



Written by [Michael Tennant](#) on October 21, 2025

FDA Ignored Its Experts' Advice on Tylenol Risks for Almost a Decade, Documents Show

Although the Food and Drug Administration (FDA) only [cautioned](#) pregnant women in September against taking excessive amounts of Tylenol because the drug has been linked to autism in children, the agency has in fact known of such links since 2016, the [Daily Caller](#) reported Tuesday.

Moreover, the FDA repeatedly refused to update its advice regarding Tylenol despite recommendations from its drug-safety experts that notifying expectant mothers of the potential risks was “needed,” “important,” or “desirable.”



AP Images

Untriggered Warnings

The Daily Caller News Foundation obtained relevant internal FDA documents from law firm Keller Postman LLC, which got them via a Freedom of Information Act request. Keller Postman is currently [appealing](#) a federal court decision in its class-action lawsuit against Kenvue, the company that manufactures the acetaminophen brand Tylenol.

Prior to this year, the only statement the FDA had made on Tylenol was a [2015 announcement](#) that it was “aware of concerns” regarding the popular painkiller. That statement was prompted by a 2014 [study](#) published in the *Journal of the American Medical Association* finding that “maternal acetaminophen use during pregnancy is associated with a higher risk for [hyperkinetic disorders] and ADHD-like behaviors in children.”

In 2016, FDA Senior Medical Officer Andrew Mosholder produced a [22-page report](#) summarizing the results of eight studies, all but one of which found “an association between acetaminophen and issues including attention deficits, delayed motor development and autistic behaviors,” penned the Daily Caller.

Mosholder, the website added,

recommended that FDA issue a nuanced warning: Tylenol in pregnancy could cause neurological harm and the drug should be used sparingly, but other painkillers are associated with more definite risks and Tylenol will sometimes be necessary to reduce fever.

Similarly,

Both the FDA [Division of Pediatric and Maternal Health](#) and FDA [Division of Bone, Reproductive, and Urologic Products](#) recommended issuing nuanced communications to the public in 2016-2017.



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Noncommittal Committee

By 2018, the FDA appeared ready to act. In January, Mosholder and Valerie Pratt, who oversaw the safety of over-the-counter drugs, gave a presentation to a decision-making committee headed by Janet Woodcock, then-director of the Center for Drug Evaluation and Research (CDER). “By this time,” noted the Daily Caller, “the scientists had reviewed 21 studies, three-fourths of which indicated a risk of Tylenol in pregnancy, the [slides](#) show.”

Woodcock served as CDER director for all but three years between 1994 and 2021. During that time, her division [approved](#) several drugs, including OxyContin, that have contributed greatly to the opioid crisis; [tried to bury](#) a 2003 Mosholder report linking children’s antidepressant use and suicide rates; and [delayed](#) issuing a warning about the risk of myocarditis associated with the Covid-19 mRNA vaccines.

It comes as little surprise, then, that her committee did not endorse Mosholder’s recommended public statement and postponed further decisions for six months. At the follow-up meeting, the committee made no changes to the agency’s Tylenol advice even though “the FDA’s toxicology division shared their hypothesis that Tylenol could impede blood flow to the growing infant,” the Daily Caller reported based on a [heavily redacted copy of the meeting’s minutes](#).

The next month, the European Medicines Agency [informed](#) the FDA that it planned to issue a Tylenol warning to patients. Still there was silence from the FDA.

Mosholder conducted two more epidemiological reviews of the literature on Tylenol. According to the Daily Caller, a 2019 review “concluded an association also existed between Tylenol in pregnancy and defects in the urinary tract or the reproductive tract,” while a 2022 review once again connected Tylenol to ADHD. With both reviews, Mosholder recommended the FDA warn women of the risks of overusing Tylenol during pregnancy.

The FDA did nothing.

FDA Finally Follows the Science

Mosholder and other experts did not oversell their findings. They consistently stated that the available literature had limitations that made drawing firm conclusions difficult. But they also thought it, in Mosholder’s words, “prudent ... to issue a communication emphasizing that [Tylenol] use in pregnancy should be judicious” because it is “not necessarily free of risk.” Mosholder also pointed out that Tylenol use during pregnancy could still be justified in certain circumstances, particularly when it comes to fever reduction.

Thus, when the FDA finally updated its advice last month — to the howls of the “pro-science” Left — it was only doing what its own experts had been urging it to do for nearly a decade. Its [press release](#) announcing the change was every bit as calm and judicious as Mosholder’s reports had been. It explained that studies had suggested but not proved a “causal relationship” between pregnant women’s Tylenol use and their children’s adverse “neurological conditions.” It further stated:

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.

In the press release, FDA Commissioner Marty Makary said:



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The FDA is taking action to make parents and doctors aware of a considerable body of evidence about potential risks associated with acetaminophen. 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.

Those scenarios do not, however, include [tossing back Tylenol on TikTok](#) to show just how much you "believe in science."



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