IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

EILEEN SCANLON	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civ. No. 13-224-SLR
	)	
MEDTRONIC SOFAMOR DANEK USA INC. and MEDTRONIC, INC.	)	
	)	
	)	
Defendants.	)	

Jeffrey M. Gentilotti, Esquire and Robin M. Grogan, Esquire of Bifferato Gentilotti LLC, Wilmington, Delaware. Counsel for Plaintiff. Of Counsel: Aaron J. Freiwald, Esquire and Glenn A. Ellis, Esquire of Layser & Freiwald, P.C.

M. Duncan Grant, Esquire and James H.S. Levine, Esquire of Pepper Hamilton LLP, Wilmington, Delaware. Counsel for Defendants. Of Counsel: Murray S. Levin, Esquire and Sean P. Fahey, Esquire of Pepper Hamilton LLP and Daniel L. Ring, Esquire and Andrew E. Tauber, Esquire of Mayer Brown LLP.

MEMORANDUM OPINION

Dated: July 18, 2014
Wilmington, Delaware

ROBINSON, District Judge

I. INTRODUCTION

On May 11, 2012, plaintiff Eileen Scanlon ("plaintiff") filed this action in the Court of Common Pleas of Philadelphia County, Pennsylvania. On June 7, 2012, defendants Medtronic Sofamor Danek USA, Inc. and Medtronic, Inc. (collectively "defendants") removed this action to the United States District Court for the Eastern District of Pennsylvania. (D.I. 1) On July 5, 2012, plaintiff filed an amended complaint alleging violations of Delaware law. (D.I. 8) Defendants moved to dismiss the amended complaint.[1] (D.I. 13) The court took the motion to dismiss under advisement and granted plaintiff leave to file a second amended complaint by December 13, 2012. (D.I. 23) Plaintiff moved for discovery on December 13, 2012 and separately filed a second amended complaint on December 17, 2012. (D.I. 24; D.I. 25) On January 3, 2013, defendants moved to dismiss the second amended complaint. (D.I. 28) On January 11, 2013, the court determined that diversity jurisdiction was proper, but that the United States District Court for the District of Delaware was the proper venue. The court ordered the action transferred and the outstanding motions were denied without prejudice for reconsideration by the transferee court. (D.I. 31)

After transfer to this court, on April 3, 2013, the court denied plaintiff's request for limited discovery and ordered briefing on defendants' arguments regarding dismissal for failure to state a claim. Currently before the court is defendants' motion to dismiss for failure to state a claim. (D.I. 43) The court has jurisdiction over these matters pursuant to 28 U.S.C. §§ 1332(a)(1) and 1332(c)(1). Venue is proper under 28 U.S.C. § 1391(b).

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[1]Later denied as moot. (D.I. 31)

II. STANDARD OF REVIEW

A motion filed under Federal Rule of Civil Procedure 12(b)(6) tests the sufficiency of a complaint's factual allegations. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007); *Kost v. Kozakiewicz*, 1 F.3d 176, 183 (3d Cir. 1993). A complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief, in order to give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Twombly*, 550 U.S. at 545 (internal quotation marks omitted) (interpreting Fed. R. Civ. P. 8(a)). Consistent with the Supreme Court's rulings in *Twombly* and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), the Third Circuit requires a two-part analysis when reviewing a Rule 12(b)(6) motion. *Edwards v. A.H. Cornell & Son, Inc.*, 610 F.3d 217, 219 (3d Cir. 2010); *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009). First, a court should separate the factual and legal elements of a claim, accepting the facts and disregarding the legal conclusions. *Fowler*, 578 F.3d. at 210-11. Second, a court should determine whether the remaining well-pled facts sufficiently show that the plaintiff "has a 'plausible claim for relief.'" *Id.* at 211 (quoting *Iqbal*, 556 U.S. at 679). As part of the analysis, a court must accept all well-pleaded factual allegations in the complaint as true, and view them in the light most favorable to the plaintiff. *See Erickson v. Pardus*, 551 U.S. 89, 94 (2007); *Christopher v. Harbury*, 536 U.S. 403, 406 (2002); *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 231 (3d Cir. 2008). In this regard, a court may consider the pleadings, public record, orders, exhibits attached to the complaint, and documents incorporated into the complaint by reference. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007); *Oshiver v. Levin,*

Fishbein, Sedran & Berman, 38 F.3d 1380, 1384-85 n.2 (3d Cir. 1994).

The court's determination is not whether the non-moving party "will ultimately prevail" but whether that party is "entitled to offer evidence to support the claims." *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 302 (3d Cir. 2011). This "does not impose a probability requirement at the pleading stage," but instead "simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of [the necessary element]." *Phillips*, 515 F.3d at 234 (quoting *Twombly*, 550 U.S. at 556). The court's analysis is a context-specific task requiring the court "to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 663-64.

III. BACKGROUND

A. Statutory and Regulatory Framework

The Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040, as amended, 21 U.S.C. § 301 et seq., has long required approval by the Food and Drug Administration ("FDA") for the introduction of new drugs into the market. The introduction of new medical devices was left largely for the states to oversee. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315 (2008). As more complex medical devices entered the marketplace,[2] Congress passed the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360c et seq.,[3] "which swept back some state obligations and imposed a regime of detailed

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[2]And failed. Introduced in 1970, "the Dalkon Shield intrauterine device . . . was linked to serious infections and several deaths, not to mention a large number of pregnancies." *Riegel*, 552 U.S. at 315.

[3]The MDA amended the Federal Food, Drug, and Cosmetic Act, (collectively referred to as the "FDCA").

federal oversight." *Riegel*, 552 U.S. at 316.

The MDA divides medical devices into three classes and provides varying levels of oversight for each, according to the risks they present. Class III devices, defined as such because they are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or . . . present[] a potential unreasonable risk of illness or injury." § 360c(a)(1)(C)(ii). Class III devices receive the most oversight and undergo a rigorous premarket approval process. *Riegel*, 552 U.S. at 316-17.

The approval process starts with the manufacturer submitting a multivolume application to the FDA, which spends an average of 1,200 hours reviewing each such application. *Id.* at 318. The FDA grants premarket approval ("PMA") only if it finds that there is "a reasonable assurance of safety and effectiveness, [and] if the proposed labeling is neither false nor misleading." § 360e(d). The agency must "weig[h] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." § 360c(a)(2)(C). "It may thus approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives." *Riegel*, 552 U.S. at 317-18.

Once a device has received PMA, "the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Id.* at 319 (citing § 360e(d)(6)(A)(i)). Should the applicant wish to make such a change, it must submit an application for supplemental premarket approval, which the FDA evaluates under largely the same criteria as an initial application. § 360e(d)(6); 21 CFR §

814.39(c); *Riegel*, 552 U.S. at 319. Medical devices are subject to continuing reporting requirements, § 360i, including

> the obligation to inform the FDA of new clinical investigations or scientific studies concerning the device which the applicant knows of or reasonably should know of, 21 CFR § 814.84(b)(2), and to report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred, § 803.50(a).

Riegel, 552 U.S. at 319. The FDA retains the power to withdraw PMA based on newly reported data or existing information. Further, it must withdraw approval if it finds "that such device is unsafe or ineffective under the conditions of use prescribed, recommended, or suggested in the labeling thereof." § 360e(e)(1); see also § 360h(e) (recall authority); *Riegel*, 552 U.S. at 319-20.

The MDA contains an express preemption provision:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). The exception contained in subsection (b) permits the FDA to exempt some state and local requirements from preemption.

B. Infuse Device

The device at issue ("the infuse device") is a Class III medical device, approved

by the FDA through the PMA process,[4] made by defendants. The infuse device consists of a recombinant human bone morphogenetic protein ("rhBMP-2") embedded in a collagen sponge (collectively, "the infuse bone graft component") and an interbody fusion device ("a cage"). The infuse device is used in a surgical spinal fusion to treat degenerative disc disease and has been approved for use in anterior lumbar interbody fusion procedures (lumbar surgery that is performed through the abdomen) involving a single level fusion in the L4-S1 region of the lumbar spine. The infuse device was initially approved on July 2, 2002. The FDA has since approved forty-four supplements to its PMA. (D.I. 25; D.I. 44 at 5-6)

C. Plaintiff

After suffering from back pain for a number of years, plaintiff was "diagnosed with lumbar discogenic back pain and radiculopathy with severely collapsed and degenerative L5-S1 disk space." (D.I. 25 at ¶¶ 35-36) Plaintiff's doctor recommended that she undergo an anterior lumbar interbody fusion of the L5-S1, in which he would use a SynFix interbody cage along with the infuse bone graft component.[5] (*Id.* at ¶¶ 38-39) The doctor discussed the off-label use of the infuse bone graft component with

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[4]In October 1996, Sofamor Danek (purchased by Medtronic in 1999) filed an application for an Investigational Device Exemption with the FDA to conduct a pilot study on the effects of recombinant human bone morphogenetic protein in humans. Medtronic filed its application for PMA on January 12, 2001. (D.I. 25 at ¶¶ 18, 26, 27, 29)

[5]Plaintiff's complaint uses "INFUSE" to refer to both the infuse device (D.I. 25 at ¶ 20) and the infuse bone graft component (*id.* at ¶ 28). Plaintiff uses "BMP" to refer to the recombinant protein rhBMP-2 and to such rhBMP-2 embedded in a collagen sponge. (*Id.* at ¶¶ 35-57). The court has assigned the broadest meaning to plaintiff's allegations.

plaintiff and assured her it was safe and effective. (*Id.* at ¶¶ 39-42) On November 4, 2009, plaintiff underwent the spinal fusion. After her surgery, plaintiff experienced a system wide inflammatory reaction, which included debilitating headaches, loss of balance, vertigo and pain.[6] (*Id.* at ¶¶ 51-52, 84)

Plaintiff alleges that she understood the following. Defendants' representatives ("the representatives") "aggressively, intentionally and systemically marketed and sold its [infuse device or infuse bone graft component] for off[-]label uses not covered by the FDA review or approval," including using the infuse bone graft component with any fusion cage. (*Id.* at ¶¶ 33, 43) Her doctor preferred to use the SynFix cage and discussed this preference with the representatives, who assured him that "he could continue using the SynFix cage in combination with [the infuse bone graft component]."[7] (*Id.* at ¶¶ 45-50)

Plaintiff further alleges that defendants "misrepresented the safety and efficacy data of [the infuse bone graft component]" to her doctor, who in turn "passed on those misrepresentations to [her]." (*Id.* at ¶¶ 53-54) Plaintiff alleges that defendants "altered the safety data on [the infuse device] by paying authors to downplay and in some cases hide the adverse consequences of using [the infuse bone graft component]" and "paid physicians to publish articles describing off-label uses of [the infuse bone graft component], which were presented as safe and effective." (*Id.* at ¶¶ 56-57) According

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[6]Plaintiff's original complaint alleged that she was injured by the entry of rhBMP-2 into her spinal fluid through a "dural tear." (D.I. 1 at ¶¶ 26–29)

[7]Defendants "flew [plaintiff's doctor] to Russia to attend a conference on the off[-]label use of [the infuse device] and its superior safety and efficacy over allografts and autografts." (D.I. 25 at ¶ 49)

to plaintiff, defendants' representatives "falsified or distorted safety data to help sell [the infuse device] for off[-]label uses." (*Id.* at ¶ 65)

Plaintiff asserts the following claims: (1) negligence for the off-label use of the infuse device; (2) negligent misrepresentation concerning the risk of the infuse device; (3) fraud based on defendants' agents and sales representatives making material misrepresentations regarding off-label uses; (4) failure to warn of known dangers based on the off-label use; and (5) breach of express warranty. (*Id.* at ¶¶ 85-129)

IV. DISCUSSION

A. Preemption

Congress has empowered the FDA to regulate medical devices, enacting a rigorous approval process for both medical devices and their labeling. The MDA expressly preempts most state laws attempting to create requirements having to do with medical devices. 21 U.S.C. § 360k(a). The Supreme Court has stated that "the only indication available—the text of the statute—suggests that the solicitude for those injured by FDA-approved devices, which the dissent finds controlling, was overcome in Congress's estimation by solicitude for those who would suffer without new medical devices if juries were allowed to apply the tort law of [fifty] States to all innovations." *Riegal*, 552 U.S. at 326. The Supreme Court acknowledged that "[t]he dissent would narrow the pre-emptive scope . . . on the grounds that it is 'difficult to believe that Congress would, without comment, remove all means of judicial recourse' for consumers injured by FDA-approved devices. But, as we have explained, this is exactly what a pre-emption clause for medical devices does by its terms." *Id.*

The Supreme Court has directed that courts analyze express preemption in two steps: first, courts should "determine whether the Federal Government has established requirements applicable to" the accused medical device; and second, courts should determine whether state law claims asserted against the medical device manufacturer are based upon requirements "with respect to the device that are 'different from, or in addition to,' the federal ones, and that relate to safety and effectiveness." *Id.* at 321-22 (citing § 360k(a)). In doing so, "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Id.* at 330.

Implied preemption is based on the fact that any suit to enforce the FDCA "shall be by and in the name of the United States." 21 U.S.C. § 337(a). "[T]he federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and . . . this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001). The Supreme Court in *Buckman* found that "fraud [on the FDA] claims exist solely by virtue of the FDCA disclosure requirements" and are impliedly preempted by federal law as they "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *Id.* at 350, 353. The Supreme Court further noted:

> As a practical matter, complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants - burdens not contemplated by Congress in enacting the FDCA and the MDA. Would-be applicants may be discouraged from seeking § 510(k) approval of devices with potentially beneficial off-label uses for fear that such

> use might expose the manufacturer or its associates (such as petitioner) to unpredictable civil liability. In effect, then, fraud-on-the-FDA claims could cause the Administration's reporting requirements to deter off-label use despite the fact that the FDCA expressly disclaims any intent to directly regulate the practice of medicine,. . . and even though off-label use is generally accepted.

Id. at 350-51.

In light of the *Riegel* and *Buckman* preemption schemes, courts have generally agreed that there is a narrow path that plaintiffs must follow to successfully assert state-law claims against medical device manufacturers. "In order to survive preemption, such claims 'must be premised on conduct that both (1) violates the FDCA and (2) would give rise to a recovery under state law even in the absence of the FDCA.'" *Schouest v. Medtronic, Inc.*, Civ. No. 13-203, 2014 WL 1213243, at 5 (S.D. Tex. 2014) (citing *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009)). *See also In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1205 (8th Cir. 2010); *Caplinger v. Medtronic, Inc.*, 921 F. Supp. 2d 1206, 1215 (W.D. Okla. 2013).

B. Application to Plaintiff's Claims

The infuse device (and its labeling) is regulated by the FDA. Moreover, the Supreme Court recognized in *Buckman* that "'off-label' usage of medical devices . . . is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine." *Buckman*, 531 U.S. at 350. Thus, allegations of off-label use and the promotion thereof do not immunize a plaintiff's claims from preemption. *See Caplinger*, 921 F. Supp. 2d at 1215 ("[N]othing in § 360k(a) suggests that the preemption analysis somehow depends on how the device is

being promoted to be used."). Morever, contrary to plaintiff's suggestion, "plaintiff's off-label promotion allegations do not somehow turn plaintiff's claims into 'parallel' claims that are not preempted." *Id.* at n.4. Instead, plaintiff's claims are subject to the preemption analysis discussed above.

Plaintiff alleges that Medtronic "had a duty to warn," and should have "performed the studies and reported the actual results necessary to determine that [the infuse device] should not be used off[-]label . . . ." (D.I. 25 at ¶¶ 87, 92) Plaintiff alleges that Medtronic "failed to provide warnings of the product[']s known dangers, including the known dangers associated with the off[-]label usage that Medtronic was promoting." (*Id.* at ¶ 120) Plaintiff also alleges that Medtronic negligently "failed to disclose material facts concerning the risks" of the infuse device. (D.I. 25 at ¶ 96)

Plaintiff's negligence cause of action[8] would impose requirements on Medtronic - to perform and report additional studies - which are different from and in addition to those imposed by the FDA. Plaintiff's failure to warn cause of action[9] would require that Medtronic provide warnings in addition to or different from those required by the FDA.[10]

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[8]Count I.

[9]Count IV.

[10]Plaintiff appears to argue in its briefing that Medtronic should have sought FDA approval to change the labeling of the infuse device to reflect such dangers. (D.I. 49 at 18) However, such an allegation requires additional action than that required by the FDCA. *See McMullen v. Medtronic, Inc.*, 421 F.3d 482, 482, 489 (7th Cir. 2005) ("Where a federal requirement permits a course of conduct and the state makes it obligatory, the state's requirement is in addition to the federal requirement and thus is preempted.").

To the extent plaintiff's cause of action for negligent misrepresentation[11] alleges that Medtronic failed to disclose material facts, plaintiff has not alleged that Medtronic's warning label for the infuse device did not comply with the FDA. Therefore, any "material facts" which plaintiff asserts are missing would require a change in those warnings or disclosures required by the FDA.[12] Each of these causes of action is expressly preempted. *See, e.g., Caplinger*, 921 F. Supp. 2d at 1219 (finding certain claims preempted when allowing them "would establish labeling and warning requirements different from, or in addition to, federal requirements for the Infuse Device"); *Ledet v. Medtronic*, Civ. No. 13-200, 2013 WL 6858858, at *5 (S.D. Miss. Dec. 30, 2013).

Plaintiff additionally alleges that Medtronic "negligently misrepresented" the infuse device, i.e., made representations (through its representatives) which plaintiff alleges were false. (*Id.* at ¶¶ 96-97) Moreover, plaintiff alleges that Medtronic representatives made false representations with the intent to defraud, deceive, and mislead. (*Id.* at ¶¶ 112-13) Plaintiff claims that defendants "downplayed, understated and/or disregarded their knowledge of the serious and permanent side effects associated with the use of their products, despite the existence of information available to [d]efendants that should have demonstrated that Medtronic products were likely to cause serious injuries to product users." (*Id.* at ¶ 112) Plaintiff superficially alleges that

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[11]Count II.

[12]Plaintiff's allegation that she was injured by the entry of rhBMP-2 into her spinal fluid through a "dural tear" is a risk noticed in the Important Medical Information, which lists "dural tears" as one of the "potential adverse events which may occur with spinal fusion surgery with the" infuse device. (D.I. 44, ex. 5 at 9-10)

Medtronic did not report adverse events to the FDA. (*Id.* at ¶ 92; D.I. 49 at 19-20)

Plaintiff's negligent misrepresentation[13] and fraud[14] causes of action each allege that Medtronic representatives made false representations regarding the infuse device and its use. The FDCA governs both marketing and promotion of medical devices (even off-label). To the extent plaintiff asserts that such representations are "fraud on the FDA," these claims "exist solely by virtue of the FDCA disclosure requirements," and are impliedly preempted. *Buckman*, 531 U.S. at 350, 353. To the extent plaintiff asserts such representations are parallel claims, the court disagrees. While such conduct (making false representations regarding the infuse device) might violate the FDCA, such conduct would not exist apart from the FDCA. The same analysis applies to plaintiff's allegations that Medtronic did not report adverse events.[15] Therefore, these causes of action likewise are preempted. *See, e.g., Caplinger*, 921 F. Supp. 2d at 1219; *Ledet v. Medtronic*, Civ. No. 13-200, 2013 WL 6858858, at *4 (S.D. Miss. Dec. 30, 2013).

As to plaintiff's breach of express warranty claim, plaintiff fails to respond to defendants' argument regarding disclaimer of warranty. The document titled "Important Medical Information for Infuse Bone Graft/LT–Cage Lumbar Tapered Fusion Device,"

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[13]Count II.

[14]Count III.

[15]Moreover, plaintiff does not and cannot show that reporting adverse events would necessarily have resulted in a change in the labeling or warnings of the infuse device.

on file on the FDA's website, includes a conspicuous disclaimer of all warranties.[16] Delaware law permits such disclaimers. 6 Del. C. § 2-316; *see also, Strange v. Keiper Recaro Seating, Inc.*, 117 F. Supp. 2d 408, 411 (D. Del. 2000). The court concludes that the disclaimer language is sufficient and dismisses this cause of action.[17] *See Scovil v. Medtronic, Inc.*, 2014 WL 502923, at *11 (D. Ariz. Feb. 7, 2014).

V. CONCLUSION

For the aforementioned reasons, defendants' motion to dismiss is granted. An appropriate order shall issue.

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[16]Defendants request that the court take judicial notice of the FDA document titled InFUSE Bone Graft/LT-CAGE Lumbar Tapered Fusion Device Important Medical Information ("Important Medical Information"), available on the FDA's public website. (D.I. 44 at n.3, ex. 5) Plaintiff does not specifically oppose the request, instead arguing that defendants' inclusion of many additional documents converts the motion to dismiss into a motion for summary judgment. As to the Important Medical Information document, such document reflects final agency action and is included in a database maintained by the FDA in the normal course of business. The court takes judicial notice of the veracity of the document.

[17]Without reaching defendants' preemption arguments.

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v.	)	Civ. No. 13-224-SLR
	)	
	)	
MEDTRONIC SOFAMOR DANEK USA INC. and MEDTRONIC, INC.	)	
	)	
	)	
Defendants.	)	

ORDER

At Wilmington this 18th day of July, 2014, consistent with the memorandum opinion issued this same date;

IT IS ORDERED that defendants' motion to dismiss (D.I. 43) is granted.

United States District Judge