



Written by [Veronika Kyrylenko](#) on September 23, 2025

HHS Unveils “Bold” Autism Plan: Treatments, Warnings, Unanswered Questions

The U.S. government is launching a sweeping new initiative to address autism spectrum disorder, a condition that has grown to epidemic levels in the United States. President Donald Trump and Health and Human Services (HHS) Secretary Robert F. Kennedy, Jr. [announced the plan](#) on Monday.

Autism now affects one in 31 American children, according to recent Centers for Disease Control and Prevention (CDC) data. That is nearly five times higher than when tracking began in 2000, when just one in 150 children was diagnosed.



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The sharp rise has left many families without clear answers or options. Kennedy promised that will change:

For too long, families have been left without answers or options as autism rates have soared.... Today, we are taking bold action — opening the door to the first FDA-recognized treatment pathway, informing doctors and families about potential risks, and investing in groundbreaking research. We will follow the science, restore trust, and deliver hope to millions of American families.

Indeed, families have waited decades for action. Now Washington, which has no constitutional authority to manage healthcare, is stepping in with urgency. But critical questions remain: Will this initiative deliver truthful answers and lasting solutions? Or will it become yet another chapter in a long history of promises without reliable cures, answers, or accountability?

New Treatment: Leucovorin

The centerpiece of the announcement is the recognition of leucovorin, a folate-based drug, as the first FDA-recognized therapy for children with autism symptoms linked to cerebral folate deficiency (CFD). Also called folinic acid, leucovorin can bypass a defective transport system that blocks folate from reaching the brain, per the [fact sheet](#) accompanying the announcement.

The FDA published a Federal Register notice outlining the label update, making leucovorin an official treatment option for speech and language deficits in certain children. The change means state Medicaid programs will be able to cover the drug in partnership with the Centers for Medicare & Medicaid Services.

“This action establishes the first FDA-recognized therapeutic for children with cerebral folate deficiency and autistic symptoms,” reads the announcement. The fact sheet noted that analysis of 23 publications from 2009–2024 showed “85% of patients experienced some type of clinical benefit including improved



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speech/communication capabilities.”

Officials emphasized that leucovorin is not a cure. Benefits may be limited and use must be monitored by doctors and paired with behavioral therapies. The National Institutes of Health (NIH) will launch confirmatory trials and safety studies.

The [FDA announced](#) it is now working with pharmaceutical giant GlaxoSmithKline (GSK), the original maker of leucovorin (branded as Wellcovorin), to expand the official drug label for use in both children and adults with CFD. Officials stressed that more research is still needed for broader populations with autism-like symptoms, but called the move an important step in repurposing existing drugs to address chronic conditions.

New Safety Guidance on Acetaminophen

The administration also turned to acetaminophen, sold under brand names such as Tylenol and similar products. It is the most common drug used during pregnancy and often the only over-the-counter option for treating fever, which itself carries risks such as neural-tube defects and preterm birth, per the HHS.

The department now points to evidence of acetaminophen’s “potential risks” to neurodevelopment. The FDA will issue a physician notice, update labeling, and HHS will launch a public campaign to share the findings.

“The FDA is responding to prior clinical and laboratory studies that suggest a potential association between acetaminophen use during pregnancy and adverse neurodevelopmental outcomes,” the announcement said. It also acknowledged “contrary studies showing no association and that there can be risks for untreated fever in pregnancy, both for the mother and fetus.”

With scientific evidence being so “conflicting,” the HHS is urging caution:

Given the conflicting literature and lack of clear causal evidence, HHS wants to encourage clinicians to ... prescribe the lowest effective dose for the shortest duration when treatment is required.

More Research

The third prong of the initiative is a major investment in research. NIH will fund 13 projects under the Autism Data Science Initiative (ADSI), with more than \$50 million in new awards. The projects, chosen from 248 applications, cover prevalence, causes, treatments, and replication studies.

The fact sheet said ADSI will integrate “large-scale biological, clinical, and behavioral data with an exposomics approach that examines environmental, nutritional, medical, and social factors alongside genetics.” Methods include machine learning, causal inference, and organoid models.

Projects will study both children and adults. Replication hubs promise to ensure rigor, and each project will include structured partnerships with autistic individuals, families, and clinicians.

NIH Director Dr. Jay Bhattacharya called the initiative transformative. “Millions of American families who care for autistic kids need scientists to apply gold standard science, expertise, and open minds to figure out how to help these kids,” he said.

Earlier this year, [NIH also began assembling](#) what could become one of the largest centralized health databases in U.S. history. The platform will draw from pharmacy transactions, lab results, genomic files



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from the VA and Indian Health Service, Medicare and Medicaid claims, private insurance billing, and even wearable devices. A new national registry for autism diagnoses will be added. Bhattacharya says the goal is to fix the “fragmentation” of current health data.

Elephant in the Room: Vaccines

For years, Robert F. Kennedy, Jr. and his nonprofit, Children’s Health Defense (CHD), have argued that childhood vaccines play a central role in the autism epidemic. His once-consistent calls for transparency in government data, along with his book [Vaxxed-Unvaxxed](#), have made Kennedy one of the most controversial figures in modern medical debate. Now, as HHS secretary, he oversees an agency pledging to study “medical and perinatal influences, including medications, vaccinations, obstetric complications, and neonatal intensive care experiences.” Yet despite the sweeping scope, the announcement offered no clear timeline for when these studies would be completed or when families might see results.

Mainstream institutions continue to insist there is no link between vaccines and autism. Public health agencies, medical associations, and most major media outlets dismiss the vaccine-autism connection as a “conspiracy theory.” Parents, however, have been telling a different story for decades.

CHD has long documented these accounts alongside peer-reviewed studies. Its files include testimonies from parents who believe routine immunizations marked the turning point in their child’s development. At a recent Senate hearing, Toby Rogers of the Brownstone Institute [cited](#) data showing that 88 percent of autism cases involve regression. He argued the pattern points to “acute toxic exposure” and noted that thousands of parents identify vaccination as the moment it began.

This is the debate no federal initiative has resolved. HHS now promises to examine vaccines as one possible factor, but whether it will do so with independence and transparency remains in doubt. Until then, the elephant in the room will remain — too large to ignore, and still unaddressed.

Related articles:

[CDC Set to Hand Autism-Vaccine Study to Single Institution](#)

[What the MAHA Report Says About Childhood Vaccines — and What It Leaves Out](#)

[HHS Assembles National Health Data Platform and Autism Registry](#)

[HHS to Use Medicare and Medicaid Data in Federal Autism Platform](#)



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