UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

KEITH EDWARDS,

Plaintiff,

v.

Case No.: 2:05-cv-657
JUDGE SMITH
Magistrate Judge Abel

WARNER-LAMBERT, *et al.*,

Defendants.

OPINION AND ORDER

Plaintiff Keith Edwards, acting *pro se*, initiated this action in 2004 in the Franklin County Court of Common Pleas. The case was removed to this Court in 2005. The case was then transferred to the United States District Court for the District of Massachusetts on August 15, 2005. The case was then officially remanded back to this Court on May 24, 2011, based on a finding by the Court in the District of Massachusetts that all remaining issues are case-specific. (*See* Docs. 10 and 15). Defendants Warner-Lambert LLC, Parke-Davis Co., and Pfizer Inc. now move for judgment on the pleadings (Doc. 24). Plaintiff has responded and this matter is now ripe for review. For the reasons that follow, Defendants' Motion is **DENIED**.

I. BACKGROUND

On or about April 12, 2002, through April 15, 2002, Plaintiff Keith Edwards was an inmate under the custody, care and control of the Ohio Department of Rehabilitation and Correction. Plaintiff Edwards was transferred from the Richland Correctional Institution to the Corrections Medical Center for an unrelated medical problem. While at the medical facility,

Plaintiff was overdosed 9,000 mg of Crizivan over a seventy-two hour period. As a result of this alleged overdose, Plaintiff suffered elevated blood pressure, elevated liver ALT levels, exacerbation of pain and numbness to his lower legs and feet, increased levels of HIV viral loan and/or complications, placing Plaintiff in jeopardy that his immune system might fail. Plaintiff asserts that as a result of the prior medication error, he was prescribed Neurontin to treat the nerve pain and numbness that he was experiencing in his lower legs and feet. Plaintiff was administered the drug Neurontin for over one and a half years. (Pl.'s Compl. ¶¶ 8-11). Plaintiff claims that as a result of taking Neurontin, he suffered from fatty tumors, stomach problems (convulsions), sleep disorder, nervousness and severe depression, and thoughts of suicide.

Plaintiff alleges that Defendant Warner-Lambert marketed Neurontin to treat a wide array of ailments for which the drug was not approved, such as bipolar mental disorder, various pain disorders, Amyotrophic Lateral Sclerosis ("ALS"), attention deficit disorder, migraine headaches, drug and alcohol withdrawal seizures, restless leg syndrome, and epilepsy.

Defendant Parke-Davis is a division of Warner-Lambert Company, which is now owned by Pfizer. On January 15, 1992, Parke-Davis submitted a New Drug Application ("NDA") to the FDA seeking approval for Neurontin as an adjunctive therapy for epilepsy. As part of its submission, Parke-Davis submitted data documenting adverse events reported in its clinical trials. For example, seventy-eight individuals, or 5.3 percent of the total exposed patient population of the NDA, reported depression as an adverse event. Seven instances of depression were categorized as "serious" events, and nine patients withdrew from studies because of depression. There were also numerous mood and behavioral disturbances, or "psychobiologic" adverse events, reported in the studies. The FDA concluded its review of Neurontin's NDA by stating

that Neurontin was "approvable with appropriate and prominent labeling for use in a specific population."

On or about December 15, 1992, the Peripheral and Central Nervous System Drugs Advisory Committee to the Department of Health and Human Services voted to recommend Neurontin for a very specific use in a limited population, the adjunctive treatment for refractory epilepsy. Approximately one year later, on December 30, 1993, the company received FDA approval to market Neurontin for the adjunctive treatment of epilepsy in adults. The FDA stated that the drug is only effective at 900 to 1800 milligrams per day. Later, in 2002, the FDA approved Neurontin for the management of post-herpetic neuralgia (pain resulting from nerve damages caused by shingles or herpes zoster) in adults.

Beginning in 1995, Defendants engaged in a multi-faceted marketing campaign designed to increase off-label sales of Neurontin. Defendants began to illegally market and promote the sale of Neurontin for "off-label uses" which were not approved by the FDA, such as the treatment of pain, bipolar disorder and anxiety. Sales representatives made presentations to doctors' offices promoting Neurontin for pain and for reflex sympathetic dystrophy, a nerve damage syndrome. Defendants trained their sales representatives to promote off-label uses and motivated sales representatives to encourage prescription amounts for dosages higher than approved by the FDA. Additional off-label usages of Neurontin that were promoted by Defendant were for a variety of conditions including migraines, post-herpetic neuralgia, restless leg syndrome, bipolar disorder, and "ALS". Medical liaisons also falsely informed doctors that early results from clinical trials evaluating Neurontin for the treatment of bipolar disorder, peripheral and diabetic neuropathy, and other pain syndromes, indicated 90% response rates.

Clinical evidence emerged from the FDA trials that did not support Pfizer's promotion of Neurontin as safe and effective for off-label uses. Defendants and their representatives nonetheless promoted off-label uses even where there was contradictory clinical evidence. For example, Defendants sponsored a study conducted at the Harvard Bipolar Research Program in 1998, which concluded that patients receiving Neurontin did worse than those patients on placebo sugar pills. Although Defendants were aware of the results of this study, they did not publish the study's results until 2000, after a significant number of physicians were induced to prescribe Neurontin.

Defendant Warner-Lambert Company LLC was charged in the United States District Court for the District of Massachusetts with improper off-label marketing in violation of 21 U.S.C. §§ 331(a), 331(d), 333(a)(2), 352(f)(1) and 355(a), and pled guilty to the charges on June 7, 2004.

Plaintiff Edwards alleges two causes of action against Defendants: fraud and civil conspiracy.

II. STANDARD OF REVIEW

Federal Rule of Civil Procedure 12(c) provides that "[a]fter the pleadings are closed-but early enough not to delay trial-a party may move for judgment on the pleadings." It is well-settled that the standard of review for a motion for judgment on the pleadings under Rule 12(c) is the same as that used to address a motion to dismiss under Rule 12(b)(6). *See, e.g., Lindsay v. Yates*, 498 F.3d 434, 438 (6th Cir. 2007); *Morgan v. Church's Fried Chicken*, 829 F.2d 10, 11 (6th Cir. 1987) (noting that where a Rule 12(b)(6) defense of failure to state a claim upon which relief may

be granted is raised by a Rule 12(c) motion for judgment on the pleadings, the Court must apply the standard for a Rule 12(b)(6) motion).

Rule 12(b)(6) permits dismissal of a lawsuit for "failure to state a claim upon which relief can be granted." A Rule 12(b)(6) motion to dismiss is directed solely to the complaint and any exhibits attached to it. *Roth Steel Prods. v. Sharon Steel Corp.*, 705 F.2d 134, 155 (6th Cir. 1983). The merits of the claims set forth in the complaint are not at issue on a motion to dismiss for failure to state a claim. Consequently, a complaint will be dismissed pursuant to Rule 12(b)(6) only if there is no law to support the claims made, or if the facts alleged are insufficient to state a claim, or if on the face of the complaint there is an insurmountable bar to relief. *See Rauch v. Day & Night Mfg. Corp.*, 576 F.2d 697, 702 (6th Cir. 1978). Rule 12(b)(6) must be read in conjunction with Rule 8(a) of the Federal Rules of Civil Procedure, which requires the complaint to contain a "short and plain statement of the claim showing that the pleader is entitled to relief[.]"

A court, in considering a 12(b)(6) motion to dismiss, must "construe the complaint in the light most favorable to the plaintiff," accepting as true all the plaintiff's factual allegations. *Gunasekera v. Irwin*, 551 F.3d 461, 466 (6th Cir. 2009). Although in this context all of the factual allegations in the complaint are taken as true, a court is "not bound to accept as true a legal conclusion couched as a factual allegation." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Consequently, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1949 (2009).

Furthermore, to survive dismissal pursuant to Rule 12(b)(6), a claim must contain sufficient factual matter to "state a claim to relief that is plausible on its face." *Twombly*, at 570.

"A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, at 1950. While a complaint need not contain "detailed factual allegations," its "factual allegations must be enough to raise a right to relief above the speculative level on the assumption that all the allegations in the complaint are true." *Twombly*, at 555. "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged – but it has not 'show[n]' – 'that the pleader is entitled to relief.' " *Iqbal*, at 1950 (quoting Fed. Rule Civ. Proc. 8(a)(2)). In the final analysis, the task of determining plausibility is "context-specific [and] requires the reviewing court to draw on its judicial experience and common sense." *Id.*

Accordingly, the Court will grant a motion for judgment on the pleadings if there is an absence of law to support a claim of the type made, or of facts sufficient to make a valid claim, or if on the face of the complaint there is an insurmountable bar to relief indicating that the plaintiff does not have a claim. *Little v. UNUM Provident Corp.*, 196 F. Supp.2d 659, 662 (S.D. Ohio 2002) (Graham, J.) (citing *Rauch*). Stated differently, "[f]or purposes of a motion for judgment on the pleadings, all well-pleaded material allegations of the pleadings of the opposing party must be taken as true, and the motion may be granted only if the moving party is nevertheless clearly entitled to judgment." *JPMorgan Chase Bank, N.A. v. Winget*, 510 F.3d 577, 581 (6th Cir. 2007) (internal citations and quotation marks omitted).

III. DISCUSSION

Defendants Warner-Lambert LLC, Parke-Davis Co., and Pfizer Inc. move for judgment on Plaintiff's Complaint. Defendants argue that Plaintiff's fraud claim cannot withstand scrutiny

because it is barred by the Ohio Product Liability Act ("OPLA"), Ohio Revised Code § 2317.71 *et seq*. Additionally, Defendants argue that Plaintiff's civil conspiracy claim fails because there is no underlying tort claim upon which it can be based. Plaintiff responds with what is captioned a "Motion to Strike." (Doc. 25). Plaintiff appears to be arguing that Defendant's Motion for Judgment on the Pleadings is not proper because it is a delay tactic and was not timely. In the alternative, Plaintiff argues that his claim is not barred by the OPLA because his claims arose between 2002 and 2004. The Court will first address Plaintiff's Motion to Strike and then address Defendants' Motion for Judgment on the Pleadings.

A. Motion to Strike

Rule 12(f) of the Federal Rules of Civil Procedure provides that a court "may strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Fed. R. Civ. P. 12(f). Pleadings are defined as "a complaint; an answer to a complaint; an answer to a counterclaim designated as a counterclaim; an answer to a crossclaim; a third-party complaint; an answer to a third-party complaint; and, if the court orders one, a reply to an answer." Fed. R. Civ. P. 7(a). It is well settled that under Rule 12(f), "a court may strike only material that is contained in the pleadings," which does not include a motion for judgment on the pleadings. *See Fox v. Michigan State Police Dep't*, 173 Fed. Appx. 372, 2006 U.S. App. LEXIS 5019, at *2 (6th Cir. Feb. 24, 2006) (declining to strike attachment to a Rule 12(b)(6)/Rule 56 motion because they were not part of the pleadings). Moreover, an order to strike is a "drastic remedy" that "should be sparingly used by the courts." *Mapp v. Bd of Educ*., 319 F.2d 571, 576 (6th Cir. 1963).

Plaintiff has argued that Defendant's Motion is a delay tactic, however, Defendant's Motion was proper in accordance with this Court's Preliminary Pretrial Order (Doc. 18). Therefore, in accordance with Rule 12(f) of the Federal Rules of Civil Procedure and this Court's preliminary pretrial order, Defendant's Motion for Judgment on the Pleadings is proper and shall not be stricken from the record. Plaintiff's Motion to Strike is therefore **DENIED**. However, the Court will construe Plaintiff's Motion as a response in opposition to Defendant's Motion for Judgment on the Pleadings.

B. Motion for Judgment on the Pleadings

Defendants assert that Plaintiff's fraud claim is barred by the OPLA. In 1988, the Ohio legislature passed a tort reform bill that was intended to regulate product liability causes of action, including abrogating all common law causes of action related to products liability. Thereafter, the Ohio Supreme Court decided *Carrel v. Allied Products Corp.*, 78 Ohio St. 3d 284 (1997), which held that the common law cause of action of negligent design survived the enactment of the codification of the Ohio products liability law. Then, the Ohio legislature acted again and superseded *Carrel* with legislation that became effective April 7, 2005. Notes from the legislation specifically state: "The General Assembly declares its intent that the amendment made by this act to section 2707.71 of the Revised Code is intended to supersede the holding of the Ohio Supreme Court in *Carrel v. Allied Products Corp.* (1997), 78 Ohio St. 3d 284, that the common law product liability cause of action of negligent design survives the enactment of the Ohio Product Liability Act. . . and to abrogate all common law

product liability causes of action." Therefore, Ohio Revised Code Section 2307.71, was amended to include the following express statement of intent to supersede common law: "(B) Sections 2307.71 to 2307.80 of the Revised Code are intended to abrogate all common law product liability causes of action."

The legislation that defines the statutory causes of action is found in Ohio Revised Code Section 2307.71, which provides:

> (13) "Product liability claim" means a claim or cause of action that is asserted in a civil action pursuant to sections 2307.71 to 2307.80 of the Revised Code and that seeks to recover compensatory damages from a manufacturer or supplier for death, physical injury to person, emotional distress, or physical damage to property other than the product in question, that allegedly arose from any of the following:
>
> (a) The design, formulation, production, construction, creation, assembly, rebuilding, testing, or marketing of that product;
>
> (b) Any warning or instruction, or lack of warning or instruction, associated with that product;
>
> (c) Any failure of that product to conform to any relevant representation or warranty.
>
> "Product liability claim" also includes any public nuisance claim or cause of action at common law in which it is alleged that the design, manufacture, supply, marketing, distribution, promotion, advertising, labeling, or sale of a product unreasonably interferes with a right common to the general public.

Defendants argue that Plaintiff did not allege any claims against Pfizer until May 16, 2005, and "[a]ccordingly, he must have become aware of his causes of action after the April 7, 2005 effective date of the amended OPLA.

Plaintiff, however, argues in response that although he did not file the amended complaint in this case until May 16, 2005, "the date arising to the incident and injuries of this complaint occured [sic] initially between August 19, 2002 and January 13, 2004 and therefore falls after the decision in Carrel Supra (1997) and before the amended OPLA in April 2005. This cause of action therefore survives the enactment of the codification of the Ohio Product Liability law with regard to negligent fraudulent design." (Pl.'s Mot. at 3). In the alternative, Plaintiff seeks permission to file an amended complaint.

Defendants then respond that nothing in Plaintiff's pleadings support the interpretation that his cause of action accrued in 2004. The Court disagrees. Plaintiff is *pro se* and though his complaint could be clearer, there is no question that the alleged harm occurred from 2002 when Plaintiff was first prescribed the drug Neurontin, until approximately one and a half years later presumably when Plaintiff was no longer administered the drug. Courts have long construed the pleadings of *pro se* litigants liberally, holding them "to less stringent standards than formal pleadings drafted by lawyers." *Estelle v. Gamble*, 429 U.S. 97, 106 (1976)(internal quotation marks and additional citations omitted). Nonetheless, even *pro se* plaintiffs must allege facts that are sufficient "to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555, 127 S.Ct. at 1965.

Further, Defendants' alternative argument is that Plaintiff's fraud claim must also fail because he fails to state a claim upon which relief may be granted. Specifically, that the fraud

claim is not pled with the requisite particularity in accordance with Rule 9 of the Federal Rules of Civil Procedure.

The Court agrees that Plaintiff's Complaint is deficient, however, he has requested to amend his Complaint, albeit in his Motion to Strike. This is technically not the proper procedure to request leave of this Court to file an amended complaint, however, the Court will allow it, giving deference to Plaintiff because he is *pro se*. Further, Plaintiff should be permitted to amend his complaint in consideration of the well-established legal principle that cases should be decided on the merits and not on procedural technicalities. *See* Fed. R. Civ. P. 15(a)(2) (A court "should freely give leave" to amend "when justice so requires."). Taking into consideration Plaintiff's *pro se* status and the nature of the claim, the undersigned finds that a short additional time period within which Plaintiff may amend his complaint will not prejudice the Defendants. To the extent that Plaintiff files an amended complaint, he should include any additional relevant facts to maintain his fraud claim as argued in response to Defendants' Motion for Judgment on the Pleadings.

This decision is not intended to express any opinion on whether the allegations contained in Plaintiff's response to Defendants' pending motion are sufficient to rectify the obvious deficiencies in his current complaint. Nonetheless, Plaintiff will be permitted to file an amended complaint in this case. The amended complaint shall be filed with this Court on or before January 20, 2012. Defendants may then respond as they see fit. An additional motion to dismiss and/or motion for judgment on the pleadings is permissible as there has been no decision on the merits of this motion. Accordingly, the Court **DENIES** Defendants' Motion for Judgment on the Pleadings.

IV. DISPOSITION

For the foregoing reasons, the Court **GRANTS** Plaintiff's Motion to file an amended complaint and **DENIES** Defendants' Motion for Judgment on the Pleadings. Plaintiff shall file his amended complaint on or before January 20, 2012.

The Clerk shall remove Documents 24 and 25 from the Court's pending motions list.

IT IS SO ORDERED.

s/ George C. Smith
GEORGE C. SMITH, JUDGE
UNITED STATES DISTRICT COURT