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COMMONWEALTH OF MASSACHUSETTS

NORFOLK, ss.

SUPERIOR COURT
CIVIL ACTION NO.
2018-00721

PATRICIA M. DUNN

vs.

GENZYME CORPORATION

MEMORANDUM OF DECISION AND ORDER ON DEFENDANT'S MOTION TO DISMISS AND/OR STRIKE PLAINTIFF'S FIRST AMENDED COMPLAINT

In this action, plaintiff Patricia M. Dunn alleges that immediately after her physician injected her knees with Synvisc-One®, a viscosupplement used to treat knee pain associated with osteoarthritis, she suffered from adverse side effects that led to permanent injury. Synvisc-One® is a Class III medical device that was approved by the United States Food and Drug Administration ("FDA") through the pre-market approval ("PMA") process established by the Medical Device Amendments to the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et. seq. ("MDA"). Dunn maintains that Genzyme failed to comply with both the PMA requirements that the FDA imposed on the device and the FDA's Current Good Manufacturing Practices, and that as a result, she was provided with "adulterated" Synvisc-One® injections. Dunn asserts four common law claims against Genzyme – negligent failure to warn, breach of warranty, negligent manufacture, and products liability – as well as a claim under G. L. c. 93A. Genzyme now moves to dismiss all the claims asserted against it, arguing the claims are preempted under the MDA.[1] For the reasons that follow, the motion is **DENIED**.

[1] Initially, Genzyme also moved to strike Count V (violation of G. L. c. 93A) of the First Amended Complaint as untimely. However, in its reply brief, Genzyme made clear it was no longer pressing this argument.

DISCUSSION

"[T]he MDA expressly pre-empts ... state requirements 'different from, or in addition to, any requirement applicable ... to the device' under federal law." *Riegel* v. *Medtronic, Inc.*, 552 U.S. 312, 321 (2008), quoting 21 U.S.C. § 360k(a). "State requirements" include common law duties. *Id* at 324. The statute, however, "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. Accordingly, plaintiffs may still bring so-called "parallel claims," i.e., tort and other claims that are based on the violation of federal regulations. See *id.* See also *Bausch* v. *Stryker Corp.*, 630 F.3d 546, 552 (7th Cir. 2010) ("[S]ection 360k protects a medical device manufacturer from liability to the extent that it has *complied* with federal law, but it does not extend protection from liability where the [state tort] claim is based on a *violation* of federal law.").

In the context of the present motion, the parties dispute the specificity with which a plaintiff must allege a violation of FDA regulations to properly plead a parallel claim and avoid dismissal under Rule 12(b)(6). Genzyme argues that plaintiffs are required to point to the specific FDA regulations allegedly violated and that therefore Dunn's First Amended Complaint must be dismissed because she only alleges general violations of the FDA's PMA requirements and Current Good Manufacturing Practices. Dunn, in turn, argues that such generality is sufficient to state a parallel claim.

Neither the U.S. Supreme Court nor the First Circuit Court of Appeals has squarely addressed the required level of pleading specificity. Other circuits are apparently split on the issue. The Eleventh Circuit and several federal district courts have indicated that plaintiffs must point to the precise requirement violated to survive preemption. See *Wolicki-Gables* v. *Arrow Int'l*, 634 F.3d 1296, 1301-1302 (11th Cir. 2011); *In re Medtronic, Inc. Sprint Fidelis Leads*

Prods. Liab. Litig., 592 F.Supp.2d 1147, 1158 (D. Minn. 2009), aff'd sub nom., 623 F.3d 1200 (8th Cir. 2010); *Ilarraza* v. *Medtronic. Inc.,* 677 F. Supp. 2d 582, 588-589 (E.D.N.Y. 2009); *Parker* v. *Stryker Corp.*, 584 F. Supp. 2d 1298, 1301 (D. Colo. 2008); *White* v. *Stryker Corp.*, 818 F. Supp. 2d 1032, 1039 (W.D. Ky. 2011).[2] The Seventh and Fifth Circuits and several other federal district courts, however, have indicated that plaintiffs need only allege a manufacturing defect which plausibly resulted from violation of the FDA requirements. *Bausch*, 630 F.3d at 560; *Bass* v. *Stryker Corp.*, 669 F.3d 501, 510-511 (5th Cir. 2012); *Hofts* v. *Howmedica Osteonics Corp.*, 597 F. Supp. 2d 830, 838 (S.D. Ind. 2009); *Steiden* v. *Genzyme Biosurgery*, 2012 U.S. Dist. LEXIS 99689, *8-13 (W.D. Ky. July 18, 2012); *Rosen* v. *St. Jude Med., Inc.*, 41 F. Supp. 3d 170, 181 (N.D.N.Y. 2014).[3]

After carefully reading these and other decisions on the issue, the Court agrees with those courts that have imposed a less exacting pleading standard upon plaintiffs alleging violations of FDA requirements. See *Waltenburg* v. *St. Jude Med., Inc.*, 33 F. Supp. 3d 818, 832 (2014) (after

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[2] The Court notes that one federal district court has commented that:

> [T]he Eleventh Circuit ... appears to have stepped back from *Wolicki-Gable*'s requirements. In *Mink* [v. *Smith & Nephew, Inc.*, 860 F.3d 1319 (11th Cir. 2017)] and *Godelia* [v. *Doe 1*, 881 F.3d 1309 (11th Cir. 2018)], the Eleventh Circuit ruled that a claim for manufacturing defect passes muster even if a plaintiff fails to identify device-specific regulations that were violated. *Mink*, 860 F.3d at 1331 n.3 ("To the extent [the defendant] argues that some of the federal regulations cited by [the plaintiff] are not sufficiently device-specific, we reject its argument."); and *Godelia*, 881 F.3d at 1320 ("The fact that the regulations identified are not device-specific is of no moment."). The holdings in *Mink* and *Godelia* are directly at odds with *Wolicki-Gables*, and appear to announce a new standard the Eleventh Circuit is directing courts to apply.

Rowe v. *Mentor Worldwide, LLC*, 297 F. Supp. 3d 1288, 1299 (M.D. Fla. 2018).

[3] Even the Superior Court seems divided on the issue. Compare *Morris* v. *Rotolo*, 2014 Mass. Super. LEXIS 220 *4-5 (January 15, 2014) (Budd, J.) (plaintiff required to allege in detail the federal requirement violated) with *Phillips* v. *Medtronic, Inc.*, 2012 Mass. Super. LEXIS 3435, *18-21 (Mass. Super. Ct. July 10, 2012) (Troy, J.) (concluding that "plaintiffs need not plead a parallel claim with any degree of heightened specificity"). The Court notes, however, that *Morris* adopted the higher pleading standard without explanation, while *Phillips* declined to do so after examining the circuit split highlighted above.

reviewing case law discussing issue, reaching same result). In so ruling, the Court finds the reasoning in *Bausch* especially persuasive. The Seventh Circuit Court explained:

> [I]n the context of Class III medical devices, much of the critical information is kept confidential as a matter of federal law. The specifications of the FDA's premarket approval documents, for example, are confidential, and there is no public access to complete versions of these documents. An injured patient cannot gain access to that information without discovery.... If plaintiffs must allege that the defendant violated a particular FDA-approved specification before discovery, then it is difficult to appreciate how any plaintiff will ever be able to defeat a Rule 12(b)(6) motion.... [I]n analyzing the sufficiency of pleadings, a plaintiff's pleading burden should be commensurate with the amount of information available to them.

630 F.3d at 560-561 (internal quotation marks and citations omitted). Here, there is nothing to indicate that Dunn had access to any publicly available information which would have permitted her to plead with greater specificity. Accordingly, the Court concludes that, given the amount of information to which she had access, Dunn has provided sufficient allegations to avoid preemption and survive Genzyme's motion. See *Steiden*, 2012 U.S. Dist. LEXIS 99689, at *12-13 (denying motion to dismiss similarly pled complaint alleging that plaintiff was injected with adulterated Synvisc-One®).[4]

CONCLUSION AND ORDER

For the forgoing reasons, the Defendant's Motion to Dismiss and/or Strike Plaintiff's First Amended Complaint is **DENIED**.

Elaine M. Buckley
Justice of the Superior Court

Dated: April 16, 2019

[4] The Court also rejects Genzyme's alternative argument that, even if the claims are not preempted, the First Amended Complaint otherwise fails to comply with the standard set out in *Iannochino* v. *Ford Motor Co.*, 451 Mass. 623, 636 (2008). Although the complaint is certainly pled in a bare bones fashion, the allegations state a plausible claim for relief. Dunn has provided a sufficient causal connection between a potential violation of the FDA's regulations and the alleged injuries she suffered.

From: AppealsCtClerk@appct.state.ma.us
Sent: Friday, June 07, 2019 4:00 PM
To: Dougherty, John C.
Subject: 2019-J-0239 - Notice of Docket Entry

COMMONWEALTH OF MASSACHUSETTS

APPEALS COURT CLERK'S OFFICE

June 7, 2019

RE: No. 2019-J-0239
Lower Ct. No.: 1882CV00721

PATRICIA M. DUNN
vs.
GENZYME CORPORATION

NOTICE OF DOCKET ENTRY

Please take note that on June 7, 2019, the following entry was made on the docket of the above-referenced case:

ORDER: The plaintiff brings state common law claims arising out of the administration to her of defendant's medical device, a viscosupplement used to treat knee pain. Because the product is a class III medical device approved under the Medical Device Amendments to the Food, Drug and Cosmetic Act, 21 U.S.C. s.s. 301 et seq., plaintiff's state law claims are expressly preempted if they purport to impose duties that are "different from, or in addition to, any requirement applicable . . .to the device under federal law." 21 U.S.C. s. 360k(a). Accordingly, to survive preemption the plaintiff must allege that the defendant violated federal law, and the issue before me on this c. 231, s. 118 petition is whether the plaintiff pled her claims with sufficient particularity to avoid the preemption statute. The defendant claims that the plaintiff must specifically identify the federal law that the defendant allegedly violated, and how the law was violated. The plaintiff's complaint, as pled, does not contain such specificity, but does contain general allegations that the defendant violated FDA "premarket approval requirements" for the product, as well as "Good Manufacturing Practices." The motion judge held that the pleading was sufficient, and denied the defendant's motion to dismiss. As the motion judge recognized, however, there is a diversity of opinion -- both in the federal circuit courts of appeal and the trial courts of the commonwealth -- over how specific a pleading must be to allow a case to move forward in the face of the federal preemption statute. Compare Wolicki-Gables v. Arrow Int'l, Inc., 634 F.3d 1296 (11th Cir. 2011) and Bryant v. Medtronic, Inc., 623 F.3d 1200 (8th Cir. 2010) with Bausch v. Stryker Corp., 630 F.3d 546, 560 (7th Cir. 2010). See also Phillips v. Medtronic, SUCV2009-05286-A (Mass. Super. 2012); Morris v. Rotolo, No. 12-04046, (Mass. Super. 2014).

The defendant asks that I grant it leave to take an interlocutory appeal from the denial of its motion to dismiss. The defendant raises a serious legal issue as to whether the plaintiff's pleading is sufficient to avoid preemption. I note as well that the pleading issue raised here could evade review, absent interlocutory appeal.

The petition for leave to appeal is granted. The defendant is to file a notice of appeal in the Superior Court forthwith, after which the record is to be assembled and transmitted to this court. The case is stayed in the Superior Court pending the decision from this court. (Englander, J.) *Notice/Attest/Buckley, J

Very truly yours,

The Clerk's Office

Dated: June 7, 2019

To: John Dougherty, Esquire
Matthew J. Dunn, Esquire
Norfolk Superior Court Dept.

If you have any questions, or wish to communicate with the Clerk's Office about this case, please contact the Clerk's Office at 617-725-8106. Thank you.

CERTIFICATE OF SERVICE

I, John C. Dougherty, attorney for Genzyme Corporation, hereby certify that on this 10th day of September, 2019, true and correct copies of the foregoing BRIEF OF DEFENDANT-APPELLANT GENZYME CORPORATION were electronically filed pursuant to the Massachusetts Rules of Electronic Filing, and served by first-class mail, postage prepaid, on the following counsel of record for the Plaintiff:

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/s/ John C. Dougherty
John C. Dougherty