UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: ACETAMINOPHEN – ASD-ADHD PRODUCTS LIABILITY LITIGATION	:	Case No. 1:22-md-03043-DLC
This Document Relates to:	:	**RETAILER DEFENDANTS' MEMORANDUM IN SUPPORT OF THEIR MOTION TO DISMISS**
All Cases	:	

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INTRODUCTION

Plaintiffs bring eleven claims against fourteen retailers under the laws of sixteen states. According to Plaintiffs, each Retailer Defendant violated state law by selling acetaminophen products that contained the exact pregnancy warning required by FDA. But, as also explained by Johnson & Johnson Consumer Inc. ("JJCI") in its motion to dismiss, none of these claims can survive a motion to dismiss. First and foremost, Plaintiffs' claims are preempted by federal law, which prohibits the Retailer Defendants from adding the pregnancy warning that Plaintiffs demand. The pregnancy warning prescribed by federal law is exclusive and, in any event, the warning advocated by Plaintiffs would be misleading and would misbrand the products at issue. Apart from that legal defect, Plaintiffs' claims also fail to satisfy the applicable pleading standards. Plaintiffs' claims fail to satisfy Rule 8 because Plaintiffs have not adequately pleaded elements of their claims, including causation and knowledge. And Rule 9(b) forecloses the consumer protection and misrepresentation claims because Plaintiffs have not identified any of the key facts that Rule 9(b) requires.

Moreover, the Retailer Defendants' compliance with federal law forecloses certain claims for reasons beyond those set forth in JJCI's motion. Federal law requires a specific pregnancy warning to appear on the products at issue, and Plaintiffs' own allegations establish that the acetaminophen products the Retailer Defendants sold contained the requisite federal warning. Congress confirmed the sufficiency of this pregnancy warning in 2020 when it established that the products at issue are "deemed to be generally recognized as safe and effective" if they conform to FDA's monograph and other relevant regulatory requirements (like the pregnancy warning). 21 U.S.C. § 355h(a)(1); Compl. ¶ 109. Separate from the conflict preemption analysis, this congressional act, coupled with the products' compliance with federal law, impacts this litigation in three important ways. *First*, Congress has expressly preempted Plaintiffs' claims that are not

brought under state product liability law. 21 U.S.C. § 379r(a), (e). Because many state consumer protection statutes do not encompass claims for personal injury, those consumer protection claims necessarily fall outside the product liability exception to § 379r(a)'s express preemption provision and must be dismissed. *Second*, as a matter of *state* law, compliance with federal law triggers the safe harbor provisions of many consumer protection statutes, meaning that Plaintiffs' consumer protection claims under those states' laws cannot proceed. And *third*, compliance with federal law also triggers other state safe harbor provisions and doctrines that bar common law claims as well as statutory consumer protection claims, so all of Plaintiffs' claims under those states' laws must be dismissed.

State product liability statutes also foreclose many of Plaintiffs' claims. In two states at issue—Louisiana and Tennessee—the state product liability statute subsumes all the claims that Plaintiffs assert, both under the common law and under the consumer protection statutes of those states. And in three other states at issue—Kentucky, Texas, and Washington—the state product liability statute subsumes all the common law claims asserted in this action. Plaintiffs' subsumed claims must be dismissed.

Finally, the Retailer Defendants' status as retailers provides unique defenses that warrant the dismissal of certain claims. In most states, the law views sellers as different from manufacturers, with different duties that result in manufacturers being subject to different standards of product liability. Plaintiffs try to circumvent this critical distinction in two ways: First, they contend that the Retailer Defendants can be held liable for a separate claim of "apparent manufacturer liability" because they supposedly held themselves out as manufacturers. But most states have rejected or not adopted "apparent manufacturer liability," and even for states that employ the doctrine, many do not treat it as a standalone claim. And second, they allege that the

Retailer Defendants had control over manufacturing or labeling. But the very documents on which Plaintiffs rely establish that the manufacturer (not the Retailer Defendants) remained in control.

Plaintiffs have had more than six months to plead a viable cause of action against the Retailer Defendants. They have failed to do so. This Court should thus dismiss all the claims against the Retailer Defendants with prejudice.

FACTUAL AND PROCEDURAL BACKGROUND

Acetaminophen Labeling and the Monograph System. Acetaminophen has been sold since 1955. Compl. ¶ 80. An acetaminophen product "is generally recognized as safe and effective and is not misbranded if it meets each condition in this [monograph] in addition to each of the general conditions established in § 330.1 of this chapter." Compl. ¶ 102 (quoting Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; Tentative Final Monograph, 53 Fed. Reg. 46,204, 46,255 (Nov. 16, 1988) ("Acetaminophen Monograph")). Plaintiffs do not dispute that each product at issue bore the pregnancy warning prescribed by FDA regulations and thus complied with the monograph's conditions. *See* 21 C.F.R. § 201.63(a).

Instead, Plaintiffs argue that the monograph conditions and FDA's specified warning were insufficient and that the Retailer Defendants should have given different or additional pregnancy warnings. *See* Compl. ¶ 104. According to Plaintiffs, around two dozen studies released between 2013 and 2021 "identif[y] positive associations with acetaminophen exposure during pregnancy and ASD or ADHD." Compl. ¶ 351.

But there is a good reason why the warning prescribed by FDA regulations and the monograph has not changed. In 2015, FDA addressed certain studies—including two studies Plaintiffs cite—on acetaminophen use during pregnancy and determined that no additional

warning was needed.[1] FDA promised publicly that it would continue to monitor studies on the risks of acetaminophen use during pregnancy,[2] and FDA has, in fact, done so. Between 2015 and 2022, FDA has repeatedly evaluated the literature on acetaminophen use during pregnancy, each time declining to impose a new warning or to change its current public statement on acetaminophen use during pregnancy. *See, e.g.*, Danielle Abraham & Andrew Mosholder, *Epidemiology: Review of Published Studies* (July 15, 2022), Declaration of Sarah E. Johnston Esq., Ex. G (JJCI Brief). Congress too has spoken clearly on the adequacy of the existing FDA warnings. In 2020, Congress passed the CARES Act, in which it "deemed" drugs in compliance with a final or tentative final monograph (like the acetaminophen products at issue) "to be generally recognized as safe and effective." *See* Coronavirus Aid, Relief, and Economic Security Act, Pub. L. No. 116-136, § 3851, 134 Stat. 281, 435 (2020) (codified at 21 U.S.C. § 355h(a)(1)); *see also* Compl. ¶ 109. In light of these actions by FDA and Congress, acetaminophen product manufacturers continued to label acetaminophen in compliance with federal law. And the Retailer Defendants continued to sell those acetaminophen products.

Procedural History. In June 2022, plaintiffs began to file lawsuits against the Retailer Defendants, contending that acetaminophen products should have warned of a potential link between acetaminophen use during pregnancy and ASD and/or ADHD. *See, e.g.*, Complaint, *Foley v. Wal-Mart Stores, Inc.*, No. 3:22-cv-05040 (W.D. Mo. June 1, 2022), ECF No. 1. After the JPML ordered consolidation, Transfer Order, MDL No. 3043 (J.P.M.L. Oct. 5, 2022), ECF No. 92, this Court ordered the filing of two master complaints, with short-form complaints to follow. PTO

[1] *FDA Drug Safety Communication: FDA has reviewed possible risks of pain medicine use during pregnancy*, FDA.gov (Jan. 9, 2015), https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-has-reviewed-possible-risks-pain-medicine-use-during-pregnancy.

[2] *Id.*

Scheduling Master Compls., ECF No. 235; *see also* Supplemental PTO Scheduling Master Compls., ECF No. 257.

Plaintiffs' Allegations. Plaintiffs are parents or legal guardians who are suing on behalf of their children or on their own behalf, alleging that the Retailer Defendants violated state law despite complying with the labeling rules imposed by FDA and Congress. According to Plaintiffs, acetaminophen use during pregnancy caused ASD and/or ADHD in the Plaintiff children. Compl. ¶¶ 418–30. Plaintiffs plead eleven claims: (1) strict products liability for failure to warn, Compl. at 91–94; (2) strict products liability design defect due to warnings and precautions, Compl. at 94–98; (3) negligence, Compl. at 99–102; (4) negligent misrepresentation, Compl. at 102–04; (5) strict liability misrepresentation, Compl. at 104–06; (6) violation of consumer protection laws, Compl. at 107–11; (7) breach of implied warranty, Compl. at 111–13; (8) liability as apparent manufacturer, Compl. at 113–17; (9) breach of express warranty, Exhibit A to Short Form Complaint ¶¶ 1–13, *Crawford v. Target Corp.*, No. 1:22-cv-09022-DLC (S.D.N.Y. Jan. 20, 2023), ECF No. 39-1; Exhibit A to Short Form Complaint ¶¶ 1–13, *Taylor v. Wal-Mart Stores Inc.*, No. 1:22-cv-08930-DLC (S.D.N.Y. Jan. 20, 2023), ECF No. 48-1; (10) violation of Louisiana Product Liability Law, Short Form Complaint at 18, *Norris v. Wal-Mart Stores, Inc.*, No. 1:23-cv-00214-DLC (S.D.N.Y. Jan. 24, 2023), ECF No. 22; and (11) redhibition, *id*. Plaintiffs have asserted claims under the laws of these sixteen states: Arizona, California, Colorado, Florida, Illinois, Kentucky, Louisiana, Minnesota, Missouri, Nevada, New York, Oregon, Pennsylvania, Tennessee, Texas, and Washington.[3]

[3] A chart identifying the state law claims asserted by Plaintiffs in each case pending against the Retailer Defendants and arguments for dismissal of each claim is attached in Exhibit 1. As discussed in prior submissions to the Court, in filing this Motion to Dismiss, the Retailer Defendants seek dismissal of all cases pending against them. To the extent an argument advanced in this Motion applies only to certain cases, the Retailer Defendants have prepared (and reference

LEGAL STANDARD

To survive a motion to dismiss 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*, 556 U.S. 662, 678 (2009) (quotation marks omitted). Plaintiffs are required to allege well-pleaded, non-conclusory facts supporting each element of each of their claims. *See In re Rezulin Prods. Liab. Litig.*, 2003 WL 21396744, at *1 (S.D.N.Y. June 17, 2003). "The court is 'not bound to accept as true legal conclusions couched as factual allegations.'" *Watkins v. Smith*, 2012 WL 5868395, at *2 (S.D.N.Y. Nov. 19, 2012) (Cote, J.) (quoting *Iqbal*, 556 U.S. at 678) (granting motion to dismiss). When a plaintiff "fail[s] to adequately plead facts giving rise to a plausible claim for relief," a motion to dismiss should be granted. *Joester Loria Grp. v. Licensing Co.*, 2011 WL 1642736, at *1 (S.D.N.Y. Apr. 29, 2011) (Cote, J.).

ARGUMENT

I. All of Plaintiffs' Claims Against the Retailer Defendants Fail for the Reasons Identified in JJCI's Brief.

As explained in JJCI's brief, Plaintiffs' claims against JJCI are subject to dismissal based on preemption, failure to state a claim under Rule 8, and failure to satisfy the pleading requirements of Rule 9. These deficiencies apply with equal force to Plaintiffs' claims against the Retailer Defendants and require their dismissal.

herein) exhibits identifying those cases for the Court's convenience. This Motion addresses all SFCs filed on or before February 6, 2023. The Retailer Defendants anticipate that additional cases will be filed, including during the briefing schedule and before the Court rules on this Motion. The Retailer Defendants reserve the right to request the opportunity to brief Rule 12 issues and/or seek relief from the Court as to any such case, or as to new or distinct issues presented by any such SFCs, at a later date.

A. Plaintiffs' Claims Are Preempted.

The Retailer Defendants incorporate the preemption arguments included in Part I of JJCI's brief. As JJCI's brief shows, federal law prohibits adding to acetaminophen product labels the warning Plaintiffs say state law requires because (1) federal regulations require a single pregnancy warning that cannot be altered or supplemented and, (2) in any event, any warning that would satisfy Plaintiffs' state-law demands would render acetaminophen products misbranded and would be rejected by FDA.[4] These arguments foreclose Plaintiffs' claims against the Retailer Defendants, and all claims against them should therefore be dismissed.[5]

In addition to the preemption grounds set forth in JJCI's brief, preemption forecloses any claims based on acetaminophen products sold under an Abbreviated New Drug Application (ANDA). Although Plaintiffs claim that acetaminophen products are "governed by the monograph system," Compl. ¶ 90, that is not universally true. The Retailer Defendants sell OTC acetaminophen products, including extended-release tablets, under several ANDAs, including ANDA076200, ANDA207229, ANDA211544, and ANDA215486.[6] As Plaintiffs acknowledge,

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[4] Retailer Defendants also incorporate JJCI's argument that, at a minimum, all claims based on acetaminophen use before 2017 are preempted. For a chart of cases in which Plaintiffs assert claims against Retailer Defendants based on alleged acetaminophen use before 2017, *see* Exhibit 2.

[5] All Retailer Defendants make the preemption arguments contained in this Motion with respect to all cases with one exception: In light of the Court's previous order, Walmart does not make these arguments with respect to the *Roberts* and *Hatfield* complaints, though it continues to believe the claims in those complaints are preempted as set forth in its pending motion for reconsideration. *See* ECF Nos. 203, 204.

[6] *See National Drug Code Directory*, FDA.gov (Feb. 2, 2023), https://www.accessdata.fda.gov/scripts/cder/ndc/index.cfm (the products sold under these ANDAs can be seen by selecting "Application Number" and then searching for each of these ANDA numbers); *see also generally OTC Drug Review Process; OTC Drug Monographs*, FDA.gov (June 28, 2022), https://www.fda.gov/drugs/otc-drug-review-process-otc-drug-monographs; *Small Business Assistance: Frequently Asked Questions on the Regulatory Process of Over-the-Counter (OTC) Drugs*, FDA.gov (Nov. 18, 2022), https://www.fda.gov/drugs/cder-small-business-industry-

"an ANDA holder's warning label must match the NDA holder's label verbatim," and "[t]his means that . . . ANDA holders cannot avail themselves of the CBE regulation to unilaterally strengthen warnings or precautions even in the face of new information." Compl. ¶¶ 95–96. Because federal law requires that ANDA "drug labels be the same at all times as the corresponding brand-name drug labels," it "was not lawful under federal law" for the Retailer Defendants "to do what state law [purportedly] required of them." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618 (2011). As Judge Briccetti has explained, "state law failure to warn claims" may "'not go forward against *generic* drug manufacturers, as it is impossible for them to comply simultaneously with their state duty to adequately warn and their federal duty of sameness.'" *Frei v. Taro Pharms. U.S.A., Inc.*, 443 F. Supp. 3d 456, 466 (S.D.N.Y. 2020) (quoting *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578, 580 (6th Cir. 2013)), *aff'd,* 844 F. App'x 444 (2d Cir. 2021) (mem.). Any claims premised on acetaminophen products governed by an ANDA must be dismissed.

This result is so well settled under established precedent that Plaintiffs may have chosen to ignore the ANDA-governed acetaminophen products and instead aimed this litigation only at monograph products. But choosing not to target ANDA products does not solve Plaintiffs' preemption problem, because the clear preemption of any claims involving ANDA products exposes a potentially serious inconsistency: It would make no sense—and cause considerable consumer confusion—for acetaminophen products lying side-by-side on store shelves to bear different warnings, despite containing the same ingredient and posing the same alleged risk. Just as federal law prohibits generic manufacturers from unilaterally adding warnings for good reason—to ensure that generic drugs are the same as their brand-drug equivalents—federal law

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assistance-sbia/small-business-assistance-frequently-asked-questions-regulatory-process-over-counter-otc-drugs.

prohibits adding an additional pregnancy warning to a monograph product for equally good reason—to "ensure that consumers receive clear, unambiguous, and consistent information on the labeling of OTC drugs concerning use by pregnant or nursing women." 47 Fed. Reg. 54,750, 54,756 (Dec. 3, 1982). Because the pregnancy warning and the federal misbranding prohibition bar all acetaminophen products from carrying the warning Plaintiffs demand, all of Plaintiffs' claims are preempted as to all of Retailers' acetaminophen products.

B. Plaintiffs Have Not Adequately Stated any Claim Under Rule 8.

Apart from being preempted, Plaintiffs' claims also do not pass muster under Rule 8. To begin with, Plaintiffs do not allege any facts establishing that prenatal exposure to acetaminophen causes ASD and/or ADHD. And Plaintiffs do not—and cannot—allege any facts plausibly establishing that any Retailer Defendant knew or should have known that acetaminophen causes ASD and/or ADHD. At the very least, the allegations in the Complaint are devoid of any basis for concluding that any Retailer Defendant knew or should have known of this purported risk before 2013. Rule 8 also makes short work of the express warranty claim that several Plaintiffs included on their short form complaints.

1. Plaintiffs have not plausibly alleged causation.

Retailers incorporate Part II.A of JJCI's brief. Central to all of Plaintiffs' legal theories is whether prenatal exposure to acetaminophen caused the injury they assert. Plaintiffs' obligation at the pleading stage thus was to include in the Complaint "enough fact to raise a reasonable expectation that discovery will reveal evidence supporting" their claim that *in utero* exposure to acetaminophen ***causes*** children to develop ASD and ADHD. *Utts v. Bristol-Myers Squibb Co.*, 251 F. Supp. 3d 644, 657 (S.D.N.Y. 2017) (Cote, J.) (quoting *Pension Benefit Guar. Corp. ex rel. St. Vincent Catholic Med. Ctrs. Retirement Plan v. Morgan Stanley Inv. Mgmt. Inc.*, 712 F.3d 705, 729 (2d Cir. 2013) (Straub, J., dissenting in part)).

As JJCI's brief explains, Plaintiffs have not done so. The studies on which they rely, which suggest (at best) an association between exposure and injury, cannot satisfy the plausibility requirement because "[i]n law, as in science, '[c]orrelation is not causation.'" *Manuel v. Pepsi-Cola Co.*, 2018 WL 2269247, at *11 (S.D.N.Y. May 17, 2018) (quoting *Norfolk & W. Ry. Co. v. Ayers*, 538 U.S. 135, 173 (2003) (Kennedy, J., concurring in part and dissenting in part)). Moreover, the September 2021 statement on which Plaintiffs place great weight ***avoided*** any inference of causality. *See* Compl. ¶¶ 5, 353–56. Emphasizing as much, the authors of this 2021 statement clarified that "limitations and uncertainties remain despite the large body of available data" and that is why the authors "avoided any inference of causality."[7] Plaintiffs cannot plead causation by relying on literature that expressly disclaims a causal conclusion. All claims must be dismissed.

2. Plaintiffs have not plausibly alleged knowledge.

Retailers incorporate Part II.B of JJCI's brief. All but one of Plaintiffs' claims—Count V (strict products liability misrepresentation)—require Plaintiffs to show that each Retailer knew or should have known that acetaminophen products cause ASD and ADHD. *See generally* 63A Am. Jur. 2d Prods. Liab. § 934 (2d ed.) ("Under the negligence, breach of warranty, or strict liability theories, the general rule is the same: that the supplier of a product is liable to expected users for harm that results from foreseeable uses of the product if the supplier has reason to know that the product is dangerous and fails to exercise reasonable care so as to inform the user."). Plaintiffs have not—and cannot—plead this element. The truth is that no one knows this alleged fact even

[7] Ann Z. Bauer et al., *Reply to 'Paracetamol Use in Pregnancy—Caution over Causal Inference from Available Data'; 'Handle with Care—Interpretation, Synthesis and Dissemination of Data on Paracetamol in Pregnancy,'* 18 Nature Revs. Endocrinology 192, 192 (2022) (emphasis added).

today—not FDA; not the scientists whose work Plaintiffs rely on, who disclaim an inference of causation; and certainly not the Retailer Defendants.

As an initial matter, Plaintiffs' bare allegations that the Retailer Defendants "knew or should have known" of the alleged harm caused by acetaminophen products are "conclusory and insufficient." *Pina-Rodriguez v. Garbutt*, 2021 WL 2535537, at *4 (S.D.N.Y. June 21, 2021). Reciting legal standards is not enough to state a claim. Moreover, Plaintiffs rely on the same sweeping, shotgun allegations about ***all*** Retailer Defendants, with no attempt to differentiate between the many unrelated entities identified.[8] This type of group pleading fails to give each defendant "fair notice of what the plaintiff[s'] claim is and the ground upon which it rests," and thus fails to satisfy even the minimal standards of Rule 8. *Atuahene v. City of Hartford*, 10 F. App'x 33, 34 (2d Cir. 2001) (quotation marks omitted) ("lumping all the defendants together in each claim and providing no factual basis to distinguish their conduct" fails to satisfy Rule 8); *see also Nesbeth v. N.Y.C. Mgmt. LLC*, 2019 WL 110953, at *3 (S.D.N.Y. Jan. 4, 2019) ("[I]t is well-established in this Circuit that plaintiffs cannot simply lump defendants together for pleading purposes" under Rule 8 (quotation marks omitted)). The Retailers are not a monolith; they are separate corporate entities, with separate business operations. Plaintiffs' generalized assertions are all the more problematic because each Retailer began selling acetaminophen products at different points in time and therefore may not be similarly situated as to the products themselves, or the

[8] *See e.g.*, Compl. ¶¶ 446, 469, 492 ("The Retailer Defendants knew or should have known about these risks and had a duty to warn Plaintiffs about them."); Compl. ¶¶ 451, 474, 501 ("The Retailer Defendants knew or should have known that prenatal ingestion of acetaminophen could cause ASD and/or ADHD in children."); Compl. ¶ 512 ("The Retailer Defendants knew or should have known about each of these risks to warn consumers, specifically pregnant women.").

state of knowledge about the science allegedly underpinning Plaintiffs' claims.[9] Plaintiffs cannot bypass their pleading obligations by simply lumping everyone together. The Complaint does not afford any Retailer Defendant with any real notice of the facts alleged against it specifically. *See Atuahene*, 10 F. App'x at 34.

The only *facts* in the Complaint that appear to address knowledge are the studies on which Plaintiffs rely to allege causation. But studies themselves do not purport to establish a causal link—indeed, some expressly disclaim doing so. Plaintiffs thus cannot establish that an acetaminophen product retailer knew or should have known of this alleged causation. *Cf. Hornsby v. Alcoa, Inc.*, 715 F. App'x 642, 644 (9th Cir. 2017) (holding that plaintiff failed to plausibly plead actual knowledge in part because the studies cited "merely show that a connection between aluminum particles and pulmonary fibrosis is '*plausible*' or '*thought to be* directly correlated'"). Plaintiffs' allegations indicate that ***no one*** studying the issue has claimed to know that acetaminophen usage during pregnancy causes ASD or ADHD. This is all the more apparent, given that all of the claims in this litigation stem from acetaminophen usage before 2021. Plaintiffs' causation theory (and in turn their purported knowledge theory) are based on what they claim is "overwhelming science." Compl. ¶ 353. But Plaintiffs themselves appear to concede that no single study establishes causation, and no single study could have served to inform the Retailer Defendants of any purported theory of causation. Rather, as pleaded, it was only in September 2021 that any contingent of the medical community issued a "call to action" because certain scientists believed

[9] *See e.g.*, Compl. ¶ 17 ("7-Eleven first introduced its over-the-counter store brand acetaminophen to the market in or around November 2014."); ¶ 23 ("In or around 2016, Big Lots became the labeler of Sound Body Acetaminophen"); ¶ 39 ("Dollar Tree Stores, Inc. first introduces its over-the-counter store brand acetaminophen . . . for adult use to the market in or around April 2018"); ¶ 56 ("Safeway first introduced its over-the-counter store brand acetaminophen for . . . adult use in or around August 2015.").

the "combined weight of animal and human scientific evidence" was such that pregnant women should be cautioned about the risk of "indiscriminate" APAP use. *See* Compl. ¶ 354. But this statement cannot establish that any Retailer Defendant knew or should have known that acetaminophen was purportedly defective at the time it sold acetaminophen products to any Plaintiffs because every Plaintiff's claims stem from acetaminophen use before September 2021. *Witt v. Stryker Corp.*, 648 F. App'x 867, 871 (11th Cir. 2016) (dismissing failure-to-warn claim because the defendant "could not have warned [the plaintiff] in 2008 about data that had been reported some two years later in 2010").

FDA's actions further illustrate that it is implausible to conclude that the studies cited by Plaintiffs should have led the Retailer Defendants to know about the purported causal link alleged by Plaintiffs. In 2015, FDA publicly announced that it had reviewed studies on acetaminophen and the risk of ADHD.[10] And FDA concluded that it could not "draw[] reliable conclusions" from the studies it reviewed.[11] FDA thus retained its "recommendations on how pain medicines are used during pregnancy," and FDA promised "to monitor and evaluate the use of pain medicines during pregnancy" and "update the public as new safety information becomes available."[12] Since then, despite monitoring the issue, FDA has made no public announcement so much as suggesting that new information has shown that acetaminophen use causes ASD or ADHD, and its public 2015 announcement remains published on its website. *Cf.* Abraham & Mosholder, *Epidemiology:*

[10] *FDA Drug Safety Communication*, *supra* note 1. *See Casey v. Odwalla, Inc.*, 338 F. Supp. 3d 284, 294 (S.D.N.Y. 2018) (noting that "[c]ourts may take judicial notice of public documents," "matters of public record," and "records of administrative bodies."); *see also* Fed. R. Evid. 201(b) ("The court may judicially notice a fact that is not subject to reasonable dispute because it: (1) is generally known within the trial court's territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned.")

[11] *FDA Drug Safety Communication*, *supra* note 1.

[12] *Id.*

Review of Published Studies, Johnston Decl., Ex. G (JJCI Brief) at 4, 5, 33 (internal 2022 FDA review of published studies, including the literature review published in 2021 by Bauer et al., concluding that there are "study limitations and inconsistent study findings that prohibit causal interpretations of the association between APAP exposure and functional neurobehavioral outcomes as well as urogenital outcomes"). The fact that FDA did not suggest at any time relevant to these cases that prenatal exposure to acetaminophen causes ASD or ADHD—and, in fact, re-committed to its recommendations on how pain medicines are used during pregnancy—shows the implausibility of Plaintiffs' conclusory allegation that the Retailer Defendants knew or should have known of that alleged causal relationship.

The regulatory scheme further undermines any allegation of knowledge. Under the monograph system, FDA issues a comprehensive regulation setting forth the ingredients, conditions, and labeling under which drugs are "generally recognized as safe and effective." Compl. ¶ 99. In the CARES Act, Congress in 2020 clarified that a drug is "deemed to be generally recognized as safe and effective," so long as it is in conformance with a final or tentative final monograph and other applicable federal regulations. 21 U.S.C. § 355h(a)(1). Applying this standard, Congress accordingly deemed acetaminophen products to be "generally recognized as safe and effective" when labeled with the pregnancy warning mandated by FDA.

The determination of whether a complaint states a plausible claim for relief is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *EEOC v. Port Auth. of N.Y. & N.J.*, 768 F.3d 247, 258 (2d Cir. 2014) (quoting *Iqbal*, 556 U.S. at 679). Here, the studies Plaintiffs cite, the warning and public disclosure from FDA, and the judgment from Congress all defeat any inference that the Retailer Defendants somehow knew or should have known that acetaminophen use causes ADHD and/or ASD. For this reason, all the

claims in the Master Complaint against the Retailer Defendants (except the claim for strict liability misrepresentation) must be dismissed.[13]

At the very least, Plaintiffs have failed to plead facts establishing knowledge in the past. Plaintiffs' allegations regarding the Retailer Defendants' purported knowledge of the risk of ASD/ADHD following prenatal acetaminophen use absolutely cannot extend to any claim arising before 2013 because Plaintiffs have not cited a single publication before then on this subject. *See* Compl. Preamble at 2, ¶ 335 (referring only to publications "[s]ince 2013").[14] All the knowledge-based claims accordingly must be cut off based on acetaminophen use before 2013.

3. Plaintiffs have failed to plead an express warranty claim.

Although the Master Complaint does not contain an express warranty claim, two Plaintiffs have alleged such a claim in their short form complaints.[15] The claim should be dismissed. To state a claim for express warranty, "a plaintiff must show," among other things, that "'the manufacturer made an express warranty regarding the product.'" *Fuller v. Eisai Inc.*, 513 F. Supp. 3d 710, 721 (E.D. La. 2021) (quoting *Guidry v. Janssen Pharms., Inc.*, 206 F. Supp. 3d 1187, 1199 (E.D. La.

[13] Plaintiffs' Master Complaint includes a prayer for punitive damages. *See* Compl. at 117 (Prayer for Relief); *see also* Compl. ¶¶ 436–40. Plaintiffs' inability to establish that any of the Retailer Defendants knew or should have known that prenatal exposure to acetaminophen causes ASD or ADHD precludes those damages. However, because Plaintiffs do not plead a standalone claim of punitive damages, Retailer Defendants do not move here under Rule 12(b)(6) to dismiss the punitive damages request. *See City Nat'l Specialty Co. v. Ashley Furniture Indus., LLC*, 2022 WL 2918121, at *3 (E.D.N.Y. July 21, 2022) (explaining that a request for punitive damages "is not a cause of action subject to dismissal"). Retailer Defendants intend to challenge the punitive damages request at a later date. Plaintiffs' counsel has informed the Retailer Defendants that although they do not believe this preservation of rights is necessary, Plaintiffs do not object to Defendants raising issues related to punitive damages in future dispositive motion practice.

[14] For a chart of cases in which Plaintiffs assert claims against Retailer Defendants based on alleged acetaminophen use before 2013, *see* Exhibit 3.

[15] *Crawford v. Target Corp.*, No. 1:22-cv-09022-DLC (S.D.N.Y.); *Taylor v. Wal-Mart Stores Inc.*, No. 1:22-cv-08930-DLC (S.D.N.Y.).

2016)). Plaintiffs fail to plead this element. Rather than identify an express warranty, they merely assert that the Retailer Defendants "expressly warranted that the APAP Products were safe for use and reasonably fit for their intended purposes." Exhibit A to Short Form Complaint ¶ 2, *Crawford*, No. 1:22-cv-09022-DLC; Exhibit A to Short Form Complaint ¶ 2, *Taylor,* No. 1:22-cv-08930-DLC. Vague allegations that products do not conform to "express representations because they are not safe and they have numerous serious side effects . . . [are] not sufficient to withstand a Rule 12(b)(6) challenge." *Lopez-Camou v. I-Flow Corp.*, 2010 WL 11515204, at *5 (D. Ariz. Apr. 15, 2010) (quotation marks omitted). To survive a motion to dismiss, "the plaintiff must make more than a general reference to the alleged warranty" or a claim that a product "did not conform to Defendant's express warranties that [the product] was safe to use and effective to use." *Fuller*, 513 F. Supp. 3d at 723 (quotation marks omitted) (dismissing express warranty claim). But Plaintiffs have provided no detail about the content of the alleged express warranty, nor about when or how the alleged warranty was made. Without any of these basic facts, the claim must be dismissed. *Id.* at 723–24; *Lopez-Camou*, 2010 WL 11515204, at *5.

C. Plaintiffs' Misrepresentation and Consumer-Protection Claims Do Not Satisfy Rule 9(b).

The Retailer Defendants incorporate Part III of JJCI's brief. As with JJCI, Plaintiffs' misrepresentation claims (Count IV, Count V) and consumer protection claims (Count VI) against the Retailer Defendants are subject to Rule 9(b) because these claims either incorporate misrepresentation as an element or at their core rely on underlying allegations of fraud or misrepresentation. *See* JJCI Br. at 39–41 (discussing supporting caselaw).[16] Here, Plaintiffs

[16] For a list of cases in which Plaintiffs assert negligent misrepresentation claims (Count IV) against Retailer Defendants, *see* Exhibit 4. For a list of cases in which Plaintiffs assert strict liability misrepresentation claims (Count V) against Retailer Defendants, *see* Exhibit 5. For a list

generally allege that the Retailer Defendants made misrepresentations about the safety and risks of acetaminophen products' use during pregnancy on product labels and/or in unspecified advertising and promotional materials. *See, e.g.*, Compl. ¶¶ 513, 515 (generally alleging that the Retailers made misrepresentations in acetaminophen labels and/or in unspecified advertising and promotional materials for acetaminophen in support of negligent misrepresentation claim); *id.* ¶ 532 (alleging unspecified "misrepresentations to the public" in support of strict-liability misrepresentation claim); *id.* ¶ 550 (alleging the Retailers made "knowing[] and false[] representat[ions]" in support of consumer protection claim). But because the more stringent pleading standards of Rule 9 apply, Plaintiffs must plead the who, what, when, where, and how of their claims. The Complaint fails to meet this threshold pleading requirement for three reasons.

First, the Complaint impermissibly makes shotgun pleading-style arguments against all Retailer Defendants, such that there is no specificity as to any individual Retailer's alleged conduct. Although the Complaint identifies which Retailer Defendants are being sued and some of their products, that is where the specificity ends. What follows is a series of blanket statements about all Retailer Defendants, impermissibly grouped together, without any attempt to distinguish their alleged conduct or statements at issue in this case. *See, e.g.*, Compl. ¶¶ 435, 515 (broadly alleging that all Retailer Defendants, without differentiation among the separate entities, concealed or misrepresented the safety of acetaminophen).

"[I]n cases involving multiple defendants," however, "a plaintiff cannot rely upon blanket references to acts or omissions by all of the defendants, for each defendant named in the complaint is entitled to be [apprised] of the circumstances surrounding the fraudulent conduct with which he

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of cases in which Plaintiffs assert consumer protection statute claims (Count VI) against Retailer Defendants, see Exhibit 6.

individually stands charged." *Fisher v. APP Pharms., LLC*, 783 F. Supp. 2d 424, 433 (S.D.N.Y. 2011) (quotation marks omitted) (finding complaint failed to satisfy the heightened pleading requirement under Rule 9 because it "fail[ed] to differentiate among the named Defendants in each allegation and thus fail[ed] to inform each defendant of the circumstances surrounding the fraudulent conduct with which he individually st[ood] charged"); *see also O'Brien v. Nat'l Prop. Analysts Partners*, 719 F. Supp. 222, 225–26 (S.D.N.Y. 1989) ("Where there are multiple defendants, the complaint must disclose the specific nature of each defendant's participation in the alleged fraud."). Here, Plaintiffs fail to plead the acts or omissions giving rise to their claims with respect to each Retailer Defendant, such that *each* Retailer Defendant can be apprised of the specific basis for its alleged liability.

Second, and relatedly, neither the Complaint nor the SFCs plead facts about the specific misrepresentations Plaintiffs allegedly heard or saw, much less any detail or facts going to reliance. Rather, Plaintiffs simply point to generalized statements about product safety and quality—taken out of context from various Retailer Defendants' websites—as examples of purported misrepresentations. But none of these statements specifically address acetaminophen. *See* Compl. ¶¶ 359–96. In fact, some websites cited by Plaintiffs do not even broadly apply to acetaminophen because they discuss policies for non-drug products. *See, e.g., id.* ¶ 363 n.168 (citing "Removing Chemicals of Consumer Concern" webpage that discusses removal of certain ingredients from beauty and personal care products, not drug products); *id.* ¶ 378 n.183 (citing "Chemicals and Product Ingredients" webpage from the website of a Retailer Defendant's parent company—a separate entity that is not named as a defendant in this litigation—that discusses "chemicals or

ingredients in baby, personal care and household cleaning products").[17] These haphazard allegations, coupled with the dearth of any additional detail in Plaintiffs' SFCs, are insufficient to satisfy Rule 9. *See* JJCI Br. at 40–42 (discussing Rule 9 caselaw requiring specific pleading of affirmative misstatements or the elements of omission claims).

Third, any claim premised on the Retailer Defendants' alleged failure to disclose additional information about the safety of acetaminophen products runs into additional bars. As a threshold matter, omission-based claims for negligent misrepresentation and strict liability misrepresentation are not actionable; rather, the "misrepresentation must be affirmative." *Willis v. Buffalo Pumps Inc.*, 34 F. Supp. 3d 1117, 1130 (S.D. Cal. 2014) (setting forth requirement for strict liability misrepresentation under the Restatement (Second) of Torts § 402B (1965)); *Garlough v. FCA US LLC*, 2021 WL 4033177, at *4 n.2 (E.D. Cal. Sept. 3, 2021) ("Because a claim of negligent misrepresentation cannot be based on an omission, [p]laintiff's claim for negligent misrepresentation also fails.").[18] Because Plaintiffs do not allege any such affirmative misrepresentation here, the misrepresentation claims fail on that ground alone.[19]

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[17] On a Rule 12(b)(6) motion, courts may "consider extrinsic material that the complaint incorporate[s] by reference." *Lively v. WAFRA Inv. Advisory Grp., Inc.*, 6 F.4th 293, 305 (2d Cir. 2021) (quotation marks omitted).

[18] *See also, e.g.*, *Franks v. Nat'l Dairy Prods. Corp.*, 282 F. Supp. 528, 533 (W.D. Tex. 1968) (the examples of actionable conduct in Section 402B "speak only in terms of express representations"), *aff'd*, 414 F.2d 682 (5th Cir. 1969); *Am. Safety Equip. Corp. v. Winkler*, 640 P.2d 216, 221 (Colo. 1982) (en banc) (similar under Colorado law); *Klages v. Gen. Ordnance Equip. Corp.,* 367 A.2d 304, 312 (Pa. Super. Ct. 1976) (similar under Pennsylvania law); *Ladd ex rel. Ladd v. Honda Motor Co.*, 939 S.W.2d 83, 97 (Tenn. Ct. App. 1996) (applying Tennessee law).

[19] One Plaintiff from Kentucky and another from Nevada assert strict liability misrepresentation claims in their short form complaints, despite the Master Complaint's limitation of those claims to specific (other) states. *See* Short Form Complaint at 23, *Peavley Hawes v. McNeil Consumer Healthcare*, No. 1:22-cv-10698-DLC (S.D.N.Y. Jan. 20, 2023), ECF No. 13; Short Form Complaint at 23, *Chapman v. Walmart Inc.*, No. 1:22-cv-08830-DLC (S.D.N.Y. Jan. 20, 2023), ECF No. 55. Those Kentucky and Nevada strict liability misrepresentation claims should be dismissed because neither state appears to recognize such a claim. *See, e.g.*, *Forest v. E.I. DuPont*

Further, even if some states were to recognize omission-based theories for some of these claims, Plaintiffs do not meet the pleading standard, as they concede that the acetaminophen product labels at all times contained the pregnancy-specific language required by 21 C.F.R. § 201.63(a). *See* Compl. ¶¶ 448–49. And although they contend that the warning should have said *more* about the risk of acetaminophen products, they do not identify any language that they believe *should* have been provided. And finally, as explained in the JJCI motion, all the "scientific evidence" cited by Plaintiffs, which they allege was "known but non-public information . . . over which the Retailer Defendants had exclusive control" (Compl. ¶ 435), is, by Plaintiffs' own admission, public information. *See, e.g.*, *id.* ¶¶ 4, 336 (alleging that the "scientific evidence" was published in a "prominent scientific journal" and "a well-known, peer-reviewed publication"); *see also, e.g.*, *id.* ¶¶ 2, 5, 332, 335, 338–46, 349. Plaintiffs' own allegations thus undermine their contention that the Retailers concealed any information from the public, including Plaintiffs. *See* JJCI Br. at 42–45.

II. The Retailer Defendants' Compliance with Federal Law Forecloses Many State Law Claims.

As even Plaintiffs acknowledge, federal law provides clear standards for drug labeling, including for acetaminophen products. *See, e.g.*, Compl. ¶¶ 102–04. In 2020, Congress made the FDA monograph covering acetaminophen products final and deemed the products at issue in this litigation "to be generally recognized as safe and effective" so long as they complied with the monograph and other relevant regulations. 21 U.S.C. § 355h(a)(1); Compl. ¶ 109. Plaintiffs do not contend that any products at issue failed to comply with the monograph or any relevant federal

de Nemours & Co., 791 F. Supp. 1460, 1470 (D. Nev. 1992) (concluding that the "'strict liability' for misrepresentation" cause of action "fails to state a cognizable legal claim").

regulation. Plaintiffs' state law claims thus ask the Court to find that, contrary to Congress's determination, the products were unsafe and defective—and that the Retailer Defendants knew or should have known as much. Many states' laws reject such an anomalous notion. *See, e.g.*, Mich. Comp. Laws § 600.2946(5) ("a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller").

Aside from outright preemption of all the claims, the Retailer Defendants' compliance with federal requirements bars specific claims in at least three respects. *First*, as a matter of *federal* law, the express preemption provision in 21 U.S.C. § 379r(a) bars any state law non-product-liability claim that would require a warning beyond that required by federal law. As a result, certain of Plaintiffs' consumer protection (non-product-liability) claims are barred by federal law. *Second*, as a matter of *state* law, many state consumer protection statutes provide a safe harbor for conduct that complies with federal law. As a result, certain of Plaintiffs' consumer protection causes of action fail to state a valid claim under state law. And *third*, some of those states bar *any* claim—not just consumer protection claims—challenging conduct that federal law authorizes. As a result, several of Plaintiffs' common law causes of action fail to state a valid claim under state law.

A. Section 379r(a) Expressly Preempts any Claims Not Arising Under State Product Liability Law.

For nonprescription drugs like the acetaminophen products here, Congress has enacted an express preemption clause that bars states from "establish[ing] or continu[ing] in effect any requirement" that relates to an OTC drug and "is different from or in addition to, or that is otherwise not identical with," the requirements set forth under federal law. 21 U.S.C. § 379r(a);

see also Goldstein v. Walmart, Inc., --- F. Supp. 3d ---, 2022 WL 16540837, at *11 (S.D.N.Y. Oct. 28, 2022) (Federal law "preempts '*any* state law that provides for labeling requirements that are not *exactly the same* as those set forth in the FDCA and regulations.'" (quoting *Critcher v. L'Oreal USA, Inc.*, 959 F.3d 31, 35–36 (2d Cir. 2020)); *cf. Green v. BDI Pharms.*, 803 So. 2d 68, 74–75 (La. Ct. App. 2001) (concluding that § 379r(a) preempted claims arising before § 379r was enacted). The express preemption provision in § 379r(a) does not apply, however, to claims "under the product liability law of any State." 21 U.S.C. § 379r(e). To fit within this exception for product liability claims, a claim must—at least—arise from "injury to [] person or property." *Goldstein*, 2022 WL 16540837, at *12 n.7. "'[P]roduct liability' actions do not include those for pure economic loss." *Id.*

Many of Plaintiffs' consumer protection claims are brought under state statutes that do not authorize claims for personal injury. Those consumer protection claims thus do not arise "under the product liability law of [a] State" and are preempted by § 379r(e) and must be dismissed:

- **Florida**. Florida's Unfair and Deceptive Trade Practices Act (FDUTPA) "does not apply to . . . [a] claim for personal injury or death or a claim for damage to property other than the property that is the subject of the consumer transaction." Fla. Stat. § 501.212(3); *see also Dobbins v. AbbVie, Inc.*, 2021 WL 8775732, at *2 (S.D. Fla. May 21, 2021) ("FDUTPA expressly exempts personal injury claims; thus, [the plaintiff] is not able to proceed with a FDUTPA claim.").

- **Louisiana**. The Louisiana consumer protection statute does not apply to any product liability claim, as all claims involving product liability have been subsumed by the Louisiana Product Liability Act. *See Bladen v. C.B. Fleet Holding Co.*, 487 F. Supp. 2d 759, 769 (W.D. La. 2007) ("The legislature, with full knowledge of the [Louisiana Unfair Trade Practices Act], unquestionably enacted the LPLA statutory declaration of exclusive liability in the LPLA and made no exception for the LUTPA."); *see also* Part III, *infra*.[20]

[20] One plaintiff wrote in a claim for redhibition under Louisiana law. *See* Short Form Complaint at 18, *Norris*, No. 1:23-cv-00214-DLC. To the extent that claim seeks recovery for personal injury, it is subsumed by the Louisiana Products Liability Act. *Patton v. Bos. Sci. Corp.*, 2018 WL

- **Minnesota.** Private rights of action under Minnesota's Uniform Deceptive Trade Practices Act require a showing of public benefit. *Ly v. Nystrom,* 615 N.W.2d 302, 313–14 (Minn. 2000). Courts have held that personal injury actions do not meet this standard. *See, e.g.*, *Berczyk v. Emerson Tool Co.,* 291 F. Supp. 2d 1004, 1020 (D. Minn. 2003) (denying motion to amend to add claim under the Minnesota Consumer Fraud Act as futile because "the essence of the Plaintiffs' lawsuit is personal injury"); *Pecarina v. Tokai Corp.,* 2002 WL 1023153, at *5–6 (D. Minn. 2002).

- **Oregon**. The private enforcement provision of the Oregon Unlawful Trade Practices Act does not create "a new cause of action for personal injuries." *Gross-Haentjens v. Leckenby*, 589 P.2d 1209, 1211 (Or. Ct. App. 1979); *see also Allen v. G.D. Searle & Co.*, 708 F. Supp. 1142, 1158 (D. Or. 1989) (granting motion to dismiss a claim under the Oregon Unlawful Trade Practices Act because "O.R.S. 646.638 does not provide a remedy for personal injury.").

- **Pennsylvania.** Pennsylvania's Unfair Trade Practices and Consumer Protection Law "does not provide for the recovery of . . . personal injury damages." *King v. Hyundai Motor Mfg. Am.,* 2019 WL 458477, at *3 n.2 (M.D. Pa. Jan. 3, 2019), *report and recommendation adopted* (Feb. 5, 2019).

- **Tennessee**. A claim under the Tennessee Consumer Protection Act "must be dismissed where a plaintiff 'seeks to recover for injuries to his person resulting from [a defendant's] alleged violation of the TCPA." *Birdsong v. Eli Lilly & Co.*, 2011 WL 1259650, at *3 (M.D. Tenn. Mar. 31, 2011) (quotation marks omitted).

- **Washington**. "Personal injury damages . . . are not compensable [damages] under the [Consumer Protection Act] and do not constitute injury to business or property." *Ambach v. French*, 216 P.3d 405, 408 (Wash. 2009) (en banc) (quotation marks omitted).

B. Many Consumer Protection Statutes Provide Safe Harbor to Entities in Compliance with Federal Law

Apart from the federal preemption provision just discussed, many state consumer protection statutes exempt *as a matter of state law* conduct that complies with federal regulation: "[C]ompliance with FDA warning requirements is a complete defense." *Am. Home Prods. Corp. v. Johnson & Johnson*, 672 F. Supp. 135, 144 (S.D.N.Y. 1987) (applying New York law); *cf. Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 64 (2d Cir. 2016) ("representations commensurate

4760846, at *4 (W.D. La. Oct. 2, 2018). To the extent that claim is ***not*** based on product liability law and instead seeks recovery to remedy economic loss alone, it is preempted by § 379r(a).

with information in an FDA label generally cannot form the basis for Lanham Act liability"). Here, the Retailer Defendants sold acetaminophen products with labels that complied with FDA warning requirements, and many states recognize that it is not an unfair or deceptive act to follow FDA's instructions.

Acknowledging the interplay between state and federal law, at least eight states implicated in this litigation either have safe-harbor provisions built into their consumer protection statutes for actions that comply with federal standards or have adopted such a safe harbor as a matter of interpretation.[21] In these states, selling acetaminophen in compliance with federal labeling requirements cannot be a cognizable unfair or deceptive act.

- **California**. California courts have interpreted its consumer protection statutes against the backdrop of whether an activity has been made "lawful." *See Cel-Tech Commc'ns, Inc. v. L.A. Cellular Tel. Co.*, 973 P.2d 527, 541 (Cal. 1999). Both federal and California law have made it lawful to sell acetaminophen without the additional warning advocated by Plaintiffs. *See* Cal. Health & Safety Code § 110111 (adopting "[a]ll nonprescription drug regulations and any amendments to those regulations adopted pursuant to the federal act" as the "nonprescription drug regulations of the state"). Where, as here, there are "no unusual circumstances, but only the ordinary situation contemplated by the statute or administrative rule, then the minimum standard prescribed by the legislation or regulation may be accepted by . . . the court as a matter of law[] as sufficient for the occasion." *Ramirez v. Plough, Inc.*, 6 Cal. 4th 539, 548 (1993) (quotation marks omitted); *see also Loeffler v. Target Corp.*, 324 P.3d 50, 54–55, 64, 76 (Cal. 2014) (where "the statutory scheme governing the sales tax . . . *permitted but [did] not require[]*" a retailer to collect sales tax reimbursement from consumers, retailer collection of the tax from consumers was not actionable under UCL or CLRA). The claims brought under California's consumer protection statutes should be dismissed. *See* Compl. ¶ 551(e)–(f).

- **Colorado**. The Colorado Consumer Protection Act does not apply to "[c]onduct in compliance with the orders or rules of, or a statute administered by, a federal, state, or local governmental agency." Colo. Rev. Stat. § 6-1-106(1)(a). Here, the acetaminophen products' labeling and pregnancy warnings complied with the FDCA and FDA's rules. *See Shostrom v. Ethicon, Inc.,* 2021 WL 778994, at *9 (D. Colo. Mar. 1, 2021) (the relevant question is whether the defendant acted in

[21] For a list of the safe harbor provisions in state consumer protection statutes, see Exhibit 7.

compliance with laws or regulations). The claims under the Colorado Consumer Protection Act should be dismissed. *See* Compl. ¶ 551(g).

- **Florida**. Florida's Deceptive and Unfair Trade Practices Act ("FDUTPA") does not apply to "act[s] or practice[s] required or specifically permitted by federal or state law." Fla. Stat. § 501.212(1). And courts have held that this safe harbor provision precludes consumers' claims against drug manufacturers. *See, e.g.*, *Prohias v. Astrazeneca Pharms., L.P.,* 958 So. 2d 1054, 1056 (Fla. 3d DCA 2007). Because the labeling here was specifically permitted by federal law, Plaintiffs' FDUTPA claims must be dismissed. *See* Compl. ¶ 551(j).

- **Minnesota**. The Minnesota Uniform Deceptive Trade Practices Act does not apply to "conduct in compliance with the orders or rules of, or a statute administered by, a federal, state or local governmental agency." Minn. Stat. § 325D.46(1). Because the labeling here complied with the FDCA and FDA's rules, the claims under the Minnesota Uniform Deceptive Trade Practices Act must be dismissed. *See* Compl. ¶ 551(x).

- **Nevada**. Nevada's Deceptive Trade Practices Act likewise does not apply to "[c]onduct in compliance with the orders or rules of, or a statute administered by, a federal, state or local government agency." Nev. Rev. Stat. § 598.0955(1)(a). The claims under Nevada's Deceptive Trade Practices Act must accordingly be dismissed. *See* Compl. ¶ 551(cc).

- **New York**. New York's General Business Law Section 349 provides that "it shall be a complete defense that the act or practice is, or if in interstate commerce would be, *subject to and complies with* the rules and regulations of, and the statutes administered by, the federal trade commission or any official department, division, commission or agency of the United States as such rules, regulations or statutes are interpreted by the federal trade commission or such department, division, commission or agency or the federal courts." N.Y. Gen. Bus. Law § 349(d) (emphasis added). This safe harbor is a "complete defense to liability under GBL §§ 349 and 350." *Duchimaza v. Niagara Bottling, LLC*, --- F. Supp. 3d ---, 2022 WL 3139898, at *8 (S.D.N.Y. Aug. 5, 2022) (quotation marks omitted). A plaintiff can circumvent this bar only by "plausibly alleg[ing] that the Products' labels do not comply with federal law." *Gwinn v. Laird Superfood, Inc.*, --- F. Supp. 3d ---, 2022 WL 17363585, at *4 (S.D.N.Y. Dec. 1, 2022). Plaintiffs have not made such an allegation, so the claims brought under New York's General Business Law must be dismissed. *See* Compl. ¶ 551(gg).

- **Tennessee**. Tennessee law exempts from the Tennessee Consumer Protection Act "[a]cts or transactions required or specifically authorized under laws administered by, or rules promulgated by, any regulatory bodies or officers acting under the authority of this State or of the United States." Tenn. Code Ann. § 47-18-111(a)(1). Interpreting this exemption, at least one court has indicated that it would foreclose claims based on compliance with over-the-counter drug labeling as set forth by FDA. *See Am. Home Prods.*, 672 F. Supp. at 144–45 & n.2. Here, the

acetaminophen products' labeling and pregnancy warnings complied with the FDCA and FDA's rules, and Plaintiffs do not allege otherwise. The claims brought under Tennessee's Consumer Protection Act should be dismissed. *See* Compl. ¶ 551(qq).

- **Washington**. Washington law exempts from Washington's Unfair Business Practices—Consumer Protection Act any "actions or transactions permitted by any other regulatory body or officer acting under statutory authority of this state or the United States . . . ." Wash. Rev. Code Ann. § 19.86.170. Courts in Washington have thus asked whether a particular practice alleged to be unfair or deceptive is specifically "permitted, prohibited, or regulated." *Kaiser v. CSL Plasma Inc.*, 240 F. Supp. 3d 1129, 1140 (W.D. Wash. 2017) (quotation marks omitted). Here, the acetaminophen product pregnancy warning at issue is "affirmatively authorized by the agency." *Lohr v. Nissan N. Am., Inc.*, 2022 WL 1449680, at *2 (W.D. Wash. May 9, 2022) (quotation marks omitted). The claims brought under Washington's Unfair Business Practices—Consumer Protection Act should be dismissed. *See* Compl. ¶ 551(vv).

C. Compliance with Federal Law Triggers Other Safe Harbor Provisions and Doctrines.

Compliance with federal law can also be a defense against a common law product liability claim. While many states consider compliance with federal law as an evidentiary matter,[22] courts in at least two states implicated here have clarified that compliance with federal and state standards can, in addition to barring statutory consumer protection claims, bar common law claims as a matter of law:

- **California**. The California Supreme Court has recognized that "there is some room in tort law for a defense of statutory compliance." *Ramirez*, 6 Cal. 4th at 548. And when there are "no unusual circumstances, . . . then the minimum standard prescribed by the legislation or regulation may be accepted . . . by the court as a matter of law[] as sufficient for the occasion." *Id.* (quotation marks omitted). Here, there are no unusual circumstances. On the contrary, there is considerable reason to conclude that the FDA-mandated pregnancy warning satisfies the duty of care under California law because California has adopted this warning ***as its own***: "All

[22] *See, e.g.*, Colo. Rev. Stat. § 13-21-403(1), (2) ("In any product liability action, it shall be rebuttably presumed that the product which caused the injury, death, or property damage was not defective and that the manufacturer or seller thereof was not negligent if the product: . . . [c]omplied with, at the time of sale by the manufacturer, any applicable code, standard, or regulation adopted or promulgated by the United States . . . or by any agency of the United States or of this state.").

nonprescription drug regulations and any amendments to those regulations adopted pursuant to the federal act . . . shall be the nonprescription drug regulations of the state." *See* Cal. Health & Safety Code § 110111. A new state regulation may be adopted only if it "is not different from, or in addition to, any requirement for nonprescription drugs . . . ." *Id.*; *see also Mason v. Heel, Inc.*, 2013 WL 5977932, at *1 (S.D. Cal. Oct. 30, 2013) (noting that "California law adopts as its own" federal regulations for nonprescription drugs). Because the Retailer Defendants' acetaminophen products fully complied with both federal and California law on pregnancy warnings, the "prudent course is to adopt for tort purposes the existing legislative and administrative standard of care on this" pregnancy-warning issue. *Ramirez*, 6 Cal. 4th at 553. The Court should dismiss all of Plaintiffs' claims under California law.

- **Texas**. Texas law creates a rebuttable presumption of non-liability for failure-to-warn claims where a drug's warnings complied with an FDA monograph. Tex. Civ. Prac. & Rem. Code Ann. § 82.007. A plaintiff may rebut this presumption only with allegations proving specific conduct that Plaintiffs have not alleged here. *See* Tex. Civ. Prac. & Rem. Code Ann. § 82.007(b) (identifying the sole ways to rebut the presumption). Because Plaintiffs have failed to allege facts that would rebut the presumption of non-liability, dismissal is appropriate. *See Phares v. Actavis-Elizabeth LLC*, 892 F. Supp. 2d 835, 842–43 (S.D. Tex. 2012). The Court should dismiss all claims under Texas law.[23]

III. Certain Common Law and Consumer Protection Claims Must Be Dismissed Because They Have Been Subsumed by State Product Liability Statutes.

Other than their statutory consumer-protection claims,[24] Plaintiffs' claims are pleaded under common law. Five states implicated in this litigation—Kentucky, Louisiana, Tennessee, Texas, and Washington—have enacted product liability statutes that subsume other state product liability claims and provide a single path for those claims.[25] Because common law product liability claims are invalid in those states, Plaintiffs' common law claims under those states' laws must be

[23] Other state statutes likewise restrict liability for actions complying with federal law, and the Retailer Defendants expect that these state law restrictions will foreclose any of Plaintiffs' claims that remain at a later stage. *See, e.g.*, Colo. Rev. Stat. § 13-21-403; Tenn. Code Ann. § 29-28-104. For a list of state statutory safe harbor provisions found outside consumer protection statutes, see Exhibit 8.

[24] One plaintiff from Louisiana also pleads a statutory product liability claim and statutory redhibition claim. *See* Short Form Complaint at 18, *Norris*, No. 1:23-cv-00214-DLC.

[25] For a chart of state claims subsumed or replaced by state statutory product liability law, see Exhibit 9.

dismissed. Further, two of those states—Louisiana and Tennessee—have product liability statutes that additionally subsume any claims under consumer protection statutes. As a result, all the claims that Plaintiffs have asserted under those states' laws are invalid and must be dismissed. *See, e.g.*, *In re Valsartan, Losartan, & Irbesartan Prods. Liab. Litig.*, 2021 WL 364663, at *6–20 (D.N.J. Feb. 3, 2021) (dismissing plaintiffs' product liability claims brought under state common law theories and certain state consumer protection statutes because they were subsumed).[26]

- **Kentucky**. The Kentucky Products Liability Act ("KPLA") "applies to all damage claims arising from the use of products, regardless of the legal theory advanced." *Smith v. Wyeth, Inc.*, 657 F.3d 420, 423 (6th Cir. 2011) (quoting *Monsanto Co. v. Reed*, 950 S.W.2d 811, 814 (Ky. 1997)); *Mitchell v. Lupin Pharms., Inc.*, 2016 WL 6662713, at *4 (W.D. Ky. Nov. 10, 2016) (noting that claims for injuries relating to the usage of a drug are subsumed within "the Kentucky PLA"); *see also* Ky. Rev. Stat. § 411.300(1). Thus, claims arising from the use of a product must be brought under the KPLA and satisfy its requirements. *See id.*; *Anderson v. Black & Decker (U.S.), Inc.*, 597 F. Supp. 1298, 1300 (E.D. Ky. 1984) (discussing the KPLA and noting that "the clear intent of the legislature was to restrict liability in products cases" and "[t]hus, it limited the liability of retailers"). Plaintiffs have not alleged violations of the KPLA. The product liability claims brought under Kentucky's common law must therefore be dismissed. Compl. ¶¶ 441–524, 560–98.
- **Louisiana**. The Louisiana Product Liability Act ("LAPLA") "establishes the exclusive theories of liability for manufacturers for damages caused by their products." La. Stat. Ann. § 9:2800.52. And "[a] claimant may not recover from a manufacturer for damage caused by a product on the basis of any theory of liability that is not set forth" under LAPLA. *Id.*; *see also, e.g.*, *Scianneaux v. St. Jude Med. S.C., Inc.*, 961 F. Supp. 2d 808, 811–12 (E.D. La. 2013) (stating that "neither negligence, strict liability, nor breach of express warranty is any longer viable as an independent theory of recovery against a manufacturer" and dismissing claims for breach of express and implied warranty, strict liability, fraud, and negligence where plaintiff failed to allege a violation of LAPLA);

[26] Although this brief focuses on the state laws under which Plaintiffs have raised claims, *see* note 3, *supra*, other states also have product liability statutes that subsume other claims, including Alaska (The 1986 Tort Reform Act, Alaska Stat. § 09.17.900); Connecticut (Connecticut Product Liability Act, Conn. Gen. Stat. § 52-572m, *et seq.*); Idaho (Idaho Products Liability Reform Act, Idaho Code § 6-1401, *et seq.*); Indiana (Indiana Product Liability Act, Ind. Code Ann. § 34-20-1-1); Kansas (Kansas Product Liability Act, Kan. Stat. Ann. § 60-3302(c)); Mississippi (Mississippi Product Liability Act, Miss. Code Ann. § 11-1-63); New Jersey (New Jersey Products Liability Act, N.J. Stat. Ann. § 2A:58C-2, *et seq.*); North Carolina (North Carolina Product Liability Act, N.C. Gen Stat. § 99B-1.1); and Ohio (Ohio Product Liability Act, Ohio Rev. Code Ann. § 2307.71(B)).

In re Valsartan, 2021 WL 364663, at *15 (dismissing all Louisiana common law products liability claims because LAPLA subsumes all common law claims). The LAPLA subsumes statutory consumer protection claims as well. *See Bladen*, 487 F. Supp. 2d at 769 ("The legislature, with full knowledge of the [Louisiana Unfair Trade Practices Act], unquestionably enacted the LPLA statutory declaration of exclusive liability in the LPLA and made no exception for the LUTPA."). All claims brought under Louisiana law, except for the single LAPLA raised by a single Louisiana Plaintiff, must be dismissed. Compl. ¶¶ 441–524, 560–98.

- **Tennessee.** When plaintiffs seek "compensation for injuries related to the[] usage of [a] drug," their claims are "subsumed within the Tennessee Product Liability Act." *Mitchell*, 2016 WL 6662713, at *4 (citing *Strayhorn v. Wyeth Pharms., Inc.*, 737 F.3d 378 (6th Cir. 2013)); *see also Harwell v. Am. Med. Sys. Inc.*, 803 F. Supp. 1287, 1296 (M.D. Tenn. 1992) (plaintiff "asserts several distinct theories of recovery, i.e., strict liability, negligence and breach of implied warranty, all of which are covered under the [TPLA]" (citing Tenn. Code Ann. § 29-28-101, *et seq.*)); *Johnson v. Electrolux Home Prods, Inc.*, 2011 WL 4397494, at *4 (E.D. Tenn. Aug. 31, 2011) (the TPLA "was written to provide the exclusive remedy for injuries caused by products"), *report and recommendation adopted* (Sept. 20, 2011). Claims under the Tennessee Consumer Protection Act are subsumed by the TPLA as well. *Hosbrook v. Ethicon, Inc.*, 2021 WL 1599199, at *8 (S.D. Ohio Apr. 23, 2021) (granting summary judgment on plaintiff's consumer protection claim "since [it is] subsumed under the TPLA"). Plaintiffs have not alleged violations of the TPLA. All claims brought under Tennessee law must be dismissed. Compl. ¶¶ 441–538, 560–98.

- **Texas**. In Texas, "a non-manufacturing seller 'is not liable for harm caused ... by [a] product unless the claimant proves' that one of the [Texas Product Liability Act's] enumerated exceptions applies." *Amazon.com, Inc. v. McMillan*, 625 S.W.3d 101, 106 (Tex. 2021) (quoting Tex. Civ. Prac. & Rem. Code Ann. § 82.003)). Plaintiffs have not alleged that any of these exceptions applies. The product liability claims brought under Texas's common law must be dismissed. Compl. ¶¶ 441–538, 560–98.

- **Washington**. The Washington Product Liability Act ("WAPLA") provides the "exclusive remedy for product liability claims." *Macias v. Saberhagen Holdings, Inc.*, 282 P.3d 1069, 1073 (Wash. 2012) (en banc); *see also* Wash. Rev. Code Ann. § 7.72.010, *et seq*. This "reflects the legislature's goal of avoiding the imposition of liability on nonmanufacturer sellers of products (retailers) based solely on their participation in the chain of distribution." *Am. Family Mut. Ins. Co. v. Wood Stoves Etc., Inc.*, 518 P.3d 666, 668–69 (Wash. Ct. App. 2022) (quotation marks and brackets omitted); *see also In re Valsartan*, 2021 WL 364663, at *19–20 (dismissing Washington common law product liability claims because "[t]he WAPLA recognizes a single product liability cause of action"). Plaintiffs have not alleged violations of the WAPLA. All claims brought under Washington common law accordingly must be dismissed. Compl. ¶¶ 441–524, 560–98.

IV. The Retailer Defendants' Status as Retailers Limits Liability Under State Law

Most states apply different product liability standards to retailers than to a product's manufacturer. Plaintiffs know that the Retailer Defendants did not manufacture the products at issue. Yet Plaintiffs allege in a conclusory fashion that the Retailer Defendants should be treated like manufacturers based on an "apparent manufacturer liability" claim. And Plaintiffs point to out-of-context quotes from other litigation to contend that the Retailer Defendants exercised control over the actual manufacturer of the acetaminophen products at issue. But Plaintiffs have not adequately pleaded a standalone apparent manufacturer liability claim, and Plaintiffs' control allegations are conclusory and undercut by the very documents on which Plaintiffs rely.

A. The Court Should Dismiss Plaintiffs' "Apparent Manufacturer Liability" Claim.

In Count VIII, Plaintiffs set forth a claim for "liability as apparent manufacturers." Compl. ¶¶ 113–17. The Court should dismiss that claim in its entirety.

To begin with, the claim fails Rule 8's basic requirements. "Rule 8 requires that a complaint contain 'a short and plain statement of the claim showing that the pleader is entitled to relief.'" *Owens v. McCall*, 5 F. App'x 15, 16 (2d Cir. 2001). Here, it is not clear what claim Plaintiffs are asserting. Despite taking care in other counts to identify the law being invoked, *see, e.g.*, Compl. Count V & ¶ 551(a)–(yy), here, Plaintiffs purport to plead only an apparent manufacturer claim "as recognized by certain states' laws," Compl. ¶ 577. This ambiguous reference to "certain states' laws" does not give Defendants adequate notice of what claims Plaintiffs are asserting. *Cf. Gustafson v. Wells Fargo Home Mortg.*, 2012 WL 12903739, at *2 (N.D. Cal. Dec. 28, 2012) (dismissing complaint under Rule 8 where, among other things, the complaint "fail[ed] to identify the specific foreclosure statutes defendants allegedly violated").

Plaintiffs' vague reference to "certain states" is no accident. "Apparent manufacturer liability" is not a valid claim in every state whose laws the Complaint otherwise invokes, because some states have expressly rejected the doctrine. *See, e.g.*, *Taylor v. Southwire Tools & Equip.*, 130 F. Supp. 3d 1017, 1020–21 (E.D. Ky. 2015) ("Kentucky has not adopted the apparent manufacturer doctrine"). At least twelve states—including four at issue in this litigation—have explicitly rejected or declined to adopt a common law apparent manufacturer liability theory.[27] Another seventeen states—including five states at issue in this litigation—do not appear to have ever adopted the theory.[28] Given the apparent manufacturer doctrine's "limited application in the modern products liability landscape in most jurisdictions," there is no justification to expand the doctrine under the law of a state where no court of that state has done so. *Rushing v. Flerlage Marine Co.*, 2011 WL 4538075, at *2–3 (W.D. Ky. Sept. 29, 2011).

Even where apparent manufacturer liability has been acknowledged, states generally describe it not as a standalone claim of its own, but rather as a "doctrine," "principle," or "theory" that treats retailers like manufacturers for purposes of other claims when specific conditions are met. *See, e.g.*, *In re TMJ Prods. Liab. Litig.*, 880 F. Supp. 1311, 1321 (D. Minn. 1995) (referring to the apparent manufacturer "doctrine"); *Dildine v. Clark Equip. Co.*, 666 S.W.2d 692, 695 (Ark.

[27] Those four states are Arizona, Kentucky, Illinois, and Texas. *See Torres v. Goodyear Tire & Rubber Co.*, 867 F.2d 1234, 1236 (9th Cir. 1989) ("Arizona has not adopted the apparent manufacturer doctrine."); *Taylor*, 130 F. Supp. 3d at 1020–21 (rejecting apparent manufacturer liability as being "'in tension or outright conflict' with the Kentucky Products Liability Act" (quoting *Rushing v. Flerlage Marine Co.*, 2011 WL 4538075, at *3 (W.D. Ky. Sept. 29, 2011))); *Goesel v. Boley Int'l (H.K.) Ltd.*, 664 F. Supp. 2d 923, 925 (N.D. Ill. 2009) (predicting that "the Illinois Supreme Court would find that the statutory provisions of the [innocent seller statute] have trumped the earlier judge-made [apparent manufacturer] doctrine and have defined the sole predicate for the potential imposition of strict liability on a nonmanufacturer"); *Crawley v. Applica Consumer Prods. Inc.*, 2007 WL 9702888, at *6 (W.D. Tex. June 26, 2007) ("The Texas Legislature replaced the 'apparent manufacturer' doctrine with section 82.003.8.").

[28] Retailer Defendants have found no opinions affirmatively adopting apparent manufacturer liability in California, Florida, Nevada, Oregon, and Pennsylvania.

1984) (describing apparent manufacturer liability as a "principle"); *cf.* Compl. ¶ 445 (alleging that the Retailer Defendants were apparent manufacturers under certain States' laws for purposes of the strict liability for failure to warn claim). To the extent Plaintiffs seek to state a standalone "liability as apparent manufacturer claim[] against Defendants," Compl. ¶ 10, this Court should dismiss that claim across the board.

Finally, even as a doctrine, the "apparent manufacturer" theory conflicts with the facts in this case. The apparent manufacturer theory is that a seller "who puts out as his own product a chattel manufactured by another is subject to the same liability as though he were its manufacturer." Restatement (Second) of Torts § 400 (1965). The point of the theory is to "estop[]" a seller "from denying it was the manufacturer when a buyer has no reasonable means to determine the true manufacturer, and the seller concealed that identity to the buyer." Justin J. Hagel, *Torts - Product Liability: North Dakota Rejects the Apparent Manufacturer Doctrine* Bornsen v. Pragotrade, LLC*, 2011 ND 183, 804 N.W.2d 55*, 88 N.D. L. Rev. 477, 481 (2012); *see also Seasword v. Hilti, Inc.*, 537 N.W.2d 221, 224 (Mich. 1995) (observing that "the apparent-manufacturer doctrine serves the purpose of assuring that some entity in the product enterprise remains answerable for injuries caused by defective products").

Here, however, Plaintiffs' own allegations undercut this theory. The Master Complaint repeatedly acknowledges that it is not the Retailer Defendants that manufacture the acetaminophen products. *See* Compl. ¶¶ 105, 117, 146, 161, 232, 248, 264, 291, 306 (identifying LNK International, Inc. ("LNK") as an actual manufacturer of the products). And it expressly admits what the manufacturer's role is in crafting the labeling at the root of Plaintiffs' claims: "LNK must use its professional judgment to create packaging that complies with FDA regulations." Compl. ¶ 105 (quoting Complaint ¶ 17, *L.N.K. Int'l, Inc. v. Cont'l Cas. Co.*, No. 22-cv-5184 (E.D.N.Y.

Aug. 30, 2022), ECF No. 1); *see Soo Line R.R. v. St. Louis Sw. Ry., Co.*, 125 F.3d 481, 483 (7th Cir. 1997) ("A plaintiff can 'plead himself out of court by alleging facts which show that he has no claim.'" (quoting *Jackson v. Marion County*, 66 F.3d 151, 153 (7th Cir. 1995))). Plaintiffs' tacit acknowledgment that LNK, like other manufacturers of acetaminophen products, is the entity that (1) makes the product and (2) crafts the labeling of the product, including its warnings, exposes Plaintiffs' allegations for what they are: An attempt to plead around the simple and plain fact that Retailers are nothing more than the sellers of these products, and therefore cannot and should not be held liable as manufacturers of the acetaminophen products at issue.

The apparent manufacturer liability theory is especially inapt for Costco Wholesale Corporation.[29] The label on Costco's Kirkland-branded products specifically identifies LNK International as the manufacturer. *See* Compl. ¶ 387 ("Manufactured by: LNK INTERNATIONAL, INC." on bottom left corner of the label). When a product's label "clearly and accurately identif[ies] the actual manufacturer of the product," a company cannot be considered an "apparent manufacturer" for purposes of any claim. *See Brock v. Baxter Healthcare Corp.*, 96 F. Supp. 2d 1352, 1358 (S.D. Ala. 2000) (holding that a company did not put out a product as its own where the product "clearly and accurately identif[ied] the actual manufacturer of the product").

In sum, Plaintiffs have failed to adequately state a standalone claim for apparent manufacturer liability. This Court should dismiss Count VII in its entirety as to all Retailer Defendants.

[29] For a list of cases asserting a "liability as apparent manufacturer" claim against Costco, see Exhibit 11.

B. Many States Insulate Retailers from Liability for the Products They Sell.

Twenty-eight states—including nine at issue here—have enacted laws shielding "innocent sellers" from certain product liability causes of action. Although their precise contours vary, these innocent seller statutes generally exculpate sellers from product liability claims unless the seller alters or exercises control over the product, or the product's manufacturer cannot possibly be sued.[30] Tennessee's innocent seller law, for example, provides that "[n]o product liability action . . . shall be commenced or maintained against any seller, other than the manufacturer," subject to certain exceptions. Tenn. Code Ann. § 29-28-106. These exceptions apply when (1) the seller "exercised substantial control" over the relevant aspect of the product's "design, testing, manufacture, packaging, or labeling"; (2) the seller "[a]ltered or modified the product," and that alteration or modification caused the plaintiff's injury; (3) the seller "gave an express warranty" about the product; (4) the product's "manufacturer or distributor . . . is not subject to service of process" in Tennessee; or (5) "[t]he manufacturer has been declared judicially insolvent." *Id.* Other states have similar statutes.[31]

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[30] Some innocent seller statutes also create an exception for knowledge of the defect. For the reasons set forth in Part I.B.2, *supra*, and Part II.B. of JJCI's brief, Plaintiffs have failed to adequately plead knowledge.

[31] *See, e.g.*, Colo. Rev. Stat. § 13-21-402 ("No product liability action shall be commenced or maintained against any seller of a product unless said seller is also the manufacturer of said product or the manufacturer of the part thereof giving rise to the product liability action . . . [or unless] jurisdiction cannot be obtained over a particular manufacturer of a product or a part of a product alleged to be defective . . . ."); Ky. Rev. Stat. § 411.340 ("In any product liability action, if the manufacturer is identified and subject to the jurisdiction of the court, a wholesaler, distributor, or retailer who distributes or sells a product, upon his showing by a preponderance of the evidence that said product was sold by him in its original manufactured condition or package, or in the same condition such product was in when received by said wholesaler, distributor or retailer, shall not be liable to the plaintiff for damages arising solely from the distribution or sale of such product, unless such wholesaler, distributor or retailer, breached an express warranty or knew or should have known at the time of distribution or sale of such product that the product was in a defective condition, unreasonably dangerous to the user or consumer."); La. Civ. Code Ann. art. 2531 ("A

Plaintiffs attempt to circumvent innocent seller statutes by including conclusory allegations that the Retailer Defendants exerted control over the acetaminophen products' labeling and manufacturing. *See, e.g.*, Compl. ¶¶ 116, 118 (contending that certain Retailer Defendants maintained "substantial control" and "ultimate control and authority" over their respective products). But "[c]onclusory allegations of control are insufficient as a matter of law." *In re Global Crossing, Ltd. Sec. Litig.*, 2005 WL 1875445, at *3 (S.D.N.Y. Aug. 5, 2005).

Plaintiffs' factual allegations are limited to fragments of documents from litigation involving an actual manufacturer of the acetaminophen products at issue: LNK International, Inc. But these papers establish that LNK—not the Retailer Defendants—had control over the labeling of the products it manufactured to ensure that they "compl[y] with FDA regulations." Compl. ¶ 105 (quoting Complaint ¶ 17, *L.N.K. Int'l*, No. 22-cv-5184). Specifically, the documents establish that retailers "rely on LNK to review and interpret the FDA's 'OTC monograph' applicable to each respective drug and to create packaging and labeling that satisfy the conditions—including the labeling requirements—set forth therein." Complaint ¶ 16, *L.N.K. Int'l*, No. 22-cv-5184. Although Plaintiffs point to snippets of contracts between LNK and various

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seller who did not know that the thing he sold had a defect is only bound to repair, remedy, or correct the defect."); Tex. Civ. Prac. & Rem. Code Ann. § 82.003(a) (effective Sept. 2009) ("[a] seller that did not manufacture a product is not liable for harm caused to the claimant by that product" unless one of the following seven exceptions applies: (1) the seller participated in designing the product; (2) the seller altered the product, and plaintiff's harm resulted from that alteration; (3) the seller installed the product or had it installed on another product, and plaintiff's harm resulted from that installation; (4) the seller substantially controlled the content of the product's warning or instruction, the warning or instruction was inadequate, and plaintiff's harm resulted from that inadequacy; (5) the seller made an express, incorrect factual representation about an aspect of the product, plaintiff relied on that representation, and had the product conformed to that representation, plaintiff would have suffered less harm or no harm at all; (6) the seller knew of a defect when it sold the product, and plaintiff's harm resulted from that defect; and (7) the product's manufacturer is insolvent or not subject to the court's jurisdiction).

An appendix compiling the innocent seller laws for the states at issue in this litigation is attached as Exhibit 10.

retailers to suggest the retailers were pulling the strings, the full quotations prove just the opposite. For example, Plaintiffs state that "LNK represented and warranted that it would 'comply with all specifications' contained in every Sam's Club order." Compl. ¶ 266 (quoting Complaint Exhibit 8 at 4, ¶ 13, *L.N.K. Int'l, Inc.*, No. 22-cv-5184 (Contract between Sam's Club, Walmart, and LNK)). But the broader quotation tells a different story: "By acceptance of an Order, Supplier [LNK] represents, warrants, and guarantees that: (a) The Merchandise will be new and not used, remanufactured, reconditioned, or refurbished, and will comply with all specifications contained in such Order and will be of equal or better quality as all samples delivered to Company." Complaint Exhibit 8 at 4, ¶ 13, *L.N.K. Int'l, Inc.*, No. 22-cv-5184. This is standard form purchasing order language; it does not show that Sam's Club or Walmart controlled drug manufacturing or labeling.

To survive a motion to dismiss, Plaintiffs were required to plead meaningful factual allegations, not legal conclusions, to establish each claim. Here, however, no well-pleaded facts show that the Retailer Defendants substantially controlled labeling and manufacturing, let alone that any Retailer Defendant substantially controlled or altered the purportedly defective use-during-pregnancy warning at issue. The innocent seller defense therefore applies, and the Court should dismiss all claims under Colorado, Kentucky, Louisiana, Tennessee, and Texas law and all strict liability claims under Illinois and Minnesota law.[32]

CONCLUSION

For all these reasons, the Court should dismiss Plaintiffs' claims.

[32] Minnesota and Illinois's innocent seller statutes contemplate a procedural path to identifying a product's actual manufacturer. *See* Minn. Stat. § 544.41(1); 735 Ill. Comp. Stat. § 5/2-621(a). Here, however, Plaintiffs have already pleaded the identity of an actual manufacturer of the acetaminophen products. *See* Compl. ¶¶ 105, 117, 146, 161, 232, 248, 264, 291, 306.

Dated: February 10, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on February 10, 2023, a copy of **RETAILER DEFENDANTS' MEMORANDUM IN SUPPORT OF THEIR MOTION TO DISMISS** was electronically filed with the Clerk of Court using the CM/ECF system, which will send notification of such filing to all registered users.

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