UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
FORT MYERS DIVISION

PETER GEROLD,

Plaintiff,

v. Case No: 2:15-cv-475-FtM-99CM

ASTELLAS PHARMA US, INC. and
MCKESSON CORPORATION,

Defendants.

OPINION AND ORDER

This matter comes before the Court on review of Defendant Astellas Pharma US, Inc.'s Motion to Dismiss Plaintiff's Second Amended Complaint (Doc. #42) filed on May 17, 2016. Plaintiff filed a Memorandum in Opposition to Defendant Astellas Pharma US, Inc.'s Motion to Dismiss Plaintiff's Second Amended Complaint (Doc. #45) on May 25, 2016. Also before the Court is defendant McKesson Corporation's Motion to Dismiss Plaintiff's Second Amended Complaint (Doc. #43) filed on May 17, 2016. Plaintiff filed a Memorandum in Opposition to Defendant McKesson Corporation's Motion to Dismiss Plaintiff's Second Amended Complaint (Doc. #44) on May 25, 2016.

I.

Plaintiff's Second Amended Complaint (Doc. #41), the operative pleading before the Court, contains the following allegations:

On March 14, 2012, plaintiff Peter Gerold ("Gerold") went to Advanced Heart Center for routine cardiac testing, including an MPI stress test. (Id. ¶ 23.) He was taken by staff to the testing area where it was explained to him that a medication called Lexiscan was going to be administered to him. (Id.) Lexiscan is a drug used in cardiac stress tests. (Id. ¶ 13.) Plaintiff was told that Lexiscan mimics exercising on a treadmill by dilating the blood vessels, thereby increasing blood flow. (Id. ¶ 23.) He was also told that following the administration of the drug, he may feel some heaviness in the chest, shortness of breath, nausea, and possibly a headache, none of which should last for an extended duration. (Id.) He was instructed that should he feel any of these symptoms, he should stomp his feet. (Id.) Plaintiff was not advised of any other adverse side effects from being administered Lexiscan. (Id.) Lexiscan was administered by a technician, but prescribed by Dr. Muppala. (Id.) Plaintiff alleges that had he been warned of the severe adverse side effects, he would have declined the administration of Lexiscan. (Id. ¶¶ 8, 23.)

Approximately five minutes after the test was completed, plaintiff was in the waiting area when he began to experience chest pain and suffer from a heart attack. (Id. ¶ 24.) Plaintiff was transported to the cath lab at Health Park where suffered heart rhythms which required defibrillation. (Id.) Plaintiff also went into cardiac arrest requiring CPR. (Id.) Plaintiff was admitted into the ICU where he stayed for five and a half days. (Id.)

As a result of the incident, plaintiff has permanent heart damage and mental impairment due to the lack of oxygen. (Id. ¶ 25.) An External Cardiac Defibrillator/Pacemaker that requires constant monitoring and causes plaintiff ongoing discomfort and deformity was subsequently implanted in plaintiff. (Id. ¶ 26.) Plaintiff's medical bills total over $210,000 and are steadily increasing due to ongoing medical care and treatment. (Id. ¶ 27.)

Gerold seeks to hold defendants Astellas Pharma US, Inc. ("APUS") and McKesson Corporation ("McKesson") responsible for their involvement in the marketing and distribution of Lexiscan in Florida, specifically to Lee Memorial Health Systems. (Id. ¶¶ 9-15.) Plaintiff alleges that APUS sold pharmaceuticals in the State of Florida under a fraudulently obtained license and that McKesson acted in concert with APUS to market, promote, sell, and distribute Lexiscan. (Id.)

Plaintiff alleges that defendants distributed Lexiscan with inadequate instructions regarding warning patients of serious

adverse reactions. (Id. ¶ 16.) Defendants were aware of a safer drug alternative that was available for the same testing, but promoted and marketed Lexiscan instead. (Id. ¶ 17.) The alternative, Adenoscan, had reported less adverse reactions over a longer period of time than Lexiscan. (Id. ¶ 18.) There were 1,703 adverse incidents reported following the administration of Lexiscan between 2008 and 2014 as opposed to 317 adverse incidents reported following the administration of Adenoscan between 1995 and 2008. (Id. ¶ 19.) Plaintiff alleges that defendants had a monetary incentive to promote Lexiscan instead of Adenoscan. (Id. ¶ 20.)

Defendant APUS made a video available to providers titled "patient video" detailing what to expect during the administration of Lexiscan. (Id. ¶ 28.) The video describes the following common side effects: "slight discomfort, pressure on the throat upward to the face, heavy breathing, out of breath, chest discomfort or pressure, tired, flushed or headache." (Id.) The video is available for use by providers when informing patients about the procedure, how it works, and what to expect. (Id. ¶ 29.) The video did not advise of any more serious adverse reactions that could occur from the administration of Lexiscan. (Id.)

In the summer of 2012, plaintiff reviewed the labeling information provided with Lexiscan. (Id. ¶ 30.) Plaintiff discovered that APUS's instructions in their Patient Counseling

Section were grossly inadequate. (Id. ¶ 31.) The Patient Counseling Section provided the following instruction: "Prior to Lexiscan administration, patients should be informed of the most common reactions (such as shortness of breath, headache and flushing) that have been reported in association with Lexiscan during MPI." (Id. ¶ 32.) The healthcare professional that administered Lexiscan to plaintiff on March 14, 2012 followed APUS's instructions. (Id. ¶ 34.)

Plaintiff sent correspondence dated August 30, 2012 to Lee Memorial Health Management's risk management department advising of the side effects he experienced on March 14, 2012. (Id. ¶ 35.) Lee Memorial subsequently implemented a new form informing patients of the potential serious adverse effects that could occur from the administration of Lexiscan. (Id.) Plaintiff also submitted a claim to APUS, which was denied as "not warranted." (Id. ¶¶ 36-38.)

In July of 2014, defendants' sister company made an application to the FDA to revise the existing label to include severe adverse reactions as well as the common ones. (Id. ¶ 39.) The changes were approved and the Patient Counseling Section now reads: "Advise patients that they may be at increased risk of fatal and non-fatal heart attacks, abnormal heart rhythms, cardiac arrest, significant increase or decrease in blood pressure, hypersensitivity reactions, seizures, bronchoconstriction or

cerebrovascular accident (stroke) with the use of Lexiscan." (Id. ¶ 40.)

Gerold filed this action in the Circuit Court of the Twentieth Judicial Circuit in and for Lee County on July 10, 2015 against APUS and McKesson. (Doc. #2.) Defendants removed the case to the United States District Court for the Middle District of Florida, Fort Myers Division (Doc. #1) on August 7, 2015. Following the Court's Orders denying plaintiff's Motion to Remand and dismissing plaintiff's Complaint and Amended Complaint as shotgun pleadings (Doc. ##24, 39), on May 3, 2016 plaintiff filed a Second Amended Complaint (Doc. #41). Plaintiff's Second Amended Complaint asserts one claim for Strict Products Liability for Failure to Warn against defendants. (Id.)

Defendants APUS and McKesson filed Motions to Dismiss (Doc. ##42, 43) on May 17, 2016, to which plaintiff filed Responses (Docs. ##44, 45) on May 25, 2016.

II.

Under Federal Rule of Civil Procedure 8(a)(2), a Complaint must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). This obligation "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007)(citation omitted). To survive dismissal, the factual allegations must be

"plausible" and "must be enough to raise a right to relief above the speculative level." Id. at 555. See also Edwards v. Prime Inc., 602 F.3d 1276, 1291 (11th Cir. 2010). This requires "more than an unadorned, the-defendant-unlawfully-harmed-me accusation." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009)(citations omitted).

In deciding a Rule 12(b)(6) motion to dismiss, the Court must accept all factual allegations in a complaint as true and take them in the light most favorable to plaintiff, Erickson v. Pardus, 551 U.S. 89 (2007), but "[l]egal conclusions without adequate factual support are entitled to no assumption of truth," Mamani v. Berzain, 654 F.3d 1148, 1153 (11th Cir. 2011)(citations omitted). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." Iqbal, 556 U.S. at 678. "Factual allegations that are merely consistent with a defendant's liability fall short of being facially plausible." Chaparro v. Carnival Corp., 693 F.3d 1333, 1337 (11th Cir. 2012)(internal quotation marks and citations omitted). Thus, the Court engages in a two-step approach: "When there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." Iqbal, 556 U.S. at 679.

"Generally, the existence of an affirmative defense will not support a motion to dismiss," Quiller v. Barclays Am./Credit, Inc.,

727 F.2d 1067, 1069 (11th Cir. 1984), aff'd on reh'g, 764 F.2d 1400 (11th Cir. 1985) (en banc) (per curiam) (reinstating panel opinion), because plaintiffs are not required to negate an affirmative defense in their complaint. La Grasta v. First Union Sec., Inc., 358 F.3d 840, 845 (11th Cir. 2004). A complaint may be dismissed, however, when the existence of an affirmative defense "clearly appears on the face of the complaint." Quiller, 727 F.2d at 1069. See also La Grasta, 358 F.3d at 845 ("[A] Rule 12(b)(6) dismissal on statute of limitations grounds is appropriate only if it is 'apparent from the face of the complaint' that the claim is time-barred") (quoting Omar ex rel. Cannon v. Lindsey, 334 F.3d 1246, 1251 (11th Cir. 2003)); Douglas v. Yates, 535 F.3d 1316, 1321 (11th Cir. 2008)(same).

A pleading drafted by a party proceeding *pro se*, like the Second Amended Complaint at issue here, is held to a less stringent standard than one drafted by an attorney, and the Court will construe the allegations contained therein liberally. Jones v. Fla. Parole Comm'n, 787 F.3d 1105, 1107 (11th Cir. 2015). "This liberal construction, however, does not give a court license to serve as de facto counsel for a party, or to rewrite an otherwise deficient pleading in order to sustain an action." Hickman v. Hickman, 563 F. App'x 742, 743 (11th Cir. 2014) (citations omitted). *Pro se* parties are still required to conform to the procedural rules. Id.

III.

Defendants APUS and McKesson assert that plaintiff has failed to state a claim for strict liability failure to warn because "Plaintiff fails to allege and support with facts any of the elements of his failure to warn claim . . . ." (Doc. #42, pp. 3-4; Doc. #43, p. 4.) Specifically, defendants assert that (1) plaintiff has failed to identify inadequate warnings to plaintiff's prescribing physician and many of the facts within the Second Amended Complaint take place after the alleged incident; (2) plaintiff's claim is precluded by the learned intermediary doctrine; and (3) plaintiff's Second Amended Complaint does not make a single allegation against McKesson and instead only alleges that APUS failed to warn plaintiff. (Doc. #42, pp. 4-7; Doc. #43, pp. 2, 4-8.) In response, plaintiff asserts that he has properly stated a claim for failure to warn and the learned intermediary doctrine is inapplicable. (Docs. #44, 45.)

A. Failure to State a Claim

Under Florida law, to establish strict liability for failure to warn, a plaintiff must prove that the defendant (1) is a manufacturer or distributor of the product at issue and (2) did not adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of the manufacture and distribution. Thomas v. Bombardier Recreational Prods., Inc., 682

F. Supp. 2d 1297, 1300 (M.D. Fla. 2010). The plaintiff must also establish that the inadequate warning was a proximate cause of his injury. Hoffmann La Roche, Inc. v. Mason, 27 So. 3d 75, 77 (Fla. 5th DCA 2009).

When the product is a prescription drug, as is the case in this matter, the manufacturer or distributor's duty to warn is directed to physicians rather than patients under Florida's "learned intermediary doctrine." Id. (citing Felix v. Hoffmann–La Roche, Inc., 540 So. 2d 102, 104 (Fla. 1989)). Thus, a drug manufacturer or distributor's duty to warn is satisfied if it gives an adequate warning to the physician who prescribes the drug. Buckner v. Allergan Pharms., Inc., 400 So. 2d 820, 822 (Fla. 5th DCA 1981). The rationale behind the learned intermediary doctrine is as follows:

> Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative. Pharmaceutical companies then, who must warn ultimate purchasers of dangers inherent in patent drugs sold over the counter, in selling prescription drugs are required to warn only the prescribing physician, who acts as a "learned intermediary" between manufacturer and consumer.

Id. (quoting Reyes v. Wyeth Labs., 498 F.2d 1264, 1276 (5th Cir. 1974)).

Plaintiff has adequately alleged that APUS and McKesson distributed Lexiscan. (Doc. #41, ¶¶ 11-12.) As to the second element, defendants contend that plaintiff's Second Amended Complaint is devoid of any factual details concerning the allegedly inadequate warnings to plaintiff's prescribing physician. (Doc. #42, p. 4; Doc. #43, p. 4.) Specifically, defendants assert that plaintiff has failed to provide any facts regarding which warnings his prescribing physician received regarding Lexiscan and how those warnings were inadequate. (Id.)

Plaintiff's Second Amended Complaint asserts that the Physician Counseling Section of what is referred to as the Lexiscan labeling information and an online video made available by APUS failed to include instructions on warning patients as to more serious adverse side effects. (Doc. #41, ¶¶ 16, 28-29, 31-32.) The Second Amended Complaint alleges (1) that the Physician Counseling Section and video only instructed physicians to warn of the common side effects, (2) they did not warn of the serious side effects such as the ones experienced by plaintiff following the administration of Lexiscan, and (3) if plaintiff would have been warned, he would have not have accepted the administration of Lexiscan. (Id. ¶¶ 8, 16, 28-29, 31-32.) Plaintiff has identified the more serious side effects that he experienced, i.e. heart attack/cardiac arrest. (Id. ¶ 24.) Viewing the allegations in

the light most favorable to the plaintiff, the Court finds these allegations state a claim for strict liability failure to warn.

Defendants also assert that plaintiff's claim is barred by the learned intermediary doctrine. (Doc. #42, pp. 4-7; Doc. #43, pp. 5-8.) As previously stated, plaintiff has alleged that defendants failed to instruct physicians to warn patients of the serious adverse risks of Lexiscan. This is sufficient to withstand the learned intermediary doctrine at this stage of the proceedings.

B. Allegations Against McKesson

McKesson argues that plaintiff's Second Amended Complaint fails to assert a single allegation against it and therefore requests the claim against it be dismissed. (Doc. #43, p. 2.) The general allegations of plaintiff's Second Amended Complaint assert that "Defendants APUS and MCK acting in concert and with a common goal and purpose, by and through one another . . . were in the business of marketing, promoting, selling and or distributing Lexiscan" and that "Defendants provided the drug Lexiscan with inadequate instructions regarding the warning of patients to the more serious adverse reactions." (Doc. #41, ¶¶ 11, 16 (citing to Ex. G, Patient Counseling Section)). Within plaintiff's strict liability count, plaintiff points to the instructions in the

patient video and Patient Counseling section – both of which are alleged to have been provided by APUS.[1] (Id. ¶¶ 28-29, 30-31.)

Contrary to McKesson's assertion, plaintiff's Second Amended Complaint contains allegations against McKesson. Plaintiff alleges that McKesson distributed Lexiscan to Lee Memorial Health System, it had insufficient warnings that failed to warn of the side effects that plaintiff experienced, and McKesson was aware of these more serious side effects. See Bailey v. Janssen Pharmaceutica, Inc., 288 F. App'x 597, 604 (11th Cir. 2008) (discussing that strict liability claims may be brought against all parties in a product's chain of distribution)). While plaintiff only points to the warnings provided by APUS, if McKesson was aware of more serious side effects yet distributed Lexiscan with only the warnings provided by APUS, McKesson may be liable as well as a distributor of the drug. Further, plaintiff has alleged a common plan or purpose between APUS and McKesson to distribute the drug without warning of the more serious side effects that defendants were aware of.

[1] Although plaintiff has not explicitly incorporated his "Facts in Support of Claims" paragraphs into his Strict Liability Count, due to plaintiff's pro se status and the desire to move this case forward, the Court will interpret the Complaint as if they were incorporated into the single count for strict liability. The risk of including allegations unrelated to plaintiff's strict liability claim is obsolete due to there only being one count asserted in the Second Amended Complaint.

Although the factual allegations against McKesson are slim, viewing the allegations in the light most favorable to the plaintiff, the Court finds that the Second Amended Complaint contains allegations sufficient to support a claim against McKesson as a distributor of Lexiscan.

Accordingly, it is now

ORDERED:

Defendant Astellas Pharma US, Inc.'s Motion to Dismiss Plaintiff's Second Amended Complaint (Doc. #42) and Defendant McKesson Corporation's Motion to Dismiss Plaintiff's Second Amended Complaint (Doc. #43) are **DENIED.** Defendants shall have **fourteen (14) days** from the date of this Opinion and Order to file a responsive pleading to plaintiff's Second Amended Complaint.

DONE AND ORDERED at Fort Myers, Florida, this __4th__ day of November, 2016.

JOHN E. STEELE
SENIOR UNITED STATES DISTRICT JUDGE

Copies:
Plaintiff
Counsel of record