UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

PHIL BARTLETT, et al. Plaintiffs, v. PFIZER, INC. Defendant.	)	C. A. No. 11-254M

MEMORANDUM & ORDER

JOHN J. MCCONNELL, JR., United States District Judge.

This matter is before the Court on Defendant Pfizer Inc.'s Motion to Dismiss for failure to state a claim upon which relief can be granted pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. (ECF No. 6.) Plaintiffs Phil and Natalie Bartlett have filed an objection and attached extensive exhibits. (ECF No. 7.) After thorough oral argument on Defendant's motion by both parties, the Court permitted supplemental briefing. (*See* ECF Nos. 15, 16, 17, 18.) After a review of all the pleadings, exhibits, and the relevant substantive and procedural law, the Court GRANTS Defendant's Motion to Dismiss.

I. FACTS ALLEGED IN THE COMPLAINT

Phil Bartlett and his spouse, Natalie Bartlett ("Plaintiffs") bring this lawsuit against Pfizer, Inc. ("Defendant" or "Pfizer"), a pharmaceutical manufacturer. In their *pro se* complaint, Plaintiffs allege that two of Mr. Bartlett's physicians prescribed Lyrica[1] for spinal stenosis, an application Plaintiffs allege was off-label, not clinically tested, and not approved by the Federal

[1] Lyrica is Defendant's brand name for the drug Pregabalin. Lyrica is prescribed for the management of fibromyalgia and other nerve pain. (ECF No. 6-2.)

Drug Administration ("FDA"). (*See* ECF No. 1.) Mr. Bartlett took the prescribed Lyrica between July 15, 2008 and late August 2008. (*Id.* at 2.)

During that approximately six week period, Plaintiffs allege that Mr. Bartlett fell five times, causing significant disabilities and permanent physical impairment.[2] (*Id.*) Mr. Bartlett's falls resulted in second- and third-degree burns to his lower right leg and foot. He also had to undergo emergency surgery to replace the titanium rod in his hip, which was fractured during one of his falls. (*Id.* at 3.) Mr. Bartlett alleges that these falls and the injuries resulting have caused him permanent balance problems, significant daily pain, daily sleep deprivation, and difficulty walking. (*Id.* at 7.)

II. STANDARD OF REVIEW

In reviewing a motion to dismiss filed pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, a court accepts as true the factual allegations of the complaint and draws all reasonable inferences in favor of the plaintiff. *Cook v. Gates*, 528 F.3d 42, 48 (1st Cir. 2008) (citation omitted); *McCloskey v. Mueller*, 446 F.3d 262, 266 (1st Cir. 2006) (citations omitted). To withstand a motion to dismiss, "a complaint must allege 'a plausible entitlement to relief.'" *ACA Fin. Guar. Corp. v. Advest, Inc.*, 512 F.3d 46, 58 (1st Cir. 2008) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)); *Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1950 (2009).

Because Plaintiffs have filed this complaint *pro se*, the Court will view Plaintiffs' pleadings liberally. The Court is "solicitous of the obstacles that pro se litigants face, and while such litigants are not exempt from procedural rules, [the Court] hold[s] pro se pleadings to less demanding standards than those drafted by lawyers and endeavor, within reasonable limits, to guard against the loss of pro se claims due to technical defects." *Dutil v. Murphy*, 550 F.3d 154,

[2] Plaintiff Natalie Bartlett's claims for services provided to Mr. Bartlett due to his injuries are derivative of her husband's claims. (ECF No. 1 at 7.)

158-159 (1st Cir. 2008) (citing *Haines v. Kerner*, 404 U.S. 519, 520 (1972); *Boivin v. Black*, 225 F.3d 36, 43 (1st Cir. 2000); *Instituto de Educacion Universal Corp. v. U.S. Dep't of Educ.*, 209 F.3d 18, 23 (1st Cir. 2000)).

"A Rule 12(b)(6) motion will be granted only if, when viewed in this manner, the pleading shows no set of facts which could entitle plaintiff to relief." *Gooley v. Mobil Oil Corp.*, 851 F.2d 513, 514 (1st Cir. 1988) (citing *Conley v. Gibson*, 355 U.S. 41, 45-48 (1957)). "Therefore, the Court must deny a motion to dismiss if the allegations of the complaint permit relief to be granted on any theory, even one not expressly stated therein." *O'Neil v. Q.L.C.R.I., Inc.*, 750 F. Supp. 551, 553 (D.R.I. 1990) (citing *Adams v. Bell*, 711 F.2d 161, 187 (D.C.Cir. 1983). These "minimal requirements are not tantamount to nonexistent requirements. The threshold may be low, but it is real - and it is the plaintiff's burden to take the step which brings his case safely into the next phase of the litigation." *Gooley*, 851 F.2d at 514. "[A] plaintiff . . . is . . . required to set forth factual allegations, either direct or inferential, respecting each material element necessary to sustain recovery under some actionable legal theory." *Id.* at 515.

III. LEGAL ANALYSIS

Plaintiffs' complaint is not a traditional one in that it does not set forth elements of established common law or statutory causes of action. In Count I, Plaintiffs allege that, during the approximately six weeks that Mr. Bartlett used Lyrica for an off-label application, he fell five times in June, July, and August of 2008. (ECF No. 1 at 3.) In Count II, Plaintiffs allege that a settlement between Defendant Pfizer and the U.S. Department of Justice in 2009 concerning Pfizer's illegal promotion of Lyrica establishes that this illegal promotion was widespread. *Id.* In Count III, Plaintiffs allege that Pfizer failed to clinically test Lyrica for use with Mr. Bartlett's condition, spiral stenosis. (*Id.*) Count IV contains allegations of Pfizer's alleged inappropriate

conduct such as oversimplification and omission of known Lyrica side effects and failure to report adverse events related to side effects as specified in a warning letter from the FDA in May of 2009. (*Id.* at 5-7.) At oral argument, Plaintiffs clarified the bases for their claims against Pfizer—that Mr. Bartlett was prescribed Lyrica for an off-label use, that there was no timely clinical testing of Lyrica for treating Mr. Bartlett's condition, and that Pfizer improperly marketed and promoted Lyrica for off-label uses. Therefore, despite the unconventional format of Plaintiffs' complaint, the Court finds that, based on the complaint, Mr. Bartlett's clarifying arguments and supplemental memorandum, Plaintiffs' allegations in Counts II and IV are based on Defendant's alleged violation of certain provisions of the Federal Food, Drug, and Cosmetic Act ("FDCA") and Counts I and III pertain to Defendant's negligence toward doctors and Lyrica users, specifically Mr. Bartlett.[3]

A. NEGLIGENCE

While Plaintiffs do not specifically allege a negligence claim, setting forth its elements and facts supporting those elements, they do allege that Defendant had two duties to Plaintiffs that it failed to fulfill: a duty to warn Mr. Bartlett and his doctors about using Lyrica for an off-label application and a duty to test Lyrica for off-label applications. Plaintiffs allege that Defendant failed to adequately warn about and test Lyrica, placing their allegations in this regard within Rhode Island negligence jurisprudence. Defendant counters that any duty to warn ran to Mr. Bartlett's physicians not to himself, but nevertheless contends that Plaintiffs' complaint fails to allege any facts supporting a claim that Defendant's warnings to Mr. Bartlett's physicians were inadequate.

[3] Count V articulates Plaintiff Philip Bartlett's specific wage related damages and Count VI appears to state a loss of society claim on behalf of Plaintiff Natalie Bartlett. Neither of these counts represents independent causes of action and, as such, will not be addressed herein. (ECF No. 1 at 7.)

"It is well settled that in order to gain recovery in a negligence action, a plaintiff must establish a legally cognizable duty owed by a defendant to a plaintiff, a breach of that duty, proximate causation between the conduct and the resulting injury, and the actual loss or damage." *Jenard v. Halpin*, 567 A.2d 368, 370 (R.I. 1989) (per curiam) (citing *Atl. Home Insulation, Inc. v. James J. Reilly, Inc.*, 537 A.2d 126, 128 (R.I. 1988)). "In Rhode Island, a defendant has a duty to warn if [it] knew or should have known about the product's dangerous propensities which caused plaintiff's injuries." *La Plante v. Am. Honda Motor Co., Inc.*, 27 F.3d 731, 739 (1st Cir. 1994) (citing *Thomas v. Amway Corp.*, 488 A.2d 716, 722 (R.I. 1985); *Scittarelli v. Providence Gas Co.*, 415 A.2d 1040, 1043 (R.I. 1980)). "Failure to properly perform this duty as a reasonably prudent manufacturer would have under the same or similar circumstances, constitutes actionable negligence." *Id.* (citing *Scittarelli*, 415 A.2d at 1043).

Plaintiffs' complaint is replete with general allegations about Defendant and its drug Lyrica, but fails to link those generalities with their injuries. In their complaint, Plaintiffs allege that Defendant failed to warn Mr. Bartlett that taking Lyrica would cause him to fall, but do not allege any connection between this failure to warn and the Bartlett's injuries. Moreover, Plaintiffs' complaint does not link Defendant's conduct with Mr. Bartlett's physicians' decision to prescribe Lyrica for his spinal stenosis. In fact, according to Plaintiffs, Mr. Bartlett's treating physicians have not tied his falls to his use of Lyrica. Particularly notable is that Plaintiffs actually concede in their opposition to Defendant's Motion to Dismiss that they make no claim that the "defects of Lyrica proximately caused his injury." (ECF No. 7 at 6.)

Plaintiffs point to statistical adverse-event data compiled by various websites from Lyrica users other than Mr. Bartlett who experienced falls as evidence of a connection between his Lyrica use and his falls. (ECF Nos. 7-9, 7-11.) This type of general statistical evidence does not

go far enough to meet Rhode Island's proximate cause standard where a plaintiff must demonstrate that a defendant knew or should have known a product had the propensity to be dangerous and that that very product caused the plaintiff's injuries. *La Plante*, 27 F.3d at 739. Mr. Bartlett submitted during oral argument that his physicians never equated his falls with his use of Lyrica. The fact that other Lyrica users experienced falls does not bridge Plaintiffs' proximate causation gap. Moreover, Plaintiffs argue that Defendant was negligent in testing Lyrica for off-label uses such as the one Mr. Bartlett's doctors prescribed for him, but their complaint is devoid of any allegations that Defendant's alleged failure to test was a proximate cause of Plaintiffs' injuries.

Proximate cause is an essential element of Plaintiffs' claims and its absence from the complaint is fatal. Plaintiffs' candid assertion to the Court that they do not claim that Lyrica proximately caused their injuries is dispositive of this matter, despite all of Plaintiffs' general allegations of Pfizer's misconduct and the problems with its drugs. Therefore, Plaintiffs' negligence-based claims fail to state a claim upon which relief can be granted, and Defendant's Motion to Dismiss is granted on Counts I and III.

B. VIOLATIONS OF THE FDCA

Plaintiffs make several allegations in Counts II and IV against Defendant related to action taken by the FDA against Pfizer, specifically that Defendant settled a lawsuit in which the United States Department of Justice had charged Defendant with illegal promotion of Lyrica and other drugs, it failed to report adverse events, and otherwise failed to comply with FDA regulations. (ECF No. 1 at 4-7.) Defendant argues that these allegations, based on violations of the FDCA, must fail because there is no private right of action under that statute. (ECF No. 6 at 8-9.)

According to Defendants, the FDA alone has the power to enforce the FDCA, and as such, Plaintiffs' claims are preempted by federal law.

Defendants cite *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 349 (2001), for the proposition that there is no private right of action under the FDCA and that state law claims are preempted by federal law in the context of medical devices. (ECF No. 6 at 8-9.) Plaintiffs assert that this preemption should not apply because of the nature of Defendant's conduct and the severity of Plaintiffs' injuries. Plaintiffs allege that the 2009 settlement and other lawsuits demonstrate Defendant's wrongdoing. Specifically, in Count II, Plaintiffs direct the Court to Pfizer's 2009 settlement with the Justice Department relating to the illegal promotion and advertising of an array of products, various whistleblower suits against Pfizer, and a 2010 stockholder derivative lawsuit against Pfizer, and they have attached to their pleading, pictures of Mr. Bartlett's physical injuries. (*See, e.g.*, ECF No. 1 at 2, 4; ECF No. 7-3; ECF No. 15 at 8.) Plaintiffs argue that these lawsuits and agreements to settle establish a connection between the act of Mr. Bartlett's physicians prescribing Lyrica for an off-label use and Pfizer's alleged reckless promotion of Lyrica for off-label applications. (*See* ECF No. 1 at 1-2.) In response, Defendant argues not only that Plaintiffs do not have a private right of action under the FDCA, but also that Plaintiffs' reliance on settlements and other lawsuits is misplaced because settlements and litigation are not relevant to their tort claims, are not admissions of guilt, and did not all involve Lyrica.

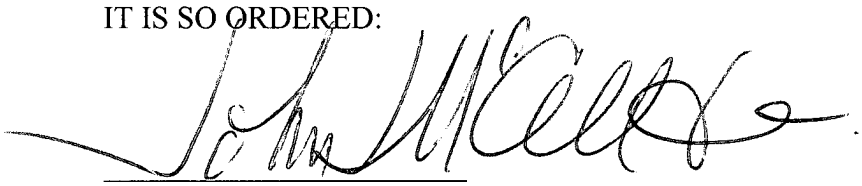
The Court finds that determining whether *Buckman* applies or whether a private cause of action exists is unnecessary in this case because Plaintiffs have failed to sufficiently allege causation *vis-à-vis* their FDCA-specific claims. Plaintiffs fail to allege any relationship between any of Pfizer's admissions that may have been contained within the lawsuits or settlement and

Plaintiffs' injuries. In Count IV, Plaintiffs do not allege any causation between Pfizer's alleged inappropriate conduct (e.g., "chang[ing] its marketing advertisement of Lyrica side effects" or, as explained in the FDA warning letter, "fail[ing] to report adverse-event[s]" of Lyrica side effects) and Mr. Bartlett's injures. (*See id.* at 5.) This proximate causation deficiency permeates Plaintiffs' claims —whether they sound in federal statutory or state common law— and, as such, Plaintiffs' claims in Counts II and IV fail.[4]

IV. CONCLUSION

For the reasons stated above, Defendant's motion to dismiss the Complaint is GRANTED.

IT IS SO ORDERED:



John J. McConnell, Jr.
United States District Judge

March 5th, 2012

[4] There was some dispute in the briefing, begun by Defendant's well-meaning attempt to interpret Plaintiffs' unconventional complaint, over whether Plaintiffs' have pled a fraud cause of action. Based on Plaintiffs' argument before the Court and supplemental, post-argument briefing where Plaintiffs acknowledged they did not plead fraud and misrepresentation and requested "Court approval to continue this Complaint under the claim of Pfizer negligence," the Court finds that Plaintiffs have not pled a fraud claim. Therefore, any arguments regarding fraud need not be discussed herein.