

November 11, 2025

*By electronic submission*

Division of Dockets Management  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**Re: Docket No. FDA-2025-P-4153-0001**

On behalf of the Society for Maternal-Fetal Medicine, the medical professional society representing more than 6,500 members and serving as the voice for clinicians and researchers with expertise in high-risk pregnancy care, we write to express our concern regarding a citizen petition filed by the Informed Consent Action Network (“Petitioner”) on September 22, 2025.<sup>1</sup> The petition requests that the Food and Drug Administration (FDA) change the labeling of over-the-counter acetaminophen products for use during pregnancy. The Petitioner’s request is contrary to medical evidence and, in fact, could lead to harm for pregnant people and their infants.

While the petition cites studies suggesting a link between prenatal acetaminophen exposure and neurodevelopmental outcomes such as autism and attention deficit hyperactivity disorder (ADHD), **a thorough review of the scientific literature shows that no causal relationship has been established.**

The studies referenced in the petition are observational in nature and are subject to considerable methodological limitations, such as confounding variables and recall bias.<sup>2,3</sup> Even the FDA’s own internal reviews have consistently concluded that the evidence is insufficient to support a labeling change.<sup>4</sup>

In contrast to the weak evidence linking acetaminophen use in pregnancy to adverse health outcomes, **untreated fever during pregnancy is known to carry significant maternal and infant health risks.** Untreated fever, especially during the first trimester, raises the risk of miscarriage, birth defects, and premature birth, and untreated pain can pose serious risks to the mother and fetus.<sup>5,6</sup> At this time, acetaminophen remains the first-line medication for fevers and pain during pregnancy.<sup>7,8</sup>

In response to recent national conversations regarding the use of acetaminophen in pregnancy, SMFM released the statement below on September 22, 2025.<sup>9</sup>

“...[The] Society for Maternal-Fetal Medicine (SMFM) reiterates its recommendation advising both physicians and patients that acetaminophen is an appropriate medication to treat pain and fever during pregnancy.

SMFM stands behind our recommendation<sup>10</sup> that acetaminophen use during pregnancy has not been shown to cause or increase the risk of autism or other neurobehavioral problems in children. And in fact, lack of treatment of fever and pain can pose an even greater risk.

SMFM supports continued research that includes pregnant patients to understand the potential causes of neurodevelopmental disabilities in children.

SMFM stands with colleagues at the world's preeminent medical societies, including the American College of Obstetricians and Gynecologists,<sup>11</sup> the International Federation of Gynecology and Obstetrics,<sup>12</sup> and the Royal College of Obstetricians and Gynecologists,<sup>13</sup> in reaffirming our position that acetaminophen is safe to use in moderate doses during pregnancy. We also lift up similar statements released by the World Health Organization<sup>14</sup> and the European Medicines Agency.<sup>15</sup>

The highest quality evidence must guide medical decision-making. Premature regulatory action based on inconclusive data risks undermining public trust in the FDA and compromising patient safety. SMFM strongly urges the FDA to deny this petition and to continue monitoring the evidence with scientific rigor. We stand ready to partner with you on this and other initiatives related to medication use in pregnancy. If you have any questions or we can be of further assistance, please contact Rebecca Abbott, SMFM's Senior Director of Advocacy (rabbott@smfm.org).

Sincerely,

A handwritten signature in black ink, appearing to read 'S. Srinivas', with a long horizontal flourish extending to the right.

Dr. Sindhu K. Srinivas, MD, MSCE  
President  
Society for Maternal-Fetal Medicine

## References

- <sup>1</sup> Citizen Petition from Siri & Glimstad LLP on behalf of Informed Consent Action Network. U.S. Food and Drug Administration. Docket No. FDA-2025-P-4153. September 25, 2025. <https://www.regulations.gov/document/FDA-2025-P-4153-0001>
- <sup>2</sup> Damkier P, et al. Handle with care - interpretation, synthesis and dissemination of data on paracetamol in pregnancy. Nat Rev Endocrinol. March 2022. <https://pubmed.ncbi.nlm.nih.gov/34907340/>
- <sup>3</sup> In re: Acetaminophen – ASD-ADHD Products Liability Litigation. United States District Court, Southern District of New York. MDL No. 22md3043 (DLC), MC No. 22mc3043 (DLC). October 5, 2022. <https://www.nysd.uscourts.gov/MDL/22md3043>
- <sup>4</sup> U.S. Food and Drug Administration. FDA Drug Safety Communication: FDA has reviewed possible risks of pain medicine use during pregnancy. January 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>
- <sup>5</sup> Dreier JW, et al. Systematic review and meta-analyses: fever in pregnancy and health impacts in the offspring. Pediatrics. March 2014. <https://publications.aap.org/pediatrics/article-abstract/133/3/e674/32335/Systematic-Review-and-Meta-analyses-Fever-in?redirectedFrom=fulltext?autologincheck=redirected>
- <sup>6</sup> Waller D, et al; National Birth Defects Prevention Study. Maternal report of fever from cold or flu during early pregnancy and the risk for noncardiac birth defects, National Birth Defects Prevention Study, 1997–2011. Birth Defects Res. March 2018. <https://pubmed.ncbi.nlm.nih.gov/29094488/>
- <sup>7</sup> Nunge R, et al. Pain medication use during pregnancy. Seminars in Perinatology. June 2025. <https://www.sciencedirect.com/science/article/pii/S0146000525000515?via%3Dihub>
- <sup>8</sup> American College of Obstetricians and Gynecologists. Acetaminophen use in pregnancy and neurodevelopmental outcomes. Practice Advisory. September 22, 2025. <https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2025/09/acetaminophen-use-in-pregnancy-and-neurodevelopmental-outcomes>
- <sup>9</sup> Society for Maternal-Fetal Medicine. SMFM response to administration announcement on acetaminophen use during pregnancy and autism. September 22, 2025. <https://www.smfm.org/news/smfm-response-to-administration-announcement-on-acetaminophen-use-during-pregnancy-and-autism>
- <sup>10</sup> Society for Maternal-Fetal Medicine. SMFM statement on acetaminophen use during pregnancy and autism. September 5, 2025 <https://www.smfm.org/news/smfm-statement-on-acetaminophen-use-during-pregnancy-and-autism>
- <sup>11</sup> American College of Obstetricians and Gynecologists. ACOG affirms safety and benefits of acetaminophen use during pregnancy. September 22, 2025. <https://www.acog.org/news/news-releases/2025/09/acog-affirms-safety-benefits-acetaminophen-pregnancy>
- <sup>12</sup> International Federation of Gynecology and Obstetrics (FIGO). Paracetamol (acetaminophen) use during pregnancy and autism risk: evidence does not support causal association. September 2025. <https://www.figo.org/paracetamol-acetaminophen-use-during-pregnancy-and-autism-risk-evidence-does-not-support-causal>
- <sup>13</sup> Royal College of Obstetricians and Gynaecologists. The Royal College of Obstetricians and Gynaecologists issues advice for pregnant women and people on the use of paracetamol to manage fever and pain. September 23, 2025. <https://www.rcog.org.uk/news/the-royal-college-of-obstetricians-and-gynaecologists-issues-advice-for-pregnant-women-and-people-on-the-use-of-paracetamol-to-manage-fever-and-pain/#:~:text=Paracetamol%20is%20recommended%20as%20the,Pregnancy%20and%20birth>

<sup>14</sup> World Health Organization. WHO statement on autism-related issues. September 24, 2025.  
<https://www.who.int/news/item/24-09-2025-who-statement-on-autism-related-issues>

<sup>15</sup> European Medicines Agency. Use of paracetamol during pregnancy unchanged in the EU. September 23, 2025.  
<https://www.ema.europa.eu/en/news/use-paracetamol-during-pregnancy-unchanged-eu>