



NATIONAL CONSUMERS LEAGUE

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November 3, 2025

Division of Dockets Management
U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Comments to Docket No. FDA-2025-P-4153

The National Consumers League (NCL) submits comments in response to the citizen petition filed by the Informed Consent Action Network (ICAN) requesting that FDA require a labeling change for over-the-counter acetaminophen-containing drug products. As America's oldest consumer advocacy organization, we are deeply concerned that the labeling changes proposed by ICAN are not supported by credible scientific evidence and will mislead and unnecessarily alarm pregnant women. Decades of research and scientific expert consensus affirm that no causal relationship has been found between acetaminophen and neurodevelopmental disorders, and that acetaminophen remains the safest over-the-counter option for managing fever or pain during pregnancy. Introducing warnings that overstate unproven risks will not protect pregnant women and children; it will create unnecessary fear and discourage appropriate treatment. It will also undermine public trust and further politicize the FDA, marking a troubling expansion of political interference into FDA's routine drug labeling decisions and eroding confidence in a process that has always been grounded in regulatory science.

To support our position and underscore the importance of maintaining science-based drug labeling, we offer the following key points:

- Research has not proven that taking acetaminophen during pregnancy causes neurodevelopmental disorders such as autism.¹ Most of the studies that have looked at this question have not shown a clear cause-and-effect link. The two

¹ [Acetaminophen in Pregnancy | ACOG](#)



highest quality studies, published in 2021² and 2024,³ give doctors and parents the most reliable evidence to date that acetaminophen is safe to use in pregnancy when needed. FDA's September 22, 2025 *Notice to Physicians on the Use of Acetaminophen During Pregnancy* reflects this, stating: "To be clear, while an association between acetaminophen and autism has been described in many studies, a causal relationship has not been established and there are contrary studies in the scientific literature."⁴

- Autism does not have a single cause and is due to many different factors, including genetics and the environment.⁵ In addition, the rise in autism is due to increased awareness and the medical community better recognizing and diagnosing it.⁶
- Untreated illness in pregnancy can be dangerous. The Society for Maternal-Fetal Medicine has stressed that "[u]ntreated fever, particularly in the first trimester, increases the risk of miscarriage, birth defects, and premature birth, and untreated pain can lead to maternal depression, anxiety, and high blood pressure."⁷ As summarized by the American College of Obstetricians and Gynecologists, "The conditions people use acetaminophen to treat during pregnancy are far more dangerous than any theoretical risks and can create severe morbidity and mortality for the pregnant person and the fetus."⁸
- Medical experts, including the American College of Obstetricians and Gynecologists,⁹ the Society for Maternal-Fetal Medicine,¹⁰ and the American Academy of Pediatrics,¹¹ have all reaffirmed that acetaminophen is safe. In

² [Acetaminophen use during pregnancy and offspring attention deficit hyperactivity disorder – a longitudinal sibling control study - Gustavson - 2021 - JCPP Advances - Wiley Online Library](#)

³ [Acetaminophen Use During Pregnancy and Children's Risk of Autism, ADHD, and Intellectual Disability | Attention Deficit/Hyperactivity Disorders | JAMA | JAMA Network](#)

⁴ [Notice to Physicians on the Use of Acetaminophen During Pregnancy](#)

⁵ [Understanding Autism: Information for Families - HealthyChildren.org](#)

⁶ [What causes autism? | Autism Speaks](#)

⁷ [SMFM Statement on Acetaminophen Use During Pregnancy and Autism - Society for Maternal-Fetal Medicine](#)

⁸ [ACOG Affirms Safety and Benefits of Acetaminophen during Pregnancy | ACOG](#)

⁹ [ACOG Affirms Safety and Benefits of Acetaminophen during Pregnancy | ACOG](#)

¹⁰ [SMFM Statement on Acetaminophen Use During Pregnancy and Autism - Society for Maternal-Fetal Medicine](#)

¹¹ [Acetaminophen is Safe for Children When Taken as Directed, No Link to Autism](#)



addition, leading autism organizations, including the Autism Science Foundation¹² and Autism Speaks,¹³ agree that acetaminophen use in pregnancy has not been proven to cause autism.

- ICAN’s proposed labeling change is inconsistent with FDA’s established position. In addition to FDA’s letter to physicians noted above, FDA’s website states: “To date, FDA has not found clear evidence that appropriate use of acetaminophen during pregnancy causes adverse pregnancy, birth, neurobehavioral, or developmental outcomes” (webpage content current as of August 14, 2025).¹⁴
- Introducing warnings that conflict with recent FDA communications risks politicizing the drug labeling process and reinforces claims that FDA decisions are arbitrary rather than science based. Such actions could further erode public trust in FDA and raise doubts about the integrity of even its most fundamental labeling decisions.
- In the short time since President Trump and Secretary Kennedy’s announcement regarding Tylenol, pregnant women across the country are confused as to what they should be doing when sick or in pain.¹⁵ Changes to acetaminophen labeling will only sow greater confusion among patients and could put women and their developing babies at risk.
- The labeling proposed by ICAN may encourage pregnant women to turn to alternative therapies that are known to be dangerous to a developing fetus or are unregulated by FDA. Pregnant women need safe and effective options to treat fever and pain, including as they juggle many responsibilities such as jobs, households, and older children. Aspirin and ibuprofen have well-documented adverse impacts on the fetus. Women could turn to alternative, unregulated products that cause harm to themselves or their unborn child.¹⁶

¹² [Statement from Autism Science Foundation Regarding Wall Street Journal Report “RFK Jr., HHS to Link Autism to Tylenol Use in Pregnancy and Folate Deficiencies” - Autism Science Foundation](#)

¹³ [Autism Speaks statement on Tylenol and leucovorin | Autism Speaks](#)

¹⁴ [Acetaminophen | FDA](#)

¹⁵ [ACOG President: Changing Tylenol's Label Will Drive Baseless Fear | MedPage Today](#)

¹⁶ [Parents flock to Tylenol alternatives amid Trump autism claims | STAT](#)



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NCL urges FDA to reject ICAN's petition and maintain the current acetaminophen labeling, which appropriately advises women to consult a healthcare professional before use. Acetaminophen is one of the few options available to pregnant women to treat pain and fever. Changing the label without clear scientific justification would increase risks to pregnant women and developing babies by discouraging the use of safe and effective treatments. Allowing political pressure to influence the drug labeling process would set a dangerous precedent, eroding public confidence in drug labeling, a fundamental regulatory responsibility of the agency and the primary way drug information is communicated to consumers. We strongly encourage FDA to continue to base all labeling decisions on the best available evidence and to protect the public from misinformation that could jeopardize public health.

Sincerely,
Sally Greenberg
Chief Executive Officer