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

RE: Comments to Docket No. FDA-2026-P-9046

The National Consumers League (NCL) submits comments in response to the citizen petition filed by Children's Health Defense (CHD) requesting that the Food and Drug Administration (FDA) withdraw over-the-counter (OTC) approval for Infants' Tylenol and other acetaminophen-containing products for children under two years of age, require a boxed warning concerning a severe risk of autism spectrum disorder (ASD) on Children's Tylenol and acetaminophen-containing products for children under six years of age, and require a boxed warning for Tylenol and acetaminophen-containing products relevant to labor and delivery. As America's oldest consumer advocacy organization, we are deeply concerned that these extraordinary changes are not supported by the best available scientific evidence and could have significant consequences for children and families.

The American Academy of Pediatrics (AAP) has stated plainly that decades of research support the safety of acetaminophen for children when administered as directed and that studies do not establish a causal link between acetaminophen use in children and autism.[1] Parents need accurate, practical information and access to safe and effective treatment options when a child is sick or in pain. The actions requested in the petition could discourage appropriate treatment and restrict access to one of the few age-appropriate medicines available to treat pediatric pain and fever. Imposing a serious FDA warning without evidence establishing the risk it conveys could also undermine public confidence in the scientific integrity of FDA's labeling decisions.

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

[1] https://www.aap.org/en/news-room/fact-checked/acetaminophen-is-safe-for-children-when-taken-as-directed-no-link-to-autism/

- Leading pediatric experts continue to reinforce that acetaminophen is safe for children when taken as directed:
    - American Academy of Pediatrics: “Studies do not point to a causal link between the use of acetaminophen and autism in children or in pregnancy, and extensive research indicates there is no single root cause of autism.”[2]
    - Children’s Hospital of Philadelphia: “Acetaminophen is a safe, trusted, and effective medicine for children and pregnant women when used as directed. It helps with fever and pain, prevents the need for riskier medicines, and has been used worldwide for decades….There is no credible evidence that acetaminophen causes autism or ADHD… It is safe to give babies, children and teenagers. It is safe to use when breastfeeding. It has been used safely for 70 years to treat pain and fever. Used only as needed, at the right dose, it may be the safest option for your child.”[3]
    - Children’s Hospital Los Angeles: “Medical experts agree that there is no connection between acetaminophen and autism. Acetaminophen is a common medicine used to treat mild pain and to relieve fever. You can get it without a prescription under brand names such as Tylenol. Acetaminophen has been studied through many years of research and results show that it is safe for children.”[4]
    - Ann & Robert H. Lurie Children’s Hospital of Chicago: “Studies do not prove a causal link between the use of acetaminophen and autism in children or in pregnancy, and extensive research indicates there is no single root cause of autism. The medication is available over the counter and is safe for children when taken, or dosed, correctly and under the guidance of a child’s pediatrician.”[5]
    - Vanderbilt Health: “When used short-term and at appropriate dosages, acetaminophen is safe during pregnancy and for children. VUMC encourages patients to talk to their health care providers about when and how to use acetaminophen for pregnant women and children.”[6]
- Federal agencies, autism advocacy organizations, and medical experts state that autism does not have a single cause and is due to many different factors,

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[2] Acetaminophen is Safe for Children When Taken as Directed, No Link to Autism

[3] Safety of Tylenol (Acetaminophen) for Children and in Pregnancy: Frequently Asked Questions | Children's Hospital of Philadelphia

[4] Autism-FAQ-2025.aspx

[5] Developmental & Behavioral Pediatrics Frequently Asked Questions | Lurie Children's

[6] Autism, acetaminophen and leucovorin information and FAQs - Vanderbilt Health News

including genetics and the environment.[7] In addition, increased awareness and improvements in the recognition and diagnosis of autism have contributed to increases in autism prevalence.[8] Families deserve rigorous research into autism and clear information that does not create false blame for the cause of autism.

- A boxed warning is among FDA's most prominent safety communications and is ordinarily intended to call attention to serious risks associated with a drug. Given the weight such a warning carries with patients and healthcare providers, FDA should require evidence commensurate with the seriousness of the risk being communicated. Leading pediatric experts have concluded that the available evidence does not establish a causal relationship between acetaminophen use in children and autism. Requiring a boxed warning identifying autism as a risk under these circumstances could convey a level of scientific certainty that the available evidence does not support.
- The actions proposed in the citizen petition would leave parents with fewer options, especially for infants. Ibuprofen is not generally recommended for use in children under six months, and aspirin is not an interchangeable pediatric alternative due to the risk of Reye's syndrome. For a young child with pain or fever, acetaminophen occupies a particularly important place in the limited set of available options.
- Parents need safe, effective, and accessible options to relieve their child's pain and discomfort when they are sick. The goal of treating a fever is often to improve a child's comfort and well-being. For families, these benefits also have important practical consequences. Parents and caregivers routinely must balance caring for a child who has a fever or is in pain with work, caring for other children, and other responsibilities. Effective treatment can also allow children who are otherwise well enough to participate in school, childcare, and other normal activities. Restricting access to a medicine that pediatric experts recognize as safe and effective when used as directed would impose real costs on families, and particularly working families with fewer resources or less flexibility to miss work or school.
- Acetaminophen plays an important role in post-surgical pain relief in children and can help reduce reliance on opioid pain relievers. AAP's clinical practice guideline on opioid prescribing for acute pain identifies acetaminophen as a key

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[7] E.g., Eunice Kennedy Shriver National Institute of Child Health and Human Development - NICHD; About Autism Spectrum Disorder | Autism Spectrum Disorder (ASD) | CDC; What causes autism? | Autism Speaks; CNS Statement on Autism – No Single Cause, No Definitive Cure - Child Neurology Society; Autism and Autism Spectrum Disorder; Autism Spectrum Disorder | AFP; Resources | Duke Center for Autism and Brain Development

[8] Understanding Autism: Information for Families - HealthyChildren.org

nonopioid analgesic in the treatment of acute pain unless contraindicated.[9] Labeling that causes families or clinicians to avoid acetaminophen without a sound scientific basis could make appropriate post-surgical pain control more difficult and run counter to efforts to minimize unnecessary opioid exposure.

- FDA labeling that is not supported by sufficient evidence and is contrary to the consensus of leading national pediatric experts risks politicizing the labeling process and creating the perception that FDA decisions are arbitrary rather than grounded in science. Such action could further erode public trust in FDA and undermine confidence in the scientific integrity of the Agency's labeling decisions more broadly.

Families have relied on acetaminophen to treat children's pain and fever for more than 70 years, and leading pediatric experts continue to recognize it as safe and effective when used as directed. NCL urges FDA to deny CHD's request to withdraw OTC status for infant acetaminophen products and to require ASD boxed warnings. FDA should continue grounding pediatric labeling decisions in the best available evidence and provide families with clear, practical communications. FDA should also continue to evaluate emerging evidence through its established pharmacovigilance and regulatory processes and take appropriate action if the evidence warrants it.

Sincerely,

Lisa Bercu
Senior Director of Health Policy

[9] Opioid Prescribing for Acute Pain Management in Children and Adolescents in Outpatient Settings: Clinical Practice Guideline | Pediatrics | American Academy of Pediatrics