

# Vaccine Injury Claims Face Grueling Fight

## Victims increasingly view U.S. compensation program as adversarial and tightfisted.

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Like good moms everywhere, Janet Zuhlke made sure her kids got their shots.

This proved disastrous for her daughter, Rachel. She was a healthy 5-year-old until a brain injury triggered by a routine vaccination left her mentally retarded, physically handicapped and legally blind.

A single mother raising three daughters in Satellite Beach, Fla., Zuhlke needed help with the enormous costs of Rachel's lifetime care. So she brought a case in a federal tribunal set up to handle vaccine injury claims.

There, opposing lawyers hired expert witnesses to prove that Rachel's injuries weren't vaccine-related. When that failed, they balked at paying for costly medicines her doctors said she badly needed.

The Zuhlkes finally won — but it took more than 10 years.

"I thought it was very cruel," Zuhlke said. "People were very aware of the fact that my family was suffering."

The lawyers who opposed the Zuhlkes were not working for a vaccine company but the Justice Department. Government attorneys fought relentlessly to defeat a mother who thought she was doing the right thing by getting her daughter a government-mandated vaccine.

It wasn't supposed to happen that way in the Vaccine Injury Compensation Program, informally known as the vaccine court. Created by Congress and jointly run by the Department of Health and Human Services, the Justice Department and the U.S. Court of Federal Claims, it was designed to shield vaccine makers from damage awards that were threatening to drive them from the business.

It also was supposed to compensate victims in rare cases of injury under a flexible, no-fault system that would avoid the rancor and delay of traditional litigation. Claims were

to be handled "quickly, easily and with certainty and generosity," said a House report accompanying the legislation in 1986.

Instead, say advocates for families with injury claims, federal officials often fight them with such zeal that many who deserve help are denied it, and even successful cases get bogged down for years.

The program "was supposed to be non-adversarial and it's become very adversarial," said Rep. Dan Burton (R-Ind.), whose House Subcommittee on Human Rights and Wellness has held hearings on the matter. Many have "had legitimate claims and they went on for eight, nine, 10 years."

Vaccine compensation officials refused to be interviewed, but in written statements they said the program had "an excellent record of promptly and appropriately compensating" valid claims.

Over the years, about \$1.5 billion has been paid out in compensation and legal fees for more than 1,800 families, most of which would have had little chance of winning a civil trial, the officials said. They insisted that the vaccine court was less adversarial than civil courts, but said they were obliged to fight claims that weren't based on good science.

This was "never intended to serve as compensation source for ... conditions that are not vaccine-related," said Joyce Somsak, the program's acting director.

But in trying to weed out undeserving claims, critics say, the government has insisted on a level of proof of injury that is almost impossible to meet.

And a Times analysis of claims data shows that the court has become more unyielding over time: Officials are much less likely than in earlier years to concede that a vaccine was responsible for an injury or death. The percentage of people getting awards also has declined.

Even when families do win compensation, officials have sometimes battled them over just a few dollars.

In one case, government representatives argued that \$150 a year was too much to spend on wheelchair maintenance. They have haggled over how much to allow for replacement shoes and braces for people with polio. Another time, they recommended rubber sheets for the bed of an incontinent person because they were cheaper, although less comfortable, than disposables costing \$135 a year.

"We never anticipated the extent [they] would go to deny these kids compensation," said Barbara Loe Fisher of the National Vaccine Information Center, who lobbied for the bill that created the program.

Viewed another way, by being tightfisted, officials have been good stewards of the

vaccine injury trust fund, the self-insurance pool that pays awards to the injured. In fact, the fund — fed by a surcharge of 75 cents per vaccine dose — has ballooned to more than \$2 billion, while earning about as much in annual interest as it pays in awards.

But the fund was not meant to be a moneymaker. The idea was that it was better to "err on the side of compensating the victim," said Rep. Henry Waxman (D-Los Angeles), sponsor of the legislation.

### **Roots of the Program**

Along with clean water and sanitation, mass immunization ranks among the great milestones in public health. Among its glittering achievements: Measles cases in the U.S. dropped from about half a million in 1960 to 42 last year, according to the Centers for Disease Control and Prevention, or CDC.

But although millions benefit, even the safest vaccines aren't safe for everyone.

Because of genetic differences, some people are harmed by vaccines "that almost everybody else responds to just fine," said Dr. Robert W. Block, former chairman of a federal advisory panel on childhood vaccines.

And some have paid a terrible price. For example, until 2000, when the U.S. switched from the oral live polio vaccine to inactivated polio shots, the vaccine itself caused a few polio cases each year.

Gordon Pierson, a 12-year-old in Jackson, Tenn., contracted polio as an infant this way and is paralyzed and unable to speak.

"We were doing what we thought was best for our son, and the exact opposite happened," said his father, Randy Pierson. "We were just heartbroken, and we are every day."

Fear of legal fallout inspired the National Vaccine Injury Compensation Act. At the time, vaccine makers were facing a surge in claims, mainly from adverse reactions to the diphtheria-pertussis-tetanus, or DPT, vaccine. An exodus from the market and shortages seemed possible. In response, Congress decreed that instead of suing vaccine makers, people would first have to seek compensation from the new vaccine court.

Health and Human Services officials would administer the trust fund and screen petitions, deciding whether to concede or oppose each claim. Justice Department lawyers would appear in court on their behalf.

Petitioners could not seek awards for punitive damages or losses to family members as they could in civil court. But they were to benefit from greater speed and flexibility, and a lower burden of proof. Moreover, the program typically would pay petitioners' legal costs once the case was over, win or lose.

However, what was meant to be a win-win proposition instead has been mostly "a stupendous success in protecting the industry," said George Washington University law professor Peter H. Meyers, who directs a group of law students who represent petitioners. As for helping victims, he said, the record is "much more spotty."

Some see this as a natural result of federal health officials' fierce devotion to the immunization program — and their fear that if enough injuries were acknowledged, people would be afraid to get their shots.

Universal immunization is a fundamental mission of Health and Human Services. One of its branches, the Food and Drug Administration, licenses vaccines, and another, the CDC, promotes their use with such slogans as "Vaccination: An Act of Love."

From the start, agency officials worried that the program might create an exaggerated public impression of the risks of vaccines. At a congressional hearing before passage of the bill, Assistant Secretary for Health Edward N. Brandt Jr. warned that despite the program's laudable goal, it could "provide a significant disincentive to childhood vaccination programs."

### **Burden of Proof Shifts**

In 1995, the government changed the rules of the vaccine court in a way that made cases more contentious, protracted and harder for petitioners to win.

Officials amended the vaccine injury table, a set of guidelines that had tilted many cases in petitioners' favor. According to the table, if certain symptoms appeared within a specified time after a shot, the vaccine was deemed the culprit unless the government could prove another cause. Many "table injuries" were simply conceded by the government, leaving only the amount of compensation to be determined.

A few amendments changed all that. In one major shift, "seizure disorder" was scratched from the table as a telltale sign of injury from a DPT shot. And a new, more restrictive definition of encephalopathy — or brain dysfunction — meant that many conditions that had been table injuries suddenly were not.

Somsak said the table was changed for one reason only: to better "conform with the scientific evidence."

But the upshot was that in many cases the burden shifted from the government to prove the shot didn't cause injury to the petitioner to show that it did. Because it's usually hard to prove with certainty that a vaccine caused harm, the effect of the change was profound.

The Times analyzed a vaccine court database of 10,741 claims filed over 16 years. The analysis showed that in the three years before the changes, the government conceded one-third of all claims. Of cases filed in that period, compensation was awarded in just over half.

But since the changes took effect March 10, 1995, the government has conceded just one claim in seven. About 35% of petitioners have received compensation.

And cases dragging beyond five years have become increasingly common.

Even the court's top judicial officer, Chief Special Master Gary J. Golkiewicz, has lamented the drift toward "full-blown litigation."

"Clearly," he said in one of his rulings, "that is not what Congress intended when it designed the program as an *alternative* to tort litigation."

Clifford J. Shoemaker, a lawyer for petitioners, said if the government softened its stance, the worst that would happen is that a "family that needs some money to deal with their profoundly injured child is going to get it."

"Is that such a terrible thing?" he asked.

Some observers have warned that the government's uncompromising attitude could backfire.

Although the law directs all claims to vaccine court, it allows those who disagree with a ruling — or have waited more than 240 days — to sue vaccine makers in civil court. So far, few have.

But by their tough stance, officials may be inviting more civil suits, Rep. Waxman said. "The whole idea of the compensation system is to be generous so they [petitioners] won't want to go to court."

### **Lost on a Technicality**

Vaccine court officials were none too generous with Veronica Spohn.

Her parents claimed that a DPT shot caused their infant daughter to suffer brain damage. But they lost on a technicality: Their petition was filed a few hours late.

Although the vaccine compensation program was billed as more flexible, its three-year statute of limitations is draconian compared with rules of civil courts in all 50 states, which place no deadlines on the filing of injury claims for minors.

In the Spohn case, the doctor's records were a mess, alternately giving July 17 and July 19, 1992, as the date of the fateful shot. The family's lawyer filed the petition July 18, 1995, thinking he had made the deadline with a day to spare. In fact, he was a day late.

Seizing on the error, the Justice Department moved for dismissal. Special Master Elizabeth Wright concurred, citing the Spohns' "failure to use due diligence in pursuing

the claim."

It was "very much an injustice," said Veronica's mother, Karen Spohn, a nurse in Butler, Pa. "I had a normal child, and all of a sudden in one day, within hours of the vaccine ... she became a child with a disability" who is "going to need assistance for the rest of her life."

"They didn't rule that she didn't have damage. All they did was say, you filed 12 hours too late — too bad on you."

Spohn said she was too heartsick at that point to look into filing a civil lawsuit.

"Emotionally I couldn't deal with" continuing the fight, said Spohn, who preferred to "accept what you're dealt with and go through life."

### **Lengthy Legal Battle**

In the case of Dustin Barton, the government fought so long that the Albuquerque boy did not live to see the resolution of his claim.

As an infant, he had suffered seizures and brain damage after a DPT shot. But Dustin had a congenital neurological condition, known as periventricular leukomalacia, that the government blamed for his injuries.

His mother, Lori Barton, filed the claim in November 1991. The case dragged on for years. Barton told friends and family that she suspected the government was waiting for Dustin to die — noting that it would be cheaper for the program to pay the death benefit of \$250,000 than to buy an annuity to cover lifetime care.

Dustin eventually did die of a seizure, nearly six years into the case, but the government continued to fight. Finally in May 2000, 8 1/2 years after the petition was filed, the family won a ruling that Dustin's injuries were vaccine-related.

Not ready to give up, Justice Department lawyers considered an appeal. Then they offered a deal: They would drop the challenge if the Bartons agreed the decision would remain unpublished. This meant it would not be sent to legal databases, such as Westlaw, where attorneys for other petitioners could see it.

Lori Barton, who has since died, described her reaction at a congressional hearing in December 2001: "To me, it was extortion." But Barton, who then was seriously ill and had borrowed thousands of dollars to pay expert witnesses, took the deal.

In a statement to The Times, the Justice Department said it had made similar deals "on very rare occasions." It happens when the government "disagrees with a decision but believes that settlement is fair and in both parties' interests."

## **Family Finances Ruined**

Rachel Zuhlke's claim was filed in September 1992. The government blamed her brain injuries on complications from a strep infection she had about the same time she got her DPT shot.

Janet Zuhlke said Rachel's illness contributed to the breakup of her marriage. She also lost her job as a dental assistant because of frequent absences to deal with Rachel's medical emergencies. Even with health insurance, the family's finances were wrecked.

"We had a lot of hot dogs," Zuhlke said. "We had two other children that went without many, many, many things ... because I couldn't afford them."

Her case moved at a crawl, getting repeatedly reassigned to different special masters, and from one Justice Department lawyer to another, who repeatedly got extensions to complete filings in the case.

Nearly eight years into the case, Golkiewicz, the chief special master, brought in a mediator for settlement talks. Zuhlke recalled her despair — and the special master's shock — when the Justice Department refused to make a settlement offer. "You should have seen Golkiewicz's face fall on the table," she said.

Golkiewicz said recently that he was disappointed that the case didn't settle, but that didn't mean "that one side or the other was at fault."

Still, he said, the case took far too long, and the Zuhlkes "had every reason to feel frustrated."

As it turned out, the government lost its all-or-nothing gamble. In July 2001, Special Master George Hastings ruled that Rachel was entitled to compensation. Fifteen months later, he granted a multimillion-dollar award, including \$925,000 for her pain and suffering, future lost earnings and past medical bills, and at least \$90,000 a year for living and healthcare costs.

Although relieved that the case is finally over, Zuhlke still struggles with grief over what happened to her child, now a young woman. Rachel's life, she said, "is so different from what it should be at 20."

And she still finds it "unfathomable" that the government fought her claim for so long, Zuhlke said. "My little girl hadn't done anything wrong."