UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: Acetaminophen – ASD-ADHD Products Liability Litigation	**22md3043 (DLC)**

This Document Related To: All Cases

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' RULE 702 MOTION TO EXCLUDE DR. MARY D'ALTON

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases — Page(s)

Rules

Plaintiffs respectfully submit this Memorandum of Law in Support of their Motion to Exclude the Opinions of Mary D'Alton, M.D.,[1] who has been offered as an expert by Defendants in the above-captioned litigation.

PRELIMINARY STATEMENT

Back in April, Plaintiffs proposed that pregnant women be warned: "Some studies show that frequent use of this product during pregnancy may increase your child's risk of autism and attention deficit hyperactivity disorder. If you use this product during pregnancy to treat your pain and/or fever, use the lowest effective dose for the shortest possible time and at the lowest possible frequency." *See* Dkt. 551 at 1.

Defendants' expert Dr. Mary D'Alton repeatedly testified that she endorses Plaintiffs' second sentence. *See* Ex. 2, D'Alton Dep. Tr. at 27:22–28:7, 52:12–15, 54:3–9, 251:1–10, 254:10–19, 322:21–323:1.[2] In her practice, "we always advise [pregnant women] not to take a drug unless it is needed for her clinical conditions. And if it is needed, to use for the shortest possible time in the lowest possible dose." *Id.* at 322:21–323:1 . And as for the first sentence in Plaintiffs' proposed label language, Dr. D'Alton noted that if pressed by a patient, she would inform them that studies show a link between prenatal acetaminophen exposure and neurodevelopmental disorders in offspring. *Id.* at 27:22–28:7 ("Q. Oh, okay. So you do discuss with them and tell them that there's literature that has been published that raises the question of whether there's risk to the

[1] Attached hereto as Exhibit 1 is the Rule 26(a)(2) Expert Disclosure of Mary E. D'Alton, M.D., dated July 21, 2023, which has annexed to it as Exhibit 1 the Expert Report of Mary E. D'Alton, M.D.

[2] Defendants' other expert agreed with the first sentence of Plaintiffs' proposed label, that "[s]ome studies show that frequent use of this product during pregnancy may increase your child's risk of autism and attention deficit hyperactivity disorder." *See* Ex. 11, Faraone et al. (2021) at 791, 795 (stating there is a "strong evidence base" that "maternal use of acetaminophen during pregnancy was associated with a 33% greater likelihood of ADHD in their children"); Ex. 12, Alexander Kolevzon Dep. Ex. 494, at 16 (concluding that "several prenatal exposures . . . emerge as potential risk factors for ASD" including "[m]ost notably . . . prenatal use of acetaminophen.").

fetus with respect to acetaminophen and ADHD and ASD? . . . [A.] You asked me if I'm asked directly about that, I do. If I'm not asked directly, I don't.").

Despite that significant point of common ground, Dr. D'Alton somehow manufactures disagreement by baldly claiming acetaminophen is perfectly safe for pregnant women. Apparently, they should use it for the shortest possible time in the lowest possible dose for no reason whatsoever. Dr. Dalton's cognitive dissonance does not withstand scrutiny. It is an opinion reached using no discernible methodology. The very epidemiologist she hired into her department, Dr. Blair Wylie, predicted OB-GYNs would hold this opinion *not* because "the epi is not good," but because of the "emotional issue" of "prioritizing [the] fetus over mother pain." *See* Ex. 3, June 24, 2022 email from Blair Wylie to Andrea Baccarelli. However well-intentioned, the law does not permit emotions to govern science, and it empowers pregnant women, not their doctors, to set their own priorities after receiving full information. Dr. D'Alton's unrigorous, conclusory assertions cannot go to a jury.

It seems that is not even Defendants' goal. From a simple review of Dr. D'Alton's testimony and report, her real function is to extol "safe" acetaminophen and besmirch Plaintiffs as "dangerous" merchants of misinformation for bringing this lawsuit in the first place. Of course, if this testimony is relevant to this litigation at all, it is certainly not relevant to general causation—the only issue presently before the Court. And at every phase of litigation, there is no place for an expert to opine on what is at bottom a legal dispute between the parties. Plaintiffs maintain that the law requires acetaminophen sellers to warn pregnant women *directly* of what Dr. D'Alton admits she would tell them if expressly asked. Her view that OG-GYNs should be the gatekeepers of information is not an expert opinion but a sincerely held conviction that is both irrelevant and out-of-step with bedrock failure-to-warn doctrine.

The Court should exclude Dr. D'Alton's testimony.

BACKGROUND

Dr. D'Alton's report considers Plaintiffs' case from the perspective of an obstetrician and maternal-fetal medicine ("OBGYN/MFM") clinician. Her two formal conclusions are that acetaminophen is "safe and effective when used as directed in pregnancy and following consultation with a physician" and "[t]he body of available literature does not show a causal relationship between the use of acetaminophen in pregnancy and ASD or ADHD." Ex. 1, D'Alton Report at 48. In addition to these conclusions, Dr. D'Alton repeatedly raises the alarm of "misinformation," including a three-page section devoted to examples of misinformation about medicines not at issue in this case, like COVID-19 vaccines, anti-depressants, seizure medications, and anti-emetics. *Id.* at 2, 29–31, 48. The "allegations in this litigation," Dr. D'Alton opines, are themselves "dangerous." *Id.* at 2.

Dr. D'Alton's conclusions are based on her "review of the literature" and her experience as a practicing OB-GYN/MFM. *Id.* at 48. Although she acknowledges that another of Defendants' experts addresses "the relevant epidemiology in full detail," she adds her opinion about causation "from the perspective of a practicing OBGYN/MFM." *Id.* at 32. Dr. D'Alton justifies this foray into epidemiological analysis by noting that OBGYN/MFMs are experienced with reviewing scientific literature to determine whether a study "can or should influence clinical practice." *Id.*

Dr. D'Alton does not include a methodology section in her report, nor does she explain her literature review process. When asked at her deposition about whether she employed any methodology in conducting her literature review or examining individual studies, she confirmed that she had not. *See* Ex. 2, D'Alton Dep. Tr. at 352:21–354:3. Despite acknowledging that she was familiar with methodologies that scientists and organizations use—including the American College of Obstetrics and Gynecology, of which she is a member—Dr. D'Alton did not use any

such methodology here. *Id.* at 88:18–22, 356:12–364:23.

Although proselytizing the putative danger this lawsuit presents, Dr. D'Alton nonetheless agrees with Plaintiffs' central premise: pregnant women should use acetaminophen judiciously during pregnancy. Dr. D'Alton testified that she concurs with "all" that "medication should not be used routinely in pregnancy," and, if it is necessary, medicines—including acetaminophen—should be taken at "the lowest dose of a medication for the shortest period of time." *Id.* at 251:1–10; *see also id.* at 322:21–323:1 ("We always advise patients not to take a drug unless it is needed for her clinical conditions. And if it is needed, to use for the shortest possible time in the lowest possible dose."); *id.* at 286:5–12 (testifying to the same). Of course, the *reason* to use acetaminophen judiciously during pregnancy is that indiscriminate use exposes the fetus to higher risk of neurodevelopmental disorders. Dr. D'Alton resists that conclusion, which is outside of her ken, but confirmed that she would tell pregnant patients about the published literature raising the risk if asked. *Id.* at 27:22–28:7. She also considers it a "require[ment]" to tell pregnant women enrolling in a clinical trial involving the effects of acetaminophen on fetuses about the risks of ASD and ADHD. *Id.* at 51:7–52:15. Moreover, Dr. D'Alton admitted that if one were to design a trial looking at the safety and efficacy of acetaminophen—something another Defense expert, Dr. Pinto Martin, says would be unethical to do, Ex. 4, Pinto-Martin Dep. Tr. at 253:13–21—then "I think [the risk of neurodevelopmental disorders] would -- in my opinion, it would require to tell patients about associations that have been reported." Ex. 2, D'Alton Dep. Tr. at 52:12–15; *see also id.* at 51:7–54:15.

LEGAL STANDARD

Plaintiffs refer the Court to the Rule 702 legal standard set forth in Plaintiffs' Memorandum in Support of their Rule 702 Motion to Exclude Dr. Wendy Chung, Dkt. 1138 at 3–5.

ARGUMENT

Plaintiffs do not challenge Dr. D'Alton's qualifications as an obstetrician or maternal-fetal medicine clinician. But those credentials do not qualify her to opine on general causation, as the subject of her report and deposition testimony make clear. And even qualified experts may only give opinions that are grounded in a reliable methodology and that serve to assist the factfinder in resolving disputed issues. *See Riegel v. Medtronic, Inc.*, 451 F.3d 104, 127 (2d Cir. 2006). Dr. D'Alton's report is deficient in all respects.

I. Dr. D'Alton's lack of methodology renders her conclusions unreliable.

Dr. D'Alton admits that she employed *no* methodology. *See* Ex. 2, D'Alton Dep. Tr. at 364:7–15 ("Well, my methodology is to go through the published literature—it doesn't have a name, My methodology is being knowledgeable of the system—of the grading system that's used by ACOG in their systematic reviews and my knowledge base as a clinician . . . ."). Knowledge and experience are crucial in *deploying* a method. But they are no stand-in for the method itself. "*Daubert* requires experts to disclose a method subject to replication and testing, for it is the testing of hypotheses to 'see if they can be falsified' that 'distinguishes science from other fields of human inquiry.'" *Daniels-Feasel v. Forest Pharms., Inc.*, No. 17 CV 4188-LTS-JLC, 2021 WL 4037820, at *21 (S.D.N.Y. Sept. 3, 2021) (citing *Daubert v. Merrell Dow Pharms, Inc.*, 509 U.S. 579, 593 (1993)), *aff'd*, No. 22-146, 2023 WL 4837521 (2d Cir. July 28, 2023). Plaintiffs and this Court cannot replicate and test Dr. D'Alton's "knowledge base as a clinician" to see if she *applied* her knowledge reasonably to the available evidence. That can be the beginning and the end of this motion.

Dr. D'Alton's reference to the ACOG system cannot salvage her testimony. ACOG

(American College of Obstetricians and Gynecologist)[3] applies the "GRADE," or "Grading of Recommendations, Assessments, Development, and Evaluations" system, which is a means for developing and presenting summaries of evidence and making clinical practice recommendations. This system allows clinicians to evaluate "how strong or not strong . . . the levels of evidence are" for a particular clinical treatment recommendation. *Id.* at 364:25–366:1.[4] It requires, among other things, setting forth a question, devising and applying an approach to identifying the evidence, and rating the evidence using objective criteria. *See* Ex. 5, Granholm (2019).

While that systematic review could well be an acceptable version of a weight-of-the-evidence methodology, Dr. D'Alton did not deploy that method. She simply noted that she was "knowledgeable" of GRADE, and thus she surely knew the difference between what she actually did and what the GRADE methodology requires. Ex. 2, D'Alton Dep. Tr. at 366:16–21 ("Q. You have articulated no grading system in your report where you even attempted to develop and use an a priori system to evaluate the literature? A. I did not do that no, I've stated that for you today."). When confronted with her lack of objective analysis of the literature, she maintained that another expert was doing that. *Id.* at 365:21–366:1. ("No, I didn't do that in my report because I was knowledgeable that an epidemiologist was doing that, and that was—that was not something that I, as a clinician, needed to weigh in on."). Notably, Dr. D'Alton has actually published on the issue of using appropriate scientific methodologies to evaluate the quality of published scientific

[3] Dr. D'Alton's relationship with ACOG runs long and deep. Even a cursory review of Dr. D'Alton's *curriculum vitae* annexed to her Report reflects decades of involvement with ACOG, including regional and national leadership positions, which Dr. D'Alton summarizes this way in her Report: "I also have served on numerous committees and in leadership roles with the American College of Obstetrics and Gynecology (ACOG)." Ex. 1, D'Alton Report at 3.

[4] An explanation of the GRADE framework is available online: https://www.gradeworkinggroup.org/. Notably, the ACOG opinion statement on acetaminophen and neurodevelopmental disorders cited in Dr. D'Alton's report is devoid of citation, and thus, to the extent that ACOG may employ the GRADE methodology elsewhere, like Dr. D'Alton, ACOG did not use GRADE in the purported analysis of the issues relevant here.

literature. *See id.* at 89:21–94:18. She simply chose not to apply those methodologies here.

In addition to committing the fatal omission of not applying an objective methodology, Dr. D'Alton also did not keep a list of search terms she used or a record of how many hits such terms returned. *Id.* at 353:11–354:22. When asked how anyone could verify whether her analysis was complete or confirm that she had conducted a comprehensive review, Dr. D'Alton responded only that she "wanted to be as complete as possible" and "hope[s] [she] did not miss anything important." *Id.* at 355:8–21. That is not enough. Without information sufficient "to reconstruct [Dr. D'Alton's] searches," it is "impossible for a court or adversary to test—or a jury to assess—[her] methodology, as applied here for veracity and reliability. . . . [E]xclusion of [Dr. D'Alton's] conclusions is mandatory under *Daubert*." *LVL XIII Brands, Inc. v. Louis Vuitton Malletier S.A.*, 209 F. Supp. 3d 612, 645 (S.D.N.Y. 2016) (internal citation omitted).

Expert witnesses must bring to "the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). Dr. D'Alton knows what methodological approach her profession requires. She has applied it in the past. She simply failed to bring those practices to this litigation. Her opinions must be excluded.

II. Dr. D'Alton cherry-picked the evidence.

Dr. D'Alton cherry-picked the literature she considered and ignored highly relevant evidence that supports Plaintiffs' position. "Cherry-picking is a form of '[r]esult-driven analysis,' which 'undermines principles of the scientific method' by 'applying methodologies (valid or otherwise) in an unreliable fashion.'" *See Daniels-Feasel*, 2021 WL 4037820 at *8 (Sept. 3, 2021) (alteration in original) (quoting *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prods. Liab. Litig. (No II) MDL 2502*, 892 F.3d 624, 634 (4th Cir. 2018)).

Dr. D'Alton admits she did not inquire or review any of Defendant Johnson & Johnson

Consumer Inc.'s ("JJCI") internal information regarding acetaminophen and neurodevelopmental disorders, even though she acknowledged that such information may be useful to reaching her opinions in this case. *See* Ex. 2, D'Alton Dep. Tr. at 390:3–11. Dr. D'Alton published a book saying a clinician should know a "manufacturer's most current product information." Mary E. D'Alton et al., *Maternal-fetal Medicine* ii (2007). And in this case, Dr. D'Alton specifically acknowledged that knowing what JJCI thought about acetaminophen could be useful. *See* Ex. 2, D'Alton Dep. Tr. at 390:9–11. JJCI's internal documents undoubtedly would have been relevant to her opinion in this case that the "allegations in this litigation [are] unsupported by science [and] dangerous to women and general public health," Ex. 1, D'Alton Report at 1, [redacted] Ex. 7, Exhibit 988 to D'Alton Dep. at § 4.6 (discussed at Ex. 2, D'Alton Dep. Tr. at 388:21–389:2).

Other internal documents also show that JJCI recognizes the risk documented in the scientific literature. [redacted] Weinstein made that comment in response to a systemic review, which concluded that "[g]iven the current findings, pregnant women should be

[redacted]

cautioned against the indiscriminate use of APAP. These results have substantial public health implications." Ann Z. Bauer et al., *Prenatal Paracetamol Exposure and Child Neurodevelopment: A Review*, 101 Hormones & Behav. 125 (2018). Dr. D'Alton neither asked to see—nor did her client, JJCI, provide her with—any of these (or other) relevant company documents concerning acetaminophen's safety. Ex. 2, D'Alton Dep. Tr. at 374:2–21.

Beyond JJCI's internal documents, Dr. D'Alton also did not review any animal studies in preparing her report:

> Q: And you did not evaluate any of the animal literature, correct?
>
> A: No. My knowledge base is not in animal research, and it is my opinion that animal research on Tylenol does not impact my clinical opinion.
>
> Q: Well, how would you know that if you haven't read any of it? . . .
>
> A: Because of what I know about animal research related to other drugs, that it has no impact on the clinical opinion when there's human data.

Ex. 2, D'Alton Dep. Tr. at 366:22–367:12. The best excuse she can offer is definitionally circular—animal studies are irrelevant to her views as a clinician because, as a clinician, she deems them irrelevant. [redacted] The FDA also disagrees with Dr. D'Alton, as the FDA stated that "[a]dditional long term studies of behavioral development in children following prenatal exposure to APAP would certainly be useful, but would not provide direct evidence of causality. Preclinical data may be more informative in that regard." Dkt. 483-1 at FDACDER000008; *see also id.* at FDACDER000115 ("To better understand the impact of prenatal APAP exposure on neurobehavioral and urogenital development, nonclinical toxicological studies continued to be needed.").

Similarly, Dr. D'Alton admitted she was unaware of the prescribing information for an IV acetaminophen drug Ofirmev, which speaks to the safety profile of acetaminophen for pregnant women. It was designated Pregnancy Category C based on preclinical studies of oral acetaminophen. Ex. 9, Exhibit 915A to D'Alton Dep. at § 8.1 (discussed at Ex. 2, D'Alton Dep. Tr. at 392:6–403:13). The Ofirmev label contains a section that describes the fetotoxic effects of human-equivalent therapeutic doses of acetaminophen observed in animal studies, which formed the basis for the Pregnancy Category C designation. *See id*. Likewise, Dr. D'Alton was not even aware of the prescribing information for Ultracet, which is manufactured by Janssen Pharmaceuticals, a Johnson & Johnson subsidiary. Ex. 10, Exhibit 915B to D'Alton Dep. (discussed at Ex. 2, D'Alton Dep. Tr. at 403:17–410:24). Like the Ofirmev label, the Ultracet label contains a description of the reproductive and developmental animal studies showing evidence of fetotoxicity at clinically relevant doses of acetaminophen. *See id* at § 8.1. The Ultracet label, which Dr. D'Alton had claimed to have never seen, instructs physicians, "Based on animal data, advise pregnant women of the potential risk to a fetus." *See id.* (discussed at Ex. 2, D'Alton Dep. Tr. at 409:14–410:24).

Apart from excluding information not even Defendants can reasonably consider irrelevant, Dr. D'Alton chose not to address, reconcile, or distinguish information that could contradict or complicate her desired result: that acetaminophen is safe. She did not check if other OBGYN/MFM practitioners agreed with her conclusions. Ex. 2, D'Alton Dep. Tr. at 453:2–13 ("[Q.] I asked you whether or not you went to the Internet, and you searched to find out if there are other qualified, competent OB/GYNs or maternal-fetal medicine experts that disagree with you. . . . [A.] No, I have not done that."). She ignores anything that could challenge her view. This failure is "large enough" to question Dr. D'Alton's conclusions and the reliability of her testimony.

Amorgianos v. Nat'l R.R. Passenger Corp., 303 F.3d 256, 267 (2d Cir. 2002) (quoting *In re Paoli R.R. Yard Litig.*, 35 F.3d 717, 746 (3d Cir. 1994)); *see also In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig. (No. II)*, 341 F. Supp. 3d 213, 242 (S.D.N.Y. 2018) ("Where an expert ignores evidence that is highly relevant to his conclusion, contrary to his own stated methodology, exclusion of the expert's testimony is warranted.").

III. Because none of the opinions in Dr. D'Alton's report adequately address causation, her testimony definitionally cannot assist the trier of fact on that element.

Even if the Court can overlook Dr. D'Alton's complete lack of methodology, her testimony should be excluded because it is not helpful to the general-causation inquiry: whether prenatal exposure to acetaminophen can cause ASD and ADHD in offspring. *See* Dkt. 391 at 1.

Dr. D'Alton's report does not grapple with that question. The only two sections that even broach causation are, by her own admission, lacking in the requisite methodology. The first is Part VI, "The Medical Community's Clinical Consensus Regarding Use of Acetaminophen in Pregnancy," which is a summary of excerpted, multi-page block quotes from various medical associations, offered without analysis. Ex. 1, D'Alton Report at 18–29. That is a book report, not admissible expert opinion. The second is Part VIII, "Clinical Analysis of Epidemiology," *id.* at 32–48, a section of her own epidemiological analysis which begins with an acknowledgment that "another expert is addressing the relevant epidemiology in full detail," and that "OBGYNs/MFMs have significant training and experience in interpreting literature pertaining to clinical treatment, and **physicians routinely review studies in order to supplement their understanding of current clinical guidelines.**" *Id.* at 32 (emphasis added).

Dr. D'Alton does not explain how her perspective as a clinician as to "clinical guidelines" would assist this Court on the issue of causation. At her deposition, Dr. D'Alton confirmed that she did not herself employ methods used by epidemiologists to review literature for causation. *See*

Ex. 2, D'Alton Dep. Tr. at 357:15–19 (affirming that she did not do a Bradford Hill analysis "because I know that there is an epidemiologist that has been charged to do that"). Nor did she use the methodologies that clinicians use to interpret medical and scientific studies, as addressed in the prior section. *See id.* at 365:16–366:1 (confirming that she did not use GRADE or review evidence in any systemic way because "an epidemiologist was doing that" and "that was not something that I, as a clinician, needed to weigh in on"). What is left is an epidemiological review that is not conducted by an epidemiologist, with the required methodology conducted elsewhere. *See In re M/V MSC FLAMINIA*, No. 12-CV-8892 (KBF), 2017 WL 3208598, at *2 (S.D.N.Y. July 28, 2017) ("[T]he Court will preclude proffered witnesses who simply aggregate or recite the opinions of others, especially if they are not qualified in the field in which they opine. A metallurgist may testify as to metallurgy; a chemist as to chemistry. They cannot speak for each other."). At base, Dr. D'Alton's causation testimony does not have "any tendency to make the existence of [any] fact [that is of consequence to the determination of the action] more or less probable than it would be without the evidence" and is therefore irrelevant. *See* Fed. R. Evid. 401.

Far from providing expert testimony relevant to the question at hand, her report is used as a conduit to relay Defendants' repeated theme that acetaminophen is a woman's only option during pregnancy and that the allegations in this case would unduly scare pregnant women. *See* Ex. 1, D'Alton Report at 18–28; Dkt. 1114 at 1 (ignoring Defendants' own internal statements to allege that the claims in this case are "scaring pregnant women about acetaminophen with no scientific basis"). By way of illustration, her report contains nearly ten pages of large block quotes as to what others have said about acetaminophen's risks and benefits, without any independent analysis. *Id.* Parroting without analysis what others wrote does not constitute "specialized knowledge that will assist the trier of fact." Fed. R. Evid. 702; *see In re Rsrv. Fund Sec. & Derivative Litig.*, No.

09 CIV. 4346(PGG), 2012 WL 12356742, at *3 (S.D.N.Y. Sept. 10, 2012) ("Inasmuch as [the proposed expert] plans to summarize these articles, his proposed testimony would bring no specialized knowledge that might assist the jury.").[6]

Because Dr. D'Alton's testimony does not contribute anything to the causation inquiry and includes irrelevant information for which expertise is not required, her opinions do not satisfy the requirements of Rule 702 and *Daubert*. The Court should exclude them.

IV. Dr. D'Alton is not qualified to opine on the causal association between acetaminophen and neurodevelopmental disorders.

As a practicing OB-GYN with a specialty in maternal fetal medicine, Dr. D'Alton does not have the requisite expertise or experience to issue a general causation opinion in this case. *See* Ex. 1, D'Alton Report at 2. "Although a lack of specialization will not always preclude an expert from testifying, obstetrics and gynecology are not closely related to the field of mental health, and Dr. [D'Alton] has demonstrated no skill, education, or expertise in the latter discipline that will be helpful to the jury." *Leavitt v. Ethicon, Inc.*, No. 2:20-cv-00176, 2021 WL 3674067, at *5 (D. Vt. Aug. 19, 2021). She is not an epidemiologist, teratologist, psychiatrist, neurologist, toxicologist or neurodevelopmental researcher. *See, e.g.*, Ex. 1, D'Alton Report at 32; *see also* Ex. 2, D'Alton Dep. Tr. at 42:20–23. Dr. D'Alton's lack of qualification in the relevant scientific/medical areas at issue here stand in stark contrast with the abundant qualifications of the Plaintiffs' experts' own education, training and experience in the very issues before the Court. And Dr. D'Alton does not make up for lack of qualifications on paper with her experience. Prior to this case, she had never

[6]Perhaps nowhere is Dr. D'Alton as forthright about her role as mouthpiece for the opinions of others than in her deposition, where she acknowledged that "I was asked as a clinician to provide a clinical lens on the issue of Tylenol use in pregnancy and as a clinician educator, my analysis of the literature, *being knowledgeable about what obstetrician, gynecologists are thinking and their societies and their professional bodies are thinking* about this around the world as to the causative link between prenatal use of acetaminophen and AH -- ADHD and ASD." Ex. 2, D'Alton Dep. Tr. at 366:2–12 (emphasis added).

investigated the association between acetaminophen and ASD and ADHD. *See* Ex. 2, D'Alton Tr at 62:2–6.

Given this total absence of expertise in the area of neurodevelopmental disorders and her failure to study the topic in question, Dr. D'Alton does not possess the requisite expertise to opine on whether or not prenatal use of acetaminophen can cause ASD or ADHD causation—the *only* issue presently before the Court. *See Leavitt*, 2021 WL 3674067, at *5 ("Dr. Lind may be qualified in obstetrics, gynecology, female pelvic medicine, and reconstructive surgery; however, beyond medical school he has no education, training, or experience in mental health diagnosis and treatment, he has no licenses or certifications related to mental health, and he has identified no instance in which he diagnosed or treated a patient's mental health impairments."); *see generally Est. of Jaquez by Pub. Adm'r of Bronx Cnty. v. City of New York*, 706 F. App'x 709, 716 (2d Cir. 2017) (upholding a district court ruling excluding expert testimony by a physician regarding a person's "psychological state" because he specialized in emergency medicine and "was not shown to have expertise in psychiatric diagnosis"). The Court should exclude her general causation opinion because she lacks the requisite expertise to opine on the topic.

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court exclude the opinions offered by Defendants' proposed expert Dr. Mary D'Alton.

Dated: September 19, 2023

Respectfully submitted,

KELLER POSTMAN LLC

/s/ Ashley C. Keller

Ashley C. Keller – *Pro Hac Vice*
KELLER POSTMAN LLC
150 N. Riverside Plaza Suite 4100
Chicago, IL 60606
Phone: (312) 741-5220
Fax: (312) 971-3502
ack@kellerpostman.com

WATTS GUERRA LLC
Mikal C. Watts (*Pro Hac Vice*)
Millennium Park Plaza RFO
Ste. 410, C112
Guaynabo, Puerto Rico 00966
(210) 447-0500
mcwatts@wattsguerra.com

THE LANIER LAW FIRM
W. Mark Lanier (*Pro Hac Vice*)
Tower 56
126 East 56th St., 6th Floor
New York, New York 10022
(212) 421-2800
mark.lanier@lanierlawfirm.com

Counsel for Plaintiffs