IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

STEPHANIE IDEUS, Plaintiff, vs. TEVA PHARMACEUTICALS USA, INC. and TEVA WOMEN'S HEALTH, INC., Defendants.	4:16-CV-3086 MEMORANDUM AND ORDER

This matter is before the Court on the defendants' motion for judgment on the pleadings. Filing 45. That motion will be granted.

The plaintiff's allegations are briefly summarized as follows. In 2010, the plaintiff, Stephanie Ideus, received a ParaGard T380 Intrauterine Copper Contraceptive—a "T" shaped device that is placed in the uterus to prevent pregnancy. Filing 1 at 2. Four years later, as her physician was removing the ParaGard, a piece of the device broke off and embedded in the myometrium of the plaintiff's uterine wall. Filing 1 at 3. The broken piece was surgically removed in 2016. Filing 50 at 2.

The plaintiff claims that she was not adequately warned of the possible risks associated with ParaGard. Filing 50 at 2. To support that contention, the plaintiff points to an "Information for Patients" brochure she received before the device was implanted, and to the product's package insert, which contains prescribing information for treating physicians. *See* filing 50 at 2-4; filing 45 at 8. Both sets of materials, the plaintiff alleges, lack any warning that the ParaGard "could break during removal," or that smaller pieces of the device (as opposed to the device as a whole) could separate and become

embedded "deep in the uterus[.]" Filing 50 at 2-3. The plaintiff has sued the manufacturers of the device, Teva Pharmaceuticals and Teva Women's Health, for failing to provide adequate warnings. *See* filing 1 at 17-18.[1]

The defendants move for judgment on the pleadings, arguing that the plaintiff's claim is preempted by federal drug labeling laws. Specifically, the defendants point to various regulations which the Federal Drug Administration (FDA) has promulgated in its enforcement of the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq*. Filing 45 at 14. Those regulations, the defendants point out, govern the allegedly deficient warnings at issue here, and were fully considered in the FDA's 2005 approval of ParaGard's labeling. Filing 45 at 10. Thus, the defendants argue, because the subject labels were federally approved, the plaintiff's state law claim is "without effect." *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981).

A Fed. R. Civ. P. 12(c) motion for judgment on the pleadings is reviewed under the same standard as a Fed. R. Civ. P. 12(b)(6) motion to dismiss. *Ginsburg v. InBev NV/SA*, 623 F.3d 1229, 1233 n.3 (8th Cir. 2010). Thus, at this stage, the Court accepts the plaintiff's factual allegations as true and grants all reasonable inferences in her favor. *Poehl v. Countrywide Home Loans, Inc.*, 528 F.3d 1093, 1096 (8th Cir. 2008). The Court will grant the defendants' motion only if there is no dispute as to any material facts and the defendants are entitled to judgment as a matter of law. *Ashley Cty. v. Pfizer, Inc.*, 552 F.3d 659, 665 (8th Cir. 2009); *Poehl*, 528 F.3d at 1096.

A federal regulation preempts state law when it is impossible for a private party to comply with both state and federal law, and when state law "stands as an obstacle to the accomplishment and execution of the full

[1] The plaintiff, in response to the present motion, voluntarily dismissed her claims for manufacturing defect, design defect, and fraud. Filing 50 at 1.

purposes and objectives of the relevant agency." *Wuebker v. Wilbur-Ellis Co.*, 418 F.3d 883, 887 (8th Cir. 2005) (internal quotations omitted). Such impossibilities exist here, the defendants argue, because they "cannot act independently under federal law to do what state law requires." Filing 45 at 21. The defendants assert that the FDCA requires them to distribute ParaGard only with the labeling approved by the FDA. And because the FDA has approved ParaGard's labeling, the defendants "cannot comply" with state laws or regulations that impose additional or contradictory duties. Filing 45 at 21.

The Supreme Court considered a similar argument in *Wyeth v. Levine*, 555 U.S. 555 (2009). In *Wyeth*, the plaintiff sued the defendant pharmaceutical company under state law for inadequate warnings on a drug called Phenergan. After an adverse jury verdict, the defendant appealed, arguing that it "would have been impossible for it to comply with [a] state-law duty to modify [the drug's] labeling without violating federal law[.]" *Id.* at 563. To support that argument, the defendant cited federal regulations which significantly curtail manufacturers' ability to change product labeling once it is approved by the FDA. *See id.* at 568; 21 C.F.R. § 314.70.

The Court rejected the defendant's argument, pointing to the FDA's "changes being effected" (CBE) regulation. 21 C.F.R. §§ 314.70(c)(6)(iii)(A). That regulation requires manufacturers to maintain and update their labeling with new safety information as it becomes available. It does so in part by allowing private entities to unilaterally "add or strengthen" warning labels without preapproval from the FDA. *Id.*; *see Wyeth*, 555 U.S. at 567. Thus, because the regulation expressly permits such unilateral changes, it is at least possible for a manufacturer to modify its labeling without violating

federal drug regulations. And that possibility rendered the defendant's preemption argument without merit. *Wyeth*, 555 U.S. at 570-71.

But the mere existence of the CBE regulation does not, itself, defeat a manufacturer's preemption defense. *See In re Fosamax Products Liability Litigation*, 852 F.3d 268, 283 (3d Cir. 2016). Indeed, unilateral changes are permitted under the CBE only upon a showing of "newly acquired information," such as data or analyses not previously submitted to the FDA. 21 C.F.R. §§ 314.70(c)(6)(iii)(A). In the absence of such information, the private entity cannot alter its product's labeling, and any state regulation or law requiring it to do so is necessarily preempted. *See Wyeth*, 555 U.S. at 569.

Less clear, however, is the issue presented here: whether the plaintiff must affirmatively plead the existence of "newly acquired information" to state a cognizable claim for relief. The plaintiff claims she does not, suggesting that the burden lies with the defendant to prove the existence of such information. Filing 50 at 7. And in any event, the plaintiff argues, "newly acquired information" continues to be adduced during discovery, rendering dismissal at this early stage unwarranted. Filing 50 at 11.

But the few courts to address this issue have held (or suggested) otherwise. *See In re Celexa and Lexapro Marketing and Sales Practices Litigation*, 779 F.3d 34 (1st Cir. 2015); *Utts v. Bristol-Myers Squibb*, 251 F. Supp. 3d 644 (S.D.N.Y. 2017); *Mitchell v. Boehringer Ingelheim Pharmaceuticals*, 2017 WL 5617473 (W.D. Tenn. 2017). For example, in *In re Celexa,* the First Circuit Court of Appeals dismissed the plaintiffs' "failure to warn" claim because the underlying complaint contained no allegations of "newly acquired information." *Id.* at 42. Thus, the Court was unable to plausibly assume that the defendant pharmaceutical company possessed the authority under governing regulations to "independently change its label

to . . . comply with California law." *Id.* at 43. Accordingly, the plaintiffs' claim was preempted, and failed as a matter of law. *Id.*

The First Circuit's decision in *In re Celexa* is consistent with the applicable standards at this stage of the proceeding. Indeed, when considering a preemption argument in the context of a motion to dismiss, the factual allegations relevant to preemption must be viewed in the light most favorable to the plaintiff. *Galper v. JP Morgan Chase Bank*, 802 F.3d 437, 444 (2d Cir. 2015). But dismissal is nonetheless appropriate under Rule 12(b)(6) if the facts alleged in the complaint "do not plausibly give rise to a claim that is not preempted." *Id.*; *see Dougherty v. Source Naturals, Inc.*, 148 F. Supp. 3d 831, 835 (E.D. Mo. 2015). And here, for the reasons described above, that requires some indication of "newly acquired information" as to trigger the applicability of the CBE regulation. *In re Celexa*, 779 F.3d at 42-43; *see Bristol Myers Squibb*, 251 F. Supp. 3d at 661 (initial burden of showing "newly acquired information" rests with the plaintiff).

The plaintiff's complaint contains no such allegations. Accordingly, the facts as alleged do not give rise to a plausible claim for relief that is not preempted by federal law. *See Galper*, 802 F.3d at 44. The defendants' motion will therefore be granted, and the plaintiff's complaint will be dismissed.

The Court will, however, grant the plaintiff an opportunity to replead her claims with greater particularity in an amended complaint. If she chooses to do so, the plaintiff must plead with specificity any "newly acquired evidence" which may have warranted a change in ParaGard's package insert[2] after 2005, when the label was federally approved, and before 2010, when the

[2] As the defendants correctly point out, it is the package insert—not the patient brochure—that is relevant under Nebraska law. *See Freeman v. Hoffman-La Roche, Inc.*, 260 Neb. 552, 570 (2000) (adopting learned intermediary doctrine for prescription drugs).

subject ParaGard was implanted. *See Bristol Myers Squibb*, 251 F. Supp. 3d at 644 (rejecting the plaintiff's citation to certain medical reports as "newly acquired information"). Additionally, the plaintiff should identify with specificity the alleged deficits in ParaGard's product insert.

The plaintiff may replead her claim in an amended complaint filed on or before December 27, 2017. If an amended complaint is not filed, judgment will be entered for the defendant and against the plaintiff without further notice.

IT IS ORDERED:

1. The defendant's motion for judgment on the pleadings (filing 45) is granted.

2. The plaintiff's complaint is dismissed.

3. The plaintiff may file an amended complaint on or before December 27, 2017. If an amended complaint is not filed, judgment will be entered for the defendant and against the plaintiff without further notice.

4. The Clerk of the Court shall set a case management deadline for December 27, 2017, with the following docket text: check for filing of amended complaint.

Dated this 12th day of December, 2017.

BY THE COURT:

John M. Gerrard
United States District Judge