UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: Acetaminophen - ASD-ADHD Products Liability Litigation	:	22md3043 (DLC) 22mc3043 (DLC)
	:	INVITATION FOR STATEMENT OF INTEREST

DENISE COTE, District Judge:

On October 5, 2022, the Judicial Panel on Multidistrict Litigation centralized this litigation pursuant to 28 U.S.C. § 1407 (the "MDL"). The plaintiffs in this MDL assert that the defendants violated their state law duties to warn consumers of the risk that children may develop autism spectrum disorder ("ASD") and/or attention-deficit/hyperactivity disorder ("ADHD") as a result of in utero exposure to acetaminophen. The defendants include a manufacturer as well as several retailers of acetaminophen products, each of whom sells private label acetaminophen products. Motions to dismiss two actions in the MDL on the ground of preemption have been denied. In re Acetaminophen - ASD-ADHD Products Liability Litigation, No. 22md3043 (DLC), 2022 WL 17348351 (S.D.N.Y. Nov. 14, 2022).

The parties are currently engaged in general causation discovery, specifically whether prenatal exposure to acetaminophen causes ASD and ADHD. The plaintiffs' expert reports are due June 16; the defendants' expert reports are due

July 14; and the plaintiffs' rebuttal expert reports are due July 21. Rule 702 motions shall be filed by September 19. The motions will be full briefed by October 20. At the Court's discretion, a hearing will be held on the Rule 702 motions during the week of December 4.

All over-the-counter drugs intended for systemic absorption, including acetaminophen, must include a general pregnancy warning: "If pregnant or breast-feeding, ask a health professional before use." 21 C.F.R. § 201.63. The monograph that governs acetaminophen contains no additional warning related to pregnancy for acetaminophen products. U.S. Food and Drug Administration, Over-the-Counter (OTC) Monograph M013: Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use (Oct. 14, 2022).

An Order of January 13, 2023 ordered the plaintiffs to file their proposed label change by April 7. The plaintiffs submitted the following language that the defendants "could have included on the labels of the acetaminophen products" at issue in this MDL ("Plaintiffs' Proposed Warning"):

> **Autism/ADHD:** 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.

This MDL raises important issues related to public health and drug safety for pregnant women and their offspring. The Court believes it would be helpful to receive the views of the United States, including the Food and Drug Administration, on the Plaintiffs' Proposed Warning. See 28 U.S.C. § 517.

Accordingly, the United States is hereby

INVITED to submit by **July 28, 2023**, or as soon thereafter as possible, the views of the United States on the following questions and the reasons for such views:

1. Should the Plaintiffs' Proposed Warning be added to acetaminophen labels?

2. As of today, does science warrant the addition to acetaminophen labels of any warning or advice regarding in utero exposure to acetaminophen and the risk of ASD or ADHD?

IT IS ORDERED that this Invitation will be delivered to the United States Attorney's Office for the Southern District of New York.

Dated: New York, New York
April 19, 2023

DENISE COTE
United States District Judge