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October 30, 2025

Department of Health and Human Services  
Food and Drug Administration  
Commissioner Marty Makary, M.D., M.P.H  
5630 Fishers Lane Rm. 1061  
Rockville, MD 20852

### **Autistic Self Advocacy Network Re: FDA-2025-P-4153-0001, Citizen Petition from Siri & Glimstad LLP on behalf of Informed Consent Action Network**

The Autistic Self Advocacy Network (ASAN) appreciates the opportunity to provide information to the Food and Drug Administration (FDA) regarding a petition submitted by the Informed Consent Action Network proposing labelling changes to acetaminophen-containing drug products. ASAN is a 501(c)(3) nonprofit disability rights advocacy organization created by and for autistic people ourselves. ASAN is writing to **oppose the petition** to add a warning regarding acetaminophen-containing drug products that would state that the use of said products has potential risks on fetal neurodevelopment, including an increased risk of autism spectrum disorder (“ASD”).

Multiple reputable studies<sup>1</sup> have demonstrated that there is no link between acetaminophen and autism, and have found that previous associations can be attributed to confounding variables, most notably uncontrolled genetic factors which mediate both acetaminophen use and child neurodevelopment. Research has additionally shown that autism is overwhelmingly<sup>2</sup> caused by genetics, and with hundreds of genes associated with autism, it is highly unlikely that a single drug could cause autism. Similarly, ample evidence exists that genetic factors for autism and other neurodevelopmental disabilities are themselves associated with a higher incidence of maternal migraine and other pregnancy pain— the very conditions for which analgesia is medically indicated<sup>3</sup>. The lack of reputable data to support the claims being

<sup>1</sup> See, Ahlqvist VH, Sjöqvist H, Dalman C, et al. *Acetaminophen Use During Pregnancy and Children’s Risk of Autism, ADHD, and Intellectual Disability*. JAMA. 2024;331(14):1205–1214. doi:10.1001/jama.2024.3172. <https://jamanetwork.com/journals/jama/fullarticle/2817406>. See also, Bérard, Anick et al. *Systematic Review and Meta-Analysis: Acetaminophen Use During Pregnancy and the Risk of Neurodevelopmental Disorders in Childhood*. Journal of the American Academy of Child & Adolescent Psychiatry, Volume 0, Issue 0 (2025). [https://www.jaacap.org/article/S0890-8567\(25\)02106-9/fulltext](https://www.jaacap.org/article/S0890-8567(25)02106-9/fulltext).

<sup>2</sup> Tick B, Bolton P, et al. *Heritability of autism spectrum disorders: a meta-analysis of twin studies*. J Child Psychol Psychiatry. 2016 May;57(5):585-95. doi: 10.1111/jcpp.12499. Epub 2015 Dec 27. PMID: 26709141; PMCID: PMC4996332. <https://pubmed.ncbi.nlm.nih.gov/26709141/>

<sup>3</sup> See Havdahl A, et. al. *Associations Between Pregnancy-Related Predisposing Factors for Offspring Neurodevelopmental Conditions and Parental Genetic Liability to Attention-Deficit/Hyperactivity Disorder, Autism, and Schizophrenia: The Norwegian Mother, Father and Child Cohort Study (MoBa)*. JAMA Psychiatry. 2022 Aug 1;79(8):799-810. doi: 10.1001/jamapsychiatry.2022.1728. PMID: 35793100; PMCID: PMC9260642.



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made in the petition should raise alarm bells to the FDA because of the agency's stated commitment to scientific integrity. Labeling decisions based on cherry-picked, poorly collected, inadequately controlled, or out-of-date data to justify medical decisions will lead individuals to be misled by the FDA. Using such data to enact sweeping policy changes, such as those proposed in the petition, is dangerous and will erode public trust that the FDA is making regulatory decisions based on the best available scientific evidence. This trust is essential to the FDA's core mission of protecting public health, and undermining it would interfere with the FDA's ability to fulfill that mission.

The weak claims presented in the petition, based on a limited number of small and poorly-controlled studies and outright health disinformation, are not the "gold-standard science" the Department has promised the American people. The FDA has previously released studies<sup>4</sup> stating that there is no link between taking acetaminophen-containing drug products and autism, and has rejected previous proposals to modify the warning label on acetaminophen products. In addition, the Secretary himself has acknowledged that the available evidence, including that which is cited in this petition, is not sufficient to support a causal inference as recently as October 29th of this year<sup>5</sup>. Without new information or further studies providing data, if pursued, this regulation would be **arbitrary and capricious** as it would be a change of the agency's historical position, without a reputable source or change in scientific knowledge to account for this change.

ASAN will continue to advocate for an autism research agenda based in science and a policy agenda that addresses the needs of autistic people and our families, like better access to services and supports. We deserve nothing less. The narrative that has been provided in this petition is harmful to the autistic community and is damaging to the study of science and drug interactions as a whole. Autism is a natural part of human diversity. Autistic people enjoy a good quality of life when we have the supports we need. Autism is not a problem for which anyone needs to be blamed. An HHS that does not further this understanding and provide accurate information to the President and the public to make safe, science-informed decisions puts the country at grave risk. From recommending against the use of the best treatment for fever and pain during pregnancy to endorsing misinformation regarding the causes of autism, the facts presented in this petition put us all in danger.

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<sup>4</sup> Food and Drug Administration, *FDA Drug Safety Communication: FDA has reviewed possible risks of pain medicine use during pregnancy*, (2016).  
<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> Heavey, S. and Aboulenein, A (2025, October 29). *US health chief says there is not enough data to show Tylenol causes autism*. Reuters.  
<https://www.reuters.com/business/healthcare-pharmaceuticals/us-health-chief-says-not-enough-data-show-tylenol-causes-autism-still-advises-2025-10-29/>



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To defend the health and well-being of autistic people, our families, and the general public, we respectfully **oppose the petition** submitted by the Informed Action Network to urge the FDA to add a warning regarding acetaminophen-containing drug products. For more information on ASAN's policy positions with respect to healthcare and research, please contact Cameron Lynch, policy analyst at [clynch@autisticadvocacy.org](mailto:clynch@autisticadvocacy.org).

Thank you for your consideration,  
**Autistic Self Advocacy Network**