IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

ANDREA IRIZARRY and MANUEL IRIZARRY,	:	
Plaintiffs,	:	CIVIL ACTION NO. 18-4232
v.	:	
ABBOTT LABORATORIES, ABBOTT LABORATORIES, INC., ABBOTT VASCULAR, INC., and JOHN DOE DISTRIBUTION, INC.,	:	
Defendants.	:	

ORDER

AND NOW, this 8th day of October, 2019, after considering the third amended complaint (Doc. No. 46), the motion to dismiss the third amended complaint (Doc. No. 47), the response in opposition to the motion (Doc. No. 48), and the reply brief in further support of the motion (Doc. No. 49), as well as the parties' arguments raised before the court at oral argument on the motion on October 1, 2019, it is hereby **ORDERED** as follows:

1. The motion to dismiss the third amended complaint is **GRANTED** and the third amended complaint is **DISMISSED WITH PREJUDICE**;[1] and

2. The clerk of clerk shall mark this matter as **CLOSED**.

BY THE COURT:

/s/ *Edward Smith*
EDWARD G. SMITH, J.

[1] The court gave the plaintiffs the opportunity to amend the complaint (for a third time) to (1) plead actual facts concerning how the Perclose device was manufactured in a way that ran afoul of the premarket approval ("PMA")

requirements applicable to the device under the Medical Device Amendments ("MDA") to the Food Drug and Cosmetic Act ("FDCA"), and (2) to articulate claims that were based on a violation of a common law duty under Pennsylvania law, rather than the FDCA itself, which does not provide a private right of action. Mar. 28, 2019 Order at 1–2, Doc. No. 36. With regard to the PMA requirements, they define the "narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption" based on the Supreme Court's holdings in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008) and *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). *In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010) (citation and internal quotation marks omitted).

Here, the plaintiffs are unable to establish that the Perclose device was manufactured in a manner that violated the PMA requirements. Essentially, their allegations do not fit through the "narrow gap" necessary to avoid preemption. The original complaint lacked any specific allegations of the way in which the device was manufactured that failed to comply with the PMA requirements. In an attempt to overcome this deficiency, the plaintiffs appended to their third amended complaint the affidavit of J. Lawrence Stevens, a purported expert with over 20 years of FDA experience. However, the court cannot consider Mr. Stevens' affidavit at this juncture of the case because it is not a "written instrument" as defined by Federal Rule of Civil Procedure 10. *See* Fed. R. Civ. P. 10(c) (providing that "written instruments" may be considered at pleading).

In *Rose v. Bartle*, 871 F.2d 331 (3d Cir. 1989), the Third Circuit determined that an affidavit did not constitute a written instrument under Rule 10. *Id.* at 339 n.3. Notably, the affidavit in *Rose* was not an expert opinion. However, the Third Circuit's logic in excluding the affidavit is instructive in the case before this court. The Third Circuit explained that "[t]he case law demonstrates . . . that the types of exhibits incorporated within the pleadings by Rule 10(c) consist largely of documentary evidence, specifically, contracts, notes, and other 'writing[s] on which [a party's] action or defense is based.'" *Id.* (citing 5 C. Wright & A. Miller, Federal Practice and Procedure § 1327, at 489). "Lengthy exhibits containing . . . evidentiary matter" do not fall into any of those permissible categories. *Id.* (internal quotation marks omitted). Mr. Stevens' affidavit is not documentary evidence on which the plaintiffs' action is based. Rather, it is much more akin to a lengthy exhibit containing evidentiary material. For this reason, this court cannot consider Mr. Stevens' affidavit at the motion to dismiss stage.

Further, the portions of Mr. Stevens' affidavit that have any potential to remedy the deficiencies in the plaintiffs' complaint are his opinions. The court can only consider facts at the motion to dismiss stage, not opinions. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) ("To survive a motion to dismiss, a complaint must contain sufficient *factual* matter, accepted as true, to state a claim to relief that is plausible on its face.") (emphasis added) (internal quotation marks omitted); *see also Kramer v. Van Dyke Pub. Sch.*, 918 F. Supp. 1100, 1104 (E.D. Mich. 1996) ("The court need not . . . accord the presumption of truthfulness to any legal conclusion, opinions or deductions, even if they are couched as factual allegations."); *Frederick v. Se. Pa. Transp. Auth.*, 892 F. Supp. 122, 124 (E.D. Pa. 1995) ("In considering a Rule 12(b)(6) motion, a court must primarily consider the allegations contained in the complaint, although matters of public record, orders, items appearing in the record of the case and exhibits attached to the complaint may also be taken into account."); *cf. Fin. Acquisition Partners LP v. Blackwell*, 440 F.3d 278, 285–86 (5th Cir. 2006) (affirming district court's decision striking opinion/conclusion portions of expert affidavit submitted with complaint when ruling on motion to dismiss under Rule 12(b)(6) because "[Private Securities Litigation Reform Act] complaints must allege specific facts demonstrating material misstatements or omissions made with scienter. Even if *non-opinion* portions of an expert's affidavit constitute an instrument pursuant to Rule 10, opinions cannot substitute for facts under the PSLRA"); *DeMarco v. DepoTech Corp.*, 149 F. Supp. 2d 1212, 1221 (S.D. Cal. 2001) (striking expert affidavit attached to class action securities complaint because "considering an expert affidavit would so complicate the procedural posture of a motion to dismiss that it would become virtually indistinguishable from a motion for summary judgment," and pointing out that "[a] better approach might be to include the expert's nonconclusory assertions within specific paragraphs in the complaint" because the court construes nonconclusory allegations of the complaint as true for purposes of a motion to dismiss under Rule 12(b)(6)).

Aside from Mr. Stevens' affidavit, the plaintiffs' only other additions to the amended complaint were two medical device reports. The plaintiffs claim that these two medical device reports—representing 0.09% of the lot—demonstrate that the Perclose device which injured Mr. Irizarry was part of a defective lot. *See* Pls.' 3d Am. Compl. at ¶¶ 27, 54, 74. However, much like previous iterations of the plaintiffs' complaint, this allegation does not articulate *how* the Perclose device violated its PMA requirements. *See Riegel*, 552 U.S. 312, 318 (2008).

This court sympathizes with the plaintiffs' inability to meet this standard without the benefit of discovery. However, the preemption of the plaintiffs' claims comports with Congress's purpose in enacting the MDA. *See* 21 U.S.C. § 360j(g)(1) ("It is the purpose of [the MDA] to encourage, to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of useful devices intended for human use and to that end to maintain optimum freedom for scientific investigators in their pursuit of that purpose.");

see also Gile v. Optical Radiation Corp., 22 F.3d 540, 541 (3d Cir. 1994) (citing 21 U.S.C. § 360j(g)(1)). Therefore, the court must put its sympathies aside and find that the PMA requirements, applicable to the Perclose device through the MDA, preempt the plaintiffs' claims.

The plaintiffs have also failed to allege any state common law duty that the defendants violated. To evade preemption, a claim must be based on a violation of a state law duty that is identical to an existing federal duty. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996). Like its predecessor, the plaintiffs' third amended complaint seeks to enforce the FDCA without providing any basis in state law. The FDCA creates no such private right of action. *See* 21 U.S.C. § 337(a) ("[A]ll . . . proceedings [under the FDCA] for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States."); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001) (holding that "state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly preempted" by FDCA, as amended by MDA); *In re Orthopedic Bone Screw*, 193 F.3d 781, 788 (3d Cir. 1999) ("It is well settled . . . that the FDCA creates no private right of action.").

The plaintiffs repeatedly assert that their claims are parallel to the FDCA. Pls' 3d Am. Compl. at ¶¶ 56–57, 76–77. However, the plaintiffs never identify the state law basis for the claims. Rather, they argue that the "violations alleged are all based on an exclusively federal statutory and regulatory standard of care, which includes no 'requirement which is different from, or in addition to, any requirement applicable under' the Food, Drug and Cosmetic Act and regulations promulgated thereunder." *Id.* at ¶ 57 (quoting 21 U.S.C. § 360k(a)). Therefore, the plaintiffs' claims are not anchored in any specific duty under Pennsylvania law. The Third Circuit has found that such "[g]eneralized common law theories of liability, such as [manufacturing defect and breach of warranty], are precisely the type of claims the MDA sought to preempt." *Williams v. Cyberonics*, 388 F. App'x 169, 171 (3d Cir. 2010).

The plaintiffs' third amended complaint fails to satisfy either of the requirements set forth in the March 28, 2019 order; thus, it appears that the inability to overcome preemption is a fatal flaw in their claims. At this stage, giving the plaintiffs "leave to file yet another amended complaint would [be] futile." *Vurimindi v. City of Philadelphia*, 521 F. App'x 62, 66 (3d Cir. 2013). Accordingly, the court dismisses the third amended complaint with prejudice.