cert. denied*, 562 U.S. 1178 (2011).

To state a claim upon which relief can be granted pursuant to Rule 12(b)(6), a complaint must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Although detailed factual allegations are not required, the complaint must set forth sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *see also Ashcroft v. Iqbal*, 556 U.S. 662, 663 (2009). Under this standard, the court must accept all well-pleaded factual allegations as true, and must draw all reasonable inferences in favor of the non-moving party. *See Turbe v. Gov't of Virgin Islands*, 938 F.2d 427, 428 (3d Cir. 1991). This determination is a context-specific task requiring the court "to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 679.

IV. DISCUSSION

A. Strict Liability

In support of the motion for judgment on the pleadings, Defendants contend that Plaintiff's cause of action for strict liability based on an alleged failure to warn fails as a matter of law because Pennsylvania, Delaware, and Massachusetts do not recognize strict liability claims in the context of prescription drugs. (D.I. 46 at 12) In response, Plaintiff offers to voluntarily dismiss her claim for product liability based on a strict liability theory. (D.I. 48 at 3) Accordingly, I recommend that the court dismiss Count 1 of Plaintiff's complaint with prejudice.

B. Negligence

1. Preemption of failure to warn claim

Plaintiff's complaint alleges that Defendants were negligent in their use of labels which failed to adequately warn consumers and health care providers of the risks of injury associated with GBCAs such as Omniscan:

> Defendants failed to exercise ordinary care in the labeling of gadolinium-based contrast agents (including Omniscan) and the labeling of MRI and MRA machines designed to be used in conjunction with gadolinium-based contrast agents and failed to issue to consumers and their health care providers adequate warnings concerning the risks of serious bodily injury due to the use of gadolinium-based contrast agents (including Omniscan) and the MRI and MRA machines designed to be used in conjunction with gadolinium-based contrast agents.

(D.I. 1 at ¶ 54) In support of their motion for judgment on the pleadings, Defendants contend that these allegations for failure to warn are preempted by the labeling regulations of the Food and Drug Administration ("FDA"). (D.I. 46 at 13) In this context, the court must consider "whether federal law (including appropriate FDA actions) prohibited the drug manufacturer from adding any and all warnings to the drug label that would satisfy state law." *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1678 (2019).

Federal preemption occurs "when it is 'impossible for a private party to comply with both state and federal requirements.'" *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1672 (2019) (quoting *Mutual Pharm. Co. v. Bartlett*, 570 U.S. 472, 480 (2013)). In accordance with the federal Food, Drug, and Cosmetic Act ("FDCA"), the Food and Drug Administration ("FDA") regulates the safety information included on the labels of prescription drugs marketed to consumers in the United States. *Id.* (citing 21 U.S.C. § 355(b)(1)(F); 21 C.F.R. § 201.57(a) (2018)). Accordingly, state common law and state statutes requiring drug manufacturers to warn consumers of the associated risks of a drug are preempted by the FDCA when there is "clear evidence" that the FDA would not have approved the warning required by state law. *Id.*; *Wyeth v. Levine*, 555 U.S. 555, 571 (2009). In *Albrecht*, the United States Supreme Court defined "clear evidence" as "evidence that shows the court that the drug manufacturer fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve a change to the drug's label to include that warning." *Albrecht*, 139 S. Ct. at 1672.

Under the FDCA, the FDA is responsible for ensuring that prescription drugs are "safe for use under the conditions prescribed, recommended, or suggested" in the drug's labeling, 21 U.S.C. § 355(d), and "a manufacturer may only change a drug label after the FDA approves a supplemental application," *Levine*, 555 U.S. at 568. Nonetheless, a state law failure-to-warn claim may survive a preemption challenge if the complaint alleges that new information became available to the drug manufacturer after the FDA's initial approval and the drug manufacturer sought to amend the label under the "changes being effected" or "CBE" regulation, 21 C.F.R. § 314.70(c)(6)(iii). *See Levine*, 555 U.S. at 568; *Bell v. Boehringer Ingelheim Pharms., Inc.*, 2018 WL 2447788, at *6 (W.D. Pa. May 31, 2018). The CBE regulation allows drug manufacturers to

make certain changes to drug labels without first obtaining FDA approval if the change is intended to "add or strengthen" a warning based on newly acquired information of a causal association between the drug and a risk of harm. *Albrecht*, 139 S. Ct. at 1673 (citing 21 C.F.R. § 314.70(c)(6)(iii)(A)). Because the CBE regulation permits drug manufacturers to change warning labels prior to FDA approval, drug manufacturers ordinarily will not be able to show an actual conflict between state and federal law that would make it impossible to comply with both, and the claim is not preempted. *Id.* at 1679; *see also Levine*, 555 U.S. at 568-72; *McGrath v. Bayer HealthCare Pharms., Inc.*, 393 F. Supp. 3d 161, 167 (E.D.N.Y. 2019).

According to Defendants, Plaintiff's failure to warn claim is preempted because the complaint fails to identify newly acquired information to correct the alleged labeling deficiency in accordance with the CBE regulation. (D.I. 46 at 16-17) The Code of Federal Regulations defines "newly acquired information" to include:

> data, analyses, or other information not previously submitted to the [FDA], which may include (but is not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data . . . if the studies, events, or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA.

21 C.F.R. § 314.3(b). Thus, this requirement "accounts for the fact that risk information accumulates over time and that the same data may take on a different meaning in light of subsequent developments." *Levine*, 555 U.S. at 569. Newly acquired information must reasonably establish a causal association between the drug and a clinically significant adverse reaction. *McGrath*, 393 F. Supp. 3d at 167 (citing 21 C.F.R. § 201.57(c)(6)(i)); *see also Utts v. Bristol-Myers Squibb Co.*, 251 F. Supp. 3d 644, 659 (S.D.N.Y. 2017). This is because "labeling that includes theoretical hazards not well-grounded in scientific evidence can cause meaningful

risk information to lose its significance." *Utts*, 251 F. Supp. 3d at 659 (internal citations and quotation marks omitted).

I recommend that the court grant Defendants' motion for judgment on the pleadings regarding Plaintiff's failure to warn claim because Plaintiff's complaint fails to identify any newly acquired information causally associated with a safety risk to patients. The complaint refers to numerous studies focusing on gadolinium retention in animals and humans with normal renal function, but these allegations do not identify any specific risks associated with the retention of gadolinium. (D.I. 1 at ¶¶ 27-32, 38-39, 43) In an analogous case assessing the sufficiency of the pleading, the *McGrath* court concluded that "allegations focus[ing] on gadolinium retention" in patients with normal renal function were insufficient to establish the requisite causal link to a "clinically significant adverse reaction" experienced by the plaintiff. *McGrath*, 393 F. Supp. 3d at 168-69 ("[I]t helps precious little to mount scientific minutiae on top of technical jargon if that information ultimately does not plead a plausible causal association between Magnevist and adverse effects, like fibrosis."). Plaintiff's complaint indicates that the FDA's National Center for Toxicological Research team is currently "working on determining the exact consequences of these new findings" of gadolinium retention in patients with normal renal function. (D.I. 1 at ¶ 41) Consistent with *McGrath*, this allegation confirms that "the incidence of any *risks* associated with gadolinium retention is inconclusive." *McGrath*, 393 F. Supp. 3d at 168 (considering allegations regarding the same 2004 and 2013 studies cited at paragraphs 38 and 43 of Plaintiff's complaint in the instant litigation); *see also Sabol v. Bayer Healthcare Pharm., Inc.*, 2020 WL 705170, at *12 (S.D.N.Y. Feb. 12, 2020) (granting Rule 12(b)(6) motion to dismiss because complaint made "only conclusory allegations that gadolinium retention can cause the kind of debilitating symptoms [plaintiff] has suffered.").

The complaint also alleges that numerous patients with normal renal function reported adverse reactions to the FDA after receiving injections with GBCAs. (D.I. 1 at ¶¶ 36-37) Under the federal regulations, such reports of adverse events may constitute newly acquired information. *See* 21 C.F.R. § 314.3(b). But the Supreme Court has cautioned that "the mere existence of reports of adverse events . . . says nothing in and of itself about whether the drug is causing the adverse events." *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 44 (2011). Here, the complaint's allegations regarding symptomatic patients likewise fail to establish a causal association between the reported symptoms and the receipt of GBCA injections. *See Sabol*, 2020 WL 705170, at *13 ("[W]hile federal regulations define 'newly acquired information' to include items such as adverse event reports . . . the CBE regulation still requires causation."). Likewise, the complaint does not establish a causal association between Plaintiff's use of Omniscan injections and her alleged symptoms of cognitive impairment, burning sensation on her skin, heart palpitations, and pain throughout her body. (D.I. 1 at ¶ 10) "The fact that a user of a drug has suffered an adverse event, standing alone, does not mean that the drug caused that event." *Matrixx*, 563 U.S. at 44.

Because the complaint fails to identify studies or other evidence establishing the clinical consequences of gadolinium retention in patients with normal renal function, the requirements to invoke the CBE regulation are not met. *See McGrath*, 393 F. Supp. 3d at 169-70. Therefore, the court need not reach the analysis of whether Defendants have shown "clear evidence" that the FDA would not have approved a change to the drug's label.[4] *See id.* at 171 ("[B]ecause Bayer

[4] The pleading in the instant case does not identify when Plaintiff was administered Omniscan in connection with any diagnostic imaging studies, beyond alleging that she discovered adverse effects in 2016. (D.I. 1 at ¶¶ 23-24) The parties do not dispute that, in 2018, the FDA issued a drug safety communication that contained the following pertinent language: "Gadolinium retention has not been directly linked to adverse health effects in patients with normal kidney

could not have amended the warning under the CBE regulation, this Court need not even consider whether there is clear evidence the FDA would not have approved a change to Magnevist's label."); *Drescher v. Bracco Diagnostics, Inc.*, 2020 WL 699878, at *4 (D. Ariz. Jan. 31, 2020) (concluding that the clear evidence standard only applies if a label change is permitted under the CBE regulations).

Plaintiff contends that, because preemption is an affirmative defense, Defendants should bear the initial burden of proof instead of improperly shifting the initial burden to Plaintiff to plead the existence of newly acquired information justifying the label change under the CBE regulation. (D.I. 48 at 4-5) The law is well-established that preemption is an affirmative defense on which the defendant bears the burden of proof, and the plaintiff need not anticipate affirmative defenses in the pleadings. *See Gomez v. Toledo,* 446 U.S. 635, 640 (1980) (concluding there was no basis to impose a burden on the plaintiff to anticipate an affirmative defense). Nonetheless, a defendant may properly move for judgment on the pleadings based on the affirmative defense of preemption. *See Benson v. Fannie May Confections Brands, Inc.*, 944 F.3d 639, 645 (7th Cir. 2019) (citing *Bausch v. Stryker Corp.*, 630 F.3d 546, 561-62 (7th Cir. 2010)); *see also In re Asbestos Prods. Liability Litig. (No. VI),* 822 F.3d 125, 133 n.6 (3d Cir.

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function." (D.I. 46, Ex. A at 2) Plaintiff "offers no persuasive reason why the Court should ignore" the FDA's 2017 notice. *Sabol v. Bayer Healthcare Pharm., Inc.*, 2020 WL 705170, at *12 (S.D.N.Y. Feb. 12, 2020). Because the FDA found no causal connection between gadolinium retention and adverse health events in patients with normal renal function in 2018, there is no basis to suggest the FDA would have approved placement of a warning label stating otherwise at the time Plaintiff discovered her injury on or before 2016. *See Smith v. GE Healthcare, Inc.*, 2020 WL 1880787, at *7 (W.D. La. Mar. 31, 2020) ("The language of the [FDA's 2018] label change, specifically stating facts contrary to the warning sought by [the plaintiff], is clear evidence that the FDA would not have approved a label change which warned of such adverse effects."), *report and recommendation adopted by* 2020 WL 1875644 (W.D. La. Apr. 15, 2020); *Thomas v. Bracco Diagnostics, Inc.*, 2020 WL 1016273 (W.D. La. Feb. 27, 2020) (same), *report and recommendation adopted by* 2020 WL 1243389 (W.D. La. Mar. 13, 2020).

2016) (recognizing that the "allocation of the burden of proof suggests that a motion under Rule 12(c) for judgment on the pleadings is a more appropriate procedural vehicle for dismissing cases on preemption grounds, instead of a motion under Rule 12(b)(6), except for cases in which preemption is manifest in the complaint itself."). Because the affirmative defense of federal preemption primarily raises a legal issue, it is properly considered at the pleading stage in the context of a Rule 12(c) motion. *See NE Hub Partners, L.P. v. CNG Transmission Corp.*, 239 F.3d 333, 344 (3d Cir. 2001).

In the narrow context of failure to warn claims brought pursuant to the CBE regulation, numerous district courts have held that dismissal at the pleading stage is appropriate if the complaint fails to "present sufficient factual allegations to show that the manufacturer could unilaterally change its label in accordance with FDA regulations." *Sabol v. Bayer Healthcare Pharm., Inc.*, 2020 WL 705170, at *6 (S.D.N.Y. Feb. 12, 2020) (citing *Utts v. Bristol-Myers Squibb Co.*, 251 F. Supp. 3d 644, 672 (S.D.N.Y. 2017)); *see also McGrath*, 393 F. Supp. 3d at 168; *Holley v. Gilead Scis., Inc.*, 379 F. Supp. 3d 809, 828-30 (N.D. Cal. 2019). If this preliminary showing is not made, the court need not reach a determination of whether the defendant has shown clear evidence that the FDA would have rejected the proposed label change. *See McGrath*, 393 F. Supp. 3d at 168 ("[B]ecause Bayer could not have amended the warning under the CBE regulation, this Court need not even consider whether there is clear evidence the FDA would not have approved a change to Magnevist's label."); *Drescher v. Bracco Diagnostics, Inc.*, 2020 WL 699878, at *4 (D. Ariz. Jan. 31, 2020) (concluding that the clear evidence standard only applies if a label change is permitted under the CBE regulations).

At least two Courts of Appeal have also held that the preemption determination may be properly resolved at the pleading stage. *See Gibbons v. Bristol-Myers Squibb Co.*, 919 F.3d 699,

708 (2d Cir. 2019) (affirming the district court's dismissal of a failure-to-warn claim where the complaint contained insufficient factual allegations to show the existence of newly acquired information); *In re Celexa & Lexapro Marketing & Sales Practices Litig.*, 779 F.3d 34, 38, 42-43 (1st Cir. 2015) (affirming district court's dismissal of failure-to-warn claim as preempted by FDA regulations). Applying Supreme Court case authorities, the Court of Appeals for the First Circuit determined that "a necessary step in defeating [the defendant's] preemption defense is to establish that the complaint alleges a labeling deficiency that [the defendant] could have corrected using the CBE regulation." *In re Celexa*, 779 F.3d at 41. The First Circuit affirmed dismissal of the complaint on preemption grounds after finding that the complaint challenged the accuracy and adequacy of studies which were known to the FDA at the time of approval. *Id.* at 38, 42-43. Similarly, the Court of Appeals for the Second Circuit upheld the dismissal of state law failure-to-warn claims as preempted when the "allegations . . . d[id] not plausibly allege the existence of newly acquired information that could have justified Defendants' revising the [drug's] label through the CBE regulation." *Gibbons*, 919 F.3d at 708. Allegations regarding post-approval reports and studies showing serious hemorrhaging in patients using the drugs did not constitute newly acquired evidence because they did not "reveal[ ] risks of a different type or greater severity or frequency than previously included in submissions to the FDA." *Id.* (quoting 21 C.F.R. § 314.3(b)). Thus, the court may grant Defendants' Rule 12(c) motion without improperly shifting the burden from Defendants to Plaintiff on the issue of federal preemption.

Plaintiff alleges that the Supreme Court's decision in *Albrecht* superseded the Second Circuit's decision in *Gibbons* by requiring a showing of "clear evidence" by the defendant and declining to "explicitly or impliedly lay any burden at the feet of the plaintiff in the impossibility preemption inquiry." (D.I. 48 at 9-10) But the issue of newly acquired information was not

before the Supreme Court in *Albrecht* because the drug manufacturer conceded that it could have changed the label under the CBE regulation: "Merck conceded that the FDA's CBE regulation would have permitted Merck to try to change the label to add a warning before 2010, but Merck asserted that the FDA would have rejected that attempt." *Albrecht*, 139 S. Ct. at 1675 (addressing preemption of failure-to-warn claims on summary judgment). In contrast, Defendants in this case allege that there is no scientific evidence that would have allowed them to strengthen the Omniscan labeling under the CBE regulation. (D.I. 49 at 4 n.1) Consistent with Defendants' position, the Supreme Court in *Albrecht* acknowledged that "manufacturers cannot propose a change that is not based on reasonable evidence" in accordance with 21 C.F.R. § 314.70(c)(6)(iii)(A). *Albrecht*, 139 S. Ct. at 1679. Further confirming this point, courts have favorably applied *Gibbons* in decisions issued following the Supreme Court's decision in *Albrecht*. *See Holley v. Gilead Scis., Inc.*, 410 F. Supp. 3d 1096, 1107 (N.D. Cal. 2019); *McGrath*, 393 F. Supp. 3d at 168-69.

For the foregoing reasons, I recommend that the court grant Defendants' motion for judgment on the pleadings as it pertains to Plaintiff's negligent failure-to-warn claim.

2. Preemption of design and manufacturing defect claim

Defendants also allege that Plaintiff's design and manufacturing defect claim is preempted because Defendants cannot alter Omniscan's FDA-approved design and manufacturing practices under the applicable federal regulations. (D.I. 46 at 18-19) In response, Plaintiff contends that its design defect claim is not preempted because it is not premised on a failure to warn theory. (D.I. 48 at 16) Instead, Plaintiff argues that the complaint pleads facts showing a safer alternative design to Omniscan already exists in Defendants' Clariscan product. (*Id.*)

I recommend that the court grant Defendants' motion for judgment on the pleadings with respect to Plaintiff's design and manufacturing defect claim. The law is well-established that, "[o]nce a drug—whether generic or brand-name—is approved, the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application.'" *Mutual Pharm. Co., Inc. v. Bartlett*, 570 U.S. 472, 477 (2013) (quoting 21 C.F.R. § 314.70(b)(2)(i)). The complaint acknowledges that Omniscan was approved by the FDA. (D.I. 1 at ¶ 31) Even assuming the truth of the complaint's allegations regarding the greater safety of the macrocyclic contrast agents over linear contrast agents like Omniscan (*id.* at ¶¶ 26, 29), Defendants would need to obtain FDA approval of such a change to the manufacture of Omniscan, *see Yates v. Ortho-McNeil-Janssen Pharms., Inc.*, 808 F.3d 281, 298 (6th Cir. 2015) (holding that post-approval design defect claims are "clearly preempted by federal law").

To the extent that Plaintiff argues Defendants should have marketed their Clariscan macrocyclic product in lieu of the linear Omniscan contrast agent, the Supreme Court has rejected the " 'stop-selling' rationale as incompatible with our pre-emption jurisprudence." *Bartlett*, 570 U.S. at 488. Specifically, "an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability." *Id.*

C. Conversion to Motion for Summary Judgment and Leave to Amend

I recommend that the court deny Plaintiff's alternative request to convert Defendants' motion for judgment on the pleadings into a motion for summary judgment. The discovery Plaintiff requests in connection with the motion goes to the "clear evidence" inquiry, and does not advance the issue of whether newly acquired information exists:

> (1) whether, in fact, GEHC ever attempted to include in its product labeling those warnings implicated by Plaintiff's state-law claim; (2) whether, in fact, GEHC

> ever requested that FDA permit such warnings; and (3) whether, in fact, FDA ever took any action—formal or otherwise—to block, forbid, or deny GEHC's request to give such warnings.

(D.I. 48 at 17) Therefore, the discovery requested by Plaintiff would not alter the outcome of the present motion.

I further recommend that the court deny Plaintiff's request for leave to amend the complaint. The deadline for amended pleadings expired on May 24, 2019, and Plaintiff offers no support for her request for leave to amend to explain how the deficiencies identified by Defendants could be overcome. (D.I. 37 at ¶ 2; D.I. 48 at 2, 18) For the reasons previously stated, it is not apparent that additional discovery would remedy these deficiencies. Consequently, leave to amend would be futile. *See Smith v. GE Healthcare, Inc.*, 2020 WL 1880787, at *1, 5, 7 (W.D. La. Mar. 31, 2020) (recommending dismissal with prejudice of the plaintiff's design defect and failure-to-warn claims on the basis of preemption), *report and recommendation adopted by* 2020 WL 1875644 (W.D. La. Apr. 15, 2020).

V. CONCLUSION

For the foregoing reasons, I recommend that the court GRANT Defendants' motion for judgment on the pleadings with prejudice. (D.I. 45)

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b)(2). The objection and responses to the objections are limited to ten (10) pages each. The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the District Court. *See Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006); *Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987).

The parties are directed to the court's Standing Order For Objections Filed Under Fed. R. Civ. P. 72, dated October 9, 2013, a copy of which is available on the court's website, http://www.ded.uscourts.gov.

Dated: May 29, 2020

Sherry R. Fallon
United States Magistrate Judge