IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS

CHARLENE EIKE, et al.,

Plaintiffs,

v.

ALLERGAN, INC., et al.,

Defendants. **No. 3:12-cv-01141-DRH-DGW**

MEMORANDUM AND ORDER

HERNDON, Chief Judge:

Now before the Court is defendants Allergan, Inc., Allergan USA, Inc., Allergan Sales, LLC, Alcon Laboratories, Inc., Alcon Research Ltd., Falcon Pharmaceuticals, Ltd., Sandoz, Inc., Bausch & Lomb Incorporated, Pfizer Inc., Merck & Co., Inc., Merck, Sharp & Dohme Corp., and Prasco, LLC's (collectively "defendants") omnibus motion to dismiss (Doc. 52). Defendants concurrently moved for oral argument (Doc. 56) and filed defendant specific motions to dismiss (Docs. 54, 55, 57). Specifically, defendants Merck & Co., Inc., Merck, Sharp & Dohme Corp., ("Merck"), and Prasco LLC ("Prasco") filed a motion to dismiss (Doc. 54), defendants Alcon Laboratories, Inc. and Alcon Research, Ltd. (collectively "Alcon"), Falcon Pharmaceuticals, Ltd. ("Falcon"), and Sandoz Inc. ("Sandoz") filed a consolidated motion to dismiss (Doc. 55), and defendant Pfizer Inc. filed a motion to dismiss (Doc. 57). Plaintiffs thereafter responded in kind

(Docs. 76, 77, 78, 79). Defendants replied (Docs. 81, 82, 83, 84). Plaintiffs then moved to strike the replies (Doc. 85) and defendants responded to the motion to strike (Doc. 89). After the motions were fully briefed, plaintiffs and defendants filed a number of supplemental briefs (Docs. 93, 99, 100, 102-1, 106-1, 109, 115).

As a preliminary matter, the motion for oral argument (Doc. 56) is **DENIED** and the motion to strike defendants' reply briefs (Doc. 85) is **GRANTED**. Pursuant to the Court's Local Rules, "**[r]eply briefs are not favored and should be filed in only exceptional circumstances**." SD Ill. L.R. 7(c) (bold in original). The Court finds that the circumstances listed in each of the replies do not meet this standard. Furthermore, oral argument on these issues, given the extensive briefing, is unnecessary. For following reasons, the motions to dismiss are **DENIED.**

I. BACKGROUND

This is an action brought by Charlene Eike, Shirley Fisher, Jordan Pitler and Alan Raymond (collectively "plaintiffs"), individually and on behalf of classes of consumers who purchased prescription eye drops manufactured and sold by defendants. In the nine-count first amended complaint filed on February 22, 2013 (Doc. 44), plaintiffs allege that defendants sell their drops in plastic bottles which produce a drop that is too big for the eye. Instead the drop creates wasted runoff down the cheek, an unavoidable injury, and causes the plaintiffs to spend more on additional purchases of the eye drop prescription products. In addition

to the added cost, plaintiffs allege that large drops can lead to a serious health risk when classes run out of their medication before their insurer or other third-party payor will reimburse them for a replacement bottle and instead they go without the medication because they are unable to afford it. Plaintiffs further assert that smaller eye drops could be produced if the dimensions of the eyedropper tip were adjusted and that smaller drops are just as effective. Plaintiffs also assert that the FDA's approval of a drug does not constrain a company's ability to modify its drop size. Plaintiffs argue that defendants actions are unfair in violation of the Illinois Consumer Fraud & Deceptive Business Practice Act ("ICFA"), 815 ILCS 505/1, et seq., and/or the Missouri Merchandising Practices Act ("MMPA"), Mo. Rev. Stat. § 407.010, et seq.

On March 29, 2013, defendants filed an omnibus motion to dismiss (Doc. 52). In their omnibus motion, defendants argue five points: 1) that plaintiffs have failed to allege sufficient facts to establish that the sale of medications that emit eye drops larger than 15 microliters violates any public policy, is coercive or oppressive, or causes substantial injury to the plaintiffs; 2) that the plaintiffs have failed to plead a causal connection between defendants' conduct and plaintiffs' alleged damages; 3) that plaintiffs have failed to alleged any actual injury; 4) plaintiffs have not satisfied federal pleading requirements under Rule 8(a); 5) the plaintiffs' claims are exempted for compliance with other laws or regulations; and 6) that the claims are preemepted by federal law.

While the omnibus motion to dismiss was submitted on behalf of all the

defendants, other motions to dismiss were filed concurrently on behalf of particular defendants. Where relevant, the Court addresses the arguments in these additional motions. Defendants and plaintiffs were also permitted to submit several supplemental briefs. After the motions were fully briefed, the Supreme Court issued its opinion in *Mutual Pharm. Co. v. Bartlett*. 133 S.Ct. 2466 (2013). The Court allowed supplemental briefing on the issues therein presented. The Court also allowed supplemental briefing regarding the issue of plaintiffs' statutory standing. The letters will be addressed herein also where relevant. Finally, the Court has also had the benefit of fully reviewing the briefing in the related case, *Fields v. Alcon Laboratories, Inc.*, No. 13-197 (S.D. Ill.) (hereinafter *Fields*).

II. ANALYSIS

A motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) challenges the sufficiency of the complaint for failure to state a claim upon which relief may be granted. *Gen. Elc. Capital Corp. v. Lease Resolution Corp.*, 128 F.3d 1074, 1080 (7th Cir. 1997). To survive a motion to dismiss, a complaint must establish a plausible right to relief. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). The allegations of the complaint must be sufficient "to raise a right to relief above the speculative level." *Id.*

In making this assessment, the district court accepts as true all well-pleaded factual allegations and draws all reasonable inferences in the plaintiff's favor. *See Rujawitz v. Martin*, 561 F.3d 685, 688 (7th Cir. 2009); *St. John's*

United Church of Christ v. City of Chi., 502 F.3d 616, 625 (7th Cir. 2007). Even though *Twombly* (and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009)) retooled federal pleading standards, notice pleading remains all that is required in a complaint: "A plaintiff still must provide only enough detail to give the defendant fair notice of what the claim is and the grounds upon which it rests, and through his allegations, show that it is plausible, rather than merely speculative, that he is entitled to relief." *Tamayo v. Blagojevich*, 526 F.3d 1074, 1083 (7th Cir. 2008) (internal quotations and citations omitted).

A. Unfair Practice

Defendants first assert that plaintiffs have failed to allege an unfair practice required by both the ICFA and the MMPA. Pfizer also addresses this argument in its defendant specific motion (Doc. 57-1, p 1-4). To determine whether a business practice is unfair, the Court considers "(1) whether the practice offends public policy; (2) whether it is immoral, unethical, oppressive, or unscrupulous; [and] (3) whether it causes substantial injury to consumers." *Robinson v. Toyota Motor Credit Corp.*, 775 N.E.2d 951, 961 (Ill. 2002). *See also Ward v. West County Motor Co., Inc.*, 403 S.W.3d 82, 84 (Mo. 2013) (defining unfair practice similarly under Missouri law). "All three criteria do not need to be satisfied to support a finding of unfairness [pursuant to the ICFA]. A practice may be unfair because of the degree to which it meets one of the criteria or because to a lesser extent it meets all three." *Id.* Unfairness under the ICFA "depends on a case-by-case analysis." *Siegel v. Shell Oil Co.*, 612 F.3d 932, 935 (7th Cir. 2010). A plain

reading of Missouri regulations indicates that the MMPA requires a finding that 1) the practice offends public policy **or** 2) is unethical, oppressive, or unscrupulous *and* presents a risk of, or causes, substantial injury to consumers. *Ward,* 403 S.W.3d at 84 (citing Mo. Code Regs. Ann. tit. 15, § 60-8.020).

The Court finds that plaintiffs have sufficiently alleged an unfair practice under both the ICFA and the MMPA. The complaint clearly alleges that defendants sell their products in containers "designed to dispense eye drops larger than the capacity of the human eye" (Doc. 44 at 36, 38). They further allege that this practice violates the public policy of both Missouri and Illinois as expressed by the Federal Trade Commission's Policy Statement on Unfairness.[1] Both the ICFA and the MMPA accept the interpretations of the Federal Trade Commission as evidencing offense of a public policy, herein relied upon by plaintiffs in their complaint. 815 ILCS 505/2; Mo. Code Regs. Tit. 15, § 60-8.020. Plaintiffs further allege that defendants violations cause plaintiffs and class members "to suffer actual damage measured by the allocated purchase price for the portion of their eye drops in excess of 15 μL" (Doc. 44 at 37, 39).

B. Proximate Cause

Defendants next assert that plaintiffs have failed to plead that defendants' unfair conduct caused them injury. Specifically, they argue that plaintiffs fail to allege proximate causation because the amended complaint does not include any allegations that establish that plaintiffs' doctors would discontinue prescribing

[1] FTC Policy Statement on Unfairness, Appended to *In the Matter of International Harvester Company*, 104 F.T.C. 949, 1070 (1984), *available at* http://www.ftc.gov/ftc-policy-statement-on-unfairness (codified at 15 U.S.C. § 45(n)).

them eye drop medications that emit the larger drops. The Court does not find that defendants have met their burden of proving that the physicians are an intervening cause. *See BCS Services, Inc. v. Heartwood 88, LLC,* 637 F.3d 750, 757 (7th Cir. 2011). It is not unforeseeable that a physician would be responsible for prescribing the prescription eye drops to plaintiffs. Nor would it be unreasonable to infer, as the Court must, that patients would buy less medication absent defendants' conduct.

C. Actual Injury

Defendants also argue that plaintiffs have not pled that they have sustained actual damages. Defendants assert that the benefit-of-the-bargain rule applies and that the measurement of damages is properly calculated as " 'the difference of between the value of the product as represented and the actual value of the product as received.' " (Doc. 53 at 11) (citing *Polk v. KV Pharmaceutical Company,* 2011 WL 6257466, at *5 (E.D. Mo. Dec. 15, 2011)). Defendants further assert that plaintiffs fail to allege any fact that establish a cost savings to plaintiffs if defendants were to sell bottles that dispense smaller drops (Doc. 53 at 11).

The Court finds that plaintiffs have plausibly pled actual damages. The benefit-of-the-bargain rule does not apply in this case. Plaintiffs are not asserting a misrepresentation but instead an unfair practice. *See Frye v. L'Oreal USA, Inc.,* 583 F.Supp.2d 954, 957 (N.D. Ill. Oct. 28, 2008). Furthermore, plaintiffs allege that the unfair practice caused "Plaintiffs and Class Members to suffered

actual damage measured by the allocated purchase price for the portion of their eye drops in excess of 15 μL" (Doc. 44 at 37, 39). At this stage of the litigation, the Court finds this sufficient to survive review.

D. Federal Pleading Requirements Pursuant to Rule 8(a) and Rule 9(b)

Defendants next assert that plaintiffs have not satisfied federal pleading requirements under Rule 8(a) because "they have not identified the specific products they each used, when they were prescribed, how long they used them, what information their healthcare providers or defendants may have provided them about administering the drops, the quantity of solution they received with each prescription, or how much solution was allegedly 'wasted' with each plaintiff's administration of the drops" (Doc. 53 at 14). Plaintiffs assert that this is truly an issue for a class certification motion. The Court allowed supplemental briefing on the issue (Docs. 106-1, 115).

The Court finds that the plaintiffs have sufficiently pled facts pursuant to Rule 8(a). Each plaintiff clearly alleges from which defendant he or she purchased and used eye drops (Doc. 44 at 4-5). Furthermore, plaintiffs' claims are premised on their seeking to represent classes of consumers who bought and used similar products from these companies. They need not have used every prescription eye drop manufactured by every defendant. The issue of substantial similarity is one for class certification review, not an issue that the Court will take up on a motion to dismiss.

In its defendant-specific motion to dismiss, Pfizer asserts that plaintiffs fail

to state any specific allegations about Xalatan (Doc. 57-1 at 4). The Courts reasoning above applies to this assertion. Pfizer also suggests that plaintiffs must meet Rule 9(b)'s heightened pleading requirement (Doc. 57-1 at 4). Rule 9(b) requires that "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." Fed. R. Civ. P. 9(b). In this case, plaintiffs allege an unfair practice not one of fraud or mistake. Therefore Rule 9(b) does not apply. *See Windy City Metal Fabricators & Supply, Inc. v. CIT Tech. Fin. Servs., Inc.*, 536 F.3d 663, 670 (7th Cir. 2008).

E. Statutory Exclusion

Defendants, both in their omnibus motion to dismiss and in Merck and Prasco's defendant-specific motion to dismiss, assert that the Court should also dismiss plaintiffs' claims because ICFA and Missouri law exempt defendants from plaintiffs' claims. The Court also addressed this issue as it applies to the ICFA in the related case *Fields*. Statutory exemption is an affirmative defense not normally appropriate for a Rule 12(b)(6) motion. Only when the affirmative defense appears clearly on the face of the complaint, is dismissal under Rule 12(b)(6) appropriate. As in *Fields*, upon a thorough review of the amended complaint, the Court finds that the affirmative defense of statutory exclusion does not appear on the face of the complaint. *See Independent Trust Corp. v. Stewart Information Services Corp.*, 665 F.3d 930, 935 (7th Cir. 2012).

Defendants admit that there is not a "similarly explicit safe-harbor provision" under Missouri law (Doc. 53 at 17). Instead defendants argue that

"there is no plausible basis to hold defendants liable under the MMPA when they fully complied with federal laws that govern the allegedly harmful acts complained of here" (Doc. 53 at 17). In support of its assertion, defendants cite to *Weber v. St. Louis County*. 342 S.W.3d 318, 324 (Mo. 2011) (en banc). This case differs, however, because in that case Saint Louis County's alleged unfair practice was explicitly provided for by county ordinance. *Id.* "It is not unlawful to enforce valid laws." *Id.* Not only is the connection defendants are trying to make to this case too attenuated to withstand review, again, plaintiffs are not required to anticipate every possible affirmative defense in their complaint.

F. FDA Preemption

Defendants also assert that plaintiffs' claims are preempted because the changes plaintiffs seek under state law conflict with federal law regulating pharmaceutical products. Defendants rely on the Supreme Court's decision in *Mensing*, asserting that the case establishes that state law claims are preempted where the defendant lacks unilateral authority under federal law to comply with an alleged state law requirement (Doc. 13 at 8). *PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567 (2011). Specifically, defendants argue that the FDA requires prior agency approval for any substantial change to a product ("major changes"). These "major changes," they assert, include the quantitative formulation of the drug product and the specifications provided in the approved application (Doc. 13 at 9) (citing 21 C.F.R. § 314.70(b)(2)(i), (ii)). Defendants further rely on FDA Guidance to suggest that a major change requiring approval includes a change in the fill

volume (Doc. 13 at 9) (citing FDA Guidance for Industry, Changes to an Approved NDA or ANDA, Questions and Answers (January 2001) at 9).

Plaintiffs respond asserting that defendants have not met their "demanding" burden of proving that smaller volumes of medication would require changes not allowed under the FDA because defendants have not identified FDA approval of the size of any of their drops. They argue that, in fact, the varied sizes of the drops belie the notion that the manufacturers cannot change drop size. Furthermore, plaintiffs argue that defendants have changed the sizes of their drops. In the alternative, plaintiffs assert that even if the FDA does approve drop size, that pursuant to *Wyeth*, the manufacturers must prove that "the FDA would not have approved a change." 555 U.S. at 571. Finally, plaintiffs argue that "there is no record here on which to decide it" (Doc. 79 at 19).

The Court also allowed and subsequently reviewed plaintiffs' and defendants' supplemental briefs regarding the federal preemption issue including their analysis of *Bartlett* (Docs. 93, 99, 100, 102-1, 109). 133 S.Ct. 2466 (2013).

The Supremacy Clause establishes that federal law "shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., Art. VI, cl. 2. Conflict preemption arises where "it is *impossible* for a private party to comply with both state and federal requirements." *Bartlett*, 133 S.Ct. at 2473 (emphasis added) (internal quotation marks omitted). Conflict may also arise when "the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of

Congress." *Hillman v. Maretta,* 133 S.Ct. 1943, 1950 (2013) (internal quotation marks omitted). Federal preemption is an affirmative defense upon which the defendants bear the burden of proof. *Village of DePue, III v. Exxon Mobil Corp.*, 537 F.3d 775, 786 (7th Cir. 2008). "The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." *Mensing*, 131 S.Ct. at 2579 (citing *Wyeth,* 555 U.S. at 573 (finding no pre-emption where the defendant could "unilaterally" do what state law required)).

As in *Fields*, upon initial review, the Court finds that there remain questions of fact yet to be determined and that the record needs to be further developed. Further, the Court concludes that plaintiffs have provided defendants with sufficient notice of a plausible claim to survive a motion to dismiss.

G. Generic Distributors and Manufacturers

In their defendant-specific motions to dismiss (Doc. 54, 55), Prasco and Alcon assert that the allegations against them are preempted pursuant to *Mensing* and its progeny. They argue that *Mensing* stands for the proposition that state law claims are only viable against entities that have unilateral authority under federal law to comply with the alleged state law requirement. They assert that distributors like Prasco, Falcon, and Sandoz are exempt because they do not have this authority. In this case, Prasco distributes authorized generic Merck products sold under Merck's NDA and Falcon and Sandoz market and sell generic products under Alcon's NDA. Therefore, they assert that they do not have the

authority to submit supplemental applications, which, as noted above, defendants argue would be required in this instance.

The Court finds this argument unpersuasive. First, as indicated above, the record has not yet been developed sufficiently to decide the federal preemption question. Second, unlike in the *Mensing* case where the generic distributor had to use the same warning label as the brand-name product, here plaintiffs indicate that the generic distributors have independent authority to modify the dropper size. Again, without commenting on the merits of this argument, the Court finds that the record requires further development.

Alcon additionally asserts that plaintiffs' claims against Alcon as a generic manufacturer should also be dismissed under *Mensing* because federal regulations require that generic products have the same route of administration, strength, and dosage as the brand products. Defendant, however, does not site to any authority in support of this assertion. Therefore, the Court concludes that Alcon has not met its burden.

H. Pfizer Label Argument

In its defendant-specific motion (Doc. 57), Pfizer argues that reducing the drop size would require a reformulation of the product and label (Doc. 57-1 at 2-4). Plaintiffs assert that the product as sold already varies from the asserted formulation and current label. Without commenting on the merits of this assertion, the Court finds that the record has not yet been sufficiently developed as to this issue to address it upon review of the motion to dismiss.

III. CONCLUSION

Accordingly, defendants' motions to dismiss (Docs. 52, 54, 55, 57) are **DENIED.** Further, defendants' motion for oral argument (Doc. 56) is **DENIED** and plaintiffs' motion to strike defendants' reply briefs (Doc. 85) is **GRANTED.**

IT IS SO ORDERED.

Signed this 18th day of March, 2014.

Chief Judge
United States District Court