UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

STEPHEN GOODELL,	*	
	*	
Plaintiff,	*	
	*	
v.	*	Civil Action No. 18-cv-10694-IT
	*	
BAYER HEALTHCARE PHARMACEUTICALS INC., et al.,	*	
	*	
Defendants.	*	

MEMORANDUM & ORDER

September 30, 2019

TALWANI, D.J.

In 2010, Plaintiff Stephen Goodell was administered an injection of Magnevist in connection with an MRI. Magnevist is a gadolinium-based contrast agent ("GBCA") manufactured, marketed, and sold by Defendants Bayer Healthcare Pharmaceuticals Inc., Bayer Corporation, and Bayer Healthcare LLC (collectively "Bayer"). Plaintiff alleges that the gadolinium from the 2010 injection remains in his body and has caused him injury. Before the court is Bayer's Motion to Dismiss [#54]. Bayer contests the court's personal jurisdiction over Bayer. Bayer also challenges Plaintiff's claims for relief, arguing that: 1) Plaintiff's claims are preempted by federal law regulating the labelling of Magnevist, 2) the complaint fails to identify a cognizable injury and causally connect that injury to Magnevist, 3) Plaintiff cannot obtain relief under Massachusetts' Consumer Protection Law because of a statutory exemption for government-approved activity, 4) Plaintiff does not have standing to seek injunctive relief, and 5) that Plaintiff's claims are time-barred. The court ALLOWS Bayer's motion to dismiss for failing to sufficiently allege personal jurisdiction over Bayer and because the claims, as pleaded,

are federally preempted. However, Plaintiff is granted leave to amend the complaint.

I. Factual Background as Set Forth in the Complaint

In 2010, when Plaintiff was administered Magnevist, studies showed that the specific type of GBCA contained in Magnevist (linear GBCAs) was more likely than another type of GBCA (macrocyclic GBCAs) to result in retention of gadolinium in the body. First Amended Complaint ¶¶ 38-39 [#49] ("Complaint"). However, the manufacturers of Magnevist and other GBCAs did not share this information with consumers or physicians. Compl. ¶ 46. Based on evidence of an association between GBCAs and a type of kidney disease, the FDA released a warning regarding the release of gadolinium from linear GBCAs like Magnevist in 2007. Compl. ¶ 47. Defendants also revised the label for Magnevist at that time to include a contraindication for use in people with kidney disease and injury. Compl. ¶ 48.

Around 2012 or 2013, researchers identified evidence that gadolinium retention was connected to illness in patients with normal kidney function. Compl. ¶¶ 52-57. In July 2015, the FDA released a public safety alert that it was investigating the risk of gadolinium retention from repeated use of GBCAs. Compl. ¶ 55. In September 2017, after the FDA voted to add concerns about gadolinium retention on warning labels, GBCA manufacturers, including Defendants, issued a new joint warning to patients with normal kidney function. Compl. ¶¶ 56-57. This warning communicated that gadolinium is retained for months to years, even in healthy patients, and that this retention was more pronounced with linear GBCAs. The warning also directed physicians to advise patients of these concerns. Compl. ¶ 57.

Until recently, members of the medical community generally were not aware of any disease associated with gadolinium for patients with normal kidney function. Compl. ¶ 50.

Plaintiff claims that Defendants failed to properly warn him of the risks posed by linear

GBCAs such as Magnevist in 2010 and failed to communicate that there were safer alternatives available (macrocylic GBCAs). Compl. ¶ 27. As a result of being administered Magnevist, Plaintiff continues to have detectable levels of gadolinium in his body. Compl. ¶ 33. This retained gadolinium can result in fibrosis in organs, skin, and bones, retained gadolinium in the brain, and related injuries. Compl. ¶ 28. Plaintiff alleges that the retained gadolinium has in fact caused him "severe and permanent physical and emotional injuries, including, but not limited to, gadolinium retention in multiple organs . . . the resulting fibrosis in organs, bone, and skin, and its tendency to cross the blood-brain barrier and deposit in . . . the brain." Compl. ¶ 88.

II. Procedural Background

Plaintiff filed his initial Complaint [#1] in the Northern District of California in October 2017. The parties agreed to transfer venue to the District of Massachusetts, the district in which Plaintiff stipulated that the Magnevist was allegedly administered. Parties' Stipulation 4-5 [#24]. However, Defendants expressly reserved the right to challenge personal jurisdiction in this district. Id. at 2. On April 6, 2018, the case was transferred to this district pursuant to 28 U.S.C. § 1406(a). Order [#25].

Following transfer, Plaintiff filed an Amended Complaint [#49] and Defendants filed the pending Motion to Dismiss [#54], which Plaintiff has opposed. Pl.'s Opp'n [#61].

III. Discussion

A. Personal Jurisdiction

Defendants assert first that the action must be dismissed for lack of personal jurisdiction. Two types of personal jurisdiction are recognized under the federal Constitution: "'general' (sometimes called 'all-purpose') jurisdiction and 'specific' (sometimes called 'case-linked') jurisdiction." Bristol-Myers Squibb Co. v. Super. Ct. of Cal., 137 S. Ct. 1773, 1780 (2017).

Plaintiff concedes that the court does not possess general jurisdiction over Bayer. Pl.'s Opp'n 4 [#61]. For specific jurisdiction, the court must consider: (1) whether the claims arise out of or are related to the defendant's in-state activities ("relatedness"), (2) whether the defendant has purposefully availed itself of the laws of the forum state ("purposeful availment"), and (3) whether the exercise of jurisdiction is reasonable under the circumstances ("reasonableness"). Nowak v. Tak How Investments, Ltd., 94 F.3d 708, 712-713 (1st Cir. 1996).

Plaintiff contends that an analysis of Massachusetts' long-arm statute is unnecessary since the bounds of the long-arm statute are coterminous with the bounds of the federal Constitution for the purpose of assessing personal jurisdiction. Pl.'s Opp'n 4-5 [#61] (citing cases). "But in recent cases, [the First Circuit] ha[s] suggested that the Commonwealth's long-arm statute may impose limits on the exercise of personal jurisdiction more restrictive than those required by the Constitution." A Corp. v. All Am. Plumbing, Inc., 812 F.3d 54, 59 (1st Cir. 2016) (reviewing cases) (internal citation omitted). Accordingly, in this diversity action, the court must also consider the forum's long-arm statute. Sawtelle v. Farrell, 70 F.3d 1381, 1387 (1st Cir. 1995). In Massachusetts, that statute is Mass. Gen. Laws ch. 223A, § 3. Section 3(a), for example, provides jurisdiction over companies "transacting any business in this commonwealth." Mass. Gen. Laws ch. 223A, § 3(a). This section has been consistently interpreted to require that the transactions occurring in this state were a "but for" cause of the harm alleged in the claim. Cossart v. United Excel Corp., 804 F.3d 13, 18 (1st Cir. 2015). In other words, the harm must arise out of the transactions that were made in this jurisdiction. Tatro v. Manor Care, Inc., 416 Mass. 763, 767 (1994).

It is the Plaintiff's burden to establish that personal jurisdiction exists over Defendants. A Corp., 812 F.3d at 58. At this stage of the litigation, the court proceeds using the prima facie

standard. Rodriguez v. Fullerton Tires Corp., 115 F.3d 81, 84 (1st Cir. 1997). To do so, the court does not find facts, but merely determines "whether the facts duly proffered, fully credited, support the exercise of personal jurisdiction." Id. The facts proffered cannot merely be "unsupported allegations" but must consist of "evidence of specific facts" that allow a determination that jurisdiction exists. A Corp., 812 F.3d at 58 (internal citations omitted). The court accepts Plaintiff's properly documented allegations as true and construes them in a light most favorable to him. Id.

Plaintiff alleges that he is a resident and citizen of Massachusetts and that the Bayer Defendants are incorporated and have their principal place of business in states other than Massachusetts. Compl. ¶¶ 11, 16-20. Plaintiff alleges that Defendants are authorized to do business in Massachusetts and derive, as Plaintiff alleges, substantial income from their systemic and continuous operations in this state. Compl. ¶¶ 8, 22. Furthermore, Plaintiff alleges that Defendants sell, advertise, market, and / or distribute the specific drug in question, Magnevist, within Massachusetts. Compl. ¶ 22-24. From these facts, Plaintiff concludes that his claim "arises out of Defendant's forum-related activities." Compl. ¶ 20.

Perhaps recognizing that this conclusory legal assessment is not sufficient for this court to exercise jurisdiction over Bayer, see A Corp., 812 F.3d at 58, Plaintiff asserts that "[d]iscovery will reveal that Plaintiff was prescribed [and] received [the injection], and suffered the injuries alleged[,] in the State of Massachusetts." Pl.'s Opp'n 7 [#61]. But the complaint itself is silent on the question of where Mr. Goodell's Magnevist was prescribed, sold, and administered.[1]

[1] Plaintiff also asserted in the Joint Stipulation 2 [#13] that "the alleged injection(s) of [Magnevist] referenced in the Complaint were administered within the District of Massachusetts." Although Plaintiff presumably has personal knowledge of such facts without awaiting discovery, these facts are notably absent from the complaint despite Defendants flagging the personal jurisdiction issue from the outset.

Plaintiff's failure to allege facts relating to this transaction makes any further analysis of the Massachusetts long-arm statute and constitutional analysis premature. The court grants Plaintiff leave to amend the complaint to address the deficiency in the pleadings as it relates to the court's jurisdiction.

B. Challenges to Plaintiff's Claims

The remaining challenges raised in the Motion to Dismiss [#54] relate to whether the claims raised in the complaint are cognizable. To survive a motion to dismiss, the well-pleaded facts in a plaintiff's complaint must "state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). In reviewing a complaint under a Rule 12 motion to dismiss, the court "must distinguish the complaint's factual allegations (which must be accepted as true) from its conclusory legal allegations (which need not be credited)." Cardigan Mountain Sch. v. New Hampshire Ins. Co., 787 F.3d 82, 84 (1st Cir. 2015) (internal citations omitted). The plausible factual allegations, taken as true, must ultimately be able to support the legal conclusion that underlies each claim for relief. See Haley v. City of Boston, 657 F.3d 39, 46 (1st Cir. 2011).

1. Preemption

Plaintiff's claims arise out of Bayer's alleged failure to provide an accurate warning of the risks associated with Magnevist on the product labels. Bayer argues that it could not amend the label on its Magnevist product without FDA approval. Accordingly, Bayer contends that it may not be held responsible under state law for wrongdoing that is effectively the result of the federal regulatory scheme within which it must operate. To do so, Bayer contends, would violate principles of federal preemption. Defs.' Mem. 9-10 [#55].

Plaintiff responds that Bayer had the capacity to change Magnevist's "approved" label

pursuant to the Changes Being Effected ("CBE") regulation. The CBE regulation "permits drug manufacturers to change a label to reflect 'newly acquired information' if the changes 'add or strengthen a . . . warning' for which there is 'evidence of a causal association', without prior approval from the FDA." Merck Sharp & Dohme Corp. v. Albrecht, 139 S. Ct. 1668, 1679 (2019) (internal citations omitted). Indeed, it is "a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times." Wyeth v. Levine, 555 U.S. 555, 570-71 (2009). This includes not only the requirement that the manufacturer craft an adequate label, but also "ensuring that its warnings remain adequate as long as the drug is on the market." Id. at 571. The manufacturer's ability to make changes under the CBE regulation is, however, not plenary; the changes must be based on "newly acquired information" and, in relevant part, be to "add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling." 21 C.F.R. § 314.70; 21 C.F.R. § 314.70(c)(6)(iii). Furthermore, the FDA is empowered to reject labelling changes made under the CBE regulation. See §§ 314.70(c)(6), (7)). Accordingly, absent "clear evidence" that the FDA would not have approved a change to the label, courts should not find that federal preemption foreclosed amendments to the label under the CBE regulation. Wyeth, 555 U.S. at 571. As a result of the CBE regulation, "a drug manufacturer will not ordinarily be able to show that there is an actual conflict between state and federal law such that it was impossible to comply with both." Merck Sharp & Dohme Corp., 139 S. Ct. at 1679.

Although state law causes of action concerning labels may thus survive preemption challenges, a complaint asserting such a claim must still allege facts that would support the labeling deficiency. This pleading requirement was recently exemplified by the First Circuit in In

re Celexa & Lexapro Mktg. & Sales Practices Litig., 779 F.3d 34, 41 (1st Cir. 2015). Under the standard applied in Celexa, the complaint must "allege[] a labeling deficiency that [Bayer] could have corrected using the CBE regulation." Id. Celexa thus requires Plaintiff to provide plausible allegations of "newly acquired information" that manifested after the FDA's approval of the Magnevist label but before Plaintiff's injury. Id. at 42. Necessarily, this requires plausible contentions that between the 2007 FDA approval and the 2010 administration of Magnevist to Plaintiff, Defendants had "newly acquired information" that would "add or strengthen a contraindication, warning, precaution, or adverse reaction for which [there is reasonable evidence of a causal association between a drug and a clinically significant hazard.]" See 21 C.F.R. §§ 314.70 and 201.57(c). The First Circuit's analysis in Celexa compels the court to evaluate any such pleadings for their factual basis and not merely accept Plaintiff's conclusory allegations that such information existed and that it was associated with a clinically significant hazard. Celexa, 779 F.3d at 42.

As Bayer points out, the complaint does not cite any newly acquired information that arose after the FDA's approval of Magnevist's revised label in 2007 and before Plaintiff was administered Magnevist in 2010. Defs.' Mem. 12 [#55]. Without factual allegations that Bayer had new information in this time period such that it could have or should have amended the label pursuant to the CBE regulation, the complaint is barred as preempted. Other district courts have reached this same conclusion. See Klein v. Bayer Healthcare Pharm. Inc., No. 2:18-cv-01424-APG-EJY, 2019 WL 3945652, at *2 (D. Nev. Aug. 21, 2019) and McGrath v. Bayer HealthCare Pharm. Inc., No. 18-cv-2134-RJD-VMS, 2019 WL 2582530 (E.D.N.Y. June 24, 2019) (Both concluding that the plaintiffs must provide, at the pleading stage, additional factual allegations of a causal association between Magnevist and clinically significant adverse reactions prior to the

injection date).

The court grants Plaintiff leave to amend the complaint to address this deficiency in the pleadings. To do so, Plaintiff must sufficiently plead newly acquired information contending that Bayer could have changed its label through the CBE procedures. Celexa., 779 F.3d at 42.

2. Strict Products Liability

Plaintiff has conceded that his claim of Strict Products Liability is not cognizable under Massachusetts law. Pl.'s Opp'n 15 [#61].

3. Cognizable Injury

As Defendants point out, Plaintiff's negligence and Ch. 93A claims require a cognizable injury. See Dusoe v. Mobil Oil Corp., 167 F. Supp. 2d 155, 162 (D. Mass. 2001) ("A negligence action may not be maintained unless one has suffered injury or damage that is causally connected to a breach of duty"); Monteferrante v. Williams-Sonoma, Inc., 241 F. Supp. 3d 264, 271 (D. Mass. 2017) ("A Chapter 93 claim does not accrue, and the limitations period does not begin, until "injury results from the assertedly unfair or deceptive act") (internal citation omitted). Defendants contend that the mere retention of gadolinium is not a cognizable injury since Plaintiff has not alleged any physical symptoms that he currently suffers as a result of this retention and mental anguish concerning the retention is not cognizable since it is not associated with "physical harm manifested by objective symptomatology." Defs.' Mem. 14-15 [#55] (citing Payton v. Abbott Labs, 386 Mass. 540, 557 (1982)). The court disagrees.

Plaintiff has plausibly pleaded that the tissues in his body have retained gadolinium. Compl. ¶ 33 (averring that a urine test taken prior to filing demonstrated continued presence of toxic levels of gadolinium in Mr. Goodell). Plaintiff has also plausibly pleaded that gadolinium retention is a health risk and that the nature of the risk it creates is still being ascertained. Compl.

¶ 57. "To recover for future injuries, plaintiff must show present objective symptoms of illness or disease and he must demonstrate a reasonable probability that injury from that disease will continue into the future. Caputo v. Bos. Edison Co., No. CIV. A. 88-2126-Z, 1990 WL 98694, at *4 (D. Mass. July 9, 1990), aff'd, 924 F.2d 11 (1st Cir. 1991) (citing Anderson v. W.R. Grace & Co., 628 F. Supp. 1219, 1229 (D. Mass. 1986)). Plaintiff has sufficiently pleaded the presence of an objective symptom by plausibly claiming that gadolinium remains in his body. Whether the gadolinium retention creates a "reasonable probability" of future injury is a fact-intensive inquiry not appropriate for resolution on the pleadings.

4. Causation

Defendants contend that Plaintiff has failed to sufficiently plead that his alleged injuries were caused by Magnevist. Defs.' Mem. 15 [#55]. To the extent that Plaintiff claims that his injury is gadolinium retention and injuries that are sequalae to the gadolinium, Plaintiff has sufficiently pleaded that the gadolinium that remains in his body is the result of the Magnevist administered to him in 2010.

5. Plaintiff's Negligence Claim and Rule 8

Defendants argue that "Plaintiff's negligence claim fails pleading rules because it provides over two pages of vague, sprawling legal conclusions, without factual support, that fail to put Bayer on notice of the claims pressed." Defs.' Mem. 15-16 [#55]. The court agrees that Plaintiff's pleadings do not clearly communicate the grounds upon which the claim of negligence rests. See Swierkiewicz v. Sorema N. A., 534 U.S. 506, 512 (2002). However, it is likely that any such deficiencies will be adequately addressed to the extent that Plaintiff is able to amend the pleadings in a manner that obviates Defendants' argument that the complaint is federally preempted. See section 3(b)(1).

6. Magnevist's Exemption from Ch. 93A Claims as a "Government-Approved" Product

Bayer claims that it cannot be sued under Massachusetts' Ch. 93A scheme because the statute excludes "transactions or actions otherwise permitted under laws as administered by any regulatory board or officer acting under statutory authority of . . . the United States." Defs.' Mem. 16-18 [#55] (citing Mass. Gen. L. Ch. 93A, § 3). However, this exemption is a difficult standard to meet: "To sustain it, a defendant must show more than the mere existence of a related or even overlapping regulatory scheme that covers the transaction. Rather, a defendant must show that such scheme affirmatively *permits* the practice which is alleged to be unfair or deceptive." Fleming v. Nat'l Union Fire Ins. Co., 445 Mass. 381, 390 (2005). It is not apparent to the court that the federal regulations affirmatively permit the conduct that Plaintiff alleges, given the availability of the CBE mechanism to amend the product label. Regardless, "[w]hether the acts here were permitted . . . is initially a matter for determination at trial." DiMarzo v. Am. Mut. Ins. Co., 389 Mass. 85, 96 (1983); see also Rafferty v. Merck & Co., 479 Mass. 141, 162 (2018) (Indicating, in dicta, that Ch. 93A claims are available against drug manufacturers for failure to warn in the absence of preemption: "Of course, if one of Merck's own consumers was injured from Merck's brand-name version of the drug as a result of its failure to warn, that failure would have been in the course of Merck's sale of its own product, and therefore 'in the conduct of any trade or commerce.' G. L. c. 93A, § 2 (a)"). Accordingly, dismissal under the exemption is not appropriate.

7. Standing to Seek Injunctive Relief

In his complaint, Plaintiff states that he is "entitled to a preliminary and permanent injunction, enjoining Defendants from continuing the unlawful and unfair business practices described above." Compl. ¶ 96. Defendants' memorandum argues that this request for relief must

be denied because "[t]here is no reason to think Plaintiff would be administered Magnevist in the future if he does not wish to use it." Defs.' Mem. 18 [#55]. Plaintiff has not moved for preliminary relief at this time, and the court finds determination of this issue premature.

8. Statute of Limitations

Defendants argue that Plaintiff's claims have 3- or 4-year statutes of limitations and are time-barred because more than seven years passed between the time when he was administered Magnevist in February 2010, and when he initiated the lawsuit in October 2017. Defs.' Mem. 18 [#55]. Defendants point to studies dating back to 1989 that have documented gadolinium retention and conclude that Plaintiff "could have known about [the gadolinium retention] nearly a decade ago." Id. at 19. According to Defendants, Plaintiff was equipped with the knowledge provided by these medical articles, and thus had "a duty to investigate his condition by seeking advice from the medical field." Id. (citing Cornell v. E.I. Dupont de Nemours & Co. Inc., 841 F.2d 23, 24 (1st Cir. 1988)).

In Massachusetts, "a cause of action does not accrue until the plaintiffs know or reasonably should have known that they were injured as a result of the defendant's conduct." Cornell, 841 F.2d at 24. In Cornell, the First Circuit ruled that the plaintiff reasonably should have known of an injury "[g]iven the nature and extent" of the plaintiff's symptoms—which included expectorating paint—and plaintiff's subjective belief that his symptoms were associated with the product in question. Id. Equipped with this knowledge, plaintiff "had a duty to investigate" by seeking medical advice. Id.

Defendants' comparison of the facts in Cornell to Mr. Goodell's case is inapposite. The complaint does not allege that Plaintiff knew or had reason to know of the articles published in medical journals concerning gadolinium retention, and alleges to the contrary that until recently,

even the medical community generally was not aware of any disease associated with gadolinium for patients with normal kidney function. Id. at ¶ 50. Plaintiff alleges no clear and obvious signs of injury of the severity present in Cornell, and instead claims that he became aware of the retained gadolinium in his body in November 2017 only as a result of a urine test. Compl. ¶ 12. Plaintiff filed this suit one month later. Accordingly, dismissal of the complaint on the pleadings as time barred is improper.

IV. Conclusion

For the reasons stated herein, Defendants' Motion to Dismiss [#54] is ALLOWED on the grounds that Plaintiff has not met his burden to show personal jurisdiction over Bayer and that Plaintiff's claims are federally preempted. Plaintiff is GRANTED leave to amend his complaint. Plaintiff's amended complaint is due **Tuesday, October 22, 2019.**

IT IS SO ORDERED.

Date: September 30, 2019

/s/ Indira Talwani
United States District Judge