**UNITED STATES DISTRICT COURT**
**NORTHERN DISTRICT OF ILLINOIS, EASTERN DIVISION**

| | | |
|---|---|---|
| MIRIAM BIRDSONG and CHERYL MIKEL, individually and on behalf of all others similarly Situated, | ) | |
| Plaintiffs, | ) | |
| v. | ) | Case No. 1:24-cv-07994-TMD |
| WALGREENS, INC., | ) | |
| Defendant. | ) | |

**DEFENDANT WALGREEN CO.'S MOTION TO DISMISS AND INCORPORATED MEMORANDUM OF LAW IN SUPPORT**

## I. INTRODUCTION

Plaintiffs Miriam Birdsong and Cheryl Mikel ("Plaintiffs") seek to hold Walgreen Co.[1] ("Walgreens") responsible for economic losses they claim to have sustained from the purchase of over-the-counter ("OTC"), Walgreens-brand "generic Mucinex" products (the "Products") that allegedly contained benzene. Plaintiffs, however, do not plausibly allege that they purchased Products containing benzene. Plaintiffs do not allege that they or anyone tested their Products (or any Product) for benzene. Nor do they allege that their Products (or any Product) were recalled or subject to FDA action. Plaintiffs appear to base their claims entirely on news articles reporting that ***one*** of several manufacturers, that makes some—but not all—of the Products, uses an inactive ingredient that ***may*** contain benzene. That is not enough to establish Article III standing or to plead the causation and injury necessary for each of Plaintiffs' claims.

Plaintiffs' claims must be dismissed for a host of additional reasons. First, the Federal Food, Drug, and Cosmetic Act ("FDCA") preempts all Plaintiffs' claims because FDA approved the Products as formulated and labeled, and Walgreens, as a retailer, cannot change the Products' formulation or add the warnings that Plaintiffs allege state law requires. Second, Illinois' economic loss rule bars Plaintiffs' negligence and strict liability claims because they allege neither personal injury nor property damage. Third, Plaintiffs cannot plausibly allege that Walgreens intentionally hid the Products' alleged benzene contamination. Finally, Plaintiffs cannot identify any express warranty regarding benzene content or safety, plead that the Products are unfit for their ordinary purpose, or establish the requisite presuit notice or demand.

[1] The Amended Complaint names as defendant "Walgreens Inc." Walgreens is unaware of an entity by that name. Should Plaintiffs' claims survive this Motion to Dismiss, Walgreens anticipates that Plaintiffs will amend to name the correct corporate entity.

Thus, the Amended Complaint should be dismissed with prejudice.[2]

## II. BACKGROUND

The Mucinex line of products includes three brand name, OTC, extended-release mucus relief medications: Mucinex (guaifenesin), Mucinex D (guaifenesin and pseudoephedrine hydrochloride), and Mucinex DM (guaifenesin and dextromethorphan hydrobromide).[3] Each of these products is also available in generic form.[4] Walgreens sells all three Product formulations, in several dosage strengths and package sizes, under its own store brand.[5] Walgreens buys the Products from several manufacturers.[6] The only manufacturer the Amended Complaint identifies (Amneal) makes only two of the three Products: guaifenesin (generic Mucinex) and guaifenesin with dextromethorphan hydrobromide (generic Mucinex DM).[7]

---

[2] Leave to amend is not warranted where "there are no further facts that [a plaintiff] could allege that would" cure the deficiencies in the Complaint." *Heiman v. Bimbo Foods Bakeries Distrib. Co.*, No. 17 CV 4065, 2017 WL 4682732, at *15 (N.D. Ill. Oct. 18, 2017). Nothing suggests Plaintiffs could cure the deficiencies in the Amended Complaint here.

[3] *See* Am. Compl. ¶¶ 3, 9; Ex. 1 (https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process ("Drugs@FDA") (searched for "Mucinex," with product tabs opened)). In fact, the "Mucinex" brand comprises dozens of products, many of which are not extended release and are not made with carbomer—the inactive ingredient at issue here. *See* Ex. 2, Mucinex Products Page, *available at* https://www.mucinex.com/collections/all.

[4] *See* Ex. 3 (Drugs@FDA (searched for "guaifenesin," with tabs open for guaifenesin, guaifenesin and dextromethorphan hydrobromide, and guaifenesin and pseudoephedrine hydrochloride)).

[5] *See* Ex. 4 (FDA NDC Directory, searches for "Walgreen" and "Walgreens" as "Labeler," each search narrowed by Keyword Search "guaifenesin," and sorted by "Application Number / Monograph ID," *available at* https://dps.fda.gov/ndc/searchresult?selection=finished_product&content=LABELERNAME&type=walgreen; https://dps.fda.gov/ndc/searchresult?selection=finished_product&content=LABELERNAME&type=walgreens.

[6] *See* Ex. 3 (identifying manufacturers for each ANDA); Ex. 4 (identifying ANDAs of Products sold by Walgreens).

[7] *See* Am. Compl. ¶ 9; Ex. 3.

Time-released generic drugs, such as the Products, must be approved by the FDA under an Abbreviated New Drug Application ("ANDA"). *See* 21 C.F.R. § 310.502(a)(14) (identifying time-released drugs as "new drugs" requiring ANDA approval). ANDAs submitted to FDA must identify, among other things, each drug product "component" and its specifications. 21 C.F.R. § 314.50(d)(1)(ii)(*a*); *id.* § 314.94(a)(9)(i) (incorporating § 314.50(d)(1) for ANDAs). ANDAs must also specifically "identify and characterize the inactive ingredients in the proposed drug product and provide information demonstrating that such inactive ingredients do not affect the safety or efficacy of the proposed drug product." 21 C.F.R. § 314.94(a)(9)(ii). And ANDAs must include descriptions of manufacturing procedures, product specifications, and proposed labeling. *See id.* §§ 314.50(d)(1)(ii)(*a*), 314.94(a)(9)(i), § 314.94(a)(8). FDA approved an ANDA for each of the Products.[8]

The Products are made with an inactive ingredient called carbomer, which creates the Products' extended-release effect. Am. Compl. (ECF 5) ¶¶ 3, 11. Certain carbomers are made with benzene and are permitted to contain up to a defined amount of benzene.[9] Although brand Mucinex does not use a carbomer that is made with benzene, at least one of the manufacturers that makes the Products uses a carbomer that is permitted to contain benzene.[10] Because carbomer is an inactive ingredient, it must be listed in the Products' FDA-approved labeling. *See* 21 C.F.R. § 201.66(c)(8).

---

[8] *See* 21 C.F.R. § 310.502(a)(14); Ex. 3.

[9] Am. Compl. ¶ 3; *see also* Ex. 5 at 2, *available at* https://www.bloomberg.com/news/articles/2024-08-12/cvs-walmart-walgreens-brand-mucinex-may-contain-cancer-causing-benzene?sref=MTy2GeXk ("US regulators have allowed drugmakers to use benzene for decades . . . .").

[10] *See* Ex. 5 at 2.

Each Plaintiff alleges that she purchased "the generic Mucinex brand from Walgreens" near her residence in South Carolina. Am. Compl. ¶¶ 12-13. Plaintiffs allege that the Products contain benzene because the carbomer "used to make the generic versions of the large retail pharmacies in the U.S. does indeed contain benzene." *Id.* ¶¶ 10-11. They allege that Walgreens did not disclose benzene in the Products' packaging or webpage, and that if Plaintiffs had known the Products contained benzene, they would not have purchased them or would have paid less. *Id.* ¶¶ 14-15. Plaintiffs allege that they suffered damages as a result. *Id.* ¶ 15.

On September 4, 2024, Plaintiffs filed both an original complaint and the Amended Complaint on behalf of themselves and putative classes. *Id.* ¶¶ 1, 18. Plaintiffs attempt to plead 11 claims: Unjust Enrichment (Count I); Breach of Express Warranty (Count II); Breach of Implied Warranty (Count III); Breach of Implied Warranty of Merchantability (Count IV); Fraudulent Concealment (Count V); Strict Liability – Failure to Warn (Count VI); Strict Liability – Design and Formulation Defect (Count VII); Negligent Failure to Warn (Count VIII); Negligent Design & Formulation Defect (Count IX); Negligence (Count X); and Violation of Illinois Consumer Fraud and Deceptive Business Practices Act ("ICFA") (Count XI). *Id.* ¶¶ 32-142.

The Amended Complaint does not allege which "generic Mucinex" Products Plaintiffs purchased;[11] when Plaintiffs purchased them; who made them; which carbomer was used to

[11] The "Equate"-branded products shown in Amended Complaint ¶ 11 are neither sold by Walgreens nor made by the manufacturer identified in the Amended Complaint. *See* Ex. 6, FDA NDC Directory, searched for NDC 79903-065-01 (the NDC visible in the Equate Mucus Relief DM image at Am. Compl. ¶ 11), *available at* https://dps.fda.gov/ndc/searchresult?selection=finished_product&content=PRODUCTNDC&type=79903-065-01 (indicating Wal-Mart, not Walgreens, as the labeler, and ANDA 207602 as the application number); Ex. 7, FDA NDC Directory searches for "Wal-Mart" and "Walmart" as "Labeler," each search narrowed by Keyword Search "guaifenesin," and sorted by "Application Number/Monograph ID, *available at* https://dps.fda.gov/ndc/searchresult?selection=finished_product&content=LABELERNAME&ty

make them; the amount of benzene, if any, in the carbomer used to make them; or the amount of benzene, if any, in the finished Products.

## III. ARGUMENT

### A. Plaintiffs Fail to Plead that They Purchased Products Containing Benzene

Plaintiffs have not plausibly pled the one fact necessary to each of their claims: that the Products ***they*** purchased contain benzene. Thus, Plaintiffs have neither pled a concrete and particularized injury-in-fact necessary to establish Article III standing nor plausibly stated a claim upon which relief can be granted under Rule 12(b)(6).

#### 1. Legal standard for Article III standing.

To establish standing, a plaintiff must plead that she "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robin*s, 578 U.S. 330, 338 (2016). The injury in fact must be "concrete, ***particularized***, and ***actual*** or imminent." *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 149 (2010) (emphasis added). And the injury "must affect the plaintiff in a ***personal and individual way***." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 n.1 (1992) (emphasis added). Thus, even if a court accepts a plaintiff's economic loss theory generally, the plaintiff still must plausibly plead that the product ***he or she*** purchased was contaminated. *See Nelson v. John Paul Mitchell Sys.*, 2024 WL 4265198, at *8-10 (N.D. Ill. Sept. 23, 2024) (dismissing claims where plaintiff failed to plausibly allege that the products they purchased were defective); *In re Recalled Abbott Infant Formula Prods. Liab. Litig.*, 2023 WL

---

pe=wal-mart; https://dps.fda.gov/ndc/searchresult?selection=finished_product&content=LABELERNAME&type=walmart (showing all "guaifenesin" monotherapy products labeled by Wal-Mart are sold under ANDAs 209215 and 209254); Ex. 3 (showing Perrigo R and D as holder of ANDA 207602, Guardian Drug as holder of ANDA 209215, and Ohm Labs as holder of ANDA 209254).

3585759, at *17-21 (N.D. Ill. May 22, 2023) (same); *see also Huertas v. Bayer US LLC*, 120 F.4th 1169, 1178 (3d Cir. 2024); *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Practices & Liab. Litig.*, 903 F.3d 278, 289 (3d Cir. 2018); *Wallace v. ConAgra Foods, Inc.*, 747 F.3d 1025, 1030 (8th Cir. 2014); *Grodnick v. Johnson & Johnson*, No. 24-2616, 2024 WL 5056411, at *5-11 (D.N.J. Dec. 10, 2024); *Bell v. Greenbrier Int'l, Inc.*, No. 24-cv-3559, 2024 WL 4893270, at *8-9 (S.D.N.Y. Nov. 26, 2024).

Conclusory allegations that a plaintiff purchased a contaminated product are not enough. *See Twombly*, 550 U.S. at 561-62. For example, in *Nelson*, the fact that a third party had tested and found benzene in three lots of dry shampoo was not sufficient to allege that the product purchased by plaintiffs contained benzene. *See Nelson*, 2024 WL 4265198, at *9. The chance that all lots contained benzene was not sufficient to confer standing "absent allegations that the product they purchased were from the tested lots." *Id.*; *see also Grodnick*, 2024 WL 5056411, at *9-10; *Bell*, 2024 WL 4893270, at *9-10, 15.

A motion to dismiss for lack of Article III standing is treated as a motion to dismiss under Federal Rule of Civil Procedure 12(b)(1). *Maya v. Centex Corp.*, 658 F.3d 1060, 1067 (9th Cir. 2011). "The plaintiff, as the party invoking federal jurisdiction, bears the burden of establishing," and "must clearly allege facts demonstrating," each element of standing. *Spokeo*, 578 U.S. at 338. Where standing is challenged on the face of the complaint, "a court should use *Twombly-Iqbal's* 'plausibility' requirement, which is the same standard used to evaluate facial challenges to claims under Rule 12(b)(6)." *Silha v. ACT, Inc.*, 807 F.3d 169, 174 (7th Cir. 2015).

**2. Legal standard for dismissal under Rule 12(b)(6).**

Under Rule 12(b)(6), "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*, 129 S. Ct. 1937, 1949 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A plaintiff must

provide "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action" and must establish "more than a sheer possibility that a defendant has acted unlawfully." *Iqbal*, 556 U.S. at 678; *Twombly*, 550 U.S. at 555 (citations omitted). "Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." *Iqbal*, 556 U.S. at 678. On a motion to dismiss pursuant to Rule 12(b)(6), courts "may take judicial notice of documents in the public record . . . without converting a motion to dismiss into a motion for summary judgment." *Pugh v. Tribune Co.*, 521 F.3d 686, 691 n.2 (7th Cir. 2008).

**3. Plaintiffs have not plausibly pled that they purchased Products containing benzene.**

Plaintiffs plead no facts to support the necessary contention that they purchased Products containing benzene. They do not identify which Products they purchased,[12] when they purchased them, or who made them. The do not allege that any Products—let alone the Products ***they*** purchased—tested positive for benzene, have been recalled (which itself would not be sufficient anyway—*see Huertas*, 120 F.4th at 1178), or have been subject to FDA action. All Plaintiffs allege is that one manufacturer[13] that makes only two of the three Products[14] uses a carbomer that ***may*** contain benzene. Am. Compl. ¶¶ 9-10. Even if Plaintiffs had plausibly pled that they purchased a Product made by that manufacturer, which they do not, Plaintiffs do not plead that

[12] The Amended Complaint does not even identify whether the Products that Plaintiffs purchased were extended-release products made with carbomer. *See* Ex. 2 & *supra* note 3.

[13] Plaintiffs seem to assume, incorrectly, that because "the major US chains all source their extended mucus-relief medicine from the same New Jersey company," Am. Compl. ¶ 9, that Walgreens and other retailers source generic Mucinex ***only*** from that company. As discussed throughout this Memorandum, that is definitively not the case.

[14] *See* Ex. 3.

***any*** finished Product made by that manufacturer actually contains benzene, let alone the Products that Plaintiffs purchased.[15] Without these critical facts, Plaintiffs fail to plausibly plead that they suffered an injury-in-fact; consequentially, they lack standing to bring any claim and fail to state a claim under which relief may be granted under Rule 12(b)(6).[16]

**B. The FDCA Preempts All of Plaintiffs' Claims**

**1. 21 U.S.C. § 379r expressly preempts Plaintiffs' claims.**

When federal and state law conflict, the Constitution's Supremacy Clause requires preemption of state law. *See* U.S. Const. art. VI, cl. 2; *Nelson v. Great Lakes Educ. Loan Servs.*, 928 F.3d 639, 646 (7th Cir. 2019). Two kinds of preemption apply here: express preemption and conflict preemption, a type of implied preemption. *See Nelson*, 928 F.3d at 646-47. Express preemption occurs when a statute includes "explicit pre-emptive language." *Pacific Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm'n*, 461 U.S. 190, 203-04 (1983). The FDCA expressly preempts any state law claim that "relate[s] to the regulation of" an OTC drug and "that is different from or in addition to, or that is otherwise not identical with, a requirement under [the FDCA], the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.), or the

[15] The Amended Complaint cites a *New York Post* article for the proposition that the carbomer used in the manufacture of the Products "does indeed contain benzene." Am. Compl. ¶ 11 & n.14. That article relies in turn on an article from *Bloomberg* that merely states that the carbomer in the manufacturer's product is "made using benzene," not that the carbomer, much less the finished product, ***contains*** benzene. *See* Ex. 8, *available at* https://nypost.com/2024/08/12/business/generic-version-of-mucinex-sold-by-cvs-walmart-walgreens-and-target-contain-cancer-causing-chemical-report/; Ex. 5 (*Bloomberg* article).

[16] Because Plaintiffs' fraudulent concealment and ICFA claims, like all of their claims, fail under the general pleading standard, those claims also must be dismissed for failure to plead with particularity under Rule 9(b). *See* Fed. R. Civ. P. 9(b); *see also Camasta v. Jos. A. Bank Clothiers, Inc.*, 761 F.3d 732, 737 (7th Cir. 2014) (applying Rule 9(b) to an ICFA claim based on an "unfair practice" because it was "clearly premised" upon allegations of fraud).

Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.)." 21 U.S.C. § 379r(a).[17] Specifically, "[a] state can't add to the list of disclosure requirements imposed by the FDA. So, if the FDA requires a drug maker to disclose A, B, and C, a state can't add to the list and force a drug maker to disclose A, B, C, and D." *Calchi v. TopCo Assocs., LLC*, No. 22-cv-747, 2024 WL 4346420, at *24 (N.D. Ill. Sept. 30, 2024); *see also Gibson v. Albertson's Co.*, 2024 WL 4514041, at *19-20 (N.D. Ill. Oct. 17, 2024).

Here, the FDCA expressly preempts Plaintiffs' state law claims because those claims ostensibly would require Walgreens to add disclosures that the Products contain benzene or could cause cancer, in direct conflict with the FDA-approved labeling (which does not include benzene or cancer warnings), as well as with FDA's approval of the Products' formulation and FDA's determination the Products are safe and effective when manufactured pursuant to the specifications and processes set forth in the Products' ANDAs. *See* 21 U.S.C. § 355(b), (j); 21 C.F.R. §§ 314.94(a)(8)(ii), (9), 314.50(d)(ii)(a); Ex. 3. Indeed, the Product ANDAs must specifically identify the carbomer used in the Products and include the manufacturing processes for the Products, the specifications for benzene in the carbomer and finished Products, and the current labeling. *See* 21 C.F.R. §§ 314.94(a)(8)(ii), (9), 314.50(d)(ii)(a). With this information, FDA approved the Products as safe and effective. *See* 21 U.S.C. § 355(a), (b), (j); Ex. 3. Because Plaintiffs' state law claims would require additional disclosures, the FDCA preempts them.

In addition, while Plaintiffs claim that state law requires Defendants to include benzene

[17] Section 379r provides an exception for state law products liability claims, *see* 21 U.S.C. § 379r(e), but Plaintiffs cannot plausibly argue that their claims sound in products liability. Plaintiffs and the putative class seek relief only for economic loss, and product liability claims—*i.e.*, strict liability and negligence claims—based on pure economic loss are barred as a matter of law. *See In re Chi. Flood Litig.*, 680 N.E.2d 265, 274 (Ill. 1997) (citing *Moorman Mfg. Co. v. National Tank Co.*, 435 N.E.2d 443, 453 (Ill. 1982)). As explained *infra* at 12-13, even if Plaintiffs brought products liability claims here, they would be barred by the economic loss rule.

on the Product labeling,[18] the FDCA prohibits it. The FDCA provides that only "active ingredients" and "inactive ingredients" may be listed on the labeling. 21 U.S.C. § 352(e); 21 C.F.R. § 201.66. An "active ingredient" is "any component that is ***intended*** to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to affect the structure or any function of the body of humans." 21 C.F.R. § 201.66(b)(2) (emphasis added). An "inactive ingredient" is any "component" that is not an active ingredient. *Id.* § 201.66(b)(8). A "component" is "any ingredient ***intended*** for use in the manufacture of a [finished] drug product, including those that may not appear in such drug product." *Id.* § 210.3(b)(3) (emphasis added); *see also id.* § 210.3(b)(4) (defining "drug product" to mean the finished dosage form). Plaintiffs do not allege—and cannot plausibly allege—that any manufacturer uses benzene as an ingredient in the Products, only that one of the manufacturers of the Products uses a carbomer that was manufactured with, and thus ***may*** contain some residual level of, benzene. Because benzene is neither an active nor inactive ingredient, the FDCA prohibits its inclusion in the labeling. To the extent state law requires something different, as Plaintiffs allege, the FDCA expressly preempts it. *See Williams v. Galderma Lab'ys, L.P.*, No. 24 CV 2222, 2024 WL 4213220, at *7-12 (N.D. Ill. Sept. 17, 2024) (rejecting the argument that benzene was an "active ingredient" or "inactive ingredient" and thus should have been included in the label); *Howard v. Alchemee, LLC*, No. 2:24-cv-01834, 2024 WL 4272931, at *29 (C.D. Cal. Sept. 19, 2024) (same).

[18] The Amended Complaint refers specifically to the Products' "packaging or webpage," Am. Compl. ¶ 14, both of which FDA considers "labeling" subject to FDA regulations. *See* 21 U.S.C. § 321(m) (defining "labeling"); *Kordel v. United States*, 335 U.S. 345, 350 (1948) (explaining that "labeling" includes materials that supplement or explain an article and that "[n]o physical attachment one to the other is necessary"). Moreover, while the Amended Complaint references "advertising," it identifies no advertisements on which Plaintiffs' claims are based.

**2. The FDCA Impliedly Preempts Plaintiffs' Claims**

Even if the FDCA does not expressly preempt Plaintiffs' claims, it impliedly preempts them under conflict preemption. Conflict preemption applies when "compliance with both federal and state regulations is a physical impossibility." *Maryland v. Louisiana*, 451 U.S. 725, 747 (1981). Thus, where state law would require representations prohibited by or inconsistent with federal law, federal law preempts those state law claims. *See Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 480-86 (2013); *Pliva, Inc. v. Mensing*, 564 U.S. 604, 611-15 (2011).

When analyzing conflict preemption in the pharmaceutical context, courts must determine whether a drug manufacturer may unilaterally take action and comply with both state and federal law. *See Guilbeau v. Pfizer Inc.*, 880 F.3d 304, 317-18 (7th Cir. 2018) (concluding that state law claims that would require generic manufacturers to unilaterally change their labels, which is prohibited by federal law, are preempted). Where FDA pre-approval is necessary, "the drug-makers c[an]not 'independently satisfy [their] state duties for pre-emption purposes,'" and a plaintiff's state law claims are preempted. *Id.* at 311 (quoting *Pliva*, 564 U.S. at 624).

Accordingly, courts have held that the FDCA impliedly preempts claims against retailer defendants because they have no ability to unilaterally change the product labeling, formulation, or manufacture. *See In re Zantac (Ranitidine) Prods. Liab. Litig.*, 548 F. Supp. 3d 1225, 1254-55 (S.D. Fla. 2021) ("*Zantac II*") (dismissing economic loss claims against retailers of store-brand drugs because "Plaintiffs ha[d] not alleged nor argued that the Store-Brand Defendants had any greater authority under federal law to change their store-brand ranitidine products' design or labeling than did the [manufacturers]"); *In re Zantac (Ranitidine) Prods. Liab. Litig.*, 510 F. Supp. 3d 1234, 1252-54 (S.D. Fla. 2020) ("*Zantac I*") (S.D. Fla. 2020) (dismissing state law

claims against retailer defendants because they "could not correct the alleged misbranding by altering the composition of the drug, nor could the [retailer defendants] alter the drug's label").[19]

Here, Walgreens does not hold the ANDAs for any of the Products. *See* Ex. 3. Plaintiffs cannot plausibly allege that Walgreens, a retailer, has any ability whatsoever to change the Products' labeling, formulation, or manufacturing processes, let alone without prior FDA approval. Walgreens' only option to address the issues about which Plaintiffs complain would be "to stop selling the drug altogether which they are not required to do to comply with a state law duty." *Zantac I*, 510 F. Supp. 3d 1234, 1252-53 (citing *Bartlett*, 570 U.S. at 488-91); *see also Bartlett*, 570 U.S. at 488 (calling this "stop-selling" theory "incoherent[t]" and "incompatible with our preemption jurisprudence"). Thus, even if the FDCA did not expressly preempt Plaintiffs' claims—which it does—it does so impliedly through conflict preemption.

### C. The Economic Loss Rule Bars Plaintiffs' Negligence and Strict Liability Claims (Counts VI-X)

Under Illinois law, a "plaintiff cannot recover for solely economic loss under the tort theories of strict liability [and] negligence." *Moorman Mfg. Co. v. National Tank Co.*, 435 N.E.2d 443, 453 (Ill. 1982). Rather, plaintiffs may recover in negligence or strict liability only for "personal injury or property damage." *Id.* at 450; *see also Turner v. GAC Star Quality, LLC*, 671 F. Supp. 3d 897, 905 (N.D. Ill. 2023). For purposes of this economic loss rule, a defect in the product at issue is not "damage to property"; some other property must be damaged. *See Trans States Airlines v. Pratt & Whitney Can.*, 177 Ill. 2d 21, 41-42 (1997); *Turner*, 671 F. Supp. 3d at 905. Here, Plaintiffs do not allege personal injury or property damage; rather, they simply allege

[19] Moreover, not even generic manufacturers, much less retailers, may unilaterally change the safety labeling for generic drugs. *See Pliva*, 564 U.S. at 613, 618 (explaining that while a brand manufacturer "is responsible for the accuracy and adequacy of its label,"' a generic manufacturer "is responsible for ensuring its warning label is the same as the brand name's").

that "[i]f Plaintiffs had been aware of the Benzene contamination in the Products, they would not have purchased the Products or would have paid significantly less." Am. Compl. ¶ 15. Plaintiffs cannot recover for this alleged purely economic loss under negligence or strict liability theories.

**D. Plaintiffs Do Not Plausibly Plead Walgreens' Knowledge or Intent Needed for Their Fraudulent Concealment and ICFA Claims (Counts V and XI)**

Under Illinois law, fraudulent concealment and ICFA claims both require that the defendant acted with intent. *See Phillips v. DePaul Univ.*, 18 N.E.3d 1019, 1037 (Ill. Ct. App. (2021)) (fraudulent concealment); *Nofsinger v. Jackson Nat'l Life Ins. Co.*, 2021 WL 3077659, at *11 (N.D. Ill. July 21, 2021) (ICFA). "Although Rule 9(b) does not require 'particularity' with respect to the defendant's mental state, the complaint still must afford a basis for believing that plaintiffs could prove scienter." *DiLeo v. Ernst & Young*, 901 F.2d 624, 627 (7th Cir.1990); *see also Ibarolla v. Nutrex Research, Inc.*, No. 12 C 4848, 2012 WL 5381236, at *10 (N.D. Ill. Oct. 31, 2012). Where there are insufficient facts to infer that a defendant knew of a product defect or risk, a court cannot infer the defendant's intent. *See Castaneda v. Amazon.com, Inc.*, 679 F. Supp. 3d 739, 753 (N.D. Ill. 2023) (citing *Toulon v. Cont'l Cas. Co.*, 877 F.3d 725 (7th Cir. 2017)) (dismissing ICFA claims because "[i]f Amazon did not know of a design defect, then it did not engage in deception by omission."); *Ibarolla*, 2012 WL 5381236, at *12-13.

Here, Plaintiffs fail to allege any facts to infer that Walgreens, a retailer with no responsibility for the Products' manufacture or the ANDAs, knew, much less intentionally concealed, that the Products contained benzene. Plaintiffs' contentions otherwise, *see, e.g.*, Am. Compl. ¶ 79, are conclusory and insufficient to state a claim. *See Twombly*, 550 U.S. at 561-62.

**E. Plaintiffs Fail to Plead an Express Warranty (Count II)**

To plead a breach of express warranty, Plaintiffs must allege, among other things, "the terms of the warranty." *Wright v. Walmart, Inc.*, 688 F. Supp. 3d 794, 807 (S.D. Ill. 2023)

(quoting *Lambert v. Dollar Gen. Corp.*, 2017 WL 2619142, at *5 (N.D. Ill. June 16, 2017)). Plaintiffs do not do so here. The Amended Complaint refers only to "promises and affirmations of fact [by Defendant] that the products were safe to consume," Am. Compl. ¶ 41; it does not identify an express "description of goods" from the Products' packaging or advertising that made that representation. *See* 810 Ill. Comp. Stat. 5/2-313. At most, Plaintiffs allege an implicit representation of Product safety, not an express warranty. *See Wright*, 688 F. Supp. 3d at 807 (dismissing express warranty claim as the warranty "was not expressly stated").

### F. Plaintiffs' Implied Warranty Claims (Counts III-IV) Fail Because They Cannot Plead that the Products Were Unfit for Their Intended Purpose

To state a claim for a breach of implied warranty of merchantability, a plaintiff must allege, among other things, that "the defendant sold goods that were not merchantable at the time of sale." *Wright*, 688 F. Supp. 3d at 807 (citing 810 Ill. Comp. Stat. 5/2-314; *Solvay USA v. Cutting Edge Fabrication, Inc.*, 521 F. Supp. 3d 718, 725 (N.D. Ill. 2021)). To be "merchantable," goods must "pass without objection in the trade under the contract description" and must be "fit for the ordinary purposes for which such goods are used." *Id.*

Here, even if Plaintiffs plausibly plead that they purchased Products containing benzene—which they do not—they cannot allege the Products are unfit for their ordinary purpose because the FDA approved the products as safe and effective under their current formulation and labeling, and Plaintiffs do not allege any variation from the FDA-approved formulation or labeling. Plaintiffs do not plead that they were physically injured by the Products. Nor do Plaintiffs plausibly allege that they could not use the Products or that they did not work. Plaintiffs' implied warranty claims are "conclusory at best." *Wright*, 688 F. Supp. 3d at 807-08.[20]

[20] Plaintiffs assert a general "breach of implied warranty" claim. Am. Compl. ¶¶ 48-55 (Count III). But the Uniform Commercial Code, which governs the sale of goods in this case, *see* 810 Ill. Comp. Stat. 5/2-102, recognizes only two implied warranties: the implied warranty of

### G. All of Plaintiffs' Warranty Claims (Counts II-IV) Must Be Dismissed for Failure to Provide Presuit Notice and Demand

Express warranty claims require that plaintiffs make a presuit demand of the defendant. *See Wright*, 688 F. Supp. 3d at 807. Implied warranty claims require that plaintiffs provide presuit notice. *See id.* at 808; *Solvay*, 521 F. Supp. 3d at 725. Here, Plaintiffs allege neither. While Plaintiffs suggest Walgreens was on notice either "through its review of consumer complaints and other reports" or because it was "made aware of the adverse health effects caused by risk of Benzene exposure," Am. Compl. ¶¶ 53, 63, they do not identify the complaints or reports that allegedly provided constructive notice, and, in any event, the law requires ***Plaintiffs*** to notify Walgreens of the alleged breach. *See Wright*, 688 F. Supp. 3d at 807-08. Because Plaintiffs do not (and cannot) allege that they did so, their warranty claims must be dismissed.

## IV. CONCLUSION

For the foregoing reasons, the Court should dismiss Plaintiffs' claims with prejudice.

Dated: January 24, 2025

**WALGREEN CO.**

By: /s/ *Robin P. Sumner*
One of Its Attorneys

Robin P. Sumner
*robin.sumner@troutman.com*
Troutman Pepper Locke LLP
3000 Two Logan Square
18th and Arch Streets
Philadelphia, PA 19103
(215) 981-4652

merchantability and the implied warranty of fitness for a particular purpose. *See* 810 Ill. Comp. Stat. 5/2-314; 810 Ill. Comp. Stat. 5/2-315. Plaintiffs plainly do not plead a claim for breach of implied warranty of fitness for a particular purpose. *See Solvay*, 521 F. Supp. 3d at 727-28 (setting forth the requirements for pleading breach of implied warranty of fitness for a particular purpose).