BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: ACETAMINOPHEN – ASD/ADHD PRODUCTS LIABILITY LITIGATION	**MDL Docket No. 3043**

DEFENDANTS CVS PHARMACY, INC.'S, WALGREEN CO.'S, AND COSTCO WHOLESALE CORPORATION'S RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO TRANSFER ACTIONS PURSUANT TO 28 U.S.C. § 1407 FOR COORDINATED OR CONSOLIDATED PRETRIAL PROCEEDINGS

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Defendants CVS Pharmacy, Inc. ("CVS") (incorrectly named as "CVS Health Corporation"), Walgreen Co. ("Walgreens") (incorrectly named as "Walgreens Co." and "Walgreens Boots Alliance, Inc."), and Costco Wholesale Corporation ("Costco") (collectively the "Retailer Defendants") respectfully submit this response to Plaintiffs' Motion to Transfer Actions Pursuant to 28 U.S.C. § 1407 for Coordinated or Consolidated Pretrial Proceedings.

INTRODUCTION

At their core, each of the cases identified in Plaintiffs' Motion to Transfer Actions Pursuant to 28 U.S.C. § 1407 for Coordinated or Consolidated Pretrial Proceedings (the "Petition") and Plaintiffs' Schedule of Actions and Notices of Related Actions Schedule of Actions (the "Actions")[1] turns on an unsupported theory that the Retailer Defendants sold store-branded generic acetaminophen products made by others that allegedly posed prenatal risks when taken by pregnant women. Conspicuously missing from the Petition and the Actions is any mention of the manufacturers of branded acetaminophen products (*i.e.*, Tylenol®), or the manufacturers of any generic acetaminophen products. As explained herein, the only plausible explanation for the decision to proceed solely against the Retailer Defendants in the context of a pharmaceutical mass tort hinging on such claims is that Plaintiffs are attempting to manipulate forum selection for the MDL they are requesting. Failing to join indispensable parties in interest, prematurely seeking an MDL for only a nominal number of cases where such indispensable parties have not been joined, and failing to offer any support demonstrating that an MDL is necessary, let alone in the forum selected, is a mere pretext and should not be rewarded. This Panel should deny Plaintiffs' Motion for the following reasons:

[1] The Schedule of Actions, *see* ECF No. 1-2, and Notices of Related Actions Schedule of Actions, *see* ECF Nos. 24, 27, 30, 37, and 47, include twenty-nine cases naming three retail pharmacies: CVS, Walgreens, and Costco. Additional named retailers are Safeway Inc., Rite Aid Corporation, Target Corporation, and Walmart Inc./Wal-Mart Stores, Inc.

First, it cannot be disputed that the Retailer Defendants are sellers, and not manufacturers of any product at issue. Plaintiffs make clear in their Petition and in the allegations in the Actions that their claims actually depend on an inquiry not into the sale and marketing of acetaminophen products, but rather into the design, manufacture, testing, and warnings associated with these products. None of the defendants thus far named in any of these lawsuits actually manufactured acetaminophen products. The manufacturers of both branded and generic acetaminophen products are interested parties and have crucial access to primary key witnesses and evidence pertinent to Plaintiffs' claims. As cited below, Plaintiffs' own advertising confirms that Plaintiffs' true intent is to pursue their claims not against the Retailer Defendants, but against the actual manufacturers of acetaminophen products. Those parties are noticeably absent from Plaintiffs' Petition and the Actions. Centralization at this stage would reward Plaintiffs' improper attempt to JPML-forum-shop, and is, at best, premature.

Second, given the scant number of cases comprising the Actions, combined with the fact that the Retailer Defendants are separate, independent companies and not a monolith, centralization at this stage fails to promote the just and efficient conduct of these proceedings. This Panel has recognized time and again that mere puffery by Plaintiffs' counsel promising that "tens of thousands, if not hundreds of thousands, of similar follow-on actions" will be filed at some point in the future, *see* Pls.' Mot. at 12, does not warrant centralization.

Alternatively, should the Panel elect to grant Plaintiffs' Petition, all relevant factors favor the District of New Jersey as the most appropriate forum. Although Plaintiffs have proposed centralization in the Northern District of California, they do so in a single-sentence footnote in their brief, with no consideration of any of the necessary factors justifying the selection of a transferee court. More recently, one of the plaintiffs in the Actions has proposed the Western

District of Missouri as a potential forum, which this Panel should flatly reject given that none of the defendants or evidence are located there. Nor does the District of Minnesota, most recently proposed by another plaintiff, bear any pertinent relation to this litigation. The District of New Jersey, by contrast, is situated as the most likely location of relevant documents and witnesses; has a deep and experienced bench of MDL judges with pharmaceutical and product liability MDL experience; has the resources and capacity for an MDL such as this; and is centrally located and easily accessible to the parties (and anticipated parties).

In sum, and for the reasons set forth herein, the Retailer Defendants urge the Panel to decide against centralization prior to the addition of the real parties in interest—the manufacturers of acetaminophen. These anticipated parties should be given the opportunity to respond to Plaintiffs' Petition and set forth their own positions on this issue.[2] Nevertheless, if an MDL is to be formed at this early stage, it should be in a forum that will provide the best opportunity to all current parties and future necessary parties for the just and efficient conduct of these proceedings.

BACKGROUND

I. The Retailer Defendants' Sale of Acetaminophen Products

Acetaminophen, an analgesic and antipyretic agent used to treat pain and fever, has been available for non-prescription, over-the-counter ("OTC") use since 1955. *See* Exemption from Prescription Requirements, 20 FR 3499 (May 19, 1955). Currently, there are more than 600 acetaminophen-containing products on the market in the United States in OTC and prescription

[2] Although it appears highly likely based on Plaintiffs' own allegations that Plaintiffs intend to add the manufacturers of branded and generic acetaminophen as defendants in the Actions, the Retailer Defendants respectfully request clarity on this issue—*i.e.,* Plaintiffs' counsel confirming in their reply brief that they will not name manufacturers as defendants in this litigation. Otherwise, to the extent that manufacturers will be brought into the litigation, they deserve the opportunity to brief the critical issue of MDL formation.

formulations.[3] OTC formulations include branded acetaminophen products, such as Tylenol®, and store brand/generic acetaminophen products, in which acetaminophen made by a generic manufacturer often is sold with another company's (*e.g.*, a retailer's) trade dress.

Specific to the Actions, Plaintiffs' allegations—at this time—relate to generic OTC acetaminophen products sold by the Retailer Defendants. A representative inquiry into these acetaminophen products confirms that the Retailer Defendants are not the manufacturers of the products at issue in these cases. Manufacturers of generic OTC acetaminophen products sold by Costco, CVS, and Walgreens include, but are not limited to, the following: LNK International, Inc., Perrigo Company plc, Ohm Laboratories, Inc., Aurobindo Pharma Ltd., Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd., Elysium Pharmaceutical Ltd., Medgel Private Ltd., Aurohealth LLC, AptaPharma Inc., APL Healthcare, Ltd., and/or Hi-Tech Nutraceuticals, LLC. *See* Ex. A. This information regarding store brand generic acetaminophen products sold by the Retailer Defendants is publicly available and subject to the Panel's judicial notice[4]—and notably, no source points to any Retailer Defendant as the manufacturer of any acetaminophen product.[5]

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[3] *Don't Double Up on Acetaminophen*, FDA, https://www.fda.gov/consumers/consumer-updates/dont-double-acetaminophen (last visited Aug. 1, 2022).

[4] The Panel may take judicial notice of public records available on federal agency websites. *See, e.g.*, *Stanifer v. Corin USA Ltd.*, No. 6:14-CV-1192-ORL, 2014 WL 5823319, at *3 (M.D. Fla. Nov. 10, 2014) (holding that "[c]ourts in this District and elsewhere regularly take judicial notice of public records available on the FDA's website because such document[s] satisfy the requirements of Rule 201"); *Tinkler v. Mentor Worldwide, LLC*, No. 1:19-CV-23373-UU, 2019 WL 7291239, at *4 n.4 (S.D. Fla. Dec. 30, 2019) ("[I]t is well-settled that the Court can take judicial notice of FDA records located on the FDA's website—a source that cannot reasonably be questioned.").

[5] Of note, certain OTC acetaminophen products also are listed in the FDA's register for Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the FDA's Orange Book. *See Resources for Information: Approved Drugs*, FDA, https://www.fda.gov/drugs/drug-approvals-and-databases/resources-information-approved-drugs (last visited Aug. 1, 2022); *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*, FDA,

II. Plaintiffs' Allegations Against the Retailer Defendants

In the Petition and supporting briefing, Plaintiffs define the common issues of fact purportedly justifying centralization as follows:

> The Actions are brought by plaintiffs who allege both that prenatal exposure to APAP is responsible for their ASD or ADHD diagnosis and that the Defendants' labeling and marketing of their APAP products failed to warn pregnant women that prenatal APAP exposure is associated with and causes the neurodevelopmental harms of ASD and/or ADHD. . . . Common to all of the Actions are questions regarding . . . the adequateness of Defendants' warnings.

Pls.' Mot. at 9-10. In the underlying Actions, Plaintiffs also assert—without support—that the Retailer Defendants are involved not just in the sale of acetaminophen, but also in the "research, development, testing, manufacture, labeling, [and] production . . . of APAP"; these allegations are repeated almost verbatim in each of the Actions.[6] Taking these allegations together, adjudication of Plaintiffs' claims will necessarily require inquiry into not just the sale of OTC acetaminophen products, but also the "research, development, testing, manufacture, labeling, [and] production" of these products—all actions undertaken by the manufacturers, and not the retailers, of acetaminophen. Moreover, as described herein in Argument Section I.B., Plaintiffs' own advertising confirms that not only are Plaintiffs clearly targeting the manufacturers of these products, but also that they intend to consolidate cases involving both generic and branded

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https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm (last visited Aug. 1, 2022). A straightforward search of the Orange Book reveals that none of the Retailer Defendants are listed as the manufacturer of any drug containing acetaminophen. Specifically, if one searches for "acetaminophen" under "Proprietary Name, Active Ingredient or Application Number," the Orange Book lists 710 entries of acetaminophen-containing drugs. None of these 710 entries lists any of the Retailer Defendants as the applicant holder.

[6] *See, e.g.*, Pls.' Compl. ¶ 5, *Guzman v. Walgreens Co.*, 2:22-CV-00810 (W.D. Wash. June 9, 2022) (alleging Walgreens is involved in the research, development, testing, manufacture, labeling, production, marketing, promotion, and/or sale of APAP through its over-the-counter store brand, acetaminophen); Pls.' Compl. ¶ 6, *Janssen v. CVS Health Corp.*, 4:22-cv-00366 (W.D. Mo. June 7, 2022) (alleging same as to CVS and Walgreens); Pls.' Am. Compl. ¶ 5, *Springer v. Costco Wholesale Corp.*, 0:22-cv-01532 (D. Minn. June 9, 2022) (alleging same as to Costco).

acetaminophen. Despite Plaintiffs' allegations, it cannot be disputed that the Retailer Defendants are mere sellers, not manufacturers, of these products—and yet, Plaintiffs have failed to join as a defendant any manufacturer of branded or generic acetaminophen products in their Petition.

III. Current Status of Litigation

Between June 1 and June 9, 2022, Plaintiffs filed nineteen cases. Only one day later, the same plaintiffs filed their Petition. A review of the publicly available information on filed acetaminophen matters, including those purporting to assert claims against the Retailer Defendants (although some are not yet served), shows a slow and scattered progression of acetaminophen filings since the Petition date, only ten of which have been noticed as related actions. *See* ECF Nos. 24, 27, 30, 37, and 47. Eighteen additional cases[7] have been filed beyond the Actions mentioned in the various Schedules of Actions, resulting in forty-six pending matters.

As to the Retailer Defendants, cases have been filed in the following jurisdictions and each case alleges the sale of store brand OTC acetaminophen products:

Retailer	Jurisdictions Where Cases Were Filed as of August 2, 2022
Costco	4 pending matters (2 C.D. Cal.; 1 D. Minn.; 1 N.D. Cal.)
Walgreens	13 pending matters (4 N.D. Cal.; 3 W.D. Mo.; 3 C.D. Cal.; 1 D. Nev.; 1 W.D. Wash.; 1 D. Ariz.)
CVS	13 pending matters (3 W.D. Mo.; 3; N.D. Cal.; 6 C.D. Cal.; 1 D. Nev.)

[7] *See Correll v. CVS Health Corp.*, 2:22-cv-5276 (C.D. Cal.); *Mijares v. Walmart, Inc.*, 2:22-cv-05309 (C.D. Cal.); *Young v. CVS Health Corp.*, 2:22-cv-05311 (C.D. Cal.); *Bell v. Walgreens Boots Alliance*, 3:22-cv-03882 (N.D. Cal. June 30, 2022); *Contreras v. Big Lots, Inc.*, 2:22-cv-04716 (C.D. Cal.); *Wiley v. Costco Wholesale Corp.*, 3:22-cv-04083 (N.D. Cal.); *Good v. Walmart Inc.*, 4:22-cv-04442 (N.D. Cal.); *Miles v. Walgreens Boots Alliance*, 4:22-cv-04445 (N.D. Cal.); *Gevargiz v. Walgreens Boots Alliance*, 5:22-cv-04439 (N.D. Cal.); *Stark v. CVS Health Corp.*, 5:22-cv-04438 (N.D. Cal.); *Horowitz v. Costco Wholesale Corp.*, 5:22-cv-01336 (C.D. Cal.); *Ruiz v. Costco Wholesale Corp.*, 5:22-cv-01338 (C.D. Cal.); *Hillix v. Walmart Inc.*, 3:22-cv-04444 (N.D. Cal.); *Halafihi v. Walmart Inc.*, 4:22-cv-04443 (N.D. Cal.); *Hatcher v. Walmart Inc.*, 2:22-cv-01225 (D. Nev.); *Hernandez v. Walmart Inc.*, 5:22-cv-01331 (C.D. Cal.); *Gray v. Walmart Inc.*, 5:22-cv-01332 (C.D. Cal.); *Hampton v. Walmart Inc.*, 5:22-cv-01337 (C.D. Cal.).

ARGUMENT

I. Centralization Is Unwarranted and Premature at This Time

A. Plaintiffs have failed to name parties necessary for the adjudication of their claims.

The Actions center on the claim that Plaintiffs used acetaminophen products while pregnant because the Retailer Defendants marketed acetaminophen products as a safe pain reliever for pregnant women. Pls.' Mot. at 3. Plaintiffs further contend that the Retailer Defendants knew or should have known that prenatal exposure to acetaminophen can cause ASD or ADHD, and failed to warn Plaintiffs of the alleged risk. *Id.* However, Plaintiffs themselves concede that their claims hinge not on the sale and marketing of these drugs, but in reality, on the actions of the manufacturers—*i.e.*, "research, development, testing, manufacture, labeling, [and] production" of acetaminophen. *Supra* note 6 and accompanying text.

For Plaintiffs to proceed with these claims to any degree of success, the primary necessary pre-trial discovery will target the design, manufacture, testing, regulatory history, labeling history, post-market surveillance, and scientific data underlying acetaminophen and prenatal exposure. That information lies with the manufacturers of these products. Yet Plaintiffs have failed to name any such manufacturer of branded or generic acetaminophen products in their Petition. As a result, any centralization of the Actions, which currently implicate only sellers of certain of the drugs at issue, would be a futile exercise at this stage. The Petition should be denied on these grounds.

B. Plaintiffs' advertising undermines the Petition and weighs against centralization.

Although the cases listed in the Actions conveniently reference only generic acetaminophen products and retailers that allegedly sold such products, Plaintiffs' own advertisements demonstrate that this is mere gamesmanship and an attempt to obtain the forum of their choice. To be clear, any doubt about the true nature of Plaintiffs' claims is allayed by a review of plaintiffs' attorneys' own publicly available advertising, which shows that the

proceeding Plaintiffs hope to form pertains to the manufacturers of branded Tylenol® and generic acetaminophen, and is not, in fact, limited to the retailers/sellers named thus far. Plaintiffs' attorneys are actively soliciting claimants who took branded Tylenol® and generic acetaminophen.[8] To the extent that the advertisements reference "acetaminophen" generally, none of them identify any particular store brands of acetaminophen products—*i.e.*, generic products sold by the Retailer Defendants—and none of them target any retailer, by name or otherwise. For example:

- "If you're considering taking legal action against the manufacturer of Tylenol, contact our team today. We have years of experience holding negligent manufacturers accountable for the harm they cause consumers and we'll review your case at no cost." *See* Exs. F, H, K (emphasis added).

- "As a result of this research, lawsuits are being filed against Tylenol and acetaminophen manufacturers by parents whose children suffered harm because of the drug. Plaintiffs in the Tylenol lawsuit have alleged that [Johnson & Johnson] neglected to disclose the risks associated with using their product while pregnant." *See* Ex. J (emphasis added).

[8] *See, e.g.*, https://tylenolautismattorney.com (Watts Guerra LLC) (last visited June 27, 2022) (Ex. B); https://www.tylenolchildclaims.com (Bernstein Liebhard LLP) (last visited June 27, 2022) (Ex. C); https://www.rxinjuryhelp.com/tylenol/autism (Bernstein Liebhard LLP) (last visited June 27, 2022) (Ex. D); https://www.tylenolprenatalclaims.com (Keller | Postman) (last visited June 27, 2022) (Ex. E); https://www.cofmantownsley.com/cases-we-handle/drug-injury/tylenol-child-autism (Cofman Townsley) (last visited June 27, 2022) (Ex. F); http://www.tylenolbabyinjury.com (The Dampier Law Firm, P.C.) (last visited June 27, 2022) (Ex. G); https://www.nphm.com/cases-we-handle/defective-product/tylenol-child-autism (Nurenberg Paris) (last visited June 27, 2022) (Ex. H); https://personalinjurylawcal.com/mass-torts/tylenol-adhd-autism-lawsuit (Nadrich & Cohen) (Ex. I); https://www.themasstortalliance.com/tylenol-childhood-neurological-disorders-lawsuit (Mass Tort Alliance) (Ex. J); https://www.lundylaw.com/tylenol-child-autism (Lundy Law) (last visited June 27, 2022) (Ex. K); https://www.lawyerworks.com/drug-injury/other-drug-injuries/tylenol (Ferrer Poirot Wansbrough Feller Daniel) (last visited June 27, 2022) (Ex. L); https://www.tylenolclaim.com/sign-up (Troxel Law) (last visited June 27, 2022) (Ex. M); https://topclassactions.com/lawsuit-settlements/prescription/autism-after-tylenol-during-pregnancy-lawsuit-investigation (Law Office of Steven Gacovino) (last visited June 27, 2022) (Ex. N); https://www.torhoermanlaw.com/tylenol-acetaminophen-autism-adhd-lawsuit (TorHoerman Law, LLC) (last visited June 27, 2022) (Ex. O). This Panel may take judicial notice of these advertisements. *See, e.g.*, *Perkins v. LinkedIn Corp.*, 53 F. Supp. 3d 1190, 1204 (N.D. Cal. 2014) (holding that publicly available websites are proper subjects of judicial notice).

- "A lawsuit enables individuals to hold large manufacturers accountable for their actions, possibly reducing the risk of others experiencing the same complications." *See* Ex. E (emphasis added).

- "Even though studies show that exposure to Tylenol during pregnancy significantly increases the risk of ADHD and autism, the makers of Tylenol still do not warn pregnant women about the potential dangers." *See* Ex. M (emphasis added).

- "Our Tylenol child autism lawsuit attorneys have decades of experience holding drug manufacturers accountable for the harm they've caused families . . . . Reach out to our firm today . . . ." *See* Ex. L (emphasis added).

Thus, not only do the plain allegations in the Petition and the Actions confirm that necessary parties are not present, but the very nature of Plaintiffs' own advertising suggests that the ultimate goal for this litigation is to pursue their claims, at a minimum, against Tylenol® and generic acetaminophen manufacturers. Plaintiffs' Petition skirts this issue, seeking to disenfranchise entities that are at the core of Plaintiffs' claims from an opportunity to propose proper venue. The Petition should be denied, if not outright, then at least as premature, until the true interested parties are joined and can advocate on their own behalves.

C. Centralization will not promote the just and efficient conduct of these proceedings.

As this Panel has explained:

> The 'just and efficient conduct' of the actions is the most important of the statutory criteria [under section 1407]. And, as the statute and congressional reports emphasize, the existence of a common fact is not enough to justify transfer of litigation to a single district; there must be a showing that the transfer will produce 'significant economy and efficiency of judicial administration.'

In re Equity Funding Corp. of Am. Sec. Litig., 375 F. Supp. 1378, 1393-94 (J.P.M.L. 1974) (Wisdom, J., dissenting) (emphasis added).

Here, with only forty-six filed cases in different jurisdictions, the formation of an MDL will have the opposite effect—by transferring cases away from Plaintiffs' home courts and generating a proliferation of other lawsuits that would not otherwise be filed. Indeed, the Panel

has noted that where, as here, there are only a marginal number of actions pending, "'it is doubtful the transfer would enhance the convenience of parties and witnesses or promote judicial efficiency.'" *In re Scotch Whiskey*, 299 F. Supp. 543, 544 (J.P.M.L. 1969) (quoting S. Rep. No. 90-454, at 4-5 (1968)); *accord In re Highway Accident in Buffalo Cnty., Neb., on Aug. 22, 2000*, 305 F. Supp. 2d 1359, 1360 (J.P.M.L. 2004). For these reasons, this Panel has repeatedly declined to establish an MDL where the litigation involves a small number of individual product liability cases. *See, e.g.*, *In re Proton-Pump Inhibitor Prods. Liab. Litig.*, 273 F. Supp. 3d 1360, 1362-63 (J.P.M.L. 2017) (denying centralization of thirty-nine products liability actions because "although plaintiffs almost guarantee that the number of actions will increase by the hundreds if not thousands, the Section 1407 motion presently encompasses just fifteen cases and 24 tag-alongs"); *In re Intuitive Surgical, Inc., Da Vinci Robotic Surgical Sys. Prods. Liab. Litig.*, 883 F. Supp. 2d 1339, 1340 (J.P.M.L. 2012) (denying centralization of five personal injury and wrongful death actions involving alleged defects in a surgical device); *In re Abbott Labs., Inc., Similac Prods. Liab. Litig.*, 763 F. Supp. 2d 1376, 1376-77 (J.P.M.L. 2011) (denying centralization of nine actions alleging injury from recalled baby formula); *In re Prof. Basketball Antitrust Litig.*, 344 F. Supp. 1405, 1407 (J.P.M.L. 1972) (denying transfer of eight cases without prejudice because centralization was premature).

Here, Plaintiffs attempt to obscure the fact that there is no urgent need for centralization by asserting that they expect "tens of thousands, if not hundreds of thousands" of cases to be filed. *See* Pls.' Mot. at 12. But the Panel need not and should not speculate about whether and how the litigation might expand, and should instead look to the currently filed cases. *See In re Intuitive Surgical*, 883 F. Supp. 2d at 1340 (denying motion to transfer, noting, "[w]hile proponents maintain that this litigation may encompass 'hundreds' of cases or 'over a thousand' cases, we are

presented with, at most, five actions").

To date, there are just forty-six cases naming ten retailer defendants. The named defendants in the Actions vary from case to case and the jurisdictions in which they are sued, and their combination with other retailer defendants is likewise varied. Centralization thus appears unlikely to serve the convenience of most, if not all, of the currently-named defendants and their witnesses. *See, e.g.*, *In re Ambulatory Pain Pump-Chondrolysis Prods. Liab. Litig.*, 709 F. Supp. 2d 1375, 1377 (J.P.M.L. 2010) (denying centralization of 102 actions, in part because most, if not all, defendants were named "in only a minority of actions," and several were sued in "but a handful"); *In re Table Saw Prods. Liab. Litig.*, 641 F. Supp. 2d 1384, 1385 (J.P.M.L. 2009) (denying centralization of forty-two actions, where, *inter alia*, no defendant was sued in all actions, and several entities were named in, at most, two or three).

This Panel should also deny centralization because it is expected that "individualized factual issues concerning causation will predominate and diminish the potential to achieve significant efficiencies in an MDL[.]" *See In re Belviq (Lorcaserin HCI) Prod. Liab. Litig.*, 555 F. Supp. 3d 1369, 1369-70 (J.P.M.L. 2021). Although Plaintiffs' Petition lumps together ASD and ADHD as though they are indistinguishable, they are two different medical conditions with distinct causes and risk factors.[9] Moreover, ASD is, by definition, a "spectrum" disorder manifesting in myriad ways, without any definitive or single identified cause, although it is speculated that many things may or may not contribute. Plaintiffs' blanket assertion that there are common issues that warrant centralization glosses over serious issues concerning variability in

[9] *See What is Autism Spectrum Disorder?*, Center for Disease Control and Prevention, https://www.cdc.gov/ncbddd/autism/facts.html (last visited Aug. 1, 2022); *What is ADHD?*, Center for Disease Control and Prevention, https://www.cdc.gov/ncbddd/adhd/facts.html (last visited Aug. 1, 2022).

injury and causation here that actually mitigate against centralization, as each case will focus on unique specific causation issues.

Finally, the FDA's own recent pronouncements underscore that centralization is unnecessary. Despite Plaintiffs' allegations, the FDA has reviewed claims such as those made by Plaintiffs and has decided not to change any recommendations made to pregnant women taking acetaminophen. Specifically, in 2015, the FDA announced that it had reviewed research studies published in medical literature regarding the alleged risk of ADHD in children born to women who took acetaminophen during pregnancy.[10] The FDA concluded that such studies were too limited and declined to make any changes in recommendations on how to use pain medicines, such as acetaminophen, during pregnancy. *Id.* The FDA publicly reiterated this position most recently on June 14, 2022.[11]

Accordingly, the Panel can and should deny centralization at this stage.

II. If the Panel Grants the Petition, the Northern District of California, the Western District of Missouri, and the District of Minnesota Are Not Appropriate Forums

Although this Panel should reject the formation of an MDL at this time, if the Panel is inclined to centralize the Actions, then it should reject Plaintiffs' suggestion for coordination in the Northern District of California, the Western District of Missouri, or the District of Minnesota.

In selecting the transferee court, the Panel considers several factors, including, but not limited to, "where discovery has occurred, where cases have progressed furthest, the site of the

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

[11] *See Fact Check: NO Evidence Tylenol Use during Pregnancy Is Linked to Autism*, Lead Stories (July 14, 2022) https://leadstories.com/hoax-alert/2022/07/fact-check-no-evidence-tylenol-use-during-pregnancy-linked-to-autism.html.

occurrence of the common facts, where the cost and inconvenience will be minimized, and the experience, skill, and caseloads of available judges." *See* Manual for Complex Litigation (Fourth) § 20.131 (2004). Additional factors that have been considered include: (1) the location of relevant documents and witnesses, (2) the backlog of a court's civil docket and the extent to which it is overtaxed with other MDL cases, (3) a centrally located forum for national litigation, (4) the potential for state-federal coordination, and (5) the preference of the parties. *See id.* at §§ 6:1-6:23; *In re Inter-Op Hip Prosthesis Prods. Liab. Litig.*, 149 F. Supp. 2d 931, 933-34 (J.P.M.L. 2001); *In re Express Scripts, Inc., Pharmacy Benefits Mgmt. Litig.*, 368 F. Supp. 2d 1356, 1357 (J.P.M.L. 2005). Ultimately, the Panel selects a transferee forum based on a determination that the judicial district is best suited to promote the purpose of Section 1407.

A. The Northern District of California is not an appropriate or convenient forum.

Plaintiffs request—without any support—centralization in the Northern District of California. Specifically, Plaintiffs assert in a single-sentence footnote that the Northern District of California would be an appropriate transferee court. *See* Pls.' Mot. at 16. Yet Plaintiffs offer absolutely no justification for their request, and the Panel should reject it for two primary reasons:

First, the Northern District of California is not centrally located for this litigation, weighing against its selection as a potential transferee court. A simple search of publicly-available data confirms the manufacturers of OTC acetaminophen products, and the Panel must recognize that none of the manufacturers of branded or generic OTC acetaminophen has a principal place of business in California or is incorporated in California.[12] In fact, none of these companies are even

[12] LNK International, Inc., which manufactures acetaminophen products for Walgreens, CVS and Costco, is a New York corporation with its principal place of business in New York. Ohm Laboratories, Inc., which manufactures acetaminophen products for Walgreens and CVS, is a New Jersey corporation with its principal place of business in New Jersey. Hi-Tech Nutraceuticals, LLC, which manufactures acetaminophen products for Walgreens, is a Pennsylvania corporation with its principal place of business in Pennsylvania. Perrigo Company plc is a foreign entity

headquartered in a state located on the West Coast of the United States. Nor are Costco, Walgreens, or CVS based in California. Therefore, this factor weighs against centralization in the Northern District of California.

To the extent that Plaintiffs' request is based on some Plaintiffs residing in California, that fact should be inconsequential to this Panel's analysis. Assuming, *arguendo*, the truth of Plaintiffs' claim that there will be "tens of thousands, if not hundreds of thousands," of additional actions, Pls.' Mot. at 12, the litigation will almost certainly encompass plaintiffs who reside in every state of the United States. Indeed, Plaintiffs threaten that the litigation will be brought by "an omnipresent plaintiff population of mothers located across our country, with pregnancy usage and child diagnosis witnesses located everywhere." *See* Pls.' Mot. at 16 (emphasis added). Thus, the residences of certain Plaintiffs in the initial Actions is immaterial and should not bear on the Panel's forum selection.

Second, by a large margin, the majority of the relevant witnesses and documents in this litigation will not be located in California. As shown above, discovery in the Actions will doubtlessly revolve around other entities—namely, the manufacturers of branded and generic acetaminophen products. And even as to the Retailer Defendants' own operations with respect to the sale and marketing of the acetaminophen products, the Retailer Defendants are not located in California. Plaintiffs likewise have not suggested that any corporate witnesses, documents, or relevant evidence are located in California. By contrast, and as outlined below, the primary

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organized under the laws of Ireland, and runs its U.S. operations out of Michigan. Aurobindo Pharma Ltd., Humanwell PuraCap Pharmaceuticals (Wuhan) Co., Elysium Pharmaceuticals Ltd., Medgel Private Ltd., and APL Healthcare Ltd., are all foreign entities incorporated under the laws of either India or China, all of which appear to run their U.S. operations out of states other than California, including, in the case of Aurobindo Pharma, New Jersey. Johnson & Johnson Consumer Inc., which is the company that manufactures and sells branded Tylenol®, is a New Jersey corporation with its principal place of business in New Jersey.

witnesses, documents, and relevant evidence are likely located on the East Coast, and in many cases, specifically, in New Jersey or the Tri-State area.

If the Panel is ultimately inclined to form an MDL, the Actions should be centralized in a location where the evidence is likely to be located. Plaintiffs have made absolutely no showing that location is the Northern District of California.

B. The Western District of Missouri is not an appropriate or convenient forum.

On July 29, 2022, a plaintiff in one of the Actions[13] ("Plaintiff Gaddis") filed an Interested Party Response in Support of Plaintiffs' Motion to Transfer, *see* ECF No. 36, positing that the Actions should be centralized in the Western District of Missouri before Judge Stephen Bough. This Panel should reject the Western District of Missouri as a transferee court for the same reasons that it should decline to form an MDL in the Northern District of California. In particular, the Western District of Missouri is an inconvenient forum for this litigation because none of the current defendants or manufacturers of branded or generic OTC acetaminophen, *see supra* note 12, has a principal place of business in Missouri or is incorporated in Missouri, and consequently, there has been no showing that any witnesses, documents, or relevant evidence are located there.

Additionally, although Plaintiff Gaddis alludes to "significant" advancement of the cases pending in the Western District of Missouri, the procedural posture of these matters is no more advanced than that of any of the individual Actions—no defendant has filed a responsive pleading and several of the cases have been stayed in light of the Petition. Nor have any of the Actions in the Western District of Missouri been assigned to Judge Bough. Therefore, there is no basis to assert that Judge Bough has any familiarity with the subject matter of this litigation.

If the Panel decides to centralize the Actions, it should decline to select the Western District

[13] *See Gaddis v. Wal-Mart Stores, Inc.*, 4:22-cv-00367 (W.D. Mo. filed June 1, 2022).

of Missouri as a transferee court.

C. The District of Minnesota is not an appropriate or convenient forum.

On August 1, 2022, another plaintiff[14] filed an Interested Party Response in Support of Plaintiffs' Motion to Transfer, *see* ECF No. 42, suggesting the District of Minnesota as a potential forum. Like the Western District of Missouri, the District of Minnesota is also not a convenient forum. Although Target is based in Minnesota, it has only been named in two cases and CVS, Walgreens, and Costco are not based in Minnesota, nor are their suppliers. Thus, as with the Northern District of California and the Western District of Missouri, this Panel should reject the District of Minnesota as a transferee court.

D. The District of New Jersey is a more suitable forum to centralize the Actions.

In this case, the District of New Jersey is a far more appropriate transferee court for the Actions, for several crucial reasons:

First, the most concentrated volume of relevant documents and witnesses are likely to be located in or near New Jersey. Because Plaintiffs have elected to proceed at this stage solely against national retailers, it is tempting to assume that there is no central nexus for this litigation. However, looking past Plaintiffs' attempt to ignore the existence of acetaminophen manufacturers, it is clear that New Jersey provides the most opportunity for common ground respecting forum selection. The manufacturers of branded and generic acetaminophen products—including Johnson & Johnson Consumer Inc., the market share leader for acetaminophen—are based in New Jersey. *See supra* note 12. Additionally, a number of generic manufacturers also are based in New Jersey or in the Tri-State area. *Id.* As to the remaining manufacturers, most are foreign corporations with U.S. operations based in locations across the country but, notably, not in the western U.S. *Id*.

[14] *See Funk v. Walmart, Inc.*, 0:22-cv-01809 (D. Minn. filed July 18, 2022).

Consequently, the vast majority of the key evidence and witnesses, including indispensable parties' current and former employees with substantive knowledge and decision-making authority regarding the regulatory submissions, labeling, clinical trials, post-market surveillance, regulatory compliance, marketing, and sale of branded and generic acetaminophen products, are likely to be located in or near New Jersey—a fact which the Panel previously has recognized. *See, e.g.*, *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Practices & Prods. Liab. Litig.*, 220 F. Supp. 3d 1356, 1359 (J.P.M.L. 2016) ("As Johnson & Johnson is headquartered in New Jersey, relevant evidence and witnesses likely are located in the District of New Jersey"); *In re Benicar (Olmesartan) Prods. Liab. Litig.*, 96 F. Supp. 3d 1381, 1383 (J.P.M.L. 2015) (selecting the District of New Jersey for multidistrict proceedings because "defendants[] are headquartered in that district, and thus many witnesses and relevant documents are likely to be found there"); *In re Cook Med., Inc., IVC Filters Mktg., Sales Practices & Prods. Liab. Litig.*, 53 F. Supp. 3d 1379, 1381 (J.P.M.L. 2014) (establishing MDL in the Southern District of Indiana in part because "[defendant] Cook is headquartered in Indiana, where relevant documents and witnesses are likely to be found"); *In re Darvocet, Darvon & Propoxyphene Prod. Liab. Litig.*, 780 F. Supp. 2d 1379, 1382 (J.P.M.L. 2011) (granting transfer to the district where the defendant's headquarters were located, as "[r]elevant documents and witnesses" were likely located there); *In re Vytorin/Zetia Mktg., Sales Practices & Prod. Liab. Litig.*, 543 F. Supp. 2d 1378, 1380 (J.P.M.L. 2008) (same).

Second, the vast and pertinent experience of judges in the District of New Jersey suggests that it is the most appropriate forum for centralization. The District of New Jersey has a substantial bench of qualified MDL judges, many of whom have experience managing mass tort proceedings involving pharmaceuticals and product liability claims. The District of New Jersey has been recognized time and again by this Panel as an especially efficient and experienced forum for

managing pharmaceutical MDLs. This Panel has centralized numerous drug and device actions in the District of New Jersey in the last 30 years—a number of which are terminated or appear to be nearing termination—in recognition of its expertise in these matters and it being a convenient and efficient forum to litigate such disputes. *See, e.g.*, *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No. II)*, MDL No. 2243; *In re Valsartan, Losartan, and Irbesartan Prods. Liab. Litig.*, MDL. No. 2875; *In re Elmiron (Pentosan Polysulfate Sodium) Prods. Liab. Litig.*, MDL No. 2973; *In re Allergan Biocell Textured Breast Implant Prods. Liab. Litig.*, MDL No. 2921; *In re Proton-Pump Inhibitor Prods. Liab. Litig. (No. II)*, MDL No. 2789; *In re Invokana (Canagliflozin) Prods. Liab Litig.*, MDL No. 2750 (nearing termination); *In re Benicar (Olmesartan) Prods. Liab. Litig.*, MDL No. 2606 (terminated in 2020); *In re Plavix Marketing, Sales Practices & Prods. Liab. Litig.*, MDL No. 2418 (terminated in 2020); *In re Zimmer Durom Hip Cup Prods. Liab. Litig.*, MDL No. 2158 (terminated in 2020); *In re Vytorin/Zetia Marketing, Sales Practices & Prods. Liab. Litig.*, MDL No. 1938 (terminated in 2010); *In re Human Tissue Prods. Liab. Litig.*, MDL No. 1763 (terminated in 2014); *In re Pantopaque Prods. Liab. Litig.*, MDL No. 920 (terminated in 2001).

Third, the District of New Jersey's current case docket suggests that if the Actions were centralized, that court has the resources and capacity to handle such an MDL. Specifically: (1) case filings have substantially decreased from 27,050 between March 2020 and March 2021 to 17,275 during March 2021 and March 2022—a decrease of almost 10,000 cases; (2) between March 2020 and March 2021, each judgeship had 1,542 civil filings, which decreased to 957 civil filings during March 2021 and March 2022; and (3) the District of New Jersey appointed or elevated six judges to district court judgeships in 2021 and 2022.[15]

[15] *See U.S. District Courts – Federal Court Management Statistics—Profiles*, Federal Court Management Statistics, https://www.uscourts.gov/sites/default/files/fcms_na_distprofile_0331.2022.pdf (last visited Aug. 1, 2022); *see also Biographical Directory of Article III Federal Judges,*

Fourth, the District of New Jersey is centrally located and a convenient location for all counsel. Like the parties themselves, counsel for the defendants are scattered across the country, but many have offices on the East Coast, with easy access to New Jersey. Plaintiffs' lead counsel are located in Illinois and Texas, making New Jersey as convenient, if not more, than Northern California. And because the District of New Jersey generally is geographically accessible to all counsel and potential parties involved in this litigation, it is the optimal choice for a transferee forum. *See, e.g.*, *In re Comp. of Managerial, Prof'l & Technical Emp. Antitrust Litig.*, 206 F. Supp. 2d 1374, 1375-76 (J.P.M.L. 2002) (holding District of New Jersey is an "accessible, urban district[] equipped with the resources that [a] complex docket is likely to require"); *In re Nickelodeon Consumer Privacy Litig.*, 949 F. Supp. 2d 1377, 1378 (J.P.M.L. 2013) (stating that the District of New Jersey is "a convenient and accessible forum, relatively close to potential witnesses and evidence located in New Jersey and New York City. The district also has the resources and capacity to efficiently handle this litigation."); *In re Johnson & Johnson Talcum Powder Prod. Mktg., Sales Practices & Prod. Liab. Litig.*, 220 F. Supp. 3d at 1359 (providing that the District of New Jersey is "a convenient and accessible forum[,]" citing its close proximity to other jurisdictions on the East Coast); *In re Hypodermic Prods. Antitrust Litig.*, 408 F. Supp. 2d 1356, 1357 (J.P.M.L. 2005) (holding that the District of New Jersey "is an accessible location that will be geographically convenient for many of this docket's litigants, witnesses and counsel" and is "well equipped with the resources" for a complex litigation).

In sum, should the Panel elect to grant Plaintiffs' Petition, all of the above-referenced

1789-Present, Federal Judicial Center, https://www.fjc.gov/history/judges/search/advanced-search (last visited Aug. 1, 2022) (searching by D.N.J. judges nominated on or after Jan. 1, 2021).

reasons weigh heavily in favor of centralizing these cases in the District of New Jersey.[16]

CONCLUSION

For the reasons set forth above, the Retailer Defendants respectfully request that this Panel deny Plaintiffs' Petition as both unwarranted and premature. Should the Panel, however, grant the Petition, the Retailer Defendants respectfully request that the centralized proceedings be administered in the District of New Jersey.[17]

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Respectfully submitted,

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[16] If the Panel determines that the District of New Jersey is not available for centralization of this litigation, the Panel should centralize the Actions in the nearby Southern District of New York. This Panel has repeatedly acknowledged that the Southern District of New York is an "accessible, metropolitan location" well suited for an MDL. *See, e.g.*, *In re Rhodia SA. Sec. Litig.*, 398 F. Supp. 2d 1359, 1360 (J.P.M.L. 2005); *In re Keurig Green Mountain Single-Serve Coffee Antitrust Litig.*, 24 F. Supp. 3d 1361, 1363 (J.P.M.L. 2014); *In re Tribune Co. Fraudulent Conveyance Litig.*, 831 F. Supp. 2d 1371, 1372 (J.P.M.L. 2011). The Southern District of New York is also in close to proximity to New Jersey, which is where most manufacturers of branded and generic acetaminophen products are headquartered, and Rhode Island, where CVS is based. The Panel has typically transferred matters to a district within close proximity to where the relevant witnesses and documents are located. *See, e.g.*, *In re W. States Wholesale Nat. Gas Antitrust Litig.*, 290 F. Supp. 2d 1376, 1378 (J.P.M.L. 2003) (appropriate transferee forum was adjacent to, and within the same circuit as, the district with closet nexus). Thus, for the same reasons supporting coordination in the District of New Jersey, the Southern District of New York serves as a strong alternative forum.

[17] In light of the unsettled nature of Plaintiffs' claims, the Retailer Defendants anticipate that the procedural and factual landscape of the litigation will likely change significantly in advance of the hearing on the Petition on September 29, 2022. The Retailer Defendants respectfully request the opportunity to seek leave to file a sur-reply in advance of the September 29th hearing if necessary.