

THE IMMUNE RESPONSE

The Supreme Court may tell families with autistic children whether they can sue vaccine makers

BY WENDY N. DAVIS

WHEN YATES HAZLEHURST GOT THE measles, mumps and rubella vaccine in February 2001, three days before his first birthday, he had just begun to talk, uttering words like *Mama*, *Dada* and *please*.

Within a few months, Yates stopped speaking—in words, anyway—and instead became obsessed with numbers and letters. He also stopped looking people in the eye. And he developed physical ailments, including severe stomach problems and recurrent infections. He also became so rambunctious that his family started restraining him with a harness.

The changes alarmed Yates' mother, though his father initially took it all in stride. "I thought, 'Boys will be boys; he's fine,'" recalls Rolf Hazlehurst, an assistant district attorney in Jackson, Tenn.

Eventually, however, when Yates started hitting his head against the wall, Rolf couldn't deny something was wrong. "He had become a wild, uncontrollable maniac," he says.

Yates now requires intensive therapy. He talks only in one-word commands. Yates' mother, Angela, quit her job as a sales rep for GlaxoSmithKline to take care of him. The Hazlehursts recently sold their house, downsizing from 4,400 square feet to 2,000 to pay the growing medical bills.

Out-of-pocket expenses for Yates' treatment, including speech therapy and behavioral therapy, have totaled \$250,000, his father estimates. Only four people can calm Yates when he has an outburst: Rolf, Angela, her mother and one baby sitter.

When Yates was still younger than 2, the family sought medical help from a battery of doctors, including a neurologist, Dr. Jean-Ronel Corbier of Concord, N.C. He diagnosed Yates as suffering from "regressive autism"—a form of autism that doesn't manifest itself until after a child's first birthday.

Corbier also proposed a controversial theory about what caused Yates' condition: the measles, mumps and rubella vaccine. A battery of tests had ruled out known genetic causes or structural defects that can cause autism. He said that the measles virus was present in Yates' gut.

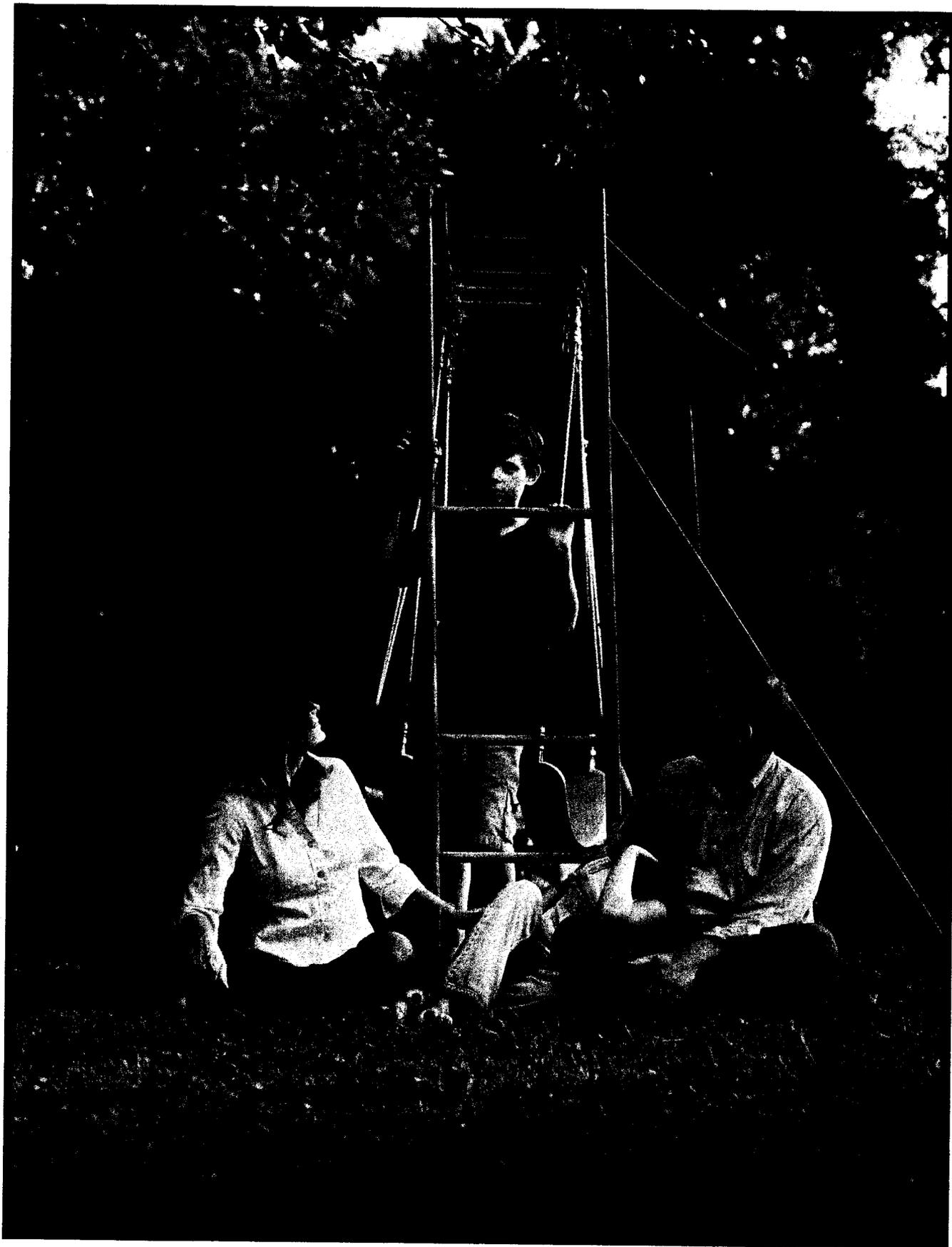
Yates, Corbier would later testify, would not have developed autism had he not received the MMR vaccine.

His family filed a claim in 2003 with the Office of Special Masters of the U.S. Court of Federal Claims, known as the "vaccine court," which compensates families whose children have been injured by vaccines.

A report in the late 1990s suggested a link between autism and vaccines. The Hazlehursts were among more than 5,000 parents of autistic children to bring cases in the vaccine court since 1999 alleging that their children developed autism as a result of vaccines. An additional 350 cases are believed to be pending in civil courts throughout the country.

They began to see vaccines as the potential next big toxic-tort battleground, on the order of Vioxx or asbestos. The cases drew the attention of toxic-tort lawyers from around the country, including the likes of Kevin Conway—one of the plaintiffs lawyers depicted in the movie *A Civil Action*.

But the vaccine court rejected the plaintiffs' medical



The Hazlehurst family

PHOTOGRAPH BY TREY CLARK

theories and threw out all of the omnibus cases in six separate rulings issued in February 2009 and this past March. The Hazlehursts and a second family, the Cedillos of Yuma, Ariz., appealed to the U.S. Court of Appeals for the Federal Circuit, which rejected both of their claims this year. The families are now considering going to civil court.

Standing in the way, however, is the U.S. Supreme Court, which will decide a case this term on whether the 1986 federal National Childhood Vaccine Injury Act, which created the special vaccine court, pre-empts their claims. Argument in *Bruesewitz v. Wyeth* is scheduled for Oct. 12.

The 3rd U.S. Circuit Court of Appeals upheld the dismissal of a lawsuit against drugmaker Wyeth by the family of Hannah Bruesewitz, who experienced seizures after receiving a DPT (diphtheria-pertussis-tetanus) shot at age 6 months in April 1992. Hannah's doctors said she had residual seizure disorder and developmental delay.

The Bruesewitz family brought a claim in vaccine court in April 1995, alleging that Hannah had suffered residual seizure disorder and encephalopathy after receiving the DPT vaccine. When the vaccine court was first launched, residual seizure disorder was considered a "table injury"—meaning it was on the table of injuries listed as caused by the DPT vaccine.

But the injury was deleted from the table by regulations effective March 10, 1995—one month before the family's petition.

The vaccine court ruled that the Bruesewitzes hadn't proved the shot caused Hannah's injuries and dismissed the petition. The family then refiled in Philadelphia Common Pleas Court in October 2005, alleging several theories, including negligent failure to design a safer vaccine. The suit was later moved to federal court.

Eventually the Philadelphia-based 3rd Circuit said the federal law creating the vaccine court pre-empted all civil actions alleging design defects—including those that resulted from negligence.

The Bruesewitz family argues that the statute itself only discusses pre-emption of unavoidable design defects, not negligent ones. The statute says that vaccine manufacturers shall not be liable in civil actions "if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied



David Bernstein

by proper directions and warnings."

Wyeth also sought Supreme Court review and, in its petition, specifically warned that a wave of autism claims could hit the courts unless the 3rd Circuit opinion is upheld. "Today, a new litigation threat to the nation's vaccine supply exists," Wyeth wrote, referencing not only the 5,000 autism cases in vaccine court but also the 350-plus civil actions in various federal and state courts.

A DEFINITION OF COINCIDENCE?

But the stakes are far greater than just 5,350 potential verdicts. Overall, about one in 110 8-year-olds in the U.S. has an autism spectrum disorder. If vaccines are to blame, the

economic liability could be enormous—especially for the most severely affected children like Yates Hazlehurst, who require around-the-clock care.

Many fear that a court ruling linking autism to vaccines could spur parents to eschew immunizations, sparking a potentially deadly epidemic. After all, while vaccines may or may not cause autism, leaving children unvaccinated will certainly result in a resurgence of potentially fatal diseases.

“There could be a huge public health disaster,” says George Mason University law professor David Bernstein, who calls the vaccine explanation junk science. “It’s really hard for individuals to accept that it could be genetics or random occurrences. Vaccines are easier for people to blame it on.”

Many doctors also say that autism is largely genetic. If children are diagnosed soon after receiving a vaccine, it’s because that’s also when language difficulties and other symptoms first manifest.

“It’s the definition of coincidence,” says Dr. Paul Offit, author of *Autism’s False Profits* and head of the division of infectious diseases at the Children’s Hospital of Philadelphia. With thousands of children diagnosed each year, it would be statistically impossible for some not to develop symptoms soon after receiving a vaccination, he says.

Parents and their lawyers, however, say they’re only trying to get help for their children, not cause a public health scare.

“We didn’t start out as being anti-vaccine,” says Robert Krakow, a New York City attorney who represents more than 100 families with autistic children—including his own. He is the father of a 10-year-old boy with autism. “We’re not opposed to vaccines as a concept. We’re the ones who vaccinated our kids.”

Krakow and others say they’re simply seeking compensation for their children’s mounting doctors’ bills. Lately they’ve been vocal critics of the vaccine court, arguing that the judges decided to “protect” the vaccine program by reassuring parents that vaccinations are safe, rather than fulfilling their responsibility to help injured children.

THE VACCINE COURT

When it was created in 1986, the vaccine court was to serve as a nonadversarial forum where families injured by immunizations could receive payments. At the time, several large jury verdicts against pharmaceutical companies sparked a fear that manufacturers would leave the market due to liability concerns, potentially putting the country’s entire inoculation program at risk. A few manufacturers had left the market.

People who allege they were injured by vaccines

must first file in vaccine court. The statute provides that if plaintiffs aren’t happy with the result, or if the vaccine court hasn’t rendered a decision within 240 days, they can bring a civil action.

But the statute also says that some claims can only be brought in vaccine court. At issue in *Bruesewitz* is whether lawsuits alleging negligent design defects can proceed in civil court, or if they are among the types of cases that can only be litigated in vaccine court.

The National Childhood Vaccine Injury Act set out a federal no-fault system for vaccine injuries; the program is funded with a 75-cent-per-vaccine tax. Claims were supposed to be handled “quickly, easily and with certainty and generosity,” according to a House report.

But advocates for claimants say the program has fallen short. Cases can linger for years, and claims sometimes face heated government opposition. What’s more, the vast majority of claimants lose. Excluding autism claims, the program has only awarded compensation in 36 percent of the 6,860 cases adjudicated. (The autism cases were dismissed in the omnibus proceeding; in cases where families were compensated after children developed autistic symptoms, autism was seen as a secondary disorder.)

“The disappointing factor here is that a court that was created to be the best venue for these injuries is not fulfilling its purpose,” says Alexandra Dunn, assistant dean of environmental law programs at Pace Law School. “Over time, when it comes to this particular type of claim, the court seems to be raising the bar for causation.”

Though the program is no-fault, people can only recover damages if they suffer an injury that falls on a table of medical conditions set out by the U.S. Department of Health and Human Services, or if they prove to a special master that a vaccine caused their injury.

Plaintiffs lawyers say that the table became far more defense-friendly in 1995 as a result of HHS revisions that eliminated or redefined some of the injuries that would be compensated following particular vaccines.

Before the revamp, the vast majority of claims alleged on-table injuries, says Peter Meyers, faculty supervisor of the Vaccine Injury Clinic at George Washington University Law School.

Such claims require judges to decide only whether injuries meet the government’s definition. For example, people who develop brachial neuritis between two and 28 days after receiving a tetanus shot are covered by the current table.

Figuring out whether someone meets those criteria

is “a narrow and a relatively easy question to decide,” Meyers says.

Proving actual causation, on the other hand, is notoriously difficult. Just as doctors often don’t know why a particular individual is stricken with, say, cancer, it’s often hard to say with certainty that a vaccine has caused a particular illness.

Showing causation is particularly hard in vaccine court because of the limited discovery, Meyers says. Claimants aren’t necessarily entitled to review pharmaceutical company research that could fill in missing gaps—such as tests showing that people developed symptoms after receiving certain shots.

NEW STANDARD

But in a move that seemed to give vaccine court plaintiffs a considerable boost, the Federal Circuit relaxed the causation standard in 2005 in a case brought by 49-year-old Margaret Althen, who developed optic neuritis after receiving a tetanus shot.

The special master denied Althen compensation because she hadn’t proved that the vaccine caused her condition, but the appellate court reversed—and announced a new standard. Going forward, claimants in vaccine court could prove causation by showing: (a) a medical theory linking the vaccine to the injury, and (b) that they developed the injury soon after being vaccinated.

If the plaintiffs meet that standard, they are entitled to recovery unless the government shows by a preponderance of the evidence that something other than the vaccine caused the injury.

“The purpose of the vaccine act’s preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body,” the court said.

The families in the autism litigation said they satisfied the “Althen test” because they presented a medical theory that supports causation and because their children became sick soon after receiving immunizations.

But Health and Human Services, which opposed the claims, argued that no reputable evidence showed any link between autism and vaccines.



Peter Meyers

The claims themselves went to trial in an unusual omnibus proceeding that involved six test cases and two theories of causation. The first theory was that the MMR vaccine in combination with a battery of other shots—all laced with the mercury-based preservative thimerosal—were responsible for autism. The Hazlehursts and the families of two other children, Michelle Cedillo and Colten Snyder, served as test cases for that theory. The second theory was that thimerosal alone was responsible.

The Hazlehursts’ claim was seen as particularly strong because Rolf had videotaped much of his first-born child’s life. The tapes document Yates’ progression from a happy, apparently normal baby

to an afflicted toddler.

Judges considered the same expert testimony in all six cases. The record included more than 900 medical and scientific journal articles and 50 expert reports in addition to the six children's medical records. Seven experts testified for the petitioners, while the government called 18 experts.

On Feb. 12, 2009, the court handed down three sweeping decisions, totaling 679 pages, rejecting all claims that the combination of thimerosal in shots and the MMR vaccines resulted in autism.

"The combination of the thimerosal-containing vaccines and the MMR vaccine are not causal factors in the development of autism and, therefore, could not have contributed to the development of Yates' autism," Special Master Patricia Campbell-Smith declared in the *Hazlehurst* opinion. "The weight of the presented evidence that is scientifically reliable and methodologically sound does not support petitioners' claim."

The two judges who wrote opinions in the other cases handed down that same day issued similarly strident opinions. The tone of all three was so adamant that many observers believe the judges were aiming to broadcast a statement to the public that vaccines are safe.

"If you read the three special masters' decisions, I don't think you can come away with any other conclusion than that they were trying to send a message to the broader world that vaccines don't cause autism," says Meyers.

AN ISSUE OF TRUST

Families and their supporters now say that the deck was stacked against them, and that the judges wrongly discounted their evidence while improperly admitting other expert testimony.

Krakow says claimants weren't able to obtain the discovery that they needed to prove their theories or to finance their own epidemiological research. Like others who believe vaccines cause autism, Krakow says the research to support the claims is still emerging. "Even since the cases have been heard, there have been more scientific studies," he says.

Ultimately, whether people believe that vaccines cause autism or that the theory is all junk science depends largely on which researchers people feel are most trustworthy. For that reason, the plaintiffs suffered a blow when the credibility of Andrew Wakefield, the most prominent proponent of the vaccines-cause-autism theory, came under attack.

Wakefield is largely responsible for popularizing the idea that vaccines cause autism. In 1998, he

wrote an article for the prestigious British medical journal *The Lancet* suggesting that the MMR vaccine was linked to intestinal inflammation and autism. That article was based on a study of 12 children with gastrointestinal ailments.

Wakefield's work sparked immediate fears about the MMR vaccine. Vaccination rates in the U.K. fell from more than 90 percent in the mid-1990s to 80 percent and even lower in some areas. The result was a new wave of measles cases, rising from less than 100 in the U.K. in 1998 to almost 1,400 in 2008. A child in the U.K. died of measles in 2006, for the first time in more than 10 years.

Earlier this year, *The Lancet* retracted Wakefield's article, stating that "several elements" of the paper were incorrect. The *Sunday Times* of London reported several years ago that at least five of the children in the study had been referred to Wakefield by plaintiffs attorneys, and that Britain's Legal Aid Board (now the Legal Services Commission) funded some of the research. Wakefield was stripped of his medical license in May.

Wakefield, however, wasn't the only scientist to allege a connection between MMR and autism. A former research collaborator, Dr. John O'Leary, a pathologist who created the Dublin-based for-profit lab Unigenetics, reported in a 2002 study that RNA from the measles virus was present in more than 80 percent of autistic children.

That finding was subsequently debunked by molecular biologist Stephen Bustin, who examined O'Leary's evidence at the request of the High Court in the U.K. Bustin concluded that Unigenetics' lab work and conclusions were flawed.

Other researchers have suggested that thimerosal contributed to rising autism rates before its use was all but eliminated by manufacturers in 2001. But because there has been no decline in autism rates since then, that relationship has been discounted in recent research.

But plaintiffs lawyers contend that thimerosal hasn't been totally eliminated from vaccines. And ultimately, they say, more research is needed. Many liken the question to debates years ago about whether cigarettes cause lung cancer.

Defense lawyers, however, say that comparison is misplaced. "Tobacco is so unpopular that plaintiffs love to analogize to it, but it's a false analogy," says Philadelphia attorney Sean Wajert, co-chair of Dechert's mass torts and product liability practice group. The link between tobacco and cancer took so long to establish because cancer can take decades to appear, he says. "What you have in the vaccine-autism context is a lot of research that's been done

that shows there's no link there."

George Mason's Bernstein goes even further, likening the claims to the Bendectin debacle. Bendectin was an anti-nausea drug given to pregnant women in the 1970s, but it was pulled from the market after lawsuits alleged it caused birth defects.

The plaintiff's main expert witness, Dr. William McBride, was subsequently found to have falsified his research and was stripped of his medical license in Australia. The case led to one of the most defense-friendly rulings in the field: *Daubert v. Merrell Dow Pharmaceuticals*, a 1993 Supreme Court ruling that made it harder for plaintiffs to present expert testimony to support novel scientific theories.

The dispute about how to interpret conflicting scientific reports is also at the center of the Hazlehursts' and Cedillos' appeals. The Federal Circuit dismissed the Hazlehursts' appeal in May and the Cedillos' in August. The court upheld the special master's findings that Bustin's report showed that the Unigenetics lab reports were unreliable.

"We see no legal error in the standards applied by the special master" in determining there was no causal connection between the mercury-based preservative in the MMR vaccine administered to Michelle Cedillo in 1995 and the autism and retardation symptoms she began to show afterward, the Federal Circuit said. Nevertheless, many of the 5,000 families whose cases were part of the omnibus proceeding are considering trying their luck in civil court, where they can get jury trials.

Meanwhile, a host of outside groups—including public interest groups like the American Association for Justice, Public Justice and Public Citizen, as well as the National Vaccine Information Center—have filed amicus briefs supporting the plaintiffs in *Bruesewitz*. Constitutional scholars Kenneth Starr and Erwin Chemerinsky filed a joint amicus brief urging the Supreme Court to reverse the appellate decision as a misuse of federal pre-emption.

Amici backing Wyeth are the U.S. solicitor general and the American Academy of Pediatrics, on behalf of itself and 21 other physician and public health groups.

AGGRAVATING AUTISM

BUT SUING IN CIVIL COURT ISN'T THE ONLY option left for parents. Another is to wait for more research to emerge. Though the omnibus cases were dismissed, several families of autistic children have been compensated in vaccine court, but only when they argued that au-

tism was a secondary disorder, not the primary one.

The family of Hannah Poling, for instance, successfully convinced the vaccine court in 2008 to compensate her after she developed autism. Her family's theory was that a vaccine she received in July of 2000 aggravated an underlying mitochondrial disorder that, in turn, predisposed her to encephalopathy with features of autism spectrum disorder.

Likewise, the family of Bailey Banks prevailed in vaccine court on the theory that the MMR vaccine—which Bailey received in March 2000 when he was 15 months old—triggered a seizure and "acute disseminated encephalomyelitis," resulting in a "pervasive developmental delay."

Krakov says there are even more unreported cases in which the vaccine court has compensated children who have developed autism after receiving vaccines. In those cases, the families argued that the vaccines caused another problem that ended up triggering autistic symptoms.

What's more, he says, it's not clear how many families of autistic children could have made similar arguments as the Polings and Bankses. In other words, he says, many children who display autistic symptoms could have another underlying disorder that's aggravated by a vaccine.

Waiting for more research to emerge could be an especially attractive option given a recent decision out of the Federal Circuit in *Cloer v. Secretary of Health and Human Services*, holding that the three-year statute of limitations in vaccine court doesn't run until "the medical community at large" recognizes a link between the vaccine and injury.

With science still developing, families might yet be able to make their case that vaccines triggered some unusual reaction in their children that left them vulnerable to autism, says George Washington's Meyers.

"Maybe in five or 10 or 15 years we'll have definitive information linking autism to these vaccines," Meyers adds. "Maybe the answer is to wait."

Krakov agrees. "We look at this as a decades-long process—like asbestos," he says. "It could take 50, 60, 70 years to get resolved."

For other parents like Rolf Hazlehurst, however, waiting for decades isn't an attractive option. As Yates is growing older and the bills continue to mount, Rolf has become increasingly frightened for his son's future. "My hope," Rolf says, "is that when I'm dead and gone, he won't have to be locked in a mental institution." ■

Wendy N. Davis is a lawyer and journalist in New York City.