

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
LOUISVILLE DIVISION**

CIVIL ACTION NO. 3:13-CV-00656-JHM

**DANIKA VANDEN BOSCH and
JACKLYN HOGUE, Individually and As
Next Friend of MARIAH RICE**

PLAINTIFFS

V.

**BAYER HEALTHCARE
PHARMACEUTICALS, INC.**

DEFENDANT

MEMORANDUM OPINION AND ORDER

This matter is before the Court on the Motion to Dismiss for Failure to State a Claim and Motion to Strike [DN 7] of Defendant Bayer Healthcare Pharmaceuticals, Inc. (“Bayer”). Fully briefed, this matter is ripe for decision. For the following reasons, Bayer’s motion is **RESERVED**.

I. BACKGROUND

This action concerns Mirena®, an intrauterine contraceptive system that was designed, manufactured, tested, marketed, and distributed by Bayer. (See Compl. [DN 1] ¶ 16-17.) Mirena is made of flexible plastic and is inserted into a patient’s uterus by a healthcare provider during an office visit. (*Id.* ¶ 28.) Once inserted, Mirena releases levonorgestrel, a synthetic progestogen, directly into the uterus for birth control. While it is not known exactly how Mirena works, it is believed that Mirena thickens cervical mucus, thins the uterine lining, inhibits sperm movement, and reduces sperm survival to prevent pregnancy. (*Id.* ¶ 30.)

In their complaint, Plaintiffs allege that they have “sustained certain . . . health consequences due to their use of MIRENA®.” (*Id.* ¶ 24.)¹ Plaintiffs allege myriad causes of action against

¹ Plaintiff Danika Vanden Bosch is an Indiana resident. (Compl. [DN-1] ¶ 1.) Plaintiffs Jacklyn Hogue and Mariah Rice are Kentucky residents. (*Id.* ¶¶ 3-4.)

Bayer, including: negligence; defective design; manufacturing defect; failure to warn; defect due to nonconformance with representations; defect due to failure to adequately test; breach of express warranty; and breach of implied warranties. (Id. ¶¶ 51-138.) Plaintiffs also allege: fraudulent misrepresentation; fraudulent concealment; negligent misrepresentation; fraud and deceit; violations of the Indiana and Kentucky Consumer Protection Statutes; and punitive damages. (Id. ¶¶ 139-227.)

Bayer has now filed a motion to dismiss Plaintiffs' complaint under Fed. R. Civ. P. 12(b)(6). (See Mot. to Dismiss for Failure to State a Cl. & Mot. to Strike [DN 7].) In addition, Bayer has asked the Court to strike certain of Plaintiffs' allegations pursuant to Fed. R. Civ. P. 12(f). (See id.)

II. STANDARD OF REVIEW

Upon a motion to dismiss for failure to state a claim pursuant to Fed. R. Civ. P. 12(b)(6), a court "must construe the complaint in the light most favorable to plaintiffs," League of United Latin Am. Citizens v. Bradesen, 500 F.3d 523, 527 (6th Cir. 2007) (citation omitted), accepting all of the plaintiffs' allegations as true. Ashcroft v. Iqbal, 556 U.S. 662, 679 (2009). Under this standard, the plaintiffs must provide the grounds for their entitlement to relief, which "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007).

The plaintiffs satisfy this standard only when they "plead[] factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Iqbal, 556 U.S. at 678. A complaint falls short if it pleads facts that are merely "consistent with a defendant's liability" or if the facts do not "permit the court to infer more than the mere possibility of misconduct." Id. at 678–79. Instead, the allegations must "'show[] that the pleader is entitled to relief.'" Id. at 679 (quoting Fed. R. Civ. P. 8(a)(2)).

When the plaintiffs plead claims which sound in fraud, those claims are subject to the heightened pleading standard of Fed. R. Civ. P. 9(b), which provides that "[i]n alleging fraud or

mistake, a party must state with particularity the circumstances constituting fraud or mistake.” Fed. R. Civ. P. 9(b). “At a minimum, the Sixth Circuit requires the allegations to contain the ‘time, place, and content 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).

III. DISCUSSION

In its motion to dismiss, Bayer argues that Plaintiffs’ complaint must be dismissed in its entirety because it fails to provide the requisite factual detail to support Plaintiffs’ claims. (See Def.’s Mem. in Supp. of Mot. to Dismiss [DN 7-1] 2.) According to Bayer, Plaintiffs’ complaint fails to meet the pleading standard of Iqbal and Twombly since it is “completely devoid of even basic factual allegations, let alone the specific allegations required of a valid pleading.” (Id.) Bayer highlights that Plaintiffs have not pleaded “how their Mirena® allegedly caused them harm; when their Mirena® was placed; which physicians prescribed and placed their Mirena®; when their Mirena® was removed and by whom; what complications, if any, were allegedly caused by Mirena®, and how Plaintiffs were allegedly injured.” (Id. at 5-6.) Bayer further highlights that Plaintiffs have not even pleaded “in which state they received their Mirena® and subsequent medical treatment.” (Id. at 6.) Bayer argues that this lack of detail is fatal to Plaintiffs’ complaint.

In addition, Bayer maintains that while Plaintiffs have identified a litany of Mirena’s alleged side effects in their complaint—ranging from ectopic pregnancy to cancer to fetal injury—they have failed to identify the specific side effects from which Ms. Vanden Bosch, Ms. Hogue, and Ms. Rice have allegedly suffered. Instead, Plaintiffs allege only that they “have suffered and/or

are at a greatly increased risk” of suffering from these side effects. (See id. ¶¶ 23, 26, 53, 61, 76, 87, 91, 96, 103, 109, 115, 125, 137, 149, 161, 169, 203.) According to Bayer, these allegations are simply insufficient to give it fair notice of “what [Plaintiffs’] claims are and the grounds upon which they rest.” (Def.’s Mem. [DN 7-1] 5 (citing Twombly, 550 U.S. at 555).)

Further, Bayer contends that Plaintiffs’ failure to allege facts is fatal to their specific causes of action. (See Def.’s Mem. [DN 7-1] 2-3.) In this respect, Bayer claims that Plaintiffs have (among other things) provided only conclusory allegations; failed to specifically describe how Mirena’s design or manufacture is defective; failed to explain how their injuries were caused by Bayer’s alleged failure-to-warn; failed to meet the heightened pleading standard for fraud-based claims; and failed to meet the legal prerequisites of certain claims. (See id. at 3-13.) Bayer also seeks to strike certain “irrelevant” allegations from Plaintiffs’ complaint, including those concerning: (1) medical monitoring and fear of future injury; (2) Bayer’s alleged violation of federal requirements; and (3) knowledge that was “concealed” from the FDA. (See id. at 13-15.)

In response to Bayer’s motion, Plaintiffs first argue that their complaint “clearly pleads sufficient factual content about the harm caused to Plaintiffs from Defendant’s defective product” (Resp. to Def.’s Mot. [DN 24] 1.) According to Plaintiffs, their complaint satisfies the pleading standard because, at the very least, it contains “facts and circumstances” that have “nudged their claims across the line from conceivable to plausible.” (See id. at 6 (quoting Twombly, 550 U.S. at 570).) In the alternative, Plaintiffs argue that they should be granted leave to file an amended complaint if the Court finds that they have failed to plead their claims properly. (See id. at 17.)

In this case, Plaintiffs’ complaint is 56 pages long, containing 227 numbered paragraphs. (See Compl. [DN 1].) However, despite its length, the Court finds that it contains both factual and legal deficiencies. Therefore, the Court must determine whether Plaintiffs should be granted leave to file an amended complaint. Fed. R. Civ. P. 15(a)(1)(B) provides that a party may amend

its pleading once as a matter of course within 21 days after service of a motion under Rule 12(b). However, the 21-day time period in this case lapsed without Plaintiffs amending their complaint. Thus, Plaintiffs may now amend “only with . . . the court’s leave.” Fed. R. Civ. P. 15(a)(2). As a general rule, courts “should freely give leave when justice so requires.” *Id.* The Sixth Circuit has held that “Rule 15 plainly embodies a liberal amendment policy.” Morse v. McWhorter, 290 F.3d 795, 800 (6th Cir. 2002).

Here, the Court finds that justice requires that Plaintiffs be granted leave to amend their complaint. The case is still in its earliest stages, having been recently filed—on April 25, 2013. Further, Plaintiffs have not previously amended their complaint or sought leave to amend. While the Court recognizes the Sixth Circuit’s holding that a “bare request in an opposition to a motion to dismiss—without any indication of the particular grounds on which amendment is sought—does not constitute a motion within the contemplation of Rule 15(a),” PR Diamonds, Inc. v. Chandler, 364 F.3d 671, 699 (6th Cir. 2004), it nevertheless finds that in this case, justice requires that the Court grant Plaintiffs leave. This will give Plaintiffs a final chance to make sufficient allegations.

The Court’s decision to grant Plaintiffs leave is supported by case law. The Sixth Circuit has held that leave to amend is appropriate in some cases, even in absence of a motion to amend. See Brown v. Matauszak, 415 Fed. App’x 608, 616 (6th Cir. 2011). Further, the Sixth Circuit has noted, “at least three circuits have held that if a complaint is vulnerable to a motion to dismiss, a district court must first permit the plaintiff to file a curative amendment, even if the plaintiff does not seek leave to amend.” *Id.* (internal citations omitted). In addition, at least two district courts in Kentucky have used their discretion to determine that certain plaintiffs should be permitted to amend their complaints despite requesting to amend in their responses—instead of in formal motions. See, e.g., Pixler v. Huff, 2011 WL 5597327, at *15-16 (W.D. Ky. Nov. 17, 2011); Cox ex rel. Dermitt v. Liberty Healthcare Corp., 622 F. Supp. 2d 487, 501-02 (E.D. Ky. 2008). Therefore,

the Court holds that Plaintiffs are granted leave to amend. They are ordered to file an amended complaint **NO LATER THAN 20 DAYS** from the entry of this Memorandum Opinion and Order.

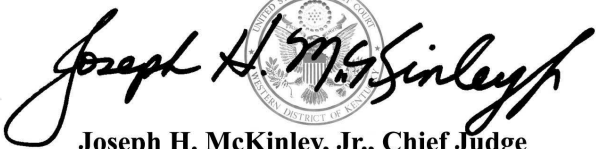
The Court notes that it is neither necessary nor desirable for it to detail the deficiencies in Plaintiffs' complaint. The Sixth Circuit has clearly stated that Plaintiffs are "not entitled to an advisory opinion from the Court informing them of the deficiencies of the complaint and then an opportunity to cure those deficiencies." Begala v. PNC Bank, 214 F.3d 776, 784 (6th Cir. 2000).

The Court also notes that because it is granting Plaintiffs leave to amend their complaint, it will **RESERVE** ruling on Bayer's motion to dismiss and strike. In the event that Plaintiffs do not file an amended complaint as required herein, the Court will grant Bayer's motion. In the event that Plaintiffs file an amended complaint as required herein, the Court will deny Bayer's motion as moot.

IV. CONCLUSION

For the reasons set forth above, **IT IS HEREBY ORDERED** that Plaintiffs submit an amended complaint no later than 20 days from the entry of this Memorandum Opinion and Order.

IT IS FURTHER ORDERED that Bayer's Motion to Dismiss for Failure to State a Claim and Motion to Strike [DN 7] is **RESERVED**.


Joseph H. McKinley, Jr., Chief Judge
United States District Court

October 16, 2013

cc: counsel of record