

FDA NEWS RELEASE

# FDA Responds to Evidence of Possible Association Between Autism and Acetaminophen Use During Pregnancy

Agency initiates safety label change and notifies physicians of possible link

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For Immediate Release: September 22, 2025

The U.S. Food and Drug Administration today initiated the process for a label change for acetaminophen (Tylenol and similar products) to reflect evidence suggesting that the use of acetaminophen by pregnant women may be associated with an increased risk of neurological conditions such as autism and ADHD in children. The agency also issued a related [letter alerting physicians](#) nationwide.

“The FDA is taking action to make parents and doctors aware of a considerable body of evidence about potential risks associated with acetaminophen,” **said FDA Commissioner Marty Makary, M.D., M.P.H.** “Even with this body of evidence, the choice still belongs with parents. The precautionary principle may lead many to avoid using acetaminophen during pregnancy, especially since most low-grade fevers don’t require treatment. It remains reasonable, however, for pregnant women to use acetaminophen in certain scenarios.”

Evidence in recent years has suggested a correlation between acetaminophen use during pregnancy and subsequent diagnosis of conditions like autism and ADHD. Multiple large-scale cohort studies, including the [Nurses’ Health Study II](#) and the [Boston Birth Cohort](#), find this association. Some studies have described that the risk may be most pronounced when acetaminophen is taken chronically throughout pregnancy.

It is important to note that while an association between acetaminophen and neurological conditions has been described in many studies, a causal relationship has not been established and there are contrary studies in the scientific literature. It is also noted that acetaminophen is the only over-the-counter drug approved for use to treat fevers during pregnancy, and high fevers in pregnant women can pose a risk to their children. Additionally, aspirin and ibuprofen have well-documented adverse impacts on the fetus.

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