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April 19, 2023

VIA ECF

The Honorable Denise L. Cote
United States District Court Judge
Southern District of New York
500 Pearl Street, Room 1910
New York, New York 10007

Re. *In Re: Acetaminophen – ASD–ADHD Products Liability Litigation*, Case No. 1:22-md-03043 (S.D.N.Y.) – Plaintiffs' Objections to Revised Draft Invitation for Statement of Interest
This Document Relates To: All Cases

Dear Judge Cote:

Pursuant to the Court's April 19, 2023 Order, Dkt. 586, Plaintiffs respectfully request that the Court revert to its original Invitation to the United States, Dkt. 561-1. Plaintiffs' principal objection to the revised draft is the second question, which is modelled on Defendants' proposal. *See* Dkt.585-1. As revised, the question asks FDA if any change or addition should be made to "the Pregnancy Warning," implying that Plaintiffs are proposing that Defendants should have modified or added to the general Pregnancy Warning contained in 21 C.F.R. § 201.63.

As the Court is well aware, that has never been Plaintiffs' position. As the preemption orders have already made clear, all acetaminophen labels must contain the Pregnancy Warning verbatim. *See* Op. & Order 20 (Nov. 14, 2022), Dkt. 145. But no law or regulation with the force of law precluded Defendants from including *additional* warnings about the risks of autism or ADHD. *Id.* at 20–24. Attempting to recast Plaintiffs' proposed language as an effort to add to or change the Pregnancy Warning is nothing more than Defendants' fourth attempt to vindicate their erroneous preemption arguments by confusing the FDA about the true nature of the actual label change Plaintiffs have suggested. Plaintiffs already *agree* that Defendants could not and cannot unilaterally change or add to the Pregnancy Warning. *See, e.g.*, Opp'n to JJCI's Mot. to Dismiss 31, Dkt. 475. There is no sense asking the United States if a Warning Defendants cannot change should nonetheless be changed.

The Court's original version of this question appropriately asked if the United States believed any change to the label could be warranted based on its review of the relevant science. That question is on point, because it is conceivable that the United States does not believe all of Plaintiffs' proposed language is warranted—which is the first question presented—but that other changes should nonetheless be implemented.

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As a much more minor quibble, Plaintiffs are not sure it is appropriate to serve the Chief Counsel of the FDA, as the revised Invitation proposes. Because 28 U.S.C. § 517 is directed to the Solicitor General, Attorney General, or officers of the Department of Justice, Plaintiffs are unaware of any invitation under the statute that has been extended to a Health and Human Services official such as the FDA's Chief Counsel. Having noted this point, Plaintiffs are willing to defer to the Court if it believes that serving the FDA's Chief Counsel would not unduly complicate the responsibilities of the executive branch officials charged with attending to the interests of the United States.

If the Court has any questions about Plaintiffs' position, we are of course at your Honor's disposal.

Respectfully submitted,

/s/ Ashley C. Keller
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