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# Exclusive: Hundreds of 'Tylenol Lawsuits' Allege Retailers, Manufacturers Knew Acetaminophen During Pregnancy Could Cause Autism, ADHD

Hundreds of "Tylenol lawsuits" already have been filed against retailers and manufacturers of acetaminophen — but that number could soon reach into the thousands, according to an attorney who spoke to The Defender.

### By Michael Nevradakis, Ph.D.

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Hundreds of "Tylenol lawsuits" already have been filed against retailers and manufacturers alleging they sold products containing acetaminophen to pregnant women, knowing the medications could harm the developing fetus.

The number of lawsuits could soon reach into the thousands, according to an attorney who spoke to The Defender.

Attorney W. Mark Lanier described the lawsuits — which allege acetaminophen use during pregnancy can cause children to be born with autism spectrum disorder (ASD) and attention-deficit/hyperactivity disorder (ADHD) — as "some of the most important health litigation pending in the United States right now."

Lanier, founder and CEO of the Houston-based Lanier Law Firm involved in several high-profile product litigation lawsuits, told The Defender:

"Autism and mental health development or mental development issues touch a huge number of Americans. We believe the science indicates that taking Tylenol can cause many of these problems, period. We think the science backs this up, we think the biology backs it up, and we are eager to prove that in a court. "The goal here is not to take Tylenol off the market. The goal here is to put a warning on it so that doctors and expectant mothers are able to make an intelligent decision of what risks they will expose their child to during pregnancy."

The U.S. Judicial Panel on Multidistrict Litigation (JPML) late last year appointed Senior U.S. District Judge Denise Cote to oversee the growing number of lawsuits brought by families, resulting in all of the claims being transferred to the U.S. District Court for the Southern District of New York.

Judge Cote last month appointed a special master to preside over all federal Tylenol autism and ADHD lawsuits.

The lawsuits allege retailers, including Walmart, CVS, Walgreens and others, falsely advertised products that contain acetaminophen as being safe for pregnant women and did not warn them about the risks posed to fetal development.

Lawsuits also are expected against Johnson & Johnson for its alleged role in encouraging widespread acetaminophen use during pregnancy, which could send the number into the thousands.

Products that contain the drug include Tylenol, Alka-Seltzer Plus, DayQuil, Excedrin, Goody's, Mucinex, NyQuil, Robitussin and some generic and store-brand equivalents.

The lawsuits allege the products have been marketed as safe for pregnant women since the 1950s, despite the existence of dozens of peer-reviewed studies showing acetaminophen poses serious risks to pregnant women and unborn children.

Lawsuits are being pursued on behalf of children under age 15 who were diagnosed with ASD between the ages of 1 and 10, and children under age 15 who were diagnosed with ADHD between the ages of 8 and 14.

The Defender examined some of the currently pending lawsuits making such allegations and the scientific literature regarding the risks of acetaminophen during pregnancy and spoke with one of the attorneys involved with the Tylenol lawsuits.

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#### Lawyer: 'we'll be talking about thousands, tens of thousands' of cases

Lanier, one of the attorneys appointed as lead counsel in the Tylenol multidistrict litigation (MDL), told The Defender, "I think at this point we're in the hundreds that have been filed. I think when all is said and done, we'll be talking about thousands, tens of thousands" of cases.

Although each of the Tylenol ASD and ADHD lawsuits will proceed separately, their consolidation into the MDL means "coordinated discovery into issues that are common to all claims" will occur, with the evidence then available to each individual case filed anywhere in the U.S.

Judge Cote likely will establish a "bellwether" process whereby "a group of representative claims will be prepared for early trial dates, to help the parties gauge how juries are likely to respond to

certain evidence and testimony about the link between Tylenol and autism that will be repeated throughout the claims."

The outcome of these "bellwether" cases will not impact any other individual case but may have a significant impact on the average settlement amount that will be agreed upon for each claim.

If the "bellwether" cases do not reach settlement, Judge Cote may remand them to the U.S. District Courts for trial.

Special Master Randi S. Ellis, a dispute resolution and settlement consulting attorney based in Louisiana, will "help the parties conduct a census of all claims being pursued by families nationwide ... so that the Court can better understand the scope of the growing litigation while planning for discovery and pretrial proceedings."

Cote appointed a group of lawyers — including Lanier — to help manage the growing number of lawsuits as part of the MDL proceedings, even though each individual plaintiff will still maintain their own legal counsel.

Lanier told The Defender that the MDL and the ongoing cases were split into two sections. He explained:

"The first section is one that focuses on science. The science really bears out the truth that Tylenol can be a cause of these brain development issues.

"If so, then the next stage becomes one of trying to understand what knowledge the companies had, were the companies responsible in the way they marketed the products, in the way they warned about the products and what kind of damages people sustained as a result."

In July 2022, several drugmakers and retailers unsuccessfully opposed the consolidation of the disparate ASD and ADHD lawsuits, claiming there were not yet enough cases filed to warrant centralization.

In June 2022, Walmart moved to dismiss two of the lawsuits filed by parents who said they used the retailer's Equate tablets, which contain acetaminophen, during pregnancy. Walmart argued these claims were preempted by federal drug labeling laws, but Cote rejected the motions. Walmart has since appealed.

#### Moms who took acetaminophen detail children's developmental issues

Multiple lawsuits filed by women who took acetaminophen-containing products during pregnancy allege the products caused severe developmental disorders in their children.

Candice Crawford sued Target, Walgreens and Walmart in the U.S. District Court for the District of Minnesota on Sept. 30, 2022, alleging the retailers "all failed to provide customers any warnings about the ADHD risks acetaminophen exposure may pose to unborn children."

Crawford claims she began using the products in November 2014, during her pregnancy, to treat aches and pains. Her child, P.C., was born in May 2015, and was later found to be suffering from speech delay, aggression and other behavioral issues and difficulty maintaining focus.

In November 2021, P.C. was diagnosed with ADHD. Crawford claims if the acetaminophen ADHD risks had been disclosed, she would not have used those medications.

Heather Strydom, who sued Walmart in the U.S. District Court for the District of Minnesota on Aug. 2, 2022, claims Walmart failed to warn pregnant women about the autism risks posed by acetaminophen products.

Strydom said she took acetaminophen products between three and six times per week for aches and pains, from late 2016 until the birth of her child, S.S., in 2017. She began noticing developmental problems in S.S. during his infancy.

S.S. was diagnosed with autism in January 2021, remained non-verbal as of the date the lawsuit was filed and is currently enrolled in special education classes. Strydom said she would never have taken acetaminophen products if autism risks were disclosed.

Abby Horowitz sued Costco in the U.S. District Court for the Central District of California on July 29, 2022. Horowitz claims Costco sold pain medications containing acetaminophen without warning about autism risks for unborn children.

Horowitz took acetaminophen between three and six times per week for pain relief during her two pregnancies. Her two children, J.S. and C.C., were born in 2014 and 2020, respectively. Horowitz's first child was diagnosed with autism in 2014, and her second child is showing signs of developmental delays and is being treated for autism.

Karleen DeGroodt is another mother who has filed a Tylenol lawsuit. She alleges her son, Devin, "never had really good eye contact" and missed several developmental milestones. DeGroodt said she took acetaminophen products several times a week for aches and pains during her pregnancy.

Devin was diagnosed with autism before his third birthday and remains non-verbal today, at the age of 14, using his iPad to communicate.

The growing number of lawsuits has captured the attention of renowned consumer advocate Erin Brockovich, spokeswoman for Autism Justice, who launched a project to help mothers sue the manufacturers and retailers of acetaminophen products.

"My work and working with these women is getting the voices of them and their concerns for their children heard when we have science, and it feels like it's being suppressed or concealed once again," Brockovich said in an interview with NewsNation.

#### Studies clearly show link between acetaminophen and autism, ADHD

As previously reported by The Defender, referencing a JAMA Pediatrics research letter stating 1 in 30 children born in the U.S. in 2020 were diagnosed with autism, and there was a 53% increase in ASD among young Americans since 2017. The Centers for Disease Control and Prevention (CDC) reported similar statistics.

A growing number of scientific, peer-reviewed studies identified links between acetaminophen use by pregnant women and the onset of ASD and ADHD, and other developmental problems, in their children.

Acetaminophen became the preferred drug to treat fevers and pain in children in the early 1980s, after aspirin became associated with Reye's syndrome. An increase in ASD has been documented as having begun during this time period.

In January 2015, the U.S. Food and Drug Administration (FDA) issued an acetaminophen pregnancy warning, stating expectant mothers should be cautious when using such products. The FDA, however, claimed there is "not enough research" to confirm safety risks for unborn children from acetaminophen exposure.

However, numerous peer-reviewed scientific studies appear to show such a link:

- Data from the ongoing Boston Birth Cohort Study, sponsored by the Johns Hopkins Bloomberg School of Public Health, has indicated that "exposure to acetaminophen in the womb may increase a child's risk for attention deficit/hyperactivity disorder and autism spectrum disorder."
- A July 2022 study of acetaminophen published in Minerva Pediatrics "offers 17 lines of evidence
  that the commonly used remedy for pain and fever may be contributing to the autism
  epidemic," as previously reported by The Defender. Dr. William Parker, lead researcher on the
  study, told The Defender at the time that "acetaminophen would never be approved for
  pediatric use by today's regulatory standards."
- A February 2022 study published in the European Journal of Pediatrics found that acetaminophen use in infants and children has never been shown to be safe for their neurodevelopment.
- In September 2021, a consensus of 91 scientists, clinicians and public health professionals published in Nature Reviews Endocrinology journal called for the FDA's 2015 recommendations to be updated. The consensus stated that "increasing experimental and epidemiological research suggests that prenatal exposure to [acetaminophen] might alter fetal development, which could increase the risks of some neurodevelopmental, reproductive and urogenital disorders." This study also found that acetaminophen was, in fact, never assessed for impact on neurodevelopment.
- A June 2021 study published in the European Journal of Epidemiology found that children exposed to Tylenol and acetaminophen during pregnancy were significantly more likely to develop ASD and ADHD symptoms.
- A September 2020 study published in JAMA Pediatrics suggested that the use of Tylenol and acetaminophen during pregnancy may impair the brain of a developing fetus. This could result in ADHD symptoms and other neurological disorders.
- A January 2020 study published in European Psychiatry found that girls whose mothers took acetaminophen during pregnancy were six times more likely to suffer from delayed language development, and used fewer words than normal by the age of 30 months.
- An October 2019 Johns Hopkins study funded by the National Institutes of Health (NIH) found
  that exposure to acetaminophen during pregnancy may increase a child's risk of developing
  autism and ADHD, as the children that had the highest acetaminophen metabolite levels in their
  blood showed the highest risk of developmental disorders. This study was published in JAMA
  Psychiatry.

- A November 2017 study published in Pediatrics, based on data from the Norwegian Mother and Child Cohort Study, found that there is a possible association between short-term acetaminophen use during pregnancy and the risk of giving birth to a child who will later develop ADHD.
- An October 2017 NIH study linked acetaminophen use by pregnant women to "lower performance intelligence quotient (IQ) ... autism spectrum disorder, neurodevelopmental problems (gross motor development, communication), attention-deficit/hyperactivity disorder, poorer attention and executive function, and behavioral problems in childhood."
- A 2017 study published in the Journal of International Medical Research by renowned autism researchers from Duke, Harvard and the University of Colorado found that "the long-term effects of acetaminophen exposure on neural development have never been evaluated in humans." The study's authors stated that even at very low doses, acetaminophen "triggers immune system activation and oxidative stress responses" — both potential warning signs of autism.
- An October 2016 study published in JAMA Pediatrics suggested that the side effects of acetaminophen, when used during pregnancy, may increase the risk of children being born with behavioral problems such as hyperactivity and emotional difficulties.
- A June 2016 study published in the International Journal of Epidemiology found that acetaminophen use during pregnancy was linked to a higher risk of autism among males, and an increased prevalence of ADHD cases among both boys and girls.
- An October 2013 study in the International Journal of Epidemiology found that children whose mothers took acetaminophen products during pregnancy for more than 28 days exhibited poorer than normal gross motor development, communication, externalizing behavior and internalizing behavior.
- A May 2013 study funded by the NIH found a link between circumcision-related acetaminophen use and the increased prevalence of autism.

Dr. Roberta Ness, an epidemiologist who helped demonstrate a link between baby powder and ovarian cancer, is also sounding the alarm.

Ness, a woman's health expert who works with Autism Justice and former dean of the University of Texas School of Public Health, told USA Today in November 2022:

"I'm not saying that acetaminophen is now the cause (of autism and ADHD). I'm saying that it's a cause.

"This is our first opportunity to find an exposure that may be preventable and may be a cause."

In a separate interview with NH Journal, Ness said, "I am absolutely convinced that it's not only a link, but it's a cause. I would say in the last seven years, the manufacturers, the FDA, OBGYNs, have been or should have been aware of this evolving literature and how convincing it is. None of them have done anything to alert the American public."

USA Today and NH Journal also quoted scientists from the American College of Obstetricians and Gynecologists, the Duke University Center for Autism and Brain Development, the Society for Maternal-Fetal Medicine and the University of Pennsylvania School of Medicine claiming that the link between acetaminophen, ASD and ADHD remains "inconclusive."

#### Lawyers: Tylenol lawsuits can still be filed

There's still time to file more lawsuits, Lanier told The Defender.

"For most people, the lawsuits are appropriately in the name of the ultimate victim," said Lanier. "And most states have a law that says that the statute of limitations ... doesn't start running until someone's 18 years old, because that's when they're old enough to make a legal decision of whether or not to file it."

#### Lanier added:

"You're looking at the last 18 years-plus of victims that can file now, but you've also got people who may be a victim this year because there's still no warning on it [acetaminophen], may be a victim next year because there's still no warning on it

"And so, you've got the autistic births for the last 18-plus years and ones that perhaps go up to the time where a warning gets put on the label."

According to a recent order in the ongoing MDL, "any plaintiff who has a case pending currently in the MDL must file a Short Form Complaint by Jan. 20," while plaintiffs in any future lawsuits "must complete a short-form complaint within 14 days of bringing the case, regardless of whether the lawsuit is filed directly with the MDL or if the case is transferred from another district."

The makers and retailers of acetaminophen products are no stranger to such lawsuits. In 2017 for instance, approximately 200 lawsuits against Johnson & Johnson alleging severe liver damage were settled out of court.

#### SUGGEST A CORRECTION



#### Michael Nevradakis, Ph.D.

Michael Nevradakis, Ph.D., based in Athens, Greece, is a senior reporter for The Defender and part of the rotation of hosts for CHD.TV's "Good Morning CHD."

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