UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: Acetaminophen – ASD-ADHD Products Liability Litigation This Document Relates To: *Chapman v. Walmart, Inc.*, 1:22-cv-08830-DLC	Docket No.: 22-md-3043 (DLC)

DEFENDANT JOHNSON & JOHNSON CONSUMER INC.'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION FOR CERTIFICATION UNDER 28 U.S.C. § 1292(b)

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Pursuant to 28 U.S.C. § 1292(b), defendant Johnson & Johnson Consumer Inc. ("JJCI") respectfully requests that the Court certify for interlocutory appeal its recent orders denying JJCI's motion to dismiss. Section 1292(b) authorizes interlocutory appeals for orders presenting (1) a controlling question of law (2) as to which there is reasonable ground for disagreement and (3) the resolution of which may materially advance disposition of the litigation. The Court's orders with respect to preemption and causation/knowledge squarely meet all three criteria.

First, the preemption issues in this case are a textbook example of the sort of issue for which 1292(b) review is appropriate.

The preemption questions in this litigation are indisputably "controlling" because they are pure questions of law that, if decided differently by the Second Circuit, would end Ms. Chapman's lawsuit. Indeed, reversal by the Second Circuit would not just be "dispositive" of this particular plaintiff's case (Preemption Opinion & Order ("Preemption Order") at 20, MDL Dkt. 589); by its precedential force, such a ruling would also effectively terminate the more than 150 cases currently pending in this MDL proceeding that are similarly based on the premise that a defendant could have unilaterally added to the specific warning prescribed by 21 C.F.R. § 201.63 without prior approval of any such change by the Food & Drug Administration ("FDA").

There is also substantial ground for a difference of opinion on the preemption issues presented by JJCI's motion. Courts in this circuit have repeatedly held that this prong is satisfied where the ruling in question raises an issue of first impression—a standard clearly met in light of this Court's recognition that "[n]either the Supreme Court nor any circuit court has addressed" the preemption question raised by JJCI's motion. (Preemption Order at 17.) This is particularly true because the lack of on-point precedent forced the Court to rely on cases involving medications governed by different labeling schemes involving prescription medications approved through a

new drug application, which JJCI respectfully maintains do not apply to the preemption question in this case. Thus and respectfully, while the Court may be confident that it decided the preemption question correctly, there is substantial ground for disagreement with its holding.

Finally, immediate appeal of the preemption decision would also materially advance the litigation's ultimate termination. A successful appeal would end this litigation, sparing the parties and the Court a tremendous investment of resources that could prove unnecessary. It makes no sense for the parties to proceed with conducting costly discovery and ultimately trying claims that are all grounded in purported state-law duties that the Second Circuit may ultimately deem to be preempted by the federal pregnancy warning. This is especially true given that the fundamental theory behind this MDL proceeding—i.e., that acetaminophen use during pregnancy can cause autism spectrum disorder ("ASD") and attention deficit/hyperactivity disorder ("ADHD") in children—is highly speculative. An immediate appeal to the Second Circuit would not only obviate potentially needless litigation; it would also effectuate the purpose for which this MDL proceeding was created in the first place. *In re Acetaminophen - ASD/ADHD Prods. Liab. Litig.*, MDL No. 3043, 2022 U.S. Dist. LEXIS 183759, at *2, *6, -- F. Supp. 3d -- (J.P.M.L. Oct. 5, 2022) (explaining that the MDL proceeding was created to "promote the just and efficient conduct of this litigation," including with respect to "defendants' common defenses concerning preemption").

Second, the Court should also certify its order denying JJCI's motion to dismiss for failure to plead causation and knowledge. (*See* MDL Dkt. 602 ("Causation Order").) An appeal on this issue would similarly resolve a pure issue of law: whether tort plaintiffs can drag defendants into years of costly litigation and discovery where, as here, their pleadings fail to cite any studies finding that the alleged exposure causes injury. And resolution of that issue would end not only Ms. Chapman's case, but as a practical matter, the claims of all other plaintiffs in this MDL

proceeding. On this issue, too, there is substantial ground for a difference of opinion. Other courts have evaluated the sufficiency of the scientific evidence offered in a complaint and concluded that allowing plaintiffs to bring tort claims based on a mere "association" in the epidemiologic literature would inappropriately outrun science. Evaluating whether epidemiological studies cited in a complaint actually support a ***plausible*** inference of causation is consistent with Rule 8's pleading standard and particularly appropriate in the context of sprawling MDL proceedings, which impose huge costs on defendants and the judicial system.

In short, the Court's recent decisions present precisely the kinds of issues that Congress sought to make immediately appealable when it enacted section 1292(b).

BACKGROUND

This case—like all actions in this MDL proceeding—is premised on the theory that defendants, including JJCI, had a state-law obligation to include an additional warning related to acetaminophen use during pregnancy beyond the one expressly required by federal regulations. In September 2022, Walmart Inc. ("Walmart") moved to dismiss *Hatfield v. Walmart Stores, Inc.*, No. 22-cv-09011-DLC, and *Roberts v. Walmart Stores, Inc.*, No. 22-cv-09012-DLC, contending that any such state-law warning would be preempted. (*See* Hatfield Dkt. 15; Roberts Dkt. 15.) The Court denied that motion in November 2022 (*see* MDL Dkt. 145), and Walmart thereafter moved for reconsideration or, in the alternative, to certify the issue for interlocutory appeal under 28 U.S.C. § 1292(b) (*see* MDL Dkt. 203). That motion was denied on April 27, 2023.[1]

[1] JJCI initially objected to Walmart's 1292(b) motion because it had not had the opportunity to weigh in on the preemption issue (*see* Letter from J. Murdica to the Hon. Denise L. Cote, Dec. 12, 2022 (MDL Dkt. 262)), and the Court denied Walmart's motion "[g]iven JJCI's December 12 letter request" (MDL Dkt. 601 at 5). Now that JJCI has had the opportunity to fully brief the question, it believes interlocutory certification is ripe and appropriate.

In February 2023, JJCI, which manufactures Tylenol®, a line of name-brand acetaminophen (or "APAP") products, also filed a motion to dismiss all cases against it, arguing both that plaintiffs' claims were preempted and that they had failed to plausibly plead causation or defendants' knowledge of any risks. In the portion of its motion addressing preemption, JJCI addressed the Court's prior ruling and highlighted FDA-related materials that the Court had not previously considered. (*See* MDL Dkt. 426.) The Court denied the preemption portion of the motion on April 20, 2023 (*see* MDL Dkt. 589), one day after requesting input from the FDA that could bear on the preemption arguments raised by JJCI (*see* MDL Dkt. 588). A week later, it also denied the causation and knowledge portion of the motion. (*See* MDL Dkt. 602.) Because both orders reveal substantial grounds for a difference of opinion, and because both present questions of law, the resolution of which would advance (and potentially resolve) this MDL proceeding, JJCI now seeks certification for interlocutory review.

ARGUMENT

Congress enacted 28 U.S.C. § 1292(b) to "assure the prompt resolution of knotty legal problems." *Tantaros v. Fox News Network, LLC*, 465 F. Supp. 3d 385, 391 (S.D.N.Y. 2020) (quoting *Weber v. United States*, 484 F.3d 154, 159 (2d Cir. 2007)). Section 1292(b) was specifically "[a]dopted with complex litigation in mind" to "provide[] a mechanism for obtaining early review of crucial orders where an appellate ruling may simplify or shorten the litigation," such as orders involving "pivotal claims or defenses." *Manual for Complex Litigation (Fourth)* § 15.11 (2004).

To achieve those objectives, section 1292(b) authorizes immediate appeal of a non-final order where (1) the order "involves a controlling question of law about which (2) there is substantial ground for difference of opinion and (3) immediate appeal from the order may materially advance the ultimate termination of the litigation." *Hymes v. Bank of America, N.A.*,

Nos. 18-CV-2352 (RRM) (ARL), 18-CV-4157 (RRM) (ARL), 2020 WL 9174972, at *3 (E.D.N.Y. Sept. 29, 2020) (citation omitted). "When a ruling satisfies these criteria and 'involves a new legal question or is of special consequence,' then the district court 'should not hesitate to certify an interlocutory appeal.'" *Id.* (quoting *Balintulo v. Daimler AG*, 727 F.3d 174, 186 (2d Cir. 2013)). This Court's ruling denying JJCI's motion to dismiss and holding that plaintiffs' claims are not preempted easily satisfies the requirements for section1292(b) certification.

I. THE COURT SHOULD CERTIFY ITS PREEMPTION ORDER FOR INTERLOCUTORY REVIEW.

A. The Preemption Issues In The Order Constitute Controlling Questions Of Law.

"[A] question of law is 'controlling' if reversal of the district court's order would terminate the action." *Klinghoffer v. S.N.C. Achille Lauro Ed Altri-Gestione Motonave Achille Lauro In Amministrazione Straordinaria*, 921 F.2d 21, 24 (2d Cir. 1990) (granting permission to appeal denial of motion to dismiss for lack of personal and subject matter jurisdiction) (citing J. Moore & B. Ward, 9 *Moore's Federal Practice* ¶ 110.22[2], at 268 (1990) (collecting cases)). In evaluating this prong of section 1292(b), "[c]ourts also require that the issue to be certified . . . be a 'pure question of law,'" *Hymes*, 2020 WL 9174972, at *4 (citation omitted), and consider whether "the certified issue has precedential value for a large number of cases," *id.* (citation omitted); *see also Tantaros*, 465 F. Supp. 3d at 390 ("question of subject matter jurisdiction is . . . a 'pure' question of law that turns on the statutory interpretation" and "has wide-reaching precedential impact"). The preemption question here is both potentially dispositive and a pure question of law.

Another MDL court recently recognized that cross-cutting preemption determinations made in multidistrict litigation are necessarily "controlling" for these reasons. *In re Taxotere (Docetaxel) Prods. Liab. Litig.*, MDL No. 2740, 2022 U.S. Dist. LEXIS 206131, at *10 (E.D. La. Nov. 14, 2022). In that litigation, the plaintiffs alleged that the labeling of the defendants' cancer-

treating medication should have warned of the potential for permanent hair loss. *Id.* at *2-4. Although the MDL court disagreed with the defendants' position on preemption (i.e., that plaintiffs had not sufficiently identified "newly acquired information" that would have permitted defendants to independently change their labels), the court certified its denial of summary judgment for interlocutory review because its ruling both "involve[d] a purely legal question" and bore on resolution of other cases pending in the litigation. *Id.* at *2-4, *10; *see also, e.g.*, *Tantaros*, 465 F. Supp. 3d at 390 n.5 ("[I]n certain circumstances an interlocutory appeal on, for instance, the question of whether a state law claim is completely preempted . . . is appropriate.") (citation omitted); *Hymes*, 2020 WL 9174972, at *4 ("the preemption issue is dispositive of the cases at bar and is a pure question of law," satisfying the "'controlling question' prong"); *Spong v. Fid. Nat'l Prop. & Cas. Ins. Co.*, 787 F.3d 296, 304 (5th Cir. 2015) ("Whether federal law preempts the Spongs' claims certainly falls within the ambit of 28 U.S.C. § 1292(b).").

The same logic applies here. As the Court recognized in its order, JJCI's motion raised a "dispositive question": "could [it] have added a truthful warning about the risks of in utero exposure to acetaminophen labels without violating federal law?" (Preemption Order at 20.) Although the Court concluded that "[t]he answer is yes" (*id.*), reversal of that conclusion would necessarily be "dispositive" of Ms. Chapman's case—the entirety of which turns on JJCI's purported "duty under state law to warn of the risks of prenatal exposure to acetaminophen." (*Id.* at 7.) Moreover, reversal by the Second Circuit would not just dispose of Ms. Chapman's case; it would effectively terminate the more than 150 cases currently pending in the MDL proceeding, which are similarly predicated on the notion that a defendant could have added to the specific warning prescribed by 21 C.F.R. § 201.63. *See In re Taxotere*, 2022 U.S. Dist. LEXIS 206131, at *10 (finding that the "controlling question" prong was satisfied even where "resolution of th[e]

[preemption] question may not end the entire MDL" because "it will have a substantial impact" on the proceeding). The fact that the Court previously denied a co-defendant's preemption-based motion to dismiss in cases involving different plaintiffs highlights the cross-cutting nature of the preemption issue and demonstrates why "guidance as to the preemption analysis [would be] applicable to the other cases . . . in this MDL." *Id.* Accordingly, the Court's denial of JJCI's motion to dismiss indisputably presents a "controlling question" of law.

B. <u>There Is Substantial Ground For A Difference Of Opinion On These Questions Of Law</u>.

There is also substantial ground for a difference of opinion on the issues of law presented by JJCI's preemption motion. One circumstance that satisfies this factor is when "the issue is particularly difficult and of first impression for the Second Circuit." *Capitol Records, LLC v. Vimeo, LLC*, 972 F. Supp. 2d 537, 551-52 (S.D.N.Y. 2013) (citation omitted); *see, e.g.*, *Tantaros*, 465 F. Supp. 3d at 388 (similar); *Aurora Maritime Co. v. Abdullah Mohamed Fahem & Co.*, 890 F. Supp. 322, 329 (S.D.N.Y. 1995) (certifying case for interlocutory appeal in part because there was "virtually no case law on point"); *In re Taxotere*, 2022 U.S. Dist. LEXIS 206131, at *11 ("Courts often find that substantial ground for difference of opinion exists if 'novel and difficult questions of first impression are presented.'") (citation omitted). That standard is satisfied here for several reasons.

First, and most fundamentally, this case presents an issue of first impression not just in this circuit, but in ***any*** circuit. As the Court itself noted: "***Neither the Supreme Court nor any circuit court has addressed preemption in the context of the Pregnancy Warning or the monograph system***." (Preemption Order at 17 (emphasis added).) As such, this Court had no on-point caselaw to guide its ruling on JJCI's motion to dismiss. That alone justifies immediate guidance by the Second Circuit.

Second, without appellate guidance on the precise issue at hand, the Court relied on cases involving prescription medications that are governed by a different regulatory regime. As the Court is aware, medications can be marketed either under the new drug application ("NDA") process or under the monograph system. To receive approval under an NDA, the manufacturer must demonstrate the safety and effectiveness of a drug, as well as the adequacy of its label, to the FDA. (*See* Preemption Order at 9.) The monograph system, which is available only for certain classes of over-the-counter ("OTC") drugs, "establishes conditions under which certain classes of drugs will be considered" generally recognized as safe and effective without an NDA. (*Id.* at 10.) Among those conditions is a prescribed product label.

The Tylenol® products at issue in this case were marketed under the monograph system. Nevertheless, the Court relied heavily on *Wyeth v. Levine*, 555 U.S. 555 (2009) and *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668 (2019), both of which involved drugs that had been approved under an NDA. (*See* Preemption Order at 19.) Those cases are inapposite because they turned on the fact that under the changes being effected ("CBE") regulation, manufacturers of drugs approved under an NDA are permitted "to make certain changes to [their] label[s] before receiving the [FDA's] approval." *Wyeth*, 555 U.S. at 568; *see Albrecht*, 139 S. Ct. at 1673 (CBE "permits [NDA] drug manufacturers to change the label without prior FDA approval if the change is designed to 'add or strengthen a . . . warning' where there is 'newly acquired information' about the 'evidence of a causal association' between the drug and a risk of harm") (citation omitted). (*See also* Preemption Order at 19 (cases "discussed the CBE regulations").) But as plaintiffs' Master Complaint concedes, there is no analogous procedure that permits changes to drug labels

approved under the monograph system, like the Tylenol® that Ms. Chapman allegedly took.[2] (*See* Master Compl. ¶ 42, MDL Dkt. 276.) Given this fundamental difference between the regulatory regime at issue in the cases relied upon by the Court and the one that governs Tylenol®, the Second Circuit could reasonably conclude that cases like *Wyeth* and *Albrecht* are not relevant to adjudicating the dispositive preemption question here.

Third, the Court's analysis of the exact-language (or exclusivity) rule, 21 C.F.R. § 330.1(c)(2), also demonstrates substantial grounds for a difference of opinion. The Second Circuit could conclude that this Court's reading of the exact-language rule as a floor—rather than a ceiling—is wrong, especially in light of the Court's apparent acknowledgment that its construction of the rule could frustrate public policy. (*See* Preemption Order at 26 ("There may be many strong policy reasons in favor of uniform warnings . . . ."); *id.* at 29 (there is "no doubt" about the "strong federal policy against 'overwarning'").)

There is also substantial ground for a difference of opinion arising from the inferences the Court apparently drew from a 1985-86 rulemaking that limited the exact-language rule in certain non-relevant respects. (*See* Preemption Order at 28-29 (citing 50 Fed. Reg. 15,810, 15,810 (Apr. 22, 1985) & 51 Fed. Reg. 16,258, 16,259 (May 1, 1986)).) In that rulemaking, the FDA "emphasize[d] that the relaxation of the exclusivity policy would apply only to indications for use" and that "all other required OTC drug labeling"—including the actual ***warnings***—"would continue to be subject to the existing exclusivity standard." 50 Fed. Reg. at 15,812; *see* 51 Fed. Reg. at 16,258 ("All required OTC drug labeling other than indications for use (e.g., statements of identity,

[2] As explained in JJCI's motion to dismiss, because there is clear evidence that the FDA would have rejected any additional warning, plaintiff's claims would be preempted if the medication at issue had been approved under an NDA. (*See* Defs.' Mem. in Supp. Mot. to Dismiss at 30-33, MDL Dkt. 426.) Since no such claims are pending in the MDL proceeding, JJCI does not address the hypothetical further.

warnings, and directions) must appear in the specific wording established under an OTC drug monograph.") (emphasis added); 51 Fed. Reg. at 16,260 ("[O]ther required OTC drug labeling continues to be subject to the existing exclusivity standard."). In short, the FDA reconsidered the exact-language policy and, with respect to warnings, clearly reaffirmed it—underscoring its continued commitment to uniform national warnings. The Court interpreted the rulemaking differently, resulting in another issue of law on which there is a substantial ground for a difference of opinion.

Finally, there are substantial grounds for disagreement with the Court's interpretation of the regulation establishing the required warning, 21 C.F.R. § 201.63, because it conflicts with the understanding held by the relevant agency—the FDA. *See Muniz v. Winn*, 462 F. Supp. 2d 175, 183-84 (D. Mass. 2006) (certifying for review because of "disagreement between certain of the district judges and the" relevant regulatory agency), *rev'd on other grounds sub nom. Muniz v. Sabol*, 517 F.3d 29 (1st Cir. 2008). As explained in JJCI's motion to dismiss, the FDA's preamble to the pregnancy warning makes it clear that the agency understood its regulation to establish "a ***single*** national pregnancy-nursing warning" that would provide "clear, unambiguous, and consistent information" to pregnant women. 47 Fed. Reg. 54,750, 54,756 (Dec. 3, 1982) (emphasis added). The FDA intended that the warning be "adjust[ed]" through "final . . . monographs" or "individual NDAs" rather than by manufacturers acting on their own or pursuant to state law. *Id.* at 54,755; *see also id.* at 54,756 (concluding that this policy would effectuate preemption of alternative state warnings). (*See* Defs.' Mem. in Supp. Mot. to Dismiss at 22-23, MDL Dkt. 426; *see also* Walmart's Mem. in Supp. Mot. for Recons. or Interloc. Appeal, MDL Dkt. 204.) The FDA could not have been more explicit on this issue: the regulation does "***not provide . . . for the voluntary addition of words to the warning***." 47 Fed. Reg. at 54,753 (emphasis added). By

contrast, this Court held that "[t]he Pregnancy Warning Regulation . . . does not speak to whether a further warning related to a drug's use during pregnancy can be added" by a manufacturer acting alone. (Preemption Order at 25.)

In short, certification is appropriate because the Court's preemption ruling presents a matter of first impression, and there are several substantial bases for a difference of opinion as to the Court's ruling.

C. Immediate Appeal Would Materially Advance The Litigation's Ultimate Conclusion.

The third factor—whether interlocutory review will materially advance termination of the litigation—is "'closely connected' to the first factor." *Tantaros*, 465 F. Supp. 3d at 392 (citations omitted). Courts place "particular weight" on this factor because it serves to "avoid protracted litigation"—the principal objective underlying section 1292(b). *See Transp. Workers Union, Loc. 100 v. N.Y.C. Transit Auth.*, 358 F. Supp. 2d 347, 350 & n.6 (S.D.N.Y. 2005) (quoting *Koehler v. Bank of Bermuda Ltd.*, 101 F.3d 863, 865-66 (2d Cir. 1996)); *see also Scott v. Chipotle Mexican Grill, Inc.*, No. 12-CV-8333 (ALC), 2017 U.S. Dist. LEXIS 156640, at *23 (S.D.N.Y. Sept. 25, 2017) ("'Courts place particular weight on the last of these three factors' which is satisfied 'if that appeal promises to advance the time for trial or to shorten the time required for trial.'") (citation omitted). While the final judgment rule is generally intended to promote efficient litigation, the fundamental principle underlying section 1292(b) is that unbending adherence to that rule can increase the risk of inefficiencies in cases where immediate interlocutory appeal could quickly end the litigation, avoiding years of wasted litigation.

Here, immediate review would materially advance the litigation because it "w[ould] provide th[e] [c]ourt with guidance as to the preemption analysis applicable to other cases . . . in th[e] MDL," *In re Taxotere*, 2022 U.S. Dist. LEXIS 206131, at *12, potentially "avoid[ing]

fruitless litigation," *Hymes*, 2020 WL 9174972, at *6 (construing third prong of section 1292(b) and noting that "[o]ne of the central goals of 28 U.S.C. § 1292(b) was 'saving trial court time by avoiding fruitless litigation'") (quoting *Koehler*, 101 F.3d at 866); *see also In re Chinese Manufactured Drywall Prods. Liab. Litig.*, MDL No. 2047, 2012 U.S. Dist. LEXIS 148501, at *18 (E.D. La. Oct. 16, 2012) ("[T]he [c]ourt finds that an immediate appeal [of the denial of a motion to dismiss for lack of personal jurisdiction] would materially advance the litigation by eliminating the possibility of a meaningless trial."); *Philip Morris Inc. v. Harshbarger*, 957 F. Supp. 327, 330 (D. Mass. 1997) ("[T]he affirmance of this [c]ourt's decision [finding no preemption] will probably not advance the termination of this litigation, but a reversal would.").

If the Second Circuit were to reverse the Court's ruling, Ms. Chapman's claims would be dismissed with prejudice. In addition, the claims of hundreds of other plaintiffs in this MDL proceeding would need to be dismissed under the same logic. Immediate appeal would thus ensure that the Second Circuit definitively resolves this threshold (and dispositive) legal issue before the parties and the Court spend years engaging in costly case-specific discovery and trying cases with outcomes that could be reversed on appeal based on a legal issue that can be resolved now. *See Hall v. Wyeth, Inc.*, No. 10-738, 2010 WL 4925258, at *2 (E.D. Pa. Dec. 2, 2010) (immediate appeal of a preemption ruling at the beginning of a case, before any discovery had commenced, would "materially advance the termination of th[e] litigation" by eliminating the need for a trial and costly discovery).

Conversely, if the Second Circuit were to affirm the Court's ruling, its holding would provide the parties and the Court with important guidance in facilitating the expeditious litigation of the underlying claims on the merits. "Either way, certifying an interlocutory appeal on the preemption issue would materially advance the ultimate disposition of this litigation." *Hymes*,

2020 WL 9174972, at *6; *see also In re Taxotere*, 2022 U.S. Dist. LEXIS 206131, at *12 ("[A]n immediate appeal from the [preemption] Order may materially advance the termination of this litigation."); *In re World Trade Ctr. Disaster Site Litig.*, 270 F. Supp. 2d 357, 381 (S.D.N.Y. 2003) (immediate appeal "will resolve the basic question of jurisdiction and thereby avoid uncertainty as to the binding effect of determinations and potential duplication of proceedings").

Resolution of "defendants' common defenses concerning preemption," *In re Acetaminophen - ASD/ADHD Prods. Liab. Litig.*, 2022 U.S. Dist. LEXIS 183759, at *2, *6, was one of the justifications for establishing this MDL proceeding in the first place. The most efficient way to resolve that issue is to certify the Court's order for appellate review now, before the parties proceed with costly litigation, all the while not knowing how the Second Circuit will rule on a fundamental and potentially dispositive legal issue.

II. THE COURT SHOULD ALSO CERTIFY ITS ORDER ON CAUSATION AND JJCI'S KNOWLEDGE FOR INTERLOCUTORY REVIEW.

The Court should also certify its order denying JJCI's arguments that Ms. Chapman has not plausibly pled that APAP can cause ASD or ADHD in children, much less that JJCI should have known of this alleged causation, and thus failed to satisfy Fed. R. Civ. P. 8. The first and third prongs of the test are easily satisfied on this issue, for much the same reason that they were met with respect to preemption. Although evaluating causation at the Rule 702, summary judgment, or trial stages of litigation may involve fact-intensive inquiries, the fundamental question of what a plaintiff must plead to advance to those stages presents a pure question of law. And resolving that legal question would clearly advance the resolution of the litigation. There is no dispute that Ms. Chapman's claims fail if she cannot sufficiently plead that Tylenol® can cause ASD and/or ADHD and that JJCI knew or should have known of that causal link. If this issue is

resolved in JJCI's favor, it would dispose of at least a large swath of the cases in the MDL proceeding, since the scientific allegations are largely the same across cases.

There are substantial grounds for a difference of opinion on this issue, too. As JJCI explained in its motion, neither the Master Complaint nor Ms. Chapman's Short Form Complaint cites a single study asserting that prenatal APAP use can cause ADHD or ASD, because none exists; to the contrary, the relevant studies disclaim causation. The Court summarily dismissed JJCI's arguments, contending that "[t]he complaint gives fair notice to the Defendants of [Plaintiff's] theory" and it was "not the vehicle for presenting . . . expert[] analysis of causation." (Causation Order at 8.) The Court also suggested that reference to the so-called "Consensus Statement" "[b]y itself" "provide[d] a more than adequate pleading of the element of causation." (*Id.*) But that statement only called for a warning as "precautionary action."[3] It does not support plaintiffs' causal theories since public health experts may urge certain steps "to err on the side of caution" based on evidence that falls far short of what is necessary to meet the "more-likely-than-not standard[] used to assess tort liability." *See In re Zantac (Ranitidine) Prods. Liab. Litig.*, --- F. Supp. 3d ---, 2022 WL 17480906, at *166-67 (S.D. Fla. Dec. 6, 2022). Indeed, the authors of the so-called Consensus Statement later made clear that they had expressly "avoided any inference of causality."[4]

Other courts, including courts in this district, have required plaintiffs to plead a more substantial set of facts that, if proven true, could demonstrate medical causation to proceed past a

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

[4] Ann Z. Bauer, et al., *Reply to 'Paracetamol Use In Pregnancy—Caution Over Causal Inference From Available Data': 'Handle With Care—Interpretation, Synthesis & Dissemination Of Data On Paracetamol In Pregnancy*,' 18 Nature Revs. Endocrinology 192, 192 (2022).

motion to dismiss. *See, e.g.*, *Manuel v. Pepsi-Cola Co.*, No. 17 Civ. 7955 (PAE), 2018 WL 2269247, at *10-12 (S.D.N.Y. May 17, 2018). Notably the Court's Causation Order did not cite any authority showing that the latter approach was incorrect, and JJCI is not aware of any dispositive Second Circuit caselaw definitively resolving the issue.

Particularly where, as here, a plaintiff must show that the defendant should have known of the alleged causation, requiring a plaintiff to identify studies that would prove causation is consistent with the general principle that a complaint must do enough to "nudge[] . . . claims across the line from conceivable to plausible." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 569 (2007). One consideration underlying this requirement is that "discovery can be expensive" and "push cost-conscious defendants to settle even anemic cases before reaching" the summary judgment stage. *Id.* at 559. Thus, the Supreme Court has recognized that a court should "'insist on some specificity in pleading before allowing a potentially massive factual controversy to proceed.'" *Id.* at 558.

The concerns underlying the Supreme Court's decision in *Twombly* apply with special force in the context of multidistrict litigation like this proceeding. Allowing plaintiffs to file hundreds or thousands of cases based on assertions of mere association—and without a single study to support a causal relationship—imposes substantial burdens on companies and courts. In this case, for example, simply litigating through the general causation Rule 702 stage will cost the defendant companies,plaintiffs, and their counsel millions of dollars in expert and legal fees. The burden placed on the judicial system by proceedings like these is, if anything, even more severe. MDL dockets have become so bloated that they account for more than half of the civil cases in the entire federal judicial system. Weeding out meritless mass torts at an early stage would thus vastly improve efficiency. The recent *Zantac* MDL demonstrates the point well. The Zantac proceeding

was created in February 2020 and grew to include thousands of cases. After almost three years of litigation, at the cost of no doubt tens of millions of dollars, the court concluded that the link between Zantac and cancer was junk science and granted summary judgment. *See In re Zantac*, 2022 WL 17480906. Interlocutory review of JJCI's motion to dismiss on causation and knowledge grounds could potentially spare the parties and the Court a similarly drawn-out process.

CONCLUSION

For the reasons set forth above, the Court should certify its orders denying JJCI's motion to dismiss under 28 U.S.C. § 1292(b).

Dated: May 2, 2023

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