UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: Acetaminophen – ASD-ADHD Products Liability Litigation This Document Relates To: All Actions	Docket No.: 22-md-3043 (DLC)

DEFENDANT JOHNSON & JOHNSON CONSUMER INC.'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO DISMISS

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INTRODUCTION

Plaintiffs seek to usurp the role of the FDA and second-guess the scientific community by pursuing speculative claims that acetaminophen ("APAP") use during pregnancy can cause autism spectrum disorder ("ASD") and attention deficit/hyperactivity disorder ("ADHD") in children. As set forth below, Plaintiffs' claims against Johnson & Johnson Consumer Inc. ("JJCI") should be dismissed for three primary reasons.

First, Plaintiffs' claims are preempted. JJCI acknowledges that the Court has already considered and denied a preemption motion brought by another defendant. In so doing, the Court correctly framed the relevant question: Could manufacturers of APAP "have unilaterally changed the label . . . without violating the [tentative final monograph governing APAP products], the regulations governing the Pregnancy Warning [in 21 C.F.R. § 201.63], and other applicable regulations?" Order at 17, ECF No. 145 (Nov. 14, 2022) ("*Hatfield* Order"). JJCI respectfully submits, however, that the Court reached the wrong answer because it did not have all the relevant considerations before it.

As a threshold matter, the Court's attention was not directed to critical language in 21 C.F.R. § 330.1(c)(2), which requires that warnings prescribed by FDA regulations "shall be stated in the exact language where exact language has been established and identified by quotation marks in an applicable OTC [i.e., over-the-counter] drug monograph or by regulation (e.g., § 201.63 of this chapter [i.e., the Pregnancy Warning])," subject to exceptions not applicable here. The FDA has referred to this provision as embodying the Agency's "exclusivity policy," which "limit[s] monograph labeling terminology to specific words and phrases considered and approved by FDA." FDA, *FDA Policy Relating to Limitations of Labeling Terminology in Over-the-Counter Drug Monographs* ("*Limitations of Labeling Terminology*"), 47 Fed. Reg. 29,002, 29,002 (July 2,

1982).[1] Although the FDA has relaxed this policy with respect to indications for use, it has retained it as to warnings, explaining that it "believes that ***concisely and consistently worded warnings are essential to the safe use of an OTC drug product*** and that permitting flexibility in this section of labeling could put consumers at risk in terms of safe use of an OTC drug product." FDA, *Labeling of Drug Products for Over-the-Counter Human Use*, 51 Fed. Reg. 16,258, 16,263 (May 1, 1986) (emphasis added).

This Court's conclusion that the Pregnancy Warning provides flexibility—i.e., that it requires a "general warning" without restricting manufacturers from adding any "specific warning" they wish—is contrary to that regulatory history. *Hatfield* Order at 21–24. The FDA's pronouncements make it clear that the FDA views the exclusivity policy as setting not only a floor but also a ceiling on warnings—which reflects the FDA's longstanding concern that excessive or additional warning language can be "too complex and lengthy for clear and easy understanding by the target population to whom [the warnings] are directed." FDA, *Over-the-Counter Nighttime Sleep-Aid and Stimulant Products*, 43 Fed. Reg. 25,544, 25,553 (June 13, 1978).

Considered in this context, the Pregnancy Warning—which is ***the*** very example referred to in 21 C.F.R. § 330.1(c)(2), as a prescribed warning that ***must*** be stated in the "exact language" established by the FDA—is plainly intended to be exclusive of any other pregnancy-related warning language that manufacturers might wish to include or states might wish to impose. Accordingly, an OTC product subject to the regulation must bear either the "general" Pregnancy Warning the FDA prescribes for most drugs or a "specific" warning where required by a monograph or an approved New Drug Application ("NDA")—***and nothing else***. 21 C.F.R.

[1] Material published in the Federal Register is subject to mandatory judicial notice. 44 U.S.C. § 1507 ("The contents of the Federal Register shall be judicially noticed . . . .").

§ 201.63(a)–(b). The FDA could not have been clearer in its dictate. As the FDA expressly states in a portion of the rulemaking that was not cited to the Court in prior briefing, the FDA "conclude[d] that the adjustments regarding the appropriate pregnancy-nursing warnings will be best handled ***in the final OTC drug monographs and in individual NDAs***." FDA, *Pregnant or Nursing Women*, 47 Fed. Reg. 54,750, 54,755 (Dec. 3, 1982) (emphasis added).

Plaintiffs' own allegations and requested relief underscore the wisdom of the exclusivity policy's prohibition on overwarning as applied to the Pregnancy Warning. The authors of the purported "consensus" statement[2] on which Plaintiffs base their claims acknowledge that "for fever and severe pain during pregnancy, APAP is a necessary and appropriate treatment."[3] This is particularly true because fever during pregnancy is itself associated with neurological problems in children.[4] Inclusion of an ASD/ADHD warning on APAP thus risks deterring patients from using the drug to avoid a speculative harm, only to unwittingly expose themselves to the established risks of maternal fever. In light of this context, the FDA has rightly concluded that

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[2] The so-called "consensus" statement does not actually reflect a scientific consensus. A "consensus counterstatement" that was "supported by 50 scientists, clinicians, epidemiologists and teratology information specialists" cautioned "against an inference of causality that is based upon inadequate evidence." Sura Alwan, et al., *Paracetamol Use In Pregnancy—Caution Over Causal Inference From Available Data*, 18 Nature Revs. Endocrinology 190 (2022). And another article noted that "the supporting evidence brought forward [wa]s weak, inconsistent and to a large extent methodologically inaccurate." Per Damkier, et al., *Handle With Care—Interpretation, Synthesis & Dissemination Of Data On Paracetamol In Pregnancy*, 18 Nature Revs. Endocrinology 191 (2022). Both papers warned that the results of reduced APAP use could lead to increased maternal fever or use of non-steroidal anti-inflammatory alternatives, worsening fetal health.

[3] Ann Z. Bauer et al., *Paracetamol Use During Pregnancy—A Call For Precautionary Action*, 17 Nature Revs. Endocrinology 757, 758 (2021) (cited in Compl., ECF No. 276, ¶¶ 4, 102–105). The Court may consider the content of the studies upon which Plaintiffs rely, as they are "'incorporated by reference'" in the Master Complaint. *Smith v. Apple, Inc.*, 583 F. Supp. 3d. 554, 565 (S.D.N.Y. 2022) (Cote, J.) (quoting *United States ex rel. Foreman v. AECOM*, 19 F.4th 85, 106 (2d Cir. 2021)); *Utts v. Bristol-Myers Squibb Co.*, 251 F. Supp. 3d 644, 657 (S.D.N.Y. 2017) (Cote, J.) ("In deciding a motion to dismiss, the court considers 'any written instrument attached to the complaint as an exhibit or any statements or documents incorporated in it by reference.'" (quoting *Stratte-McClure v. Morgan Stanley*, 776 F.3d 94, 100 (2d Cir. 2015))); *Subaru Distribs. Corp. v. Subaru of Am., Inc.*, 425 F.3d 119, 122 (2d Cir. 2005) ("The court may also consider 'documents upon which the complaint relies and which are integral to the complaint.'").

[4] Ann Z. Bauer et al., *Paracetamol Use During Pregnancy—A Call For Precautionary Action*, 17 Nature Revs. Endocrinology 757, 758 (2021).

patients are better served by being directed to "ask a health professional before use" rather than bombarding them with every conceivable risk or benefit of using APAP on product packaging.

In short, the FDA views itself as the sole purveyor of OTC pregnancy-related warnings and has left no room for variations on the Pregnancy Warning—whether by addition, subtraction, or revision. Accordingly, Plaintiffs' claims are preempted.

Alternatively, even if manufacturers were in general otherwise free to add pregnancy warnings to the label, they could not have done so in this case because the FDA has repeatedly reviewed the same literature on which Plaintiffs' allegations rest and concluded that it does not support an ASD or ADHD warning. The Court previously rejected this alternative basis for preemption on the ground that Plaintiffs rely on studies post-dating a 2015 FDA statement about the science. *Hatfield* Order at 27–28. But the Court was not previously advised that since 2015 the FDA has repeatedly reconsidered the science—including studies published post-2015—and has maintained the position it expressed then, notwithstanding any supposedly new developments. Given these determinations, it would have been impossible to comply with any state law that would have required the addition of ASD or ADHD warnings without violating federal misbranding law.

Second, the Court should also dismiss the Master Complaint because it fails to plead causation or knowledge with the requisite plausibility under Rule 8. Plaintiffs' allegations rest on epidemiology that uniformly stops short of—and even disclaims—a causal conclusion between maternal APAP use and the development of ASD or ADHD. Indeed, the authors of the 2021 "consensus" document clarified in a reply responding to their critics that "limitations and uncertainties remain despite the large body of available data, therefore, [they] avoided any

inference of causality in [their] Consensus Statement."[5] As courts in the Second Circuit have recognized, statistical correlations (particularly such modest correlations as Plaintiffs allege here) do not establish causation, and where pleadings rest on such tenuous statistical evidence, they fail to plead causation with the requisite plausibility to survive a motion to dismiss. In the alternative, and for the same reasons, the lack of a causal conclusion in the epidemiological data precludes a duty to warn of any alleged connection between APAP use during pregnancy and ASD or ADHD.

Third, Plaintiffs' claims for strict liability misrepresentation, negligent misrepresentation, and consumer protection violations should be dismissed for additional reasons. As a threshold matter, every state that recognizes the tort of strict liability misrepresentation limits liability to express affirmative misstatements (as do a number of states' negligent misrepresentation laws). Because the Master Complaint does not identify a single specific misrepresentation, these claims cannot proceed. In addition, Plaintiffs do not plead any of their misrepresentation, omission or concealment claims with the requisite particularity. Plaintiffs' Master Complaint does not identify any specific representation that they claim is misleading, much less one that any particular Plaintiff relied upon. Nor do they articulate what was omitted, which is not surprising since APAP labeling expressly directs patients to "ask a health professional before use" if pregnant or breast-feeding.

Accordingly, and as elaborated below, the Court should dismiss Plaintiffs' claims.[6]

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[5] 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). Although the Master Complaint does not cite the reply, the Court should take judicial notice of it because the article's existence cannot reasonably be questioned and should be considered as a subsequent statement on the same subject by authors on which Plaintiffs rely. *See United States v. Pickard*, 100 F. Supp. 3d 981, 989–90 (E.D. Cal. 2015) (taking judicial notice on motion to dismiss of study citing an article relied on in plaintiff's complaint under rule of completeness); *Kemp v. N.Y.C. Dep't of Health & Mental Hygiene*, 2019 WL 111045, at *4 n.3 (E.D.N.Y. Jan. 4, 2019) ("In the context of a Rule 12(b)(6) motion, a complaint is deemed to incorporate annexed documents, and a defendant is permitted to submit additional documents on the motion if the documents annexed to plaintiff's pleading tell only part of the story.").

[6] As discussed in prior submissions to the Court, JJCI seeks dismissal of all cases pending against it. To the extent an argument advanced in this motion applies only to certain cases, JJCI has prepared (and references herein) exhibits identifying those cases for the Court's convenience. This motion addresses all short form complaints ("SFCs") filed

BACKGROUND

I. COMPREHENSIVE FEDERAL REGULATORY SCHEME GOVERNING OVER-THE-COUNTER MEDICATIONS

The Food Drug & Cosmetics Act ("FDCA") vests the FDA with authority to comprehensively regulate "the manufacture, labeling, and sale of pharmaceuticals" in the United States. *Hatfield* Order at 6. The FDCA imposes two fundamental rules on drug labeling that are relevant here: First, the FDCA prohibits "misbranded" drugs, which include drugs whose "labeling is false or misleading in any particular," 21 U.S.C. § 352(a)(1), 21 U.S.C. § 355(a), (b), (c), (g), (k), and second, the FDCA requires any "new drug" to obtain the FDA's approval via an NDA before being sold, 21 U.S.C. § 355(a). These two requirements have been the central pillars of U.S. drug-labeling law for nearly a century, and date back to the original FDCA of 1938. *See* P.L. 75-717 §§ 301(a), (b), (c), (g), (k), 502(a), 505(a), 52 Stat. 1040, 1042, 1050–52 (1938).

A. The Monograph And New Drug Application Processes

The FDA utilizes two regulatory processes to ensure that drugs sold in interstate commerce are safe and effective: (1) the NDA process, which is available for all pharmaceuticals; and (2) the monograph process, which is only available for OTC medications such as Tylenol®. Under the NDA process, a manufacturer obtains federal approval for a new drug by submitting an application to the FDA. *Hatfield* Order at 7–8. The pre-market approval process for an NDA drug includes "approval of the exact text" of a proposed label. *Id.* at 7 (citation omitted). After an NDA is approved, the FDA permits the manufacturer of an NDA drug to "make certain changes to its label before receiving the agency's approval through the changes being effected ('CBE')

on or before February 6, 2023. JJCI anticipates that additional cases will be filed, including during the briefing schedule and prior to the Court's ruling on this motion. JJCI reserves 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.

regulation," *id.* at 8 (citation omitted), "to reflect newly acquired information" about the drug, 21 C.F.R. § 314.70(c)(iii).

The second process, which was established specifically for classes of OTC drug products and their active ingredients, is the monograph process. *See Hatfield* Order at 8–10. Rather than conduct an individual review of different drugs, the monograph process establishes conditions under which certain classes of drugs are considered not to be misbranded. From 1972 to 2020, that process consisted of four stages: "(1) an advisory review panel was established to evaluate the safety and effectiveness of the OTC drug; (2) the advisory review panel submitted its report to the FDA Commissioner; (3) the FDA published a tentative final monograph ('TFM'); and (4) after receiving comments on the TFM, the FDA published a final monograph." *Id.* at 10. The resulting monograph would then set out conditions with which a drug's manufacturers must comply in order for the drug to be generally recognized as safe and effective (and thus to be exempt from the NDA requirement). Congress eventually modernized the monograph process in 2020 via the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"), replacing it with an administrative order framework that streamlines the process by which the FDA may issue, revise, and amend OTC monographs. *See* 21 U.S.C. § 355h(b); *Hatfield* Order at 10. Under the current framework, if a company wishes to use a drug label that "deviate[s] in any respect from a monograph that has become final," it must file an NDA subject to plenary FDA review, 21 C.F.R. § 330.11, or request that the FDA change the monograph, *see* 21 U.S.C. § 355h(b)(5).

The FDA will also occasionally promulgate final labeling rules that apply to some or all OTC drugs, including drugs subject to a TFM. *See* 21 C.F.R. §§ 201.60–201.72. These rules expressly mandate that the "Warning" section of a label contain "the exact language" as that set forth in the final labeling rule. 21 C.F.R. § 330.1(c)(2) (requiring all OTC drug labeling, besides

indications for use, to "be stated in the exact language where exact language has been established and identified by quotation marks in an applicable . . . regulation."); *see also Limitations of Labeling Terminology*, 47 Fed. Reg. at 29,002. The policy of "limiting monograph labeling terminology to specific words and phrases considered and approved by FDA" was originally known as the "exclusivity policy." *Id.* In line with that policy, the FDA has noted that "uniformity in labeling language is essential to consumers," since "[a]llowing minor word variations, or rearrangement of the same words, would result in similar or confusing warnings which would not be in the best interest of the public." *Id.* at 29,002–03.

The policy of exclusivity is not solely based on ensuring that labels satisfy a minimum standard. The FDA has also recognized that including too much information may reduce the effectiveness of labels since "consumers are more likely to engage in behavior that they believe they can successfully complete than in behavior that appears overwhelming or that presents a 'cognitive load,' such as the task of reading densely worded consumer information." FDA, *Over-The-Counter Human Drugs; Labeling Requirements*, 64 Fed. Reg. 13,254, 13,255 (Mar. 17, 1999).

B. The FDA's "Mandatory" Pregnancy Warning

The FDA's "mandatory" Pregnancy Warning requires labels for OTC drugs "intended for systemic absorption" to include a warning that says—with the first four words in bold type—"**If pregnant or breast-feeding**, ask a health professional before use." 21 C.F.R. § 201.63(a); FDA, *Pregnant or Nursing Women*, 47 Fed. Reg. 54,750 (promulgating rule); *see also Hatfield* Order at 15 (noting that "[t]he Pregnancy Warning is mandatory unless an NDA or final monograph states otherwise, or the FDA grants a manufacturer an exemption") (citations omitted). The rationale for the FDA's general approach was simple: The FDA "believes a woman would be best advised on whether to use a particular OTC drug by a knowledgeable health professional who is either familiar

with her medical history or readily available to her and capable of assessing her situation with respect to a particular drug." *Pregnant or Nursing Women*, 47 Fed. Reg. at 54,751.

The FDA crafted the Pregnancy Warning in 1982 in response to California's adoption of a similar pregnancy warning requirement, noting that a uniform warning was "necessary to ensure that OTC drugs are used safely and for their intended purposes" and "that consumers receive clear, unambiguous, and consistent information on the labeling of OTC drugs concerning use by pregnant or nursing women." *Id*. at 54,756; *see also Hatfield* Order at 24. Relatedly, the FDA considered "the preemptive effect the FDA warning would have on the California and other similar State OTC drug labeling requirements" and concluded that because the FDA regulation would require "a single national pregnancy-nursing warning with a specified text," it would preempt conflicting state requirements "as a matter of law." *Pregnant or Nursing Women*, 47 Fed. Reg. at 54,756. As the FDA explained, "[m]anufacturers marketing their products in States with differing requirements will be able to use the new FDA labeling without also being required to use the pregnancy-nursing warning labeling required by any State." *Id.* at 54,757.

Although the Agency created this "general" Pregnancy Warning, the FDA also recognized that a "specific" warning may be more appropriate for certain OTC medications. The applicable regulations make clear, however, that any "adjustments regarding the appropriate pregnancy-nursing warnings will be best handled in the final OTC drug monographs and in the individual NDAs." *Id.* at 54,755. As the FDA further explained, "if available data show that an OTC drug poses a definite risk in pregnancy or nursing use, and is thus 'known to be dangerous,' a specific, stronger, warning will be included in the OTC monograph for that drug or required as part of an NDA." *Id.* at 54,753. If no applicable monograph or NDA provides for such a specific warning, the Pregnancy Warning requires the label to carry the "general" pregnancy warning exactly. *Id.*

II. TYLENOL®

A. Federal Regulation Of APAP And Tylenol® Products

APAP, an analgesic and antipyretic agent used to treat pain and fever, has been available for non-prescription OTC use since 1955. *See* FDA, *Exemption from Prescription Requirements*, 20 Fed. Reg. 3,499 (May 19, 1955). The FDA issued the proposed monograph for the OTC drug class to which APAP belongs in 1977, FDA, *Establishment of a Monograph for OTC Internal Analgesic, Antipyretic and Antirheumatic Products* ("*Establishment of a Monograph")*, 42 Fed. Reg. 35,346 (July 8, 1977), issued the TFM in 1988, FDA, *Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over- the-Counter Human Use; Tentative Final Monograph ("Tentative Final Monograph")*, 53 Fed. Reg. 46,204 (Nov. 16, 1988), and published the monograph as a final administrative order on October 14, 2022, *see Hatfield* Order at 12–13.[7]

The now-final monograph that applies to APAP continues to require APAP products to abide by the general OTC labeling requirements, including the Pregnancy Warning. *See Tentative Final Monograph*, 53 Fed. Reg. at 46,255–56. The FDA also continues to require APAP labels to follow these requirements to the letter to avoid being deemed misbranded. *See id.*; 21 C.F.R. § 330.10(b). The FDCA and accompanying regulations provide that if a company wishes to use a

[7] Although APAP products were sold under a TFM at times relevant to this litigation, they were still subject to (1) the FDCA's misbranding prohibition and (2) the FDCA's requirement that a drug must have an NDA or else be generally recognized as safe and effective. When in 1972 the FDA began evaluating which OTC drugs met the FDCA's then-new efficacy requirement, it classified drugs into one of three groups: Category I included drugs recognized as safe and effective, Category II included ingredients (and labeling claims and other conditions) that would result in a drug being *not* generally recognized as safe and effective, and Category III included drugs for which available data were insufficient to justify classification in either of the other two groups. *Cutler v. Hayes*, 818 F.2d 879, 883–84 (D.C. App. 1987). Using this approach, on April 20, 1972 the FDA found regular strength Tylenol® to be a safe and effective analgesic and antipyretic. FDA, *OTC Analgesic and Antipyretic Preparations; Drugs for Human Use; Drug Efficacy Study Implementation*, 37 Fed. Reg. 7820 (Apr. 20, 1972). And in 1975, the FDA approved Extra Strength Tylenol® under the then-current NDA process (NDA 17-522). When the FDA published its proposed monograph for APAP's drug category, APAP was placed in Category I—i.e., generally recognized as safe and effective. *See Establishment of a Monograph*, 42 Fed. Reg. at 35357–58. And the FDA continued this classification in the 1988 TFM. *See Tentative Final Monograph*, 53 Fed. Reg. at 46,248–49. At no point has the FDA departed from its determination—held over decades—that APAP is generally recognized as safe and effective.

drug label that "deviate[s] ***in any respect*** from a monograph that has become final," it must file an NDA subject to plenary FDA review, 21 C.F.R. § 330.11 (emphasis added), or request that the FDA issue an administrative order to change the monograph itself, 21 U.S.C. § 355h(b)(5).

There are currently more than 600 APAP-containing products on the market in the United States in both OTC and prescription formulations.[8] Tylenol® is a brand of APAP OTC drugs manufactured by JJCI. Compl., ECF No. 276, ¶ 166. While a number of different products are sold under the Tylenol® brand, including products that vary by delivery format, dose and count, the only products at issue in this litigation are Tylenol® "products with [APAP] as the ***sole*** active ingredient." Compl. at 1 n.1 (emphasis added); *see also* Compl. ¶ 9 (identifying Tylenol Regular Strength®, Tylenol Extra Strength®, and Tylenol Extra Strength Rapid Release Gels® as examples of products at issue).[9] The three Tylenol® products named in the Master Complaint and incorporated by reference in the Short Form Complaints are all subject to the monograph process described above.

There are also other OTC Tylenol® brand APAP products not specified by name in the Master Complaint that are NDA products subject to the NDA regulatory framework, such as

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[8] *See* FDA, *Don't Double Up on Acetaminophen*, https://www.fda.gov/consumers/consumerupdates/dont-double-acetaminophen. Because FDA documents on the FDA website are "publicly available and [their] accuracy cannot reasonably be questioned," the Court may consider them on a motion to dismiss. *Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 60 (2d Cir. 2016); *see also, e.g.*, *Simon v. Smith & Nephew, Inc.*, 990 F. Supp. 2d 395, 401 (S.D.N.Y. 2013) ("For the purpose of resolving the present motion [to dismiss], the Court takes judicial notice of public records contained on the FDA website."); *Colella v. Atkins Nutritionals, Inc.*, 348 F. Supp. 3d 120, 134 n.4 (E.D.N.Y. 2018) ("District courts may take judicial notice of public records of the FDA on a motion to dismiss."); *Gordon v. Target Corp.*, 2022 WL 836773, at *2 (S.D.N.Y. Mar. 18, 2022) ("[C]ourts routinely take judicial notice of FDA guidance documents and documents which are publicly available on the FDA's website.").

[9] One of the Short Form Complaints also alleges use of Tylenol PM®. *See Foster v. Johnson & Johnson Consumer Inc.*, No. 1:23-cv-00563 (S.D.N.Y.). Because Tylenol PM® is a combination product, consisting of APAP and Diphenhydramine HCI, it does not fall under the purview of this litigation or the Master Complaint, which expressly limits its scope to "only Tylenol products with acetaminophen as the sole active ingredient." Compl. at 1 n.1; *see Tylenol PM Extra Strength*, https://www.tylenol.com/products/tylenol-pm-extra-strength-caplet (indicating Tylenol PM® is a combination product).

Tylenol® 8 HR Arthritis Pain (an extended release product).[10] Importantly, however, all Tylenol® products are marketed and displayed on store shelves, side-by-side, regardless of the regulatory framework to which they are subject. Nothing on the product labels or product descriptions indicates to consumers that different regulatory frameworks apply to their manufacture and sale. Nor do their product labels differ as to the warnings for use by pregnant people: "**If pregnant or breast-feeding**, ask a health professional before use."[11]

B. Alleged Link Between Tylenol® And ASD/ADHD

As noted above, APAP has been considered safe and effective for treatment of pain and fever for over half a century. APAP is also unique among painkillers insofar as it is considered by both the FDA and the medical community to be safe for women to use during pregnancy. The FDA recommends that pregnant women use APAP over NSAIDs to treat pain and fever while pregnant,[12] and the CDC similarly recognized as recently as a few months ago that pregnant women may treat fevers experienced after receiving the COVID-19 vaccine with APAP.[13]

Treating fever and pain during pregnancy is not simply a matter of comfort. The FDA has recognized that "[s]evere and persistent pain that is not effectively treated during pregnancy can result in depression, anxiety, and high blood pressure in the mother." FDA, *Drug Safety*

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[10] *See* FDA, *New Drug Application (NDA): 019872*, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=019872. The NDA for Tylenol® 8 HR Arthritis Pain is subject to judicial notice because it is publicly available on FDA's website. *See, e.g.*, *Simon*, 990 F. Supp. 2d at 401 n.2; *In re Zyprexa Prods. Liab. Litig.*, 549 F. Supp. 2d 496, 501 (E.D.N.Y. 2008).

[11] *See* FDA, *New Drug Application (NDA): 019872*, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/019872Orig1s048lbl.pdf.

[12] *See* FDA, *FDA Recommends Avoiding Use Of NSAIDs In Pregnancy At 20 Weeks Or Later Because They Can Result In Low Amniotic Fluid* (last accessed Feb. 10, 2023) ("Other medicines, such as acetaminophen, are available to treat pain and fever during pregnancy."), https://www.fda.gov/drugs/drug-safety-and-availability/fda-recommends-avoiding-use-nsaids-pregnancy-20-weeks-or-later-because-they-can-result-low-amniotic.

[13] *See* CDC, COVID-19 Vaccines While Pregnant or Breastfeeding (Oct. 20, 2022), https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html.

Communication: FDA has reviewed possible risks of pain medicine use during pregnancy ("*2015 Drug Safety Communication*") (Jan. 9, 2015).[14] The CDC similarly recognizes that "[f]ever during pregnancy, for any reason, has been associated with adverse pregnancy outcomes."[15] And the authors of various studies cited in Plaintiffs' Master Complaint note that maternal fever "is a well-accepted risk factor for multiple disorders, including neural tube defects and later life cardiovascular disorders,"[16] and that maternal inflammation has "previously been reported to increase ADHD risk in offspring."[17]

Plaintiffs cite to 15 studies, all published in 2013 or later, to support their allegations that APAP is unsafe for pregnant women. *See generally* Compl. ¶¶ 81–105. Plaintiffs do not allege that ***any*** study affirmatively concludes that prenatal APAP use actually causes ASD and/or ADHD; nor do Plaintiffs identify a causal mechanism for how Tylenol® use by a pregnant woman would lead to the development of either ASD or ADHD. To the contrary, the studies cited in the Master Complaint acknowledge that further study of a posited autism link is needed and that "such a relationship may be difficult to establish";[18] caution that "[f]urther studies are required to elucidate

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[14] The FDA's *2015 Drug Safety Communication* is publicly available at https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-has-reviewed-possible-risks-pain-medicine-use-during-pregnancy, and its accuracy cannot be questioned; it is therefore a proper subject of judicial notice. *See, e.g.*, *Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 60 (2d Cir. 2016).

[15] CDC, COVID-19 Vaccines While Pregnant or Breastfeeding (Oct. 20, 2022), https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html. This CDC announcement is publicly available, and its accuracy cannot be questioned; it is therefore also a proper subject of judicial notice.

[16] Ann Z. Bauer et al., *Paracetamol Use During Pregnancy—A Call for Precautionary Action*, 17 Nature Revs. Endocrinology 757, 757 (2021) (cited in Compl. ¶¶ 4, 102–105).

[17] Zeyan Liew et al., *Acetaminophen Use During Pregnancy, Behavioral Problems, and Hyperkinetic Disorders*, 168 JAMA Pediatrics 313 (2014) (cited in Compl. ¶ 87).

[18] William Shaw, *Evidence that Increased Acetaminophen Use in Genetically Vulnerable Children Appears To Be a Major Cause of the Epidemics of Autism, Attention Deficit with Hyperactivity, and Asthma*, 2 J. Restorative Med. 14, 15 (2013) (cited in Compl. ¶ 83).

mechanisms behind this association as well as to test alternatives to a causal explanation";[19] and recognize that "the causal role of acetaminophen in the etiology of ADHD can be questioned."[20] Moreover, while Plaintiffs also rely heavily on a September 2021 article that they claim supports their theory,[21] the authors of that article expressly "*avoided any inference of causality*,"[22] as they admitted in responding to criticisms from two separate journal articles.[23] In short, contrary to Plaintiffs' characterization, *see* Compl. ¶ 4, the September 2021 article was not a "consensus" statement, *see supra* n. 2, and did not conclude that there is a causal relationship between prenatal use of acetaminophen and ASD and ADHD.

Notably, the FDA has repeatedly evaluated the available scientific evidence, each time concluding that it does not change the Agency's reasoned judgment that prenatal APAP exposure is safe and effective. For example, in 2015, the FDA announced that it had reviewed studies on prenatal APAP exposure and ADHD risk, and determined that the studies were "too limited to make any recommendations." *2015 Drug Safety Communication*.[24] And in 2017, the Agency drafted a memorandum noting that no causal association can be established between maternal APAP use and the development of ADHD or autism and warning that "[b]ecause there are no

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[19] Evie Stergiakouli et al., *Association of Acetaminophen Use During Pregnancy With Behavioral Problems in Childhood: Evidence Against Confounding*, 170 JAMA Pediatrics 964 (2016) (cited in Compl. ¶ 92).

[20] Eivind Ystrom et al., *Prenatal Exposure to Acetaminophen and Risk of ADHD*, 140 Pediatrics 1 (2017) (cited in Compl. ¶ 93).

[21] Ann Z. Bauer et al., *Paracetamol Use During Pregnancy—A Call for Precautionary Action*, 17 Nature Revs. Endocrinology 757, 757 (2021) (emphasis added) (cited in Compl. ¶¶ 4, 102–105).

[22] 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).

[23] *See* Sura Alwan et al., *Paracetamol use in pregnancy—caution over causal inference from available data*, 18 Nature Revs. Endocrinology 190 (2022); Per Damkier et al., *Handle with care — interpretation, synthesis and dissemination of data on paracetamol in pregnancy*, 18 Nature Revs. Endocrinology 191 (2022). The Court should take judicial notice of these documents since they prompted the authors to make their clarifying statement. *See Pickard*, 100 F. Supp. 3d at 980–90; *Kemp*, 2019 WL 111045, at *4 n.3.

[24] *See supra* note 14.

alternative OTC medications to manage pain and/or fever during pregnancy, to raise concerns of a strengthened association with 'adverse neurodevelopmental outcomes', when important limitations exist for the data and no causal relationship can be established, would have a significant public health impact for the pregnant population and their healthcare providers." Tamara Johnson, *Maternal Health Memorandum* (Apr. 7, 2017), Declaration of Sarah E. Johnston ("Johnston Decl."), Ex. A at FDACDER000053.[25] Also in 2017, the FDA reviewed the epidemiologic evidence and determined that "[a]ll of the studies" finding an association between maternal APAP use and adverse neurodevelopment outcomes "had significant limitations, uncertainties, and critical missing information" and therefore did not support "any conclusion about [] causal association." Christine Nguyen, *Memorandum of Consultation to Janice Adams-King* (Feb. 10, 2017), Johnston Decl., Ex. B at FDACDER000045–FDACDER000046.[26]

Further, the FDA recently has made statements to the media that it is still "not aware of conclusive evidence to support a causal link between acetaminophen use during pregnancy and the risk of adverse fetal outcomes."[27] In a statement provided for a story reported just yesterday, the FDA commented that it "regularly reviews the current literature and the possible risks of

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[25] The document appears to be dated April 7, 2016, but the date is presumably a typographical error because it references consults from October 2016 in the past tense, as well as certain data accessed in January 2017. The final page of the document is dated and signed on April 7, 2017.

[26] Although Exs. A and B were once internal FDA documents, the FDA recently disclosed these documents pursuant to a subpoena duces tecum issued by JJCI, which pursuant to FDA's own rules, is treated akin to any other request for documents, including via letter or FOIA. *See S.E.C. v. Selden*, 445 F. Supp. 2d. 11, 14 (D.D.C. 2006). The FDA recently advised that these documents need not be filed under seal or treated confidential. *See* ECF No. 420. Thus there are grounds to take judicial notice of these documents. *See In re Santa Fe Nat'l Tobacco Co. Mktg. & Sales Pracs. & Prods. Liab. Litig.*, 288 F. Supp. 3d 1087, 1211 (D.N.M. 2017) ("The Court concludes that the [FDA's] Memorandum of Agreement is a matter of public record, despite its confidential label and even though it is still not publicly available online, because the FOIA disclosure makes the document 'capable of accurate and ready determination by resort to [a] source[] whose accuracy cannot reasonably be questioned.'") (citing, *inter alia*, *N.Y. Times Co. v. U.S. Dep't of Justice*, 756 F.3d 100, 110 n.8 & 9 (2d Cir. 2014)).

[27] Judy Packer-Tursman, *Debate Over Possible Acetaminophen-Autism Link Heads To Court*, United Press Int'l (Oct. 28, 2022), *available at* https://www.upi.com/Health_News/2022/10/28/acetaminophen-pregnancy-autism-lawsuits/9701666296922.

acetaminophen use during pregnancy" and reiterated the Agency's longstanding position: "Pregnant women should always consult with their health care professional before taking any prescription or nonprescription medicine."[28]

In sum, the FDA continues to review the literature and continues to recommend the use of APAP over other pain relievers during pregnancy,[29] notwithstanding its review and consideration of the very studies cited by Plaintiffs in the Master Complaint.[30]

III. PROCEDURAL HISTORY

On December 16, 2022, Plaintiffs filed two Master Complaints in the MDL, one against the Retailer Defendants and the other against JJCI. ECF Nos. 276 & 277. At the time, JJCI was named in only four cases. Just over a month later, on January 20, 2023, 66 of the original "Retailer-only" cases were "amended" via Short Form Complaint to incorporate by reference the Master Complaint against JJCI. Because the Short Form Complaints are the operative pleadings against which defendants must move, JJCI is now moving to dismiss all 72 MDL cases that incorporate the Master Complaint. Johnston Decl., Ex. H identifies those cases for ease of reference.

IV. PLAINTIFFS' ALLEGATIONS AGAINST JJCI

Plaintiffs' Master Complaint is based on the theory that JJCI knew or should have known that *in utero* exposure to APAP causes children to develop ASD or ADHD, and that JJCI failed to warn of this risk. Compl. ¶¶ 169, 191, 213, 230–231, 247–248, 270, 282. The Master Complaint, incorporated by the Short Form Complaints, contains seven counts: Count I: Strict Liability for Failure to Warn; Count II: Strict Liability for Design Defect Due to Inadequate Warnings and

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[28] Kari Beal, *Can acetaminophen during pregnancy cause autism/ADHD in children?*, Fox Carolina (Feb. 9, 2023), https://www.foxcarolina.com/2023/02/09/can-acetaminophen-during-pregnancy-cause-autismadhd-children/.

[29] *See FDA Recommends Avoiding Use Of NSAIDs In Pregnancy*, *supra* note 12.

[30] For ease of reference, JJCI has prepared an exhibit that depicts the timing of studies and publications cited in the Master Complaint and the FDA's review and consideration of those papers. *See* Johnston Decl., Ex. C.

Precautions; Count III: Negligence; Count IV: Negligent Misrepresentation; Count V: Strict Liability Misrepresentation Under § 402B of the Restatement (Second) of Torts; Count VI: Violation of Consumer Protection Laws; and Count VII: Breach of Implied Warranty. Compl. ¶¶ 165–285.

ARGUMENT

I. PLAINTIFFS' CLAIMS ARE PREEMPTED

Federal law is "the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., Art. VI, cl. 2. The supremacy of federal law necessarily means that an obligation imposed by federal law overrides any conflicting state-law requirement, and the U.S. Supreme Court has thus repeatedly held, in a wide variety of contexts, that state law is "impliedly pre-empted where it is 'impossible for a private party to comply with both state and federal requirements.'" *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 480 (2013) (quoting *English v. General Elec. Co.*, 496 U.S. 72, 79 (1990)). This rule "requires no inquiry into congressional design." *Bartlett*, 570 U.S. at 480 (quoting *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43 (1963)). "When federal law forbids an action that state law requires, the state law is 'without effect.'" *Id.* at 486 (quoting *Maryland v. Louisiana*, 451 U.S. 725, 728 (1981)).

Although Plaintiffs have not specified what warning they believe state law requires manufacturers to include on APAP packaging, the gravamen of their claims is that JJCI should have somehow "warned pregnant women that ingestion of acetaminophen while pregnant can cause ASD and/or ADHD," or that studies had shown an association. Compl. ¶ 170. ***All*** of Plaintiffs' claims rest on this failure-to-warn theory. *See* Compl. ¶¶ 184–186 (Count I), 191–209 (Count II), 221–224 (Count III), 229–231 (Count IV), 247–248 (Count V), 270–275 (Count VI), 282 (Count VII).

Plaintiffs' theory of injury is preempted for three reasons. First, federal regulations prohibit JJCI from using any warning other than the "exact" one approved by the FDA. 21 C.F.R. § 330.1(c)(1)(2). Second, any warning that would satisfy Plaintiffs' state-law demands would render APAP federally misbranded. And third, JJCI could not have used the CBE regulation to change the label for any products approved under an NDA, *see Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1678 (2019), and it would make no sense to require a different warning for monograph-approved APAP versus NDA-approved APAP.

JJCI recognizes that the Court ruled in *Hatfield* that the plaintiffs' claims were not subject to impossibility preemption based on its belief that federal law permits manufacturers to add their own unapproved pregnancy warnings. But the regulatory text, regulatory structure, and rulemaking history, alongside the FDA's statements about APAP—some of which were not presented in the *Hatfield* briefing—show that Plaintiffs' claims are preempted.

A. FDA Regulations Prohibit Defendants From Adding Additional Pregnancy Warnings

The FDA has mandated a uniform national pregnancy warning for all OTC medication "intended for systemic absorption." 21 C.F.R. § 201.63(a). Under this regulation, each OTC drug label must contain precisely the following language (with the first four words in bold): "**If pregnant or breast-feeding**, ask a health professional before use." *Id.* There is no dispute that a manufacturer may not unilaterally alter this language, and that a state may not require a manufacturer to do so. Nor is there any dispute that failure to include the FDA-approved warning verbatim renders a drug per se misbranded. *See* 21 U.S.C. § 355h(a) (requiring OTC drugs to comply with the "general requirements for nonprescription drugs," which include the Pregnancy Warning); 21 U.S.C. § 352(ee) (deeming a drug that fails to do so "misbranded"). The only question is whether a state can require that a manufacturer add an additional warning on top of the

FDA-approved one. *See* Compl. ¶ 48 (stating that APAP labels should have contained "additional" warnings). The answer is no.

As a general rule, any warning in OTC drug labeling must use "the exact language" that has been prescribed by the FDA "where such exact language has been established and identified . . . in an applicable OTC drug monograph or by regulation." 21 C.F.R. § 330.1(c)(1)(2); *see also, e.g.*, 21 C.F.R. § 201.66(c)(5)(ix) (requiring warnings "in the order listed" including the "pregnancy/breast-feeding warning set forth in § 201.63(a)"); *Ramirez v. Plough, Inc.*, 6 Cal. 4th 539, 549 (1993) ("FDA regulations specify both the subject matter of required warnings and the actual words to be used," including that they "must contain a general warning on use by pregnant or nursing women."); *Estate of O'Dowd v. Sims, DPM*, 2020 WL 8414373, at *9 (N.J. Super. Ct. L. Div. June 8, 2020) (holding, in case involving an OTC monograph product, that drug manufacturers "do not have any discretion to venture outside the bounds of what is required by the FDA on the label"). Section 330.1 highlights the pregnancy warning stated at 21 C.F.R. § 201.63 as an example—in fact, the only example—of a warning that must be given in "exact language." 21 C.F.R. § 330.1(c)(1)(2); *see also* 21 C.F.R. § 330.2 (noting that "pregnancy-nursing warning for OTC drugs is set forth" in the chapter); *Pregnant or Nursing Women*, 47 Fed. Reg. at 54,753 (rejecting proposal to allow alternative language in pregnancy warning). The limited exceptions to the exact language requirement are specifically enumerated in the regulation (and do not apply here). *See* 21 C.F.R. § 330.1(c)(1)(2) (applies "except as provided in paragraphs (i) and (j) of this section").[31]

[31] Even as to those few terms, a manufacturer may only modify them if doing so would "not alter the meaning of the labeling that has been established . . . in an applicable monograph or by regulation." 21 C.F.R. § 330.1(i), (g).

The Pregnancy Warning rule and the exact-language rule are irreconcilable with the Court's conclusion in *Hatfield* that the FDA-approved warning sets only a floor and that states are free to require additional warnings on top of it. The Court correctly noted that the standard Pregnancy Warning is a "general" one and that in some circumstances a medication may require a more "specific" warning. *Hatfield* Order at 22. The path to a more specific warning, however, is not to have a jury, acting as an instrument of state law, require the manufacturer to add such a warning unilaterally. Instead, the FDA can "establish[]" a specific warning in the drug's monograph or in a response to an NDA, and if it does so, "the specific warning shall be used in place of" the ordinary one "unless otherwise stated." 21 C.F.R. § 201.63(b).

The FDA has not done so here. The APAP products mentioned in the Master Complaint and incorporated into the Short Form Complaints were not approved pursuant to an NDA[32] (because APAP is generally recognized as safe and effective without one), and the APAP monograph does not contain any APAP-specific pregnancy warning. *See Tentative Final Monograph*, 53 Fed. Reg. at 46,255–58; *see also* 21 C.F.R. § 201.326 (APAP-specific warnings). Thus, the FDA-prescribed general Pregnancy Warning must be followed.

Although a manufacturer can petition for a label change pursuant to 21 U.S.C. § 355h(b), that ability is irrelevant to the preemption issue because "[t]he question for 'impossibility' [preemption] is whether the private party could ***independently*** do under federal law what state law [allegedly] requires of it," not whether the private party could petition for a change in federal law. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 620 (2011) (emphasis added). A manufacturer cannot

[32] Other Tylenol® products, such as Tylenol® 8 HR Arthritis Pain, were approved pursuant to an NDA. The FDA has not established a specific pregnancy warning for NDA-approved APAP products either. And as discussed below, a manufacturer cannot be required to add a warning that there is clear evidence the FDA would reject. *See infra* at Section I.C.

"independently" alter an OTC drug's monograph or the required warnings it contains, as Plaintiffs would have JJCI do here. For OTC drugs subject to a specific warning requirement like the Pregnancy Warning, there is no analogue to the CBE regulation, which allows manufacturers of drugs approved pursuant to an NDA to "make [a] labeling change" under certain circumstances without "wait[ing] for FDA approval," *Wyeth v. Levine*, 555 U.S. 555, 568 (2009); *see also* Compl. ¶ 42 (conceding "no CBE exception" applies to monograph products). Put simply, nothing in the regulatory scheme establishing the Pregnancy Warning for OTC drugs suggests that manufacturers are free to add their own gloss on top of the required text the FDA has approved, or that state common law can force them to do so.

Other indicia make clear that the FDA-approved procedure is the only one available for adding more specific warnings. The FDA has referred to the exact language rule as the "'exclusivity' policy" and has described it as "limiting monograph labeling terminology to [the] specific words and phrases considered by the FDA." *Limitations of Labeling Terminology*, 47 Fed. Reg. at 29,002. In addition, reading the FDA's general pregnancy warning as a floor but not a ceiling "is . . . at odds with one of the most basic interpretive canons, that '[a regulation] should be construed so that effect is given to all of its provisions, so that no part will be . . . superfluous.'" *Corley v. United States*, 556 U.S. 303, 314 (2009). This is critical in light of the provision in the pregnancy warning regulation that specifically permits manufacturers to include one additional feature on their labels: "a symbol that conveys the intent of the warning." 21 C.F.R. § 201.63(a). The Court discounted the relevance of this provision in its earlier opinion on the ground that the FDA added the symbol option to address "concerns that consumers who do not speak English would not be able to comprehend the general warning." *Hatfield* Order at 23. But it does not matter why the FDA chose to permit one additional form of warning. The critical point is that if

a manufacturer were free to add ***any*** additional warning that it chose (whether through a symbol or text), such express permission would have been unnecessary.

The rulemaking history provides further support for this inescapable conclusion. The entire purpose of the pregnancy warning rule, as articulated in the regulatory preamble, was to create a "single national warning" for products that the FDA has not determined to pose a specific risk when used during pregnancy. That warning was designed to be "as direct and uncomplicated as possible" to avoid "confusing" the consumer. *Pregnant or Nursing Women*, 47 Fed. Reg. at 54,752. As the FDA recognized, "[d]iffering state requirements could conflict with the Federal warning, cause confusion to consumers, and otherwise weaken the Federal warning." *Id.*; *see also, e.g.*, *Over-the-Counter Nighttime Sleep-Aid and Stimulant Products*, 43 Fed. Reg. at 25,553 (noting FDA's general opinion that when a label contains too many warnings, "the impact of all warning statements on the label will be reduced"). For these reasons, the FDA repeatedly reiterated that alternative or additional specific warnings would "be best handled in the final OTC drug monographs and in the individual NDAs," not drafted by a manufacturer acting on its own or in response to state-law tort suits. *Pregnant or Nursing Women*, 47 Fed. Reg. at 54,755; *see id.* at 54,756 (if product is determined to pose pregnancy risk "a specific, stronger warning will be included in the OTC monograph or required as a part of an NDA").

The FDA's concern for nationwide uniformity is not merely "'academic.'" *Hatfield* Order at 24. In fact, Plaintiffs have admitted that because of the "vagaries of state failure to warn law," different states could well impose different requirements if left free to do so. 1/13/23 Hr'g Tr. 27:7–8. That is exactly why the FDA stated that "under the doctrine of implied preemption, [differing] state requirements ***are preempted by the regulation as a matter of law***" and explained that "[m]anufacturers marketing their products in States with differing requirements will be able

to use the new FDA labeling without also being required to use the pregnancy-nursing warning labeling required by any [s]tate." *Pregnant or Nursing Women*, 47 Fed. Reg. at 54,756–57 (emphasis added). While Plaintiffs have argued in opposition to the motion for reconsideration of the *Hatfield* Order that the Court need not defer to the FDA's conclusion that state warnings are preempted, no such deference is needed to reach the right result here. The FDA made it clear that (outside specified exceptions not relevant here) it intended the Pregnancy Warning rule to be construed to require manufacturers to use one and only one Pregnancy Warning. ***That*** interpretation is clearly entitled to deference, *see generally Auer v. Robbins*, 519 U.S. 452 (1997), and preemption of all state law that would require any different or additional warning necessarily follows from that interpretation.[33]

The Court discounted the language of the 1982 rulemaking in *Hatfield*, on the theory that "when the FDA issued a final rule on OTC drug labeling in 1999 . . . [t]he [A]gency decided against any express prohibitions on" additional state warnings. *Hatfield* Order at 24–25 (citing 21 U.S.C. § 379r(a) and *Labeling Requirements*, 64 Fed. Reg. at 13,272).[34] The 1999 rulemaking, however, merely chose not to add an ***express*** preemption provision, noting that Congress had added an express preemption provision, 21 U.S.C. § 379r(a). That decision says nothing about *implied* preemption or the meaning of the Pregnancy Warning. Neither the presence nor the

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[33] Plaintiffs also argued in their opposition to the motion for reconsideration of the *Hatfield* Order that the Court should ignore the FDA's conclusions because they are "not within its substantive expertise" and have been inconsistent. *See* ECF No. 261. But the proper content of drug warning labels is clearly an area of expertise for the FDA, and Plaintiffs' inconsistency argument conflates express preemption with implied preemption as discussed below.

[34] The Court also noted that the FDA's conclusion that state-law warning requirements would be preempted arose in the context where "a 'substantially similar' pregnancy warning was about to become operational in California." *Hatfield* Order at 24. But logically, a *dissimilar* state-law warning—which is what Plaintiffs demand here—would pose an even greater conflict with federal law than a similar one. And to the extent the Court intended to draw a distinction between the California warning proposed by state regulation and one required through state common-law torts, the U.S. Supreme Court has consistently rejected that distinction. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323–24 (2008).

absence of "an express pre-emption provision []or a savings clause bars the ordinary working of conflict preemption principles." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001). The regulatory decision not to include an express preemption provision in 1999 was thus entirely consistent with what the Agency had already determined in 1982: that neither the FDCA nor FDA regulations promulgated under the Act "***expressly*** preempt [s]tate activity," but that "***implied*** preemption . . . applies" to additional state pregnancy warnings. *Pregnant or Nursing Women*, 47 Fed. Reg. at 54,756 (emphases added).

Reading the regulations to allow states to require additional pregnancy warnings beyond those articulated by the FDA is also contrary to the strong and longstanding federal policy against overwarning. It would be pointless for the FDA to prescribe precise language if a manufacturer could turn around and qualify the required warning with any additional language that it chooses or that a state requires. It is self-evident that the exact-language rule prohibits a manufacturer from adding unapproved language to alter the perceived risk of a product: A label could not, for example, incant the approved warning and then say, "this product has been used by millions of pregnant women, and multiple studies have failed to find any proof of increased risks from prenatal exposure to this product," even if the qualifier were entirely true.

Concerns about overwarning are particularly acute in the context of OTC medications. The FDA "recognize[s] that if labeling contains too many required statements . . . the impact of all warning statements on the label will be reduced," because consumers confronted with too many warnings will be overwhelmed, leading them to simply ignore any warnings or alternatively, to avoid taking necessary or beneficial medication. *Over-the-Counter Nighttime Sleep-Aid and Stimulant Products*, 43 Fed. Reg. at 25,553 (rejecting warning to "not take this product if pregnant" for sleep-aid label "in the absence of any data or information" to support it); *cf.* FDA, CDRH,

Guidance on Medical Device Patient Labeling: Final Guidance for Industry and FDA Reviewers, at 42 (Apr. 19, 2001), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-medical-device-patient-labeling ("Including too many warnings and precautions, over-warning, dilutes the strength of all of the hazard alerts."). And the FDA specifically reiterated this concern with respect to APAP in reaffirming its views about the safety and efficacy of prenatal APAP exposure.[35]

Courts, including the U.S. Supreme Court, have echoed the FDA's concern. *See Albrecht*, 139 S. Ct. at 1673 (FDA labeling rules are intended "to prevent 'overwarning' so that less important information does not 'overshadow' more important information") (quoting FDA, *Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices*, 73 Fed. Reg. 49,603, 49,605 (Aug. 22, 2008)); *In re Zofran (Ondansetron) Prod. Liab. Litig.*, 57 F.4th 327, 330 (1st Cir. 2023) ("[O]ne of [the FDA's] objectives is to 'prevent overwarning which may deter appropriate use of medical products[] or overshadow more important warnings.'") (quoting *Supplemental Applications Proposing Labeling Changes*, 73 Fed. Reg. at 49,605); *In re Fosamax (Alendronate Sodium) Prod. Liab. Litig.*, 593 F. Supp. 3d 96, 145 (D.N.J. 2022) (recognizing it is "important" that manufacturers "not overwarn because overwarning can deter potentially beneficial uses of the drug by making it seem riskier than warranted and can dilute the effectiveness of valid warnings"). In light of these concerns, the FDA permits "only information for which there is a scientific basis to be included in the FDA-approved

[35] *See* Johnston Decl., Ex. A, at FDACDER000053 ("Because there are no alternative OTC medications to manage pain and/or fever during pregnancy, to raise concerns of a strengthened association with 'adverse neurodevelopmental outcomes', when important limitations exist for the data and no causal relationship can be established, would have a significant public health impact for the pregnant population.").

labeling" and "guards against the 'exaggeration of risk, or the inclusion of speculative or hypothetical risks.'" *In re Zofran*, 57 F.4th at 330 (quotation marks and citations omitted).

Finally, it is worth noting that unfounded fears of autism have already harmed public health in this country by dissuading parents from inoculating their children against life-threatening diseases. *See, e.g.*, Lidia V. Gabis et al., *The Myth of Vaccination & Autism Spectrum*, 36 Euro. J. of Paediatric Neurology 151 (2022). Contrary to Plaintiffs' counsel's characterizations in the Master Complaint, warnings that would lead women to avoid APAP use during pregnancy without sound science and FDA buy-in would do much more than force them to live with "minor aches and pains." Compl. ¶ 1. Without APAP, women might use non-steroidal anti-inflammatory drugs or endure untreated fever, both of which can pose serious risks to a fetus.[36] As the studies underlying Plaintiffs' Master Complaint themselves explain, maternal fever itself is associated with neurological disorders, including ADHD.[37] Balancing the potential risks and benefits of different classes of drugs is not the purview of plaintiffs' lawyers and courts; it is the job of the FDA and physicians, which is why the FDA crafted the "exact language" required to be on every APAP package in the country: "ask a health professional before use."

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[36] The FDA warned in 2020, for example, that "the use of nonsteroidal anti-inflammatory drugs (NSAIDs) around 20 weeks or later in pregnancy may cause rare but serious kidney problems in an unborn baby," which "can lead to low levels of amniotic fluid surrounding the baby and possible complications," and it directed labeling of both prescription and OTC NSAIDs to update warning language to reflect that risk. FDA, *FDA Recommends Avoiding Use Of NSAIDs In Pregnancy At 20 Weeks Or Later Because They Can Result In Low Amniotic Fluid*, Jan. 12, 2022, https://www.fda.gov/drugs/fda-drug-safety-podcasts/fda-recommends-avoiding-use-nsaids-pregnancy-20-weeks-or-later-because-they-can-result-low-amniotic.

[37] *See* Zeyan Liew et al., *Acetaminophen Use During Pregnancy, Behavioral Problems, and Hyperkinetic Disorders*, 168 JAMA Pediatrics 313 (2014) (cited in Compl. ¶ 87) (noting that maternal inflammation has "previously been reported to increase ADHD risk in offspring."); Ann Z. Bauer et al., *Paracetamol Use During Pregnancy—A Call For Precautionary Action*, 17 Nature Revs. Endocrinology 757, 758 (2021) (cited in Compl. ¶¶ 4, 102–105) (because "[f]ever is a well-accepted risk factor for multiple disorders" "the use of APAP is important for the treatment of high fever . . . that, left untreated, could potentially affect the developing fetus").

For all of these reasons, FDA regulations do not (and should not) permit a manufacturer to add its own unapproved pregnancy warning to the "single national warning" that the FDA requires, and the Court should reach a different ruling here from the one reached in *Hatfield*.

B. A Pregnancy Warning Would Be Misleading And Would Thus Render APAP Misbranded

Plaintiffs' claims are also preempted because JJCI's APAP products remain subject to the FDCA's fundamental command that a drug with labeling that is "false or misleading in any particular" is misbranded and thus unlawful. 21 U.S.C. §§ 352(a)(1), 355(a), (b), (c), (g), (k). Adding other pregnancy warnings to comply with state tort law would cause APAP to violate this misbranding provision. *See O'Neal v. Smithkline Beecham Corp.*, 551 F. Supp. 2d 993, 996 (E.D. Cal. 2008) (finding impossibility preemption because "including warning information not based on scientific evidence of known risks[] causes the drug labeling to be 'false and misleading' and lacking 'adequate directions for use' and misbranded, in violation of the FDCA"); *see also Robinson v. McNeil Consumer Healthcare*, 615 F.3d 861, 871 (7th Cir. 2010) ("[I]t would be odd to think that [the defendant] had a legal duty to guarantee against a risk that the FDA thought not worth warning against.").[38]

The FDA has made it clear that it believes unsubstantiated warnings, in the context of APAP specifically, render a product misbranded. For example, a few years ago, the FDA found that a California cancer warning on APAP products "would misbrand these products . . . and,

[38] Although *Wyeth* held that an ***NDA-approved*** drug is not "misbranded simply because the manufacturer has altered an FDA-approved label" and that "the FDA's belief that a drug is misbranded is not conclusive," that holding has no relevance to the present case. 555 U.S. at 570. A manufacturer has far less leeway to alter the label of a drug approved under a monograph, and the label Plaintiffs presumably seek here would render APAP misbranded because it would be false and misleading given the lack of scientific support for the theory APAP causes adverse outcomes, not simply because it would not be FDA-approved.

therefore, would be preempted under federal law" because "currently available data do not support a conclusion that exposure . . . causes cancer." [39]

The same logic applies to any additional pregnancy warnings. In 2015, the FDA announced that it had reviewed studies on prenatal APAP exposure and ADHD risk and determined that the studies were "too limited to make any recommendations." *2015 Drug Safety Communication*.[40] In its announcement, the FDA advised it would "continue to monitor and evaluate the use of pain medicines during pregnancy and [to] update the public as new safety information becomes available." *Id.* The FDA has fulfilled that promise. In 2017, the Agency drafted a memorandum noting that no causal association can be established between maternal APAP use and the development of ADHD or autism.[41] The memo warned that "[b]ecause there are no alternative OTC medications to manage pain and/or fever during pregnancy, to raise concerns of a strengthened association with 'adverse neurodevelopmental outcomes', when important limitations exist for the data and no causal relationship can be established, would have a significant public health impact for the pregnant population and their healthcare providers."[42] Also in 2017, the FDA reviewed the evidence and determined that "[a]ll of the studies" finding an association between maternal APAP use and adverse neurodevelopment outcomes "had significant limitations, uncertainties, and critical missing information" and therefore did not support "any conclusion about [] causal association."[43]

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[39] Ltr. from Director Janet Woodcock to Julian Leichty (Nov. 4, 2019), https://oehha.ca.gov/media/dockets/19653/19710-u.s._food_and_drug_administration_fda/fda_comments_notice_of_availability_of_hazard_identification_materials_for_acetaminophen_1142019.pdf.

[40] *See supra* note 14.

[41] *See* Johnston Decl., Ex. A.

[42] *Id.* at FDACDER00053.

[43] *See* Johnston Decl., Ex. B, at FDACDER000045–FDACDER000046.

The Court discounted the FDA's 2015 statement in *Hatfield*, in part on the ground that "Plaintiffs rely on [post-2015] studies to support their claim[s]." *Hatfield* Order at 28. But the new studies are merely cumulative of the older ones, which Plaintiffs allege date back at least to 2013, *see* Compl. ¶ 84, and there is no basis to conclude that they would change the FDA's conclusion. Notwithstanding the newer studies cited in the Master Complaint, the FDA has not altered its pregnancy warning and continues to link to the 2015 announcement on its APAP drug-information page.[44] In addition, just last year, the FDA expressed the view in a literature review that additional observational studies have not changed the scientific landscape, noting: "It is unlikely that further observational studies will provide more clarity without more mechanistic data."[45] The FDA's recent comments to the media, which reflect the Agency's view that it is still "not aware of conclusive evidence to support a causal link between acetaminophen use during pregnancy and the risk of adverse fetal outcomes," provide additional support for this conclusion. *See supra* at 15–16 (discussing the FDA's recent media statements).

The fact that the FDA has not reissued a formal statement akin to the 2015 statement with the publication of each new study should not be taken as an indication that the FDA is not up to date; rather, it is an indication that the FDA believes the 2015 statement remains current. Put simply, neither the scientific literature nor the FDA's position on it has changed, and the FDA still would not accept an additional pregnancy warning today.

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[44] *See* FDA, *Acetaminophen* (June 9, 2022), https://www.fda.gov/drugs/information-drug-class/acetaminophen (last accessed Feb. 10, 2023).

[45] *See* Johnston Decl., Ex. G. (2022 FDA review of published studies) at JJCI_APAP_FOIA000080; Danielle Abraham & Andrew Mosholder, *Epidemiology: Review of Published Studies* (July 15, 2022).

At a bare minimum, any cases that allege APAP exposure prior to the FDA's February 2017 memorandum should be dismissed as preempted.[46] Even if there had been a change in the science—which there has not been—the more recent studies could not have any relevance to the preemption question for cases that arise out of APAP use prior to their publication. *See O'Neal*, 551 F. Supp. 2d at 1007 (evaluating whether strengthened warning would have been allowed based on the evidence as it existed when plaintiffs' decedent took medication, not as it existed at time of litigation). And the 2017 FDA memoranda, along with the FDA's 2015 statement, make clear, at the very least, that the FDA would have considered an additional pregnancy warning to be improper as of 2017, and therefore would have considered APAP containing such a warning to be misbranded.

C. Federal Law Also Preempts Any Claims Related To APAP Products Approved Under An NDA

Finally, Plaintiffs' claims are also preempted because certain Tylenol® products are subject to an NDA, meaning their warnings could only be amended by JJCI through the CBE process, and for all the reasons discussed above, there is clear evidence that the FDA would reject any such amendment.

Although the Master Complaint alleges that APAP "is governed by the monograph system," Compl. ¶ 34, that is not entirely correct. APAP can be approved either via the NDA process or via the monograph process. JJCI does sell some OTC APAP products that were approved via NDA, such as eight-hour extended release tablets. *See supra* at 11–12. These products are not mentioned in the Master Complaint and have not been incorporated into any Short

[46] A list of cases in which Plaintiffs plead the use of branded Tylenol® prior to February 2017 is set forth in Johnston Decl., Ex. I.

Form Complaints, although (as APAP-only products) they are within the scope of this MDL proceeding and theoretically could be in the future.

For products approved under an NDA, FDA regulations generally prohibit changes to the approved label but permit certain unilateral changes when consistent with the terms of the CBE regulation. As the FDA explains, if "add[ing] or strengthen[ing] a contraindication, warning, precaution, or adverse reaction" is necessary "to reflect newly acquired information … for which the evidence of a causal association satisfies the standard for inclusion in the labeling under § 201.57(c)," 21 C.F.R. § 314.70(c)(6)(iii), a manufacturer can make such a change to the label after filing an application to do so with the FDA but without "wait[ing] for FDA approval," *Wyeth*, 555 U.S. at 568.[47]

The FDA can, however, disapprove changes proposed through the CBE process. Thus, federal law will preempt failure-to-warn claims as to NDA products when either: (1) no "newly acquired information" demonstrated the necessary causal association; or (2) "there is 'clear evidence' that the FDA would not have approved the warning that state law requires" (i.e., the FDA, fully informed of the purported justifications for the warning at issue, "informed the drug manufacturer that [it] would not approve a change to the drug's label to include that warning.") *Albrecht*, 139 S. Ct. at 1676, 1678. Each of these questions "is a legal one for the judge." *Id.* at 1679. And each of the answers here forecloses Plaintiffs' claims.

First, JJCI had no "newly acquired information" that met the FDA's "standard for inclusion in the labeling," 21 C.F.R. § 314.70(c)(6)(iii)—namely, "reasonable evidence of a causal association," 21 C.F.R. § 201.57(c)(6)(i). As noted above, Plaintiffs do not allege that ***any*** study

[47] The two seminal U.S. Supreme Court cases on NDA preemption, *Wyeth* and *Albrecht*, both happened to involve prescription medications, but neither the NDA process nor its preemptive consequences work any differently for OTC medications approved under an NDA.

affirmatively concludes that prenatal APAP use actually causes ASD and/or ADHD. Rather, the studies on which Plaintiffs rely repeatedly acknowledge that causation has not been established. Because such research does not provide "reasonable evidence of a causal association," the CBE regulation would not have permitted JJCI to add the warning Plaintiffs demand. *See, e.g.*, *In re Zofran*, 57 F.4th at 341 (concluding that there was "no newly acquired information that would justify invoking the CBE procedure" and holding that this "is sufficient" to preempt failure-to-warn claims); *In re Incretin-Based Therapies Prods. Liab. Litig.*, 524 F. Supp. 3d 1007, 1024 (S.D. Cal. 2021) ("The Court finds that Merck d[id] not have safety information that reveal[ed] risks of a different type or greater severity or frequency than previously included in submissions to the FDA, and thus, d[id] not have 'newly acquired information' on which to base a CBE submission."), *aff'd*, 2022 WL 898595 (9th Cir. Mar. 28, 2022).

Second, for the reasons enumerated above, the FDA has made its position on this issue clear. As explained above, the FDA considered the evidence on which Plaintiffs rely to support the supposed link between APAP and adverse neurological outcomes and determined that it would not be appropriate to change the warning. The FDA has also communicated its determinations through a public statement—means that "lie within the scope of the authority Congress has lawfully delegated." *In re Incretin-Based Therapies*, 524 F. Supp. 3d at 1030 (quoting *Albrecht*, 139 S. Ct. at 1679) (failure to require warning after "ongoing evaluation," published assessment, and rejection of citizen petition sufficient to communicate FDA's position). That suffices to establish that federal and state-law duties "irreconcilably conflict," and that the state-law claims are preempted. *Albrecht*, 139 S. Ct. at 1679.

The fact that the FDA would not approve a label change for NDA-approved APAP products also means that any such change to monograph-approved labels would be misleading—

a point the Court did not consider in *Hatfield*. JJCI's APAP products, whether approved under an NDA or a monograph, contain the same active ingredient—acetaminophen—and are all-but chemically identical. As such, they cannot present different types of pregnancy risks. In addition, they typically contain nearly identical labels and are generally sold side-by-side on product shelves. If the Court were to recognize preemption in one context, but not the other, the products would be subject to radically different treatment and would have conflicting warning labels. The result would be that consumers would be misled into believing that the different pregnancy warnings mean different pregnancy risks. Such an anomalous result is a natural consequence of the *Hatfield* ruling since, as outlined above, the clear-evidence rule would bar addition of an ASD or ADHD warning to NDA-approved Tylenol® products. Preemption law neither requires nor permits such an absurd result. As such, all of Plaintiffs' claims are preempted, regardless of the precise mechanism by which APAP products, and their labels, received FDA approval.

II. PLAINTIFFS FAIL TO PLAUSIBLY ALLEGE CAUSATION OR KNOWLEDGE

Plaintiffs' claims should also be dismissed under Fed. R. Civ. P. 8 because Plaintiffs have failed to plausibly allege that prenatal exposure to APAP causes ASD and/or ADHD in children. Alternatively, the Master Complaint fails to plead any plausible basis for concluding that JJCI knew or should have known of this purported risk prior to 2021, or at a bare minimum prior to 2013.[48]

[48] All but one of Plaintiffs' claims—Count V (strict products liability misrepresentation)—require Plaintiffs to show that JJCI knew or should have known of the risk they allege, and their failure to adequately plead this element thus requires dismissal of these claims. *See generally* 63A Am. Jur. 2d Products Liability § 934 ("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." (emphasis added)).

A. Plaintiffs Have Not Plausibly Alleged Causation

To survive a motion to dismiss, a complaint "must plead 'enough facts to state a claim to relief that is plausible on its face.'" *Green v. Dep't of Educ. of N.Y.*, 16 F.4th 1070, 1076–77 (2d Cir. 2021) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "[W]hile this plausibility pleading standard is forgiving, it is not toothless." *Mandala v. NTT Data, Inc.*, 975 F.3d 202, 207 (2d Cir. 2020). Rather, the complaint must include "'enough fact to raise a reasonable expectation that discovery will reveal evidence supporting a plaintiff's claim for relief.'" *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)). "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 (quotation marks and citation omitted).

Central to any personal injury case is the question whether the product defect, as alleged, can cause the injury asserted by plaintiffs. *See, e.g.*, *In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 398, 401–02 (S.D.N.Y. 2005). Establishing general causation requires support from the scientific and medical literature for the conclusion that "exposure to a substance can cause a particular disease." *Id.* at 402. Where (as here) the plaintiff relies on such literature at the pleading stage to support the plausibility of his or her allegations, the Court need not "take as true every inference that a plaintiff asks [the Court] to draw from those [studies], no matter how attenuated." *Mandala v. NTT Data, Inc.*, 988 F.3d 664, 666–67 (2d Cir. 2021) (Sullivan, J., concurring in denial

of rehearing en banc). Rather, the plaintiff must plausibly explain how the cited studies support the conclusions he or she would draw from them. *See Mandala*, 975 F.3d at 212.

Where the studies on which the plaintiffs rely to establish general causation in the Master Complaint only suggest (at best) an association between exposure and injury, the allegations fail 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)). In *Manuel*, for example, the plaintiffs brought consumer-fraud claims, alleging that the use of the word "Diet" in "Diet Pepsi" was misleading because the sugar substitutes used in Diet Pepsi were alleged to cause weight gain. But the 14 studies cited in the plaintiffs' complaint did not plausibly support an inference of general causation because the studies uniformly acknowledged that the posited causal theory was a hypothesis at best, and no causal conclusion had been reached. *See* 2018 WL 2269247, at *10–11.

Of note, the Diet Pepsi studies included the following statements, among others: that the posited causal relationship was "unclear" and that waist-circumference gain "may have been driven by other factors"; that there "may be no causal relationship"; that "associations have not been confirmed in experimental studies"; that "residual confounding and reverse causation could explain the[] results"; and that "[d]espite accumulating evidence of the existence of these associations, we are cautious not to conclude causality between diet soda and the diabetic or pre-diabetic condition." *Id.* Given this state of the science, the court concluded that causation could not be established and that the use of the word "Diet" in Diet Pepsi was therefore not deceptive. As the court put it, the plaintiffs "ha[d] outrun the science." *Id.* at *12 (citing *Becerra v. Coca-Cola Co.*, 2018 WL 1070823, at *4 (N.D. Cal. Feb. 27, 2018)) (complaint dismissed because the

plaintiff, "[w]ith a conclusory wave of counsel's hand, ha[d] overstated the actual science set forth in the citations"); *accord, e.g.*, *McGrath v. Bayer HealthCare Pharms. Inc.*, 393 F. Supp. 3d 161, 166, 171–72 (E.D.N.Y. 2019) (dismissing failure-to-warn claims because the complaint's "allegations regarding the causal association between [the product] and a significant adverse reaction . . . are conclusory and grounded in hypothesis rather than scientific evidence").

Plaintiffs here ask the Court to aid them in "outrun[ning] the science" just like the plaintiffs in the Diet Pepsi litigation. As noted, Plaintiffs have not cited a *single* study affirmatively finding that prenatal APAP use causes ASD and/or ADHD; nor have Plaintiffs identified a causal mechanism. *See supra* at 12–14. Rather, Plaintiffs rely on a 2013 study expressly acknowledging that further study of a posited autism link is needed and that "such a relationship may be difficult to establish";[49] a 2016 study cautioning that "[f]urther studies are required to elucidate mechanisms behind this association as well as to test alternatives to a causal explanation";[50] and a 2017 study acknowledging that "the causal role of acetaminophen in the etiology of ADHD can be questioned."[51]

Even in the September 2021 statement on which Plaintiffs place the greatest weight, the authors repeatedly equivocate, writing that "[a] ***growing*** body of experimental and epidemiological research ***suggests*** that prenatal exposure to [APAP] ***might*** alter fetal development, which ***could*** in turn ***increase the risk*** of certain neurodevelopmental, reproductive, and urogenital

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[49] William Shaw, *Evidence that Increased Acetaminophen Use in Genetically Vulnerable Children Appears To Be a Major Cause of the Epidemics of Autism, Attention Deficit with Hyperactivity, and Asthma*, 2 J. Restorative Med. 14, 15 (2013) (cited in Compl. ¶ 83).

[50] Evie Stergiakouli et al., *Association of Acetaminophen Use During Pregnancy With Behavioral Problems in Childhood: Evidence Against Confounding*, 170 JAMA Pediatrics 964 (2016) (cited in Compl. ¶ 92).

[51] Eivind Ystrom et al., *Prenatal Exposure to Acetaminophen and Risk of ADHD*, 140 Pediatrics 1 (2017) (cited in Compl. ¶ 93).

disorders."[52] Indeed, in replying to three responses to the September 2021 statement that had urged caution before jumping to causal conclusions, the authors of the September 2021 statement expressly clarified: "We agree that limitations and uncertainties remain despite the large body of available data, therefore, ***we avoided any inference of causality*** in our Consensus Statement."[53]

In sum, the literature on which Plaintiffs rely expressly ***disclaims*** a causal conclusion, even as of late 2021. For this reason, too, all of their claims must be dismissed.

B. Plaintiffs Fail To Plausibly Plead That JJCI Knew Or Should Have Known Of Any Purported Theory Of Causation

In addition to pleading causation, Plaintiffs must also plead that JJCI knew or should have known of the specific risk Plaintiffs allege. *See, e.g.*, *Krulewich v. Covidien, LP*, 498 F. Supp. 3d 566, 576–77 (S.D.N.Y. 2020). Even if the Master Complaint sufficiently pled an inference as to causation, it would still not support a plausible inference that JJCI ***knew or should have known*** that Tylenol® ingestion during pregnancy causes ASD or ADHD, especially with respect to Plaintiffs who allege use of the product ***prior to 2021***.

As set forth above, Plaintiffs themselves concede that no single study suffices to establish causation. Rather, Plaintiffs plead that ***because*** "[a]ll studies have limitations . . . scientists look for consistency when weighing the totality of the evidence" to reach a conclusion and that the body of evidence must be "[t]aken as a whole." Compl. ¶ 100. But as just discussed, the articles highlighted by Plaintiffs expressly caution against inferring a causal relationship and therefore do not suffice to trigger a duty to warn at the time they were published. *See Lightfoot v. Georgia-*

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[52] Ann Z. Bauer et al., *Paracetamol Use During Pregnancy—A Call for Precautionary Action*, 17 Nature Revs. Endocrinology 757, 757 (2021) (emphases added) (cited in Compl. ¶¶ 4, 102–105).

[53] 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).

Pacific Wood Prods., LLC, 5 F.4th 484, 494 (4th Cir. 2021) (defendants had no duty to warn during the exposure period because "[i]t was not until years after the exposure period that there was a settled scientific understanding that wood dust causes cancer" notwithstanding articles raising possibility of "*an association*" at that time); *cf. Hornsby v. Alcoa, Inc.*, 715 F. App'x 642 (9th Cir. 2017) (plaintiff failed to plausibly plead actual knowledge because the studies cited "merely show that a connection between aluminum particles and pulmonary fibrosis is 'plausible' or 'thought to be directly correlated'").

In any event, by Plaintiffs' own admissions, there was no "body" of science or cumulative theory of causation prior to the September 2021 so-called "consensus" statement. Rather, they allege that it was only in September 2021 that any contingent of the medical community issued a "call to action" because the "combined weight of scientific evidence" was such that pregnant women should be cautioned about the risk of "indiscriminate" APAP use. *See* Compl. ¶¶ 4, 102–103. Thus, any claim that JJCI knew or might have known of a possible causal trigger prior to September 2021 is implausible, as pled, and should be dismissed.[54] *See, e.g., Witt v. Stryker Corp. of Mich.*, 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").

Finally, at a bare minimum, Plaintiffs' allegations regarding JJCI's purported knowledge of the risk of ASD/ADHD following prenatal APAP use cannot plausibly extend to the *pre-2013* time period, and any claims based on Tylenol® use prior to 2013 should thus be dismissed.[55] The Master Complaint does not cite any studies regarding prenatal APAP use published prior to 2013.

[54] This is true for every case currently pending against JJCI. *See* Johnston Decl., Ex. H.

[55] *See* Johnston Decl., Ex. J (chart of cases in which Plaintiffs allege APAP use prior to 2013).

Rather, Plaintiffs only refer to publications "[s]ince 2013." Comp. ¶ 84. There is no allegation that such scientific evidence existed prior to 2013, and no allegation that JJCI had any specific knowledge regarding the 2013 studies upon which Plaintiffs rely, or any other study in the public sphere, for that matter, before or after 2013. Thus, even Plaintiffs effectively concede that they do not have viable claims for pre-2013 APAP use. Compl. ¶ 107.[56]

III. PLAINTIFFS' FRAUD-BASED CLAIMS ARE INADEQUATELY PLED

Finally, Plaintiffs' claims for negligent misrepresentation (Count IV), strict liability misrepresentation (Count V), and consumer protection (Count VI) fail for the additional reason that they are not pled with sufficient particularity under Rule 9(b).[57]

"Courts in this District are bound by Second Circuit law pertaining to the applicability of Rule 9(b) to particular claims, regardless of the source of the substantive law giving rise to those claims." *Tyman v. Pfizer, Inc.*, 16-CV-06941, 2017 WL 6988936, at *8 (S.D.N.Y. Dec. 27, 2017) (quotation marks and citation omitted), *report and recommendation adopted by*, 2018 WL 481890 (S.D.N.Y. Jan. 18, 2018). "By its terms, Rule 9(b) applies to 'all averments of fraud.'" *Rombach v. Chang*, 355 F.3d 164, 171 (2d Cir. 2004) (citing Fed. R. Civ. P. 9(b)). "This wording is cast in terms of the conduct alleged, and is not limited to allegations styled or denominated as fraud or expressed in terms of the constituent elements of a fraud cause of action." *Id.* Accordingly, the

[56] Plaintiffs' Master Complaint includes a prayer for punitive damages. *See* Compl. at 67 (Prayer for Relief); *see also* Compl. ¶¶ 160–64. Plaintiffs' inability to establish that JJCI knew or should have known of the risk of prenatal exposure to acetaminophen precludes punitive damages. Because Plaintiffs do not plead a standalone claim of punitive damages, however, JJCI does not move here to dismiss or otherwise strike Plaintiffs' 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"). JJCI intends to challenge the punitive damages request at a later date if the case is not dismissed in full. Plaintiffs' counsel has informed counsel for 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.

[57] *See* Johnston Decl., Ex. K (chart of cases in which Plaintiffs plead Count IV); Ex. L (chart of cases in which Plaintiffs plead Count V); Ex. M (chart of cases in which Plaintiffs plead Count VI).

heightened pleading requirements of Rule 9(b) apply to "any claim that 'sounds in fraud,' regardless of whether fraud is an element of the claim." *Matsumura v. Benihana Nat'l Corp.*, 542 F. Supp. 2d 245, 251 (S.D.N.Y. 2008); *see also, e.g.*, *Eaves v. Designs for Fin., Inc.*, 785 F. Supp. 2d 229, 254 (S.D.N.Y. 2011) ("[A] number of district courts in this Circuit have required negligent misrepresentation claims to satisfy Rule 9(b)."); *Elson v. Black*, 56 F.4th 1002, 1008 (5th Cir. 2023) (Rule 9 applies to a consumer protection claim if it "is premised entirely upon a course of fraudulent conduct that is not sufficiently pled"); *Laskowski v. Brown Shoe Co.*, 2015 WL 1286164, at *5 (M.D. Pa. Mar. 20, 2015) (Rule 9 applies to a Restatement § 402B strict-liability misrepresentation claim that "is grounded in a theory of fraud").

Here, Plaintiffs' negligent misrepresentation, strict liability misrepresentation, and consumer protection claims all rest on JJCI's alleged "fraudulent or deceptive conduct" Compl. ¶ 259—i.e., that JJCI "misrepresented the safety of Tylenol" and failed to disclose purported risks associated with that medication, Compl. ¶ 233 (negligent misrepresentation); *see, e.g.*, Compl. ¶ 248 (strict liability misrepresentation); Compl. ¶ 266 (consumer protection claim).) As explained below, Plaintiffs fail to adequately plead these claims under any standard, much less the stringent particularity requirement of Rule 9(b).

A. Plaintiffs Fail To Adequately Plead A Misrepresentation-Based Theory Of Liability

Despite variations in the applicable substantive laws, claims for negligent misrepresentation, strict liability misrepresentation under the Restatement (Second) of Torts § 402B and consumer fraud generally require proof of a false or misleading statement. *See, e.g.*, N.Y. Gen. Bus. Law §§ 349, 350 (prohibiting "[d]eceptive acts or practices" and "[f]alse advertising"); *Campos v. Wells Fargo Bank, N.A.*, 2015 WL 5145520, at *6 (C.D. Cal. Aug. 31, 2015) (dismissing negligent misrepresentation claim where the plaintiff "allege[d] no additional

contextual facts to indicate that the statement was actually false"); *McKinnis v. Kellogg USA*, 2007 WL 4766060, at *5 (C.D. Cal. Sept. 19, 2007) (dismissing California consumer-protection claims because packaging was "not deceptive").[58] These causes of action also require evidence that the plaintiff actually relied on the purported misstatement or, at a minimum, that the alleged fraud caused the plaintiff to purchase the product. *See, e.g.*, *Myers-Taylor v. Ornua Foods N. Am., Inc.*, 2019 WL 424703, at *5 (S.D. Cal. Feb. 4, 2019) (noting that "justifiable reliance" is an element of negligent misrepresentation claims in California); *Tuosto v. Philip Morris USA Inc.*, 2007 WL 2398507, at *14 (S.D.N.Y. Aug. 21, 2007) (similar under New York law).[59]

The Master Complaint does not sufficiently allege these essential elements under any pleading standard. While the Master Complaint repeatedly claims that JJCI made "affirmative misrepresentations . . . regarding the safety of Tylenol," Compl. ¶ 158, Plaintiffs never specify what those purported safety-related misstatements are. Instead, Plaintiffs allege that JJCI failed to disclose information (e.g., "nothing on the Tylenol label warns pregnant women that ingestion of acetaminophen while pregnant can cause ASD and/or ADHD"), Compl. ¶ 110; they display an "example" of a Tylenol® label but fail to identify any alleged misstatement on that label, Compl. ¶ 111; and they discuss a marketer's alleged ability to add a warning to a drug label, Compl. ¶ 113.

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[58] *See also, e.g.*, *Hudson River Club v. Consol. Edison Co.*, 712 N.Y.S.2d 104, 106 (N.Y. App. Div. 1st Dept. 2000) (affirming dismissal of negligent-misrepresentation claim under New York law because "there was no misrepresentation made by Con Edison"); *Willis v. Buffalo Pumps Inc.*, 34 F. Supp. 3d 1117, 1130 (S.D. Cal. 2014) ("The[] requirements and limitations [of § 402B of the Restatement] suggest that the misrepresentation must be affirmative, not one made by omission.").

[59] *See also, e.g.*, *Thorpe v. Bollinger Sports, LLC*, 2015 WL 5299614, at *4 (E.D. Pa. Sept. 9, 2015) ("Misrepresentation under § 402B requires a showing that the plaintiff's justifiable reliance on a misrepresentation was the proximate cause of his physical harm."); *In re Arris Cable Modem Consumer Litig.*, 2018 WL 288085, at *6 (N.D. Cal. Jan. 4, 2018) ("[T]o state a claim under [California consumer-protection statutes], [a plaintiff] must allege facts sufficient to show that she relied on the defendant's alleged misrepresentation." (quotation marks and citation omitted)); *Miller v. Wells Fargo Bank, N.A.*, 994 F. Supp. 2d 542, 557–58 (S.D.N.Y. 2014) ("The causation element is essential: The plaintiff must show that the defendant's material deceptive act caused the injury.").

None of this gives the slightest indication about what (if anything) JJCI supposedly affirmatively misrepresented to Plaintiffs.

Although the Master Complaint does include an "advertisement" that Plaintiffs claim "reinforced [JJCI's] message that Tylenol is safe for pregnant women," Compl. ¶ 108, Plaintiffs do not point to any specific statement in that advertisement, much less identify one that is allegedly false or misleading. Nor do they identify a source for this advertisement or even attempt to allege that any Plaintiff ever saw (let alone relied on) it. *See, e.g.*, *Dupere v. Ethicon, Inc.*, 2022 WL 523604, at *7 (S.D.N.Y. Feb. 22, 2022) (Cote, J.) (dismissing fraud-based claims because the complaint did "not specify which statements [the plaintiff] or her physician viewed or heard, how or when they were exposed to those statements, or why those statements were fraudulent"); *Gutierrez v. Johnson & Johnson Consumer Inc.*, 2021 WL 822721, at *5 (S.D. Cal. Jan. 22, 2021) ("Merely supplying a list of advertisements . . . does not show which specific advertisement[s] or statement[s] that [p]laintiffs actually saw.").[60] Instead, Plaintiffs base their allegation "on information and belief," which "do[es] not meet the requirements of Rule 9(b)" and effectively proves that it lacks any basis. *O'Brien v. Nat'l Prop. Analysts Partners*, 719 F. Supp. 222, 226 (S.D.N.Y. 1989) (allegations "based on information and belief do not meet the requirements of Rule 9(b)" where "[t]here is no reason to believe that the alleged mailings and communications with third parties and with class members constitute matters peculiarly within the opposing party's knowledge" (quotation marks and citation omitted)). Plaintiffs' allegations of purported

[60] *See also, e.g.*, *Quintana v. B. Braun Med. Inc.*, 2018 WL 3559091 (S.D.N.Y. July 24, 2018) (holding that plaintiffs' allegations regarding representations made by defendants in a product brochure "fail[ed] to sufficiently identify the speaker, state where and when the statements were made (or were viewed), and explain why the statements were fraudulent") (quotation marks and citation omitted); *Brumfield v. Merck & Co.*, 2018 WL 2277835, at *7–8 (E.D.N.Y. May 18, 2018) (holding that plaintiffs' failure to "identif[y] the specific statements or omissions that they relied on . . . or the circumstances of the purported misrepresentations" was "fatal" to their fraudulent and negligent misrepresentation claims that were based on alleged "misrepresentations and omissions regarding the safety and efficacy of [the drug]").

affirmative misrepresentations by JJCI are thus inadequately pled, and the claims relying on these allegations should therefore be dismissed.

B. Plaintiffs' Omission-Based Theory Of Liability Fails For Multiple Reasons

Given their inability to identify an affirmative misrepresentation, Plaintiffs unsurprisingly base their misrepresentation claims in large part on a theory of omission—i.e., that JJCI failed to disclose additional information about the safety of Tylenol®. *See, e.g.*, Compl. ¶ 231 (negligent misrepresentation); Compl. ¶ 247 (strict liability misrepresentation); Compl. ¶ 263 (consumer fraud). That theory cannot proceed for multiple reasons.

As a threshold matter, a claim for strict liability misrepresentation cannot be based on an omission; rather, every state that recognizes this tort has made it clear that the "misrepresentation must be affirmative." *Willis*, 34 F. Supp. 3d at 1130 (setting forth requirement for strict liability misrepresentation under the Restatement (Second) of Torts § 402B); *see also, e.g.*, *Franks v. Nat'l Dairy Prod. Corp.*, 282 F. Supp. 528, 533 (W.D. Tex. 1968) (noting 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) (similar under Colorado law); *Klages v. Gen. Ordnance Equip. Corp.*, 367 A.2d 304, 312 (Pa. 1976) (similar under Pennsylvania law); *Ladd ex rel. Ladd v. Honda Motor Co.*, 939 S.W.2d 83, 97 (Tenn. Ct. App. 1996) (similar under Tennessee law). After all, the requirement of an express affirmative misrepresentation is precisely what distinguishes strict liability misrepresentation from other forms of strict product liability (e.g., design defect or failure to warn). *Franks*, 282 F. Supp. at 533-34.

Multiple states similarly limit the tort of negligent misrepresentation to affirmative misstatements, precluding omission-based liability under that cause of action as well. *See, e.g.*, *Andersons, Inc. v. Consol, Inc.*, 348 F.3d 496, 506 (6th Cir. 2003) ("Unlike a fraud claim, however, a negligent misrepresentation claim only lies for an affirmative false statement, not an omission.");

Garlough v. FCA US LLC, 2021 WL 4033177, at *4 (E.D. Cal. Sept. 3, 2021) ("Because a claim of negligent misrepresentation cannot be based on an omission, Plaintiff's claim for negligent misrepresentation also fails."); *Burman v. Richmond Homes Ltd.*, 821 P.2d 913, 919 (Colo. App. 1991) (where no "false information was supplied, there can be no negligent misrepresentation"). And to the extent the relevant states recognize omission-based theories of negligent misrepresentation and/or consumer fraud, Plaintiffs have failed to adequately allege such a theory in their Complaint. In order to survive a motion to dismiss, a plaintiff cannot merely allege that a manufacturer failed to "disclos[e] the full breadth of the known risks" of the product; rather, she must "specifically set forth the omitted information, who was responsible for those omissions, the specific context of the omissions, and what [d]efendants obtained through concealing those matters." *Quintana*, 2018 WL 3559091, at * 8; *see also Weaver v. Chrysler Corp.*, 172 F.R.D. 96, 102 (S.D.N.Y. 1997) (dismissing plaintiff's fraud by omission claim because he failed to "specify the time, place, and content of [defendant's] representations, advertisements, and promotional materials," and because nearly the entire complaint was pled "upon information and belief'" (citation omitted)).

Plaintiffs do not come close to meeting this standard. Plaintiffs concede that JJCI's Tylenol® label at all times contained the pregnancy-specific language required by 21 C.F.R. § 201.63(a). *See* Compl. ¶¶ 171–172. Although they contend that the warning should have said *more* about the risk of Tylenol® use by pregnant women, they do not specify any verbiage that they believe *should* have been provided. Indeed, Plaintiffs previously have represented to the Court that they would need months of further consultation with experts to even articulate any such warning with specificity. *See* 1/13/23 Hr'g Tr. 8:2–10:17. In any event, no Plaintiff in any Short

Form Complaint filed to date has alleged any facts to demonstrate that he or she actually read or viewed any Tylenol® label, or any other Tylenol® advertisement, prior to purchase.

Finally, even assuming Plaintiffs had sufficiently alleged the circumstances of JJCI's alleged concealment, their claims arising out of this theory would still fail as a matter of law because the information that JJCI allegedly withheld was publicly available. *See, e.g.*, *Zirvi v. Flatley*, 838 F. App'x 582, 587 (2d Cir. 2020) (affirming dismissal of plaintiffs' claims because the allegedly fraudulently concealed information was "public information available to plaintiffs" before the statute expired); *Inn Chu Trading Co. v. Sara Lee Corp.*, 810 F. Supp. 501, 507 (S.D.N.Y. 1992) (dismissing plaintiff's fraud claims based on "upon information and belief" allegations that defendants deceptively procured certain information as lacking the requisite factual basis because "[a]t most . . . the allegations may explain how defendants learned [the information], but they do not provide a viable basis for the claim that [defendants] intended to induce [plaintiff]"); *Alexander v. Turner Corp.*, 2001 WL 225049, at *5 (S.D.N.Y. Mar. 2, 2001) ("Plaintiff cannot show misrepresentation or intent to misrepresent when the alleged fraudulently concealed information was contained in a publicly available document.").

The gravamen of Plaintiffs' concealment theory is that JJCI "had exclusive control" over the "scientific evidence" supporting their claims. Compl. ¶ 159. But at the same time Plaintiffs acknowledge that the purportedly concealed information was a matter of public record. *See* Compl. ¶¶ 3, 85 (alleging that the "scientific evidence" was published in a "prominent scientific journal" and "a well-known, peer reviewed publication"); *see also, e.g.*, Compl. ¶¶ 2, 4, 81, 84, 87–95, 98. And this issue has also been covered in general interest publications and news shows. *See, e.g.*, Perri Klass, M.D., *Does An A.D.H.D. Link Mean Tylenol Is Unsafe In Pregnancy?*, N.Y. Times (Dec. 4, 2017); Katheryn Doyle, *Too Much Tylenol In Pregnancy Could Affect Child's*

Development, Study Finds, NBC News (Nov. 22, 2013).[61] Accordingly, Plaintiffs' own allegations confirm that their concealment-based theory of liability is implausible, providing another reason why their claims for negligent misrepresentation, strict liability misrepresentation, and consumer fraud should be dismissed.

CONCLUSION

For the reasons set forth above, the Court should dismiss Plaintiffs' claims.

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[61] Courts may "take judicial notice of the fact that press coverage . . . contained certain information" in ruling on a motion to dismiss. *New York ex rel Khurana v. Spherion Corp.*, 2016 WL 6652735, at *11 (S.D.N.Y. Nov. 10, 2016) (citing *Ping Chen ex rel. U.S. v. EMSL Analytical, Inc.*, 966 F. Supp. 2d 282, 294 (S.D.N.Y. 2013)); *see also, e.g.*, *421-A Tenants Ass'n, Inc. v. 125 Ct. St. LLC*, 760 F. App'x 44, 49 n.4 (2d Cir. 2019) ("[W]e have previously made clear that it is appropriate to take news articles into account even on a Rule 12(b)(6) motion.").