U.S. Department of Justice

United States Attorney
Southern District of New York

86 Chambers Street
New York, New York 10007

September 8, 2023

By ECF

Honorable Denise Cote
United States District Judge
United States Courthouse
500 Pearl Street
New York, New York 10007

Re: The Court's Invitation to the United States in *In re Acetaminophen – ASD-ADHD Products Liability Litigation*, No. 22md3043 (DLC) (S.D.N.Y.)

Dear Judge Cote:

This Office represents the United States and, after consulting with the U.S. Food and Drug Administration ("FDA"), respectfully submits this response to the Court's Invitation for Statement of Interest, dated April 19, 2023, in which the Court solicited the United States' views concerning the warning included in labeling for over-the-counter ("OTC") acetaminophen products. *See* ECF No. 588. The United States respectfully declines the Court's invitation to submit a statement of interest in this matter, but attaches a copy of FDA's literature review, dated March 10, 2023, providing FDA's most recent review of available epidemiological evidence.[1]

Since 2014, FDA has conducted multiple reviews of relevant epidemiological data concerning prenatal exposure to acetaminophen. The agency produced past reviews to the parties in this multi-district litigation,[2] and the agency subsequently completed a new review in March 2023 (attached as Exhibit A). In that review, FDA's Division of Epidemiology I ("DEPI-I") concluded that the new "studies reviewed here are limited and do not change DEPI-I's conclusions from its most recent review—the limitations and inconsistent findings of current observational

[1] On August 1, 2023, plaintiffs invited the United States to review the parties' expert reports and attend expert depositions in this matter. *See* ECF No. 789. However, as described below, FDA reviews new safety information for drugs through certain administrative channels. On August 31, 2023, plaintiffs submitted a letter to the United States setting out their experts' conclusions and asking that the United States submit a statement of interest opining that plaintiffs' experts' testimony should survive any *Daubert* motions, given the United States' "interest in ensuring that the Federal Rules of Evidence are consistently and properly applied." Aug. 31 Ltr. from A. Keller to D. Williams at 20-21. Of course, it is for the Court, not this Office, to review the admissibility of expert or other evidence in these matters.

[2] In particular, FDA produced to the parties a May 2014 review by DEPI-I, *see* ECF No. 427-4; DEPI-I's March 2015 review, *see* ECF No. 427-5; DEPI-I's October 2016 review, *see* ECF No. 427-1; a February 2017 review by the FDA's Division of Bone, Reproductive, and Urological Products, *see* ECF No. 427-2; and DEPI-I's 2022 review, *see* ECF No. 427-7. FDA also produced its January 2015 Drug Safety Communication. *See Safety Announcement: Possible Risks of Pain Medicine Use During Pregnancy* (Jan. 9, 2015), https://perma.cc/4JY6-CN6V.

studies of [acetaminophen] and neurobehavioral and urogenital outcomes are unable to support a determination of causality." Ex. A at 3-4.

Though, as a general matter, FDA does not engage in third-party litigation of this kind, FDA monitors the safety of drug products and has several administrative channels through which new information relevant to the safety or effectiveness of OTC acetaminophen products may be submitted. New individual case reports can be submitted to the FDA's MedWatch program.[3] Other new information relevant to safety or effectiveness can be submitted to FDA's public docket related to warning and labeling changes to the monograph for Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use.[4]

We hope that this information assists the Court.

Respectfully submitted,

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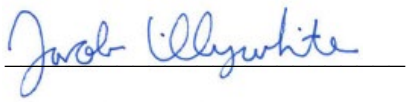
By: 

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[3] *See* https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda.

[4] *See* https://www.regulations.gov/docket/FDA-1977-N-0013. This docket was originally opened when FDA issued a final rule to require new organ-specific warnings and related labeling for OTC internal analgesic, antipyretic, and antirheumatic drug products, including acetaminophen. FDA is currently revising the process for submitting information of this sort, in response to the passage of the Coronavirus Aid, Relief, and Economic Security Act, and may offer another administrative channel to receive such information from the public.