

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
PADUCAH DIVISION
CIVIL ACTION NO. 5:14-CV-00101-TBR**

ASHLEY BABICH-ZACHARIAS

Plaintiff,

v.

BAYER HEALTHCARE
PHARMACEUTICALS, INC.

Defendant.

MEMORANDUM OPINION AND ORDER

This matter comes before the Court upon the motion to dismiss of Defendant Bayer Healthcare Pharmaceuticals, Inc. (“Bayer”). (Docket No. 8.) Plaintiff Ashley Babich-Zacharias has responded, (Docket No. 12), and Bayer has replied, (Docket No. 15). Fully briefed, this matter stands ripe for adjudication. For the reasons set forth below, the Court will DENY Bayer’s motion to dismiss.

Factual Background

This lawsuit raises products liability claims arising from Babich-Zacharias’s use of an intrauterine device (“IUD”) known as “Mirena.” Mirena is produced by Bayer, a Delaware corporation in the business of designing, manufacturing, marketing, testing, and distributing prescription drugs and women’s healthcare products. The device consists of a T-shaped polyethylene frame with a steroid reservoir that releases a certain amount of levonorgesterel, a synthetic hormone that acts as a contraceptive, into the uterus each day. A healthcare provider inserts the device into the uterus during an office visit, after which it may remain in use for up to five years.

Babich-Zacharias, a Kentucky resident, alleges that after her Mirena IUD was inserted, she developed severe headaches and vision problems that caused her to seek emergency care. After a lumbar puncture, a neurologist diagnosed Babich-Zacharias with pseudotumor cerebri, also known as idiopathic intracranial hypertension (“PTC/IIH”). PTC/IIH occurs when fluid builds up in the skull, causing

increased pressure and triggering “severe migraines or migraine-like headaches with blurred vision, diplopia (double vision), temporary blindness, blind spots, or other visual deficiencies.” (Docket No. 1 at ¶ 31.) If not correctly diagnosed and treated, PTC/IIH may cause permanent vision loss and blindness. (Docket No. 1 at ¶ 38.) Although the condition is treatable, positive outcomes are not assured.

Babich-Zacharias now maintains that levonorgestrel “causes or contributes to the development of PTC/IIH, increases the risk of developing PTC/IIH, and/or worsens or exacerbates PTC/IIH.” (Docket No. 1 at ¶ 52.) She contends that Mirena’s label and its patient information booklet fail to warn users of this “known link.” (Docket No. 1 at ¶¶ 26-29.) She further argues that despite medical literature reflecting a need for additional research, Bayer failed to conduct clinical tests investigating this purported connection. (Docket No. 1 at ¶ 30.) Finally, she points to Bayer’s “Mirena Simple Style Statements Program,” which she alleges were consumer-directed live presentations directed toward “busy moms.” According to Babich-Zacharias, the Simple Style script omitted information regarding serious risks associated with using Mirena. (Docket No. 1 at ¶¶ 69-73.) She insists that Bayer concealed its knowledge of Mirena’s defects from herself and other patients, the FDA, prescribing physicians, the healthcare community, and other foreseeable users.

Babich-Zacharias filed suit on May 15, 2014, invoking this Court’s diversity jurisdiction pursuant to 28 U.S.C. § 1332. She asserts claims against Bayer for negligence, design defects, failure to warn, strict liability, breach of implied and express warranties, negligent and fraudulent misrepresentation, and fraud by suppression and concealment. She also seeks punitive damages.

Legal Standard

The Federal Rules of Civil Procedure require that pleadings, including complaints, contain a “short and plain statement of the claim showing that the pleader is entitled to relief.” Fed. R. Civ. P. 8(a)(2). A complaint may be attacked for failure “to state a claim upon which relief can be granted.” Fed. R. Civ. P. 12(b)(6). When considering a Rule 12(b)(6) motion to dismiss, a court will presume that all the

factual allegations in the complaint are true and will draw all reasonable inferences in favor of the nonmoving party. *Total Benefits Planning Agency v. Anthem Blue Cross & Blue Shield*, 552 F.3d 430, 434 (6th Cir. 2008) (citing *Great Lakes Steel v. Degendorf*, 716 F.2d 1101, 1105 (6th Cir. 1983)). “The court need not, however, accept unwarranted factual inferences.” *Id.* (citing *Morgan v. Church's Fried Chicken*, 829 F.2d 10, 12 (6th Cir. 1987)).

Even though a “complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff’s obligation to provide the grounds of his entitlement to relief 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, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007) (citations omitted). Instead, the plaintiffs “[f]actual 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 (even if doubtful in fact).” *Id.* (citations omitted). That is, a complaint must contain enough facts “to state a claim to relief that is plausible on its face.” *Id.* at 570. A claim becomes plausible “when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009) (citing *Twombly*, 550 U.S. at 556). If, from the well-pleaded facts, the court cannot “infer more than the mere possibility of misconduct, the complaint has alleged—but has not ‘show[n]’—‘that the pleader is entitled to relief.’” *Id.* at 679 (quoting Fed. R. Civ. P. 8(a)(2)). “[O]nly a complaint that states a plausible claim for relief survives a motion to dismiss.” *Id.*

Moreover, when a plaintiff’s claims sound in fraud, those claims are subject to the heightened pleading standard of Federal Rule of Civil Procedure 9(b), “designed to prevent ‘fishing expeditions,’ to protect defendants’ reputations from allegations of fraud, and to narrow potentially wide-ranging discovery to relevant matters.” *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 4677 (6th Cir. 2011) (citing *United States ex rel. SNAPP, Inc. v. Ford Motor Company*, 532 F.3d 496, 504 (6th Cir. 2008)). “At a minimum, the Sixth Circuit requires the allegations to contain the ‘time, place, and

contend of the alleged misrepresentation on which he or she relied; the fraudulent scheme; the fraudulent intent of the defendants; and the injury resulting from the fraud.” *Our Lady of Bellefonte Hosp., Inc. v. Tri-State Physicians Network, Inc.*, 2007 WL 2903231, at *6 (E.D. Ky. Sept. 27, 2007) (quoting *Coffey v. Foamex L.P.*, 2 F.3d 157, 161-62 (6th Cir. 1993)). “Generalized and conclusory allegations that the Defendants’ conduct was fraudulent do not satisfy Rule 9(b).” *Bovee v. Coopers & Lybrand C.P.A.*, 272 F.3d 356, 361 (6th Cir. 2001).

Analysis

Bayer contends that because Babich-Zacharias has not provided the requisite detail to support her claims, her complaint fails to state a claim upon which relief can be granted. According to Bayer, the complaint contains only “formulaic recitation of elements for certain causes of action” and offers only the broadest sketches of her allegations, alluding to unnamed doctors and unspecified dates and locations. (Docket No. 8-1 at 1.)

The Court must agree. The complaint fails to provide certain bedrock facts—including, for example, the name and locations of the practitioner who placed Babich-Zacharias’s Mirena, the practitioner who removed the IUD, and the practitioner who diagnosed her with PTC/IIH. Significantly, she does not indicate when these procedures and diagnoses occurred, which could prove essential to a statute of limitations analysis. Moreover, Babich-Zacharias’s complaint does not satisfy the legal prerequisites of several of her nine claims. These deficiencies raise particular concern in the context of her fraud-based claims, which fall far short of the detail required by Sixth Circuit precedent. *See, e.g., Chesbrough*, 655 F.3d at 467. Consequently, Babich-Zacharias has failed to state a claim upon which relief may be granted.

The Court has confronted similar factual and legal deficiencies in other cases involving Mirena litigation. *See Hardwick v. Bayer Healthcare Pharmaceuticals Inc.*, No. 3:14-cv-00082-JGH (Docket No. 25) (W.D. Ky. Aug. 13, 2014); *Bosch v. Bayer Healthcare Pharmaceuticals, Inc.*, 2013 WL 5656111,

Civil Action No. 3:13-cv-00656-JHM, (W.D. Ky. Oct. 16, 2013); *Martin v. Bayer Healthcare Pharmaceuticals*, Civil Action No. 3:14-cv-00398-TBR (Docket No. 23) (WD. Ky. Dec. 9, 2014). In each of these cases, similar complaints were deemed inadequate and the Court granted Plaintiffs leave to amend their complaints.

Finding that similar relief is appropriate here, and in accordance the liberal amendment policies articulated in the Federal Rules of Civil Procedure, the Court will grant Babich-Zacharias leave to amend. *See* Federal Rule of Civil Procedure 15(a)(2) (instructing that the court should “freely give leave” to amend a pleading “when justice so requires.”). *See also Brown v. Matauszak*, 415 F. App’x 608, 614 (6th Cir. 2011) (“[I]f it is at all possible that the party against whom the dismissal is directed can correct the defect in the pleading or state a claim for relief, the court should dismiss with leave to amend.”) (quoting 6 Charles Alan Wright, Arthur R. Miller, & Mary Kay Kane, *Federal Practice and Procedure* § 1483 (3d ed. 2010).)¹

Conclusion

For the reasons set forth above, IT IS HEREBY ORDERED that Bayer’s motion to dismiss, (Docket No. 8), is DENIED WITHOUT PREJUDICE. IT IS FURTHER ORDERED that Babich-Zacharias shall submit an amended complaint no later than twenty days from the entry of this Memorandum Opinion and Order.

cc: Counsel

¹ Bayer further contends that notwithstanding the pleading deficiencies, Babich-Zacharias’s breach of warranty and negligent misrepresentation claims must be dismissed as a matter of law. Because an amended complaint is forthcoming, the Court will reserve ruling on such arguments at this time.