UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ALLISON GREAGER,	)	
	)	
Plaintiff,	)	
	)	**No. 19 C 918**
v.	)	
	)	**Judge Jorge L. Alonso**
MCNEIL-PPC, INC., MCNEIL CONSUMER HEALTHCARE, MCNEIL CONSUMER PHARMACEUTICALS CO., JOHNSON & JOHNSON CONSUMER INC., ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS INC., JOHNSON & JOHNSON, WALMART INC., PERRIGO COMPANY PLC, PERRIGO PHARMACEUTICALS COMPANY, APOTHECON LLC, BRISTOL-MEYERS SQUIBB COMPANY, TEVA PHARMACEUT-ICALS USA INC., and TEVA PHARMACEUT-ICALS INDUSTRIES LTD.	)	
	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

Plaintiff Allison Greager brings this product liability action against numerous manufacturers and sellers of ibuprofen, asserting claims of defective design, failure to warn of inherent risks, and numerous other, related state-law claims. Defendants L. Perrigo Company ("Perrigo") and Walmart Inc. ("Walmart") move to dismiss. For the following reasons, the motions are granted.

BACKGROUND

Plaintiff alleges, as relevant here, that on June 15, 2012, suffering from a fever, she ingested Motrin IB and a generic equivalent sold by Walmart under the store-brand name "Equate."[1] The

[1] Plaintiff also alleges that she ingested Principen and penicillin, and her complaint contains claims against the manufacturers of those drugs. However, plaintiff has voluntarily dismissed her claims against the Principen and penicillin defendants, namely, Apothecon LLC, Bristol-Meyers Squibb Company, Teva

active ingredient in both products is ibuprofen, a nonsteroidal anti-inflammatory drug available over the counter to reduce swelling, pain, or fever. As a result of her ingestion of these ibuprofen products, plaintiff claims, she developed a severe skin disorder, either Stevens-Johnson Syndrome or its more severe cousin, toxic epidermal necrolysis, and suffered serious injuries to her skin and other bodily organs, causing permanent damage that will require lifelong medical care. Plaintiff subsequently filed this action, asserting claims of defective design, failure to warn, negligence, consumer fraud, breach of implied warranty of merchantability, and willful and wanton misconduct.

Perrigo, which manufactures the Equate-branded ibuprofen product, and Walmart move to dismiss, arguing that plaintiff's claims are preempted as to the Equate product by the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq*., and regulations promulgated thereunder. Additionally, the moving defendants argue that plaintiff fails to state a claim against them based on her ingestion of Motrin IB. In her combined response brief, plaintiff apparently concedes that she does not state a claim against Perrigo or Walmart based on her ingestion of Motrin IB, instead focusing on her claims based on the Equate product, which she argues are not preempted.

ANALYSIS

"A motion under Federal Rule of Civil Procedure 12(b)(6) tests whether the complaint states a claim on which relief may be granted." *Richards v. Mitcheff*, 696 F.3d 635, 637 (7th Cir. 2012). Under Rule 8(a)(2), a complaint must include "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). The short and plain statement under Rule 8(a)(2) must "'give the defendant fair notice of what . . . the claim is and the grounds

Pharmaceuticals USA Inc., and Teva Pharmaceuticals Industries Ltd. As a result of the voluntary dismissal of the claims against these defendants, their pending motions to dismiss are denied as moot.

upon which it rests.'" *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)). Under federal notice-pleading standards, a plaintiff's "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Id*. Stated differently, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. 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." *Id*. (citing *Twombly*, 550 U.S. at 556). "Only when the plaintiff pleads itself out of court—that is, admits all the ingredients of an impenetrable defense—may a complaint that otherwise states a claim be dismissed under Rule 12(b)(6)." *Xechem, Inc. v. Bristol-Myers Squibb Co.*, 372 F.3d 899, 901 (7th Cir. 2004).

"The preemption doctrine is grounded in the Constitution's Supremacy Clause." *Wis. Cent., Ltd. V. Shannon*, 539 F.3d 751, 762 (7th Cir. 2008). The Supremacy Clause declares that federal law "shall be the supreme Law of the Land . . . any Thing in the Constitution or Law of any State to the Contrary notwithstanding." U.S. Const. Art. VI., cl. 2. "Where state and federal law directly conflict, state law must give way." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 617 (2011) (internal quotation marks omitted).

"Preemption can take on three different forms: express preemption, field preemption, and conflict preemption." *Aux Sable Liquid Prod. v. Murphy*, 526 F.3d 1028, 1033 (7th Cir. 2008). Express preemption is when Congress "define[s] explicitly the extent to which its enactments pre-empt state law." *English v. Gen. Elec. Co.*, 496 U.S. 72, 78 (1990). Field preemption is when "the federal regulatory scheme is so pervasive or the federal interest so dominant that it may be inferred that Congress intended to occupy the entire legislative field." *Planned Parenthood of Ind., Inc. v.*

Comm'r of Ind. State Dep't Health, 699 F.3d 962, 984 (7th Cir. 2012) (citing *Arizona v. United States*, 567 U.S. 387, 399 (2012)). Conflict preemption is when "state law conflicts with federal law to the extent that compliance with both federal and state regulations is a physical impossibility." *Id.*

"[I]n . . . disputes over drug labels, conflict preemption takes center stage." *Guilbeau v. Pfizer Inc.*, 880 F.3d 304, 310 (7th Cir. 2018). The FDCA prescribes a two-tiered application process drug manufacturers must follow before they can put their products on the market:

> [D]rug manufacturers [must] gain approval from the United States Food and Drug Administration (FDA) before introducing a drug into interstate commerce. 21 U.S.C. § 355(a). To obtain FDA approval for a new drug, a manufacturer must submit a New Drug Application (NDA), a comprehensive submission that must include, for example, detailed information about the drug's composition and full reports of investigations into the drug's safety and effectiveness. *See id.* § 355(b)(1). In addition, NDA applicants must submit "the labeling proposed to be used for [the] drug," § 355(b)(1)(F), and they are "responsible for the accuracy and adequacy of [the] label" they submit. [*Mensing*, 564 U.S. at 613] (citing 21 U.S.C. §§ 355(b)(1), (d)). Manufacturers of generic drugs, however, need not submit such comprehensive applications. Rather, the FDA will approve a generic drug pursuant to an abbreviated new drug application (ANDA) upon a showing that the generic drug is equivalent to a previously approved "reference listed drug" (RLD). *See* 21 U.S.C. § 355(j)(2)(A). The labeling proposed in the ANDA must also be "the same as the labeling approved" for the generic drug's RLD. *Id.* § 355(j)(2)(A)(v).

In re Testosterone Replacement Therapy Prod. Liab. Litig., 142 F. Supp. 3d 747, 748 (N.D. Ill. 2015).

Perrigo manufactures and markets the Equate-branded ibuprofen under an ANDA. The moving defendants argue that, given that federal law imposes a "duty of sameness," *Mensing*, 564 U.S. at 616, on generic drug manufacturers—*i.e.*, their products and their product labeling must be identical to those approved for a corresponding brand-name equivalent, or "reference listed drug"—it was impossible for them to comply with any duty under state tort law to redesign the

product or to amend or add to the warnings on its label. *See id.* at 618-19, 624-26; *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 475-76, 486-88 (2013).

The Court agrees. The Supreme Court's decisions in *Mensing* and *Bartlett* control this case, and they establish that it would be impossible for defendants to comply with state tort law as well as the FDCA and applicable regulations, which prohibited them from altering the product or its label in any way. *See Houston v. United States*, No. 14 C 1042, 2015 WL 1840685, at *1 (N.D. Ill. Apr. 20, 2015) (citing *Mensing* and *Bartlett*) ("Qualitest can only abide by these state-law duties [to design a reasonably safe product and warn of its dangerous propensities] if it changes the design or labeling of [its generic drug] Allopurinol, steps that federal law prohibits it from taking."), *aff'd*, 638 F. App'x 508 (7th Cir. 2016); *see also Gaeta v. Perrigo Pharm. Co.*, 562 F. Supp. 2d 1091, 1097-98 (N.D. Cal. 2008) (reaching similar outcome prior to *Mensing*, reasoning in part that federal law imposes a strict duty of sameness because "[o]verwarning, just like underwarning, can similarly have a negative effect on patient safety and public health" (internal quotation marks omitted)), *aff'd sub nom. Gaeta ex rel. A.G. v. Perrigo Pharm. Co.*, 469 F. App'x 556 (9th Cir. 2012).

Plaintiff argues that that this case is different because the Equate-branded ibuprofen that plaintiff ingested is available not only by prescription but over the counter. According to plaintiff, the "duty of sameness" does not apply to over-the-counter drugs, "which are governed by a different set of federal laws and regulations." (Pl.'s Combined Resp. Br., ECF No. 97 at 4.) As an example of the "different laws and regulations" applicable to nonprescription drugs, plaintiff cites 21 U.S.C. § 379r. Subsection (a) of § 379r expressly preempts most state regulation of nonprescription drugs, providing that, "[e]xcept as provided" in the other subsections of § 379r, "no State . . . may establish or continue in effect any requirement—(1) that relates to the regulation

of a [nonprescription drug]; and (2) that is different from or in addition to, or that is otherwise not identical with, a requirement under this chapter." But plaintiff points to subsection (e), which provides, "Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State." According to plaintiff, subsection (e) shows Congress' intent to "expressly preserve" product liability claims such as plaintiff's from preemption. *See Hunt v. McNeil Consumer Healthcare*, 6 F. Supp. 3d 694, 699 (E.D. La. 2014).

As defendants correctly argue in reply, the saving clause of § 379r(e) merely saves state-law product liability claims from the express preemption provision of § 379r(a), not from preemption generally. Section 379r(e) provides only that "[n]othing ***in this section*** shall be construed" to preempt product liability claims, but defendants do not rely on § 379r(a), any other portion of § 379r, or indeed any express preemption provision; their position is based on *conflict* preemption doctrine, which teaches that plaintiff's claim is preempted because it is impossible for an ANDA holder to comply with the FDCA simultaneously with the state tort duties plaintiff accuses defendants of violating. The weight of authority holds that § 379r(e) does not save product liability claims from this sort of preemption. *See Batoh v. McNeil-PPC, Inc.*, 167 F. Supp. 3d 296, 316-17 n.15, 321 n.19 (D. Conn. 2016); *Reckis v. Johnson & Johnson*, 28 N.E.3d 445, 456 (Mass. 2015); *Trejo v. Johnson & Johnson*, 220 Cal. Rptr. 3d 127, 160-61 (Ct. App. 2017) ("[We disagree with *Hunt* and instead agree with *Eckler* [*v. Neutrogena Corp.*, 189 Cal. Rptr. 3d 339, 347 (Ct. App. 2015)], *Reckis*, and *Batoh* that the savings clause does not foreclose the possibility that conflict preemption may arise from federal sources other than 21 U.S.C. § 379r."); *see also Bartlett*, 570 U.S. at 500 n.2 (Sotomayor, J., dissenting) ("Instructively, Congress included a saving clause in the statutes addressing nonprescription drugs and cosmetics, which makes clear

that ***the express pre-emption provisions*** in these statutes do not affect state product liability law.") (emphasis added); *In re Tylenol (Acetaminophen) Mktg., Sales Practices & Prod. Liab. Litig.*, 144 F. Supp. 3d 699, 725 n.150 (E.D. Pa. 2015) (citing § 379r(e) and suggesting that it is relevant only to express preemption, not other forms). This Court agrees with these decisions.

Plaintiff does not cite any other examples in support of her argument that *Mensing* and *Bartlett* do not apply because nonprescription drugs are governed by a "different set of federal laws or regulations," nor does the Court see any other basis for it. The key distinction in the relevant regulatory structure and case law is not between prescription and non-prescription drugs but between NDA holders and ANDA holders. The distinction makes a difference because of the changes-being-effected ("CBE") regulation, which permits NDA holders—but not ANDA holders—to "add or strengthen" a warning on the product's label, 21 C.F.R. § 314.70(c)(6)(iii)(A), (C), without waiting for preapproval from the FDA. *See Mensing*, 564 U.S. at 604; *Guilbeau*, 880 F.3d at 314 ("[T]he key distinction to both the Supreme Court and the FDA is the approval process."); *see generally id.* at 310-14 (examining cases). Thus, state-law product liability claims for inadequate labeling against ANDA holders are preempted, but similar claims against NDA holders may not be. *Compare Mensing*, 564 U.S. at 604 *with Wyeth v. Levine*, 555 U.S. 555, 568 (2009).

In all of the cases plaintiff has cited, the drug manufacturers asserting a preemption defense were NDA holders; Perrigo is an ANDA holder, so these cases are inapposite. The only potential exception is *In re Tylenol (Acetaminophen) Product Liability Litigation*, 144 F. Supp. 3d at 730, but as defendants explain in their reply brief, that case is the exception that proves the rule. The product at issue had been marketed for parts of its history under an NDA and for other parts under a "monograph system," which is "essentially an expanded version of administrative notice-and-

comment rulemaking" for drugs with active ingredients in longtime use. *Id.* at 708-711. The defendants argued that the claims against them were preempted because the product was no longer marketed under an NDA and could not be changed or re-labeled without FDA approval. But the court found that the former NDA holder had used the CBE process to change its product labels both before and after withdrawing its NDA, and therefore, "[d]espite the defendants' insistence that changing the Extra Strength Tylenol label would be impossible, they have already done it." *Id.* at 730. Thus, in that case as well as the others, the outcome turned on the availability of the CBE process. There is no doubt that that process is not available to defendants here, which means that plaintiff's claims are preempted. *See Mensing*, 564 U.S. at 614.

It was impossible under federal law for defendants to do what plaintiff sues them for failing to do: alter the label or the composition of the product to better reflect or reduce the product's health risks. Because all of plaintiff's claims against the moving defendants involve the same failure to warn or improve the product, they are all preempted, "regardless of how they are styled in her complaint." *See Wagner v. Teva Pharmas. USA, Inc.*, 840 F.3d 355, 358-59 (7th Cir. 2016).

CONCLUSION

For the foregoing reasons, Perrigo's motion to dismiss [56] and Walmart's motion to dismiss [81] are granted. Because plaintiff has already voluntarily dismissed Teva Pharmaceuticals USA Inc., Apothecon LLC, and Bristol-Myers Squibb Company from this case, their motions to dismiss [60 and 68] are denied as moot.

SO ORDERED. **ENTERED: October 28, 2019**

HON. JORGE ALONSO
United States District Judge