

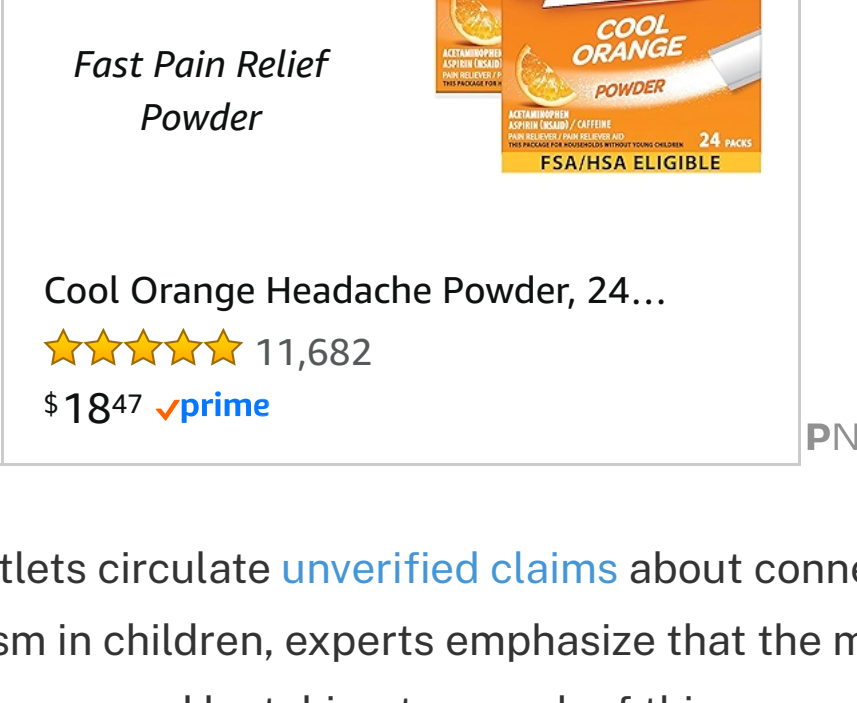
It's Not Autism: The Real Tylenol Risk People Keep Overlooking

BY UNIVERSITY OF COLORADO SCHOOL OF MEDICINE · NOVEMBER 19, 2025 · NO COMMENTS · 6 MINS READ



As speculation spreads online about unproven links between acetaminophen and childhood autism, researchers are drawing attention back to a well-documented problem: the drug remains a leading cause of overdose-related liver injury in the U.S.

Each year, acetaminophen poisoning sends about 56,000 people to U.S. emergency rooms. A CU Anschutz Emergency Medicine toxicology specialist is exploring a new approach to treatment.



As social media and news outlets circulate [unverified claims](#) about connections between acetaminophen use and autism in children, experts emphasize that the more immediate and well-documented issue is the danger posed by taking too much of this common pain and fever reducer.

According to Kennon Heard, MD, PhD, a professor in the CU Anschutz Department of Emergency Medicine and section chief of medical toxicology, acetaminophen overdose remains one of the leading reasons for hospitalization and death related to non-prescription medications in the United States.

[Estimates](#) indicate that acetaminophen poisoning leads to roughly 56,000 emergency department visits and 2,600 hospital admissions each year in the U.S. The drug is also linked to nearly [half](#) of all acute liver failure cases and contributes to about [20%](#) of liver transplants nationwide.

Heard has spent more than two decades studying acetaminophen toxicity. He is now co-leading a multiyear clinical trial that is testing whether a medication originally used for antifreeze poisoning can help protect the liver in severe acetaminophen overdose cases – a potential advancement researchers hope could improve outcomes for high-risk patients.

Heard notes that CU and Denver Health, home of the Rocky Mountain Poison & Drug Safety center, “have been the center of the acetaminophen research universe for the past 40 years. There’s been a long history of this type of work being done here, and it’s great to be a part of it.”

Many reasons for overdoses

Acetaminophen is the main component in Tylenol and many store-brand medications designed to relieve mild pain and reduce fever. It is also included in numerous combination products sold for colds, flu, menstrual symptoms, and sinus discomfort.

The drug has been used for many years and is considered both safe and effective when people follow the dosing instructions. Problems arise when someone takes more than the recommended amount – either in a single large dose or through repeated excess use – which can result in serious health risks.

“There are cases where people accidentally take too much acetaminophen,” Heard says. “Or maybe they have a really bad toothache, and they think if two is good, four is better, eight is even better, and so on. Or it’s someone who’s taking multiple repeated overdoses. Those are the people who get into trouble.”



It’s not uncommon for acetaminophen overdoses to be associated with suicide and self-harm, he added. “The No. 1 rule at the Poison Center is that if it’s available, people will take it, and a lot of people have Tylenol in their medicine chest.”

A drug called acetylcysteine has been established for decades as a highly effective antidote to acetaminophen overdose, but it becomes less effective if administered later than eight hours after ingesting the acetaminophen.

“The problem is that many patients don’t present with acetaminophen poisoning until after they have liver injury, at which point the acetylcysteine is less effective, and in some cases doesn’t really work at all,” Heard says.

Focus on fomepizole

In their current clinical trial, Heard and his colleagues are focusing on fomepizole, a drug approved for use as an antidote for poisoning by ethylene glycol and methanol, ingredients found in many types of antifreeze. Sometimes people drink antifreeze by mistake, while others with alcohol use disorder might consume antifreeze as a substitute for alcohol.

Fomepizole works by inhibiting a family of enzymes called alcohol dehydrogenase, preventing them from breaking down ethylene glycol and methanol into toxic metabolites.

Since as far back as the 1990s, when he was a medical toxicology fellow, Heard has encountered mounting indications that fomepizole might also be valuable as a treatment in acetaminophen overdoses, especially in cases of severe toxicity. Those indications came in the form of scattered case reports about individual patients and in animal studies.

A recent study reported that doctors have significantly increased their off-label use of fomepizole for acetaminophen poisoning, especially in cases of severe toxicity.

Ultimately, Richard Dart, MD, PhD, a professor of emergency medicine and Heard’s longtime mentor on acetaminophen research projects, suggested a trial to assess fomepizole to better establish its benefits. Dart has been the director of Rocky Mountain Poison & Drug Safety since 1992.

Proof of concept

The current [phase II clinical trial](#) seeks to determine if fomepizole, when added to the standard treatment of acetylcysteine, can reduce liver injury in high-risk acetaminophen poisoning patients. It’s a “proof of concept” study that aims to find out whether the combination therapy is promising enough to warrant further, larger-scale trials.

In the trial, one group of patients is given the fomepizole-acetylcysteine combination, and the other group gets acetylcysteine alone. It’s a double-blind trial, meaning neither the researchers nor the participants know who is receiving which therapy until the study is complete.

“We’ll compare the amount of liver damage, as measured by their liver enzymes, to see whether the fomepizole provides an added protective benefit beyond the standard treatment,” Heard says.

Patients are now being enrolled at Denver Health, UCHealth University of Colorado Hospital, Children’s Hospital Colorado, and a few other sites. Enrollment is going slowly because of the difficulty in finding patients who fit the trial criteria, Heard said, but investigators hope to have about 40 patients enrolled in a year to 18 months.

If results are encouraging, Heard foresees advancing to a larger trial with more patients – a trial that looks at longer-range outcomes, such as survival rates and whether patients ultimately need a liver transplant.

“The message that I would want to get out,” Heard adds, is that people using acetaminophen products should read the label and be careful not to exceed recommended doses, and also to be aware that acetaminophen might be in multiple products in a typical medicine chest.

“We’ve started to recognize that the number of people who die from an accidental overdose is pretty close to the number of people who deliberately take an overdose,” he says.

Heard’s collaborators in the trial include Dart and Andrew Monte, MD, PhD, also an emergency medicine professor.

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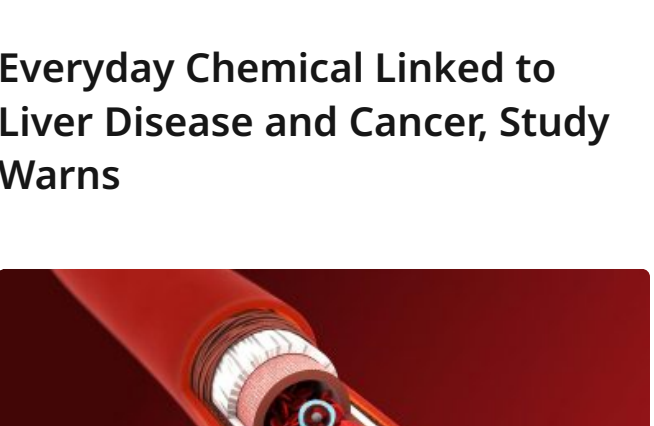
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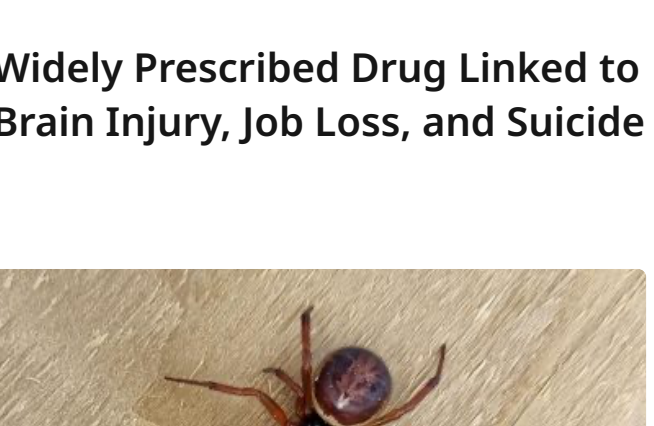
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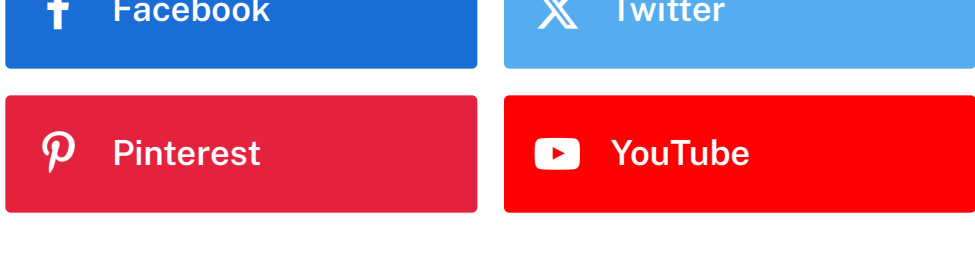
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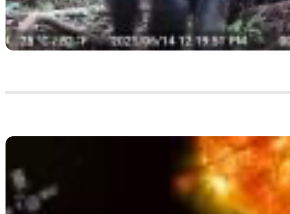
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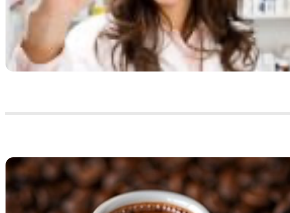
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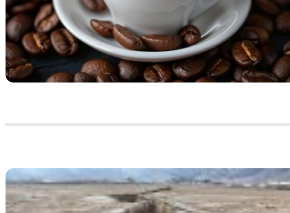
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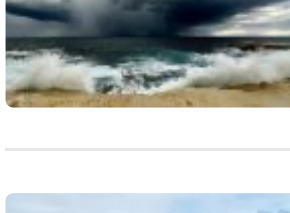
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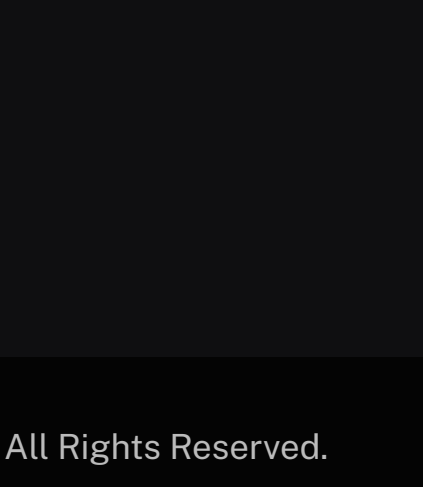
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