UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

GUY D. DALEY, STARLYNN DALEY, DANA HEAL, SHARON HEAL, and ROBERT NIELSEN,

Plaintiffs,

and

MEDICARE, WISCONSIN PIPE TRADES HEALTH FUND, UNITED HEALTH CARE CONTINENTAL, and WEA TRUST,

Involuntary Plaintiffs,

v.

SMITH & NEPHEW INC., MAXX HEALTH INC., MAXX ORTHOPEDICS INC., MIPRO US INC., PLUS ORTHOPAEDICS LLC, DISANTO TECHNOLOGY INC., and JOHN DOE CORPORATIONS 1-50,

Defendants.

Case No. 17-CV-1315-JPS

ORDER

Plaintiffs bring this action under the Court's diversity jurisdiction to recover for injuries sustained as a result of failed hip replacement implants. All of their claims are premised on Wisconsin statute or common law. (Docket #36). Presently before the Court is a motion to dismiss by Defendant DiSanto Technology Inc. ("DiSanto"). (Docket #48). DiSanto machined the femoral neck component of Plaintiffs' hip implants pursuant to a contract with Defendant MiPro U.S. Inc. ("MiPro"). Those

hip replacement implants are known as the M-COR Modular Hip System (the "M-COR"). DiSanto argues that, as a mere supplier of a component part used in the M-COR, the claims against it are preempted and barred by the Biomaterials Access Assurance Act ("BAAA"), 21 U.S.C. § 1601 *et seq.*, which insulates biomaterials suppliers from liability in medical device failure litigation, subject to a few narrow exceptions. DiSanto's motion to dismiss pursuant to the BAAA is fully briefed and, for the reasons stated below, it will be granted.

1. LEGAL STANDARD

Federal Rule of Civil Procedure 12(b) normally governs motions to dismiss a complaint. Rule 12(b)(6) allows a party to move to dismiss a complaint on the ground that it fails to state a viable claim for relief. Fed. R. Civ. P. 12(b)(6). To state a claim, a complaint must provide "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). In other words, the complaint must give "fair notice of what the. . .claim is and the grounds upon which it rests." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). The allegations must "plausibly suggest that the plaintiff has a right to relief, raising that possibility above a speculative level[.]" *Kubiak v. City of Chicago*, 810 F.3d 476, 480 (7th Cir. 2016) (citation omitted). In reviewing the complaint, the Court is required to "accept as true all of the well-pleaded facts in the complaint and draw all reasonable inferences in favor of the plaintiff." *Id.* at 480–81.

For motions to dismiss brought pursuant to the BAAA, Congress has provided special protocols. *See* 21 U.S.C. § 1603(a)(2); *Mattern v. Biomet, Inc.*, Civ. No. 12-4931 (ES), 2013 WL 1314695, at *1 (D.N.J. Mar. 28, 2013). The Act applies to "any civil action brought by a claimant, whether in a Federal or State court, on the basis of any legal theory, for harm

allegedly caused, directly or indirectly, by an implant." 21 U.S.C. § 1603(b)(1). It provides that "[a] defendant may, at any time during which a motion to dismiss may be filed under applicable law, move to dismiss an action against it on the grounds that the defendant is a biomaterials supplier," and if the defendant: (1) is not a manufacturer of the failed implant; (2) is not a seller of the failed implant; and (3) did not "furnis[h] raw materials or component parts for the implant that failed to meet applicable contractual requirements or specifications." *Id.* § 1605(a)(1)–(3); *see also Whaley v. Morgan Advanced Ceramics, Ltd.*, No. 07–cv–00912, 2008 WL 901523, at *2–3 (D. Colo. Mar. 31, 2008).

When addressing a BAAA motion to dismiss, the Court must rule solely on the basis of the pleadings and any affidavits submitted under Sections 1605(c)(2)(A) and (B). 21 U.S.C. § 1605(c)(3). The submission of affidavits concerning the supplier's liability does not automatically convert a BAAA motion to dismiss into a motion for summary judgment, as would typically occur in any other civil litigation. *See* Fed. R. Civ. P. 12(d); *Marshall v. Zimmer*, No. 99–093–E, 1999 WL 34996711, at *3 (S.D. Cal. Nov. 4, 1999) (The Act "is quite clear that the suppliers can provide affidavits to demonstrate that they are not subject to litigation for their minimal contribution to a medical device ultimately designed, made, and sold by the manufacturer.").[1] Thus, the Act allows trial courts to dismiss biomaterials suppliers from lawsuits prior to discovery. 21 U.S.C. §

[1]Plaintiffs responded to DiSanto's motion as though it was a motion for summary judgment, providing separately numbered paragraphs containing factual assertions and citations to evidence. *See* (Docket #55, #60). This was helpful to the Court in assessing the parties' respective positions, but it does not transform the motion into one for summary judgment since the BAAA authorizes the Court to consider competing affidavits on a motion to dismiss.

1605(c)(2)(A)–(B). Further, under Section 1605(e), dismissal of a supplier must be made with prejudice. *Id.* § 1605(e).[2]

2. ANALYSIS

As will be explained below, the Court finds that DiSanto is protected as a biomaterials supplier under the BAAA. Consequently, the claims against it must be dismissed. First, however, the Court must address Plaintiffs' contention that the BAAA does not govern their claims at all.

2.1 The BAAA Governs Claims Involving Section 510(k) Devices

Plaintiffs first argue that the BAAA does not preempt their claims against DiSanto because the Act does not protect the types of devices at issue here. Plaintiffs distinguish between devices that have received pre-market approval ("PMA") from the Food and Drug Administration and devices that have been authorized for sale under the "Section 510(k)" procedure. The M-COR falls within the latter category. Plaintiffs believe that the BAAA's protection extends only to claims involving PMA devices because only the rigorous PMA process results in meaningful assurances of device safety. No such distinction can be found in the statutory text, and Plaintiffs cannot engraft ambiguity into the statute where none exists.

Plaintiffs' premise is correct: the PMA process is far more meticulous as a safety assessment than the Section 510(k) process. *Medtronic v. Lohr*, 518 U.S. 470, 477 (1996). During the PMA process, "[m]anufacturers must submit detailed information regarding the safety

[2]A supplier dismissed with prejudice under Section 1605(e) may nevertheless be rejoined later in the litigation if the evidence reveals a basis for contribution or indemnification. 21 U.S.C. § 1606(a).

and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission." *Id.* Yet, not all devices subject to the PMA process actually undergo it. *See id.* In many instances, devices can be released to the public without undergoing PMA review if they are "substantially equivalent" to approved devices that predate the creation of the PMA process in the Medical Device Amendments Act of 1976 (the "MDA"). *See* 21 U.S.C. § 360e(b)(1)(B).

Devices that fall under this exception to the PMA rule can get to market if they comply with the less onerous appraisal set forth in 21 U.S.C. § 360(k). *Lohr*, 518 U.S. at 478. This is known as the "Section 510(k)" process, after the number of the section in the original act. *Id.* For a Section 510(k) examination, the manufacturer must submit a premarket notification showing that its device is substantially equivalent to a pre-existing device. *Id.* If this is shown, no further regulatory analysis is done, at least until the PMA process is initiated for the pre-existing device to which the new device is substantially equivalent. *Id.* Section 510(k) review is minimal, requiring an average of only 20 hours' work. *Id.* at 479.

While Plaintiffs' premise is correct, their conclusion concerning the reach of the BAAA is not. The Act draws no distinction between PMA and Section 510(k) devices. By its text, the BAAA applies to "any civil action brought by a claimant, whether in a Federal or State court, on the basis of any legal theory, for harm allegedly caused, directly or indirectly, by an implant." *Id.* § 1603(b)(1). An "implant" includes "a medical device" intended by its manufacturer to be surgically placed in the human body for at least thirty days. *Id.* § 1602(5)(A)(i). "Medical device" is, in turn, defined by reference to 21 U.S.C. § 321(h) and includes implants that are intended to affect the structure or function of the human body. *See* 21

U.S.C. § 321(h). Under these broad definitions, the M-COR is undoubtedly an "implant," and Plaintiffs do not argue otherwise.

Though the statute does not distinguish between the types of review imposed on implants, Plaintiffs nevertheless maintain that Congress could not have intended to preempt claims involving Section 510(k) devices because those devices do not have the same federal safety oversight that PMA devices do. Plaintiffs cite Congress' introductory findings in the BAAA, which include that "under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 *et seq.*) manufacturers of medical devices are required to demonstrate that the medical devices are safe and effective, including demonstrating that the products are properly designed and have adequate warnings or instructions." *Id.* § 1601(6). According to Plaintiffs, Congress was referring only to the PMA process here, as the Section 510(k) process does not require a determination that a device is safe and effective. (Docket #54 at 8–9). Thus, in Plaintiffs' view, the protections afforded by the BAAA should only extend to devices that undergo the PMA process, because Congress' purpose was to shield component suppliers for implants that have been thoroughly reviewed for safety and effectiveness. *Id.*

Whether or not this is a reasonable view as a matter of policy, the Supreme Court directs that a clear statutory text must be enforced as-is. *Engine Mfrs. Ass'n v. S. Coast Air Quality Mgmt. Dist.*, 541 U.S. 246, 252 (2004). Unless Congress expresses a clear intention to the contrary, a statute's plain language is conclusive. *Lamie v. U.S. Tr.*, 540 U.S. 526, 534 (2004) ("It is well established that 'when the statute's language is plain, the sole function of the courts—at least where the disposition required by the text is not absurd—is to enforce it according to its terms.'") (quoting

Hartford Underwriters Ins. Co. v. Union Planters Bank, N.A., 530 U.S. 1, 6 (2000)). In other words, if a statute's text gives a clear answer to the question presented, that is the beginning and the end of the court's inquiry. *Star Athletica, L.L.C. v. Varsity Brands, Inc.*, 137 S. Ct. 1002, 1010 (2017).

The answer afforded by the BAAA is unmistakable: no claim can proceed against a supplier of a component part for an "implant," a term which the statute defines very broadly without reference to the type of FDA review the implant receives. For that reason, Plaintiffs' reliance on *Lohr* and *Riegel* is misplaced. *Lohr*, 518 U.S. at 483–84; *Riegel v. Medtronic*, 552 U.S. 312, 323–26 (2008). In those cases, the parties disputed whether certain types of state law claims were preempted by the MDA, which preempts state law "requirements" that are "different from, or in addition to" federal requirements for medical devices. *See* 21 U.S.C. § 360k(a). In *Lohr*, the Court held that the Section 510(k) process does not impose sufficiently device-specific requirements to trigger Section 360k(a) preemption. *Lohr*, 518 U.S. at 496–501. In *Riegel*, the Court held that the PMA process does impose such requirements. *Riegel*, 552 U.S. at 323–326. In this case, unlike *Lohr* and *Riegel*, the difference between the PMA and Section 510(k) regulatory pathways is of no moment, for the BAAA's term "implant" is not ambiguous as was the MDA's term "requirements."

Additionally, in *Lohr* and *Riegel* the Court engaged in several interpretive maneuvers not available here, including applying a presumption against preemption and consulting Congress' intentions as reflected in the legislative history. *See Lohr*, 518 U.S. at 485–86. Those canons of construction are not applicable in this case, for here Congress has provided an express preemption clause, the scope of which is

determined by the plain meaning of its text. *Puerto Rico v. Franklin California Tax-Free Trust*, 136 S. Ct. 1938, 1946 (2016). Congress' intent as expressed in the BAAA's text is in no way "garbled," as Plaintiffs assert. (Docket #54 at 4). The statute plainly provides that a Section 510(k) device like the M-COR is an "implant" and is therefore governed by the BAAA, and no other portion of the statute or its general structure clearly expresses a different intention. *City of Chicago v. Sessions*, 888 F.3d 272, 284 (7th Cir. 2018) ("It is well-established that the plain language of a statute is 'the best indicator of Congress's intent,' and that '[a]bsent a clearly expressed legislative intention to the contrary, that language must ordinarily be regarded as conclusive.'") (quoting *Fed. Nat'l Mortg. Ass'n. v. City of Chicago*, 874 F.3d 959, 962 (7th Cir. 2017)).

Ultimately, Plaintiffs' argument rests on the supposition that Congress sought but failed to distinguish between PMA and Section 510(k) devices in the BAAA. Standing alone, this is a specious claim, for it is unlikely that any regulator could miss the prevalence of Section 510(k) devices in the marketplace. *See Lohr*, 518 U.S. at 479 ("[T]he § 510(k) premarket notification process [has become] the means by which most new medical devices—including Class III devices—[are] approved for the market."). For that reason, we would expect Congress to plainly express any sought-after distinction between PMA and Section 510(k) devices. It has not done so. Moreover, it would not make sense for Congress to punish component suppliers differently based on the type of regulatory approval obtained by the manufacturer of the final implant, a process in which the supplier ostensibly plays no part. Most importantly, however, Plaintiffs' argument is belied by the statutory text, which dooms their position from the start. If Plaintiffs believe that a distinction between PMA

and Section 510(k) devices is appropriate for the BAAA, their remedy lies with Congress—not this Court.

2.2 DiSanto is a Biomaterials Supplier Protected by the BAAA

Having determined that the BAAA governs Plaintiffs' claims against DiSanto, the Court turns to the statutory inquiry as to whether those claims should be dismissed.[3] As noted above, to prevail on a motion to dismiss under the BAAA, the defendant must demonstrate that: (1) it is a "biomaterials supplier"; (2) it is not a manufacturer of the failed implant; (3) it is not a seller of the failed implant; and (4) it did not provide raw materials or component parts that failed to meet applicable contractual requirements or specifications. 21 U.S.C. § 1605(a)(1)–(3).

First, DiSanto qualifies as a biomaterials supplier, which is "an entity that directly or indirectly supplies a component part or raw material for use in the manufacture of an implant." *Id.* § 1602(1)(A). A "component part" is "a manufactured piece of an implant," including a piece that: "(i) has significant non-implant applications; and (ii) alone, has no implant value or purpose, but when combined with other component parts and materials, constitutes an implant." *Id.* § 1602(3). A "raw material" is "a substance or product that[:] (A) has a generic use; and (B) may be used in an application other than an implant." *Id.* § 1602(8).

The affidavits submitted by DiSanto establish that it is a contract manufacturer whose sole role with respect to the hip implants in this case

[3]In its motion, DiSanto concedes that it manufactured the femoral necks used in the implants for Plaintiffs Guy Daley and Sharon Heal. (Docket #49 at 2). However, it asserts that it did not manufacture the femoral neck for Plaintiff Robert Nielsen's implant. *Id.* at 3. Plaintiffs agree, contending that Nielsen asserts no claims against DiSanto. (Docket #55 ¶ 10). The Court considers any potential claims by Nielsen against DiSanto to be withdrawn.

was to machine a piece of metal pursuant to contractual specifications that eventually became a component of an implant. DiSanto used a piece of titanium, as specified by MiPro, as the base material to machine the femoral neck of the M-COR. Titanium has many uses other than medical device manufacturing. DiSanto thus transformed raw material into a component part of the M-COR. The femoral necks machined by DiSanto were not completed medical devices and could not be implanted into a human being without additional components and numerous other manufacturing steps and quality checks, which for the M-COR were performed by others, not DiSanto. DiSanto therefore claims that it qualifies as a biomaterials supplier as defined in the BAAA.

Plaintiffs disagree. They contend that DiSanto incorporated many of its own design inputs into the femoral necks it produced. Plaintiffs theorize that the BAAA does not insulate component "designers" as opposed to component "manufacturers" who simply follow design specifications, particularly when, as here, Plaintiffs allege that those "poor design decisions" contributed to the failure of the M-COR as a whole. (Docket #54 at 9–10). Specifically, Plaintiffs' expert opines that DiSanto's design was flawed in three ways: (1) it used rolled plate instead of bar stock; (2) it used a wire EDM machine instead of forging or casting; and (3) it oriented the plate material incorrectly relative to the grain. *See* (Docket #57 at 4–7). According to Plaintiffs, these defects caused the femoral necks to break, requiring total hip revisions to replace the failed implants. (Docket #55 at 12–13).

Plaintiffs' proposed distinction is of their own invention and is unsupported by any legal authority. What's more, it is inconsistent with the BAAA's statutory scheme, which carefully catalogs the players in

implant production, including device manufacturers, device sellers, and component or raw materials suppliers. Even if DiSanto participated in the design of its femoral necks, a component designer is not a category recognized in the BAAA. Yet, tellingly, the Act does provide that manufacturers of the final implant are not immune from suit. In enacting this scheme, Congress apparently sought to insulate component suppliers and place all the risk on device manufacturers for the failure of the implant, whether caused by a flaw in the entire implant or one of its component parts. In this case, if MiPro is held liable for the harm Plaintiffs suffered and it believes DiSanto is responsible for indemnity or contribution, it can seek such relief. Plaintiffs desire a direct route to DiSanto's pocketbook, but Congress has forbidden this.

Additionally, Plaintiffs' designer-manufacturer division is not realistic. Of course an implant manufacturer like MiPro would expect a component supplier like DiSanto to apply some of its own metallurgical or machining expertise to its assigned task. Why else hire a specialized supplier? Given its lack of skill in this particular realm, MiPro could not be expected to dictate each and every action DiSanto was to take in creating the femoral necks. Again, the BAAA forces MiPro to shoulder the risk that DiSanto might make a mistake in producing a component of the M-COR. As a result, the Court finds that DiSanto is a biomaterials supplier under the BAAA despite the design inputs it may have provided in machining the femoral necks.

The final inquiry the Court must undertake is whether DiSanto falls outside the BAAA's protection because it was a manufacturer or a seller of the failed implant, or because its femoral necks failed to meet applicable contractual requirements or specifications. 21 U.S.C. § 1605(a)(1)–(3).

Plaintiffs concede that DiSanto was not a manufacturer or seller of the M-COR. (Docket #55 at 9–10). They argue instead that the components DiSanto supplied did not meet MiPro's specifications. *Id.* at 10–11. Under the BAAA, a biomaterials supplier may "be liable for harm to a claimant caused by an implant if the claimant in an action shows, by a preponderance of the evidence," that the supplier "fail[ed] to meet applicable contractual requirements or specifications." 21 U.S.C. § 1604(d). Additionally, the failure to meet the contractual specifications must be "an actual and proximate cause of the harm to the claimant." *Id.* § 1604(d)(2).

In this connection, Plaintiffs cite an international quality standard, ISO 13485:2003, Medical Devices—Quality Management Systems—Requirements for Regulatory Purposes. This standard was incorporated by reference into MiPro's specification. According to Plaintiffs, it required DiSanto to, among other things, obtain "design and development validation" to ensure that the femoral necks were "capable of meeting the requirements for the specified application or intended use." (Docket #56-3 at 19). Plaintiffs argument goes as follows:

> Obviously, the necks were not capable of meeting the requirements of their intended use in the case of Daley and Heal. DiSanto chose, without apparent input or approval from MiPro, the type of raw material stock and the manufacturing process without apparently validating those decision [sic]. Those acts constituted a breach of the Specification MiPro provided to DiSanto and are proximate causes of the injuries sustained by Daley and Heal in this case.

(Docket #54 at 11).

There are two strands of argument within this passage, but neither has merit. First, to the extent Plaintiffs contend that DiSanto was not

authorized to make unilateral design decisions, and therefore any design input by DiSanto constituted a violation of MiPro's specification, the evidence flatly contradicts this position. The specification DiSanto received from MiPro was not exacting in its detail. It left room for DiSanto to incorporate design decisions that would achieve the goals MiPro set. *See* (Docket #58 at 10). Plaintiffs' own expert concedes this; indeed, his theory is not that DiSanto deviated from MiPro's specification, but that DiSanto made negligent decisions about the design elements left to its discretion. *See* (Docket #57 at 4–7). As explained above, the BAAA does not remove component suppliers from its protection even when they make design decisions that allegedly contributed to harm the patient. And, certainly, ISO 13485 says nothing about whether DiSanto should have made its own design decisions, only that design validation needed to be performed "in accordance with planned arrangements," whatever that means. (Docket #56-3 at 19). Thus, the mere act of incorporating its own design input was not a deviation from specifications as contemplated in the BAAA.

Second, to the extent Plaintiffs believe that the femoral necks were not capable of meeting the requirements for their intended use, in violation of ISO 13485, simply because the implants failed, this too is incorrect. As an initial matter, the specific subsection of ISO 13485 Plaintiffs cite, Section 7.3.6, applies to designers of medical devices, not component manufacturers like DiSanto. *See id.* at 8 (providing that ISO 13485 governs the conduct of organizations that provide "medical devices"). Similar to the BAAA, the "design" at issue in ISO 13485 is that of the final implant, not its component parts.

Furthermore, the cited standard is, at best, an open-ended statement which could conceivably be violated by any defect whatsoever in the final product. Given that the purpose of the BAAA is to broadly shield component suppliers from liability in implant cases, *see* 21 U.S.C. § 1601, it follows that deviation from design specifications should be more specific than what Plaintiffs have alleged, which amounts to no more than a claim of negligence. Stated another way, it would be absurd for the "design deviation" exception to the BAAA to incorporate the functional equivalent of negligence liability, otherwise all state-law negligence claims could survive the BAAA's preemption clause. Plaintiffs cite no court espousing their view of the "design deviation" exception, and this Court will not be the first.

For these reasons, the Court concludes that DiSanto is a biomaterials supplier whose conduct does not fall within any of the exceptions to the protection of the BAAA. This, in turn, requires that the Court dismiss the claims against it with prejudice.[4]

3. CONCLUSION

For the reasons stated above, the Court is obliged to granted DiSanto's motion to dismiss the claims against it pursuant to the BAAA.[5]

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[4]In passing, Plaintiffs cite *Janusz v. Symmetry Medical Inc.*, 256 F. Supp. 3d 995 (E.D. Wis. 2017), a recent case involving similar allegations of a faulty femoral neck in an M-COR. One of the defendants who manufactured the femoral neck sought summary judgment, but not pursuant to the BAAA. Whatever the reason behind the defendant's choice not to invoke the BAAA, the result is that the *Janusz* decision has little bearing on the Court's resolution of this case.

[5]At the end of their brief, Plaintiffs make a request for additional discovery pursuant to Section 1605(c)(1)(B)(i), which allows a court to permit discovery on issues directly relevant to whether the biomaterials supplier met applicable contractual requirements or specifications. 21 U.S.C. § 1605(c)(1)(B)(i).

Accordingly,

IT IS ORDERED that Defendant DiSanto Technology Inc.'s motion to dismiss (Docket #48) be and the same is hereby **GRANTED**;

IT IS FURTHER ORDERED that Plaintiffs' motion to seal certain exhibits filed in connection with their response to DiSanto's motion (Docket #53) be and the same is hereby **GRANTED**;

IT IS FURTHER ORDERED that Plaintiffs' claims against Defendant DiSanto Technology Inc. be and the same are hereby **DISMISSED with prejudice** pursuant to 21 U.S.C. § 1605(e); and

IT IS FURTHER ORDERED that Defendant DiSanto Technology Inc. be and the same is hereby **DISMISSED** from this action.

Dated at Milwaukee, Wisconsin, this 21st day of June, 2018.

BY THE COURT:

J. P. Stadtmueller
U.S. District Judge

This request must be denied, as Plaintiffs have not identified any alleged deviation from any specification or other contractual requirement that could be established with the benefit of further discovery. (Docket #54 at 11). The mere mention of a need for discovery, without some minimal explanation of what benefit it might provide, is insufficient to delay the expeditious dismissal of biomaterials suppliers that the BAAA is designed to facilitate. 21 U.S.C. § 1601(15)(B).